The Royal College of Radiologists

Board of the Faculty of Clinical Radiology

Standards for radiofrequency ablation (RFA)

RCR Standards

The Royal College of Radiologists (RCR), a registered charity, exists to advance the science and practice of radiology and oncology.

It undertakes to produce standards documents to provide guidance to radiologists and others involved in the delivery of radiological services with the aim of defining good practice, advancing the practice of radiology and improving the service for the benefit of patients.

The standards documents cover a wide range of topics. All have undergone an extensive consultation process to ensure a broad consensus, underpinned by published evidence where applicable. Each is subject to review four years after publication or earlier if appropriate.

The standards are not regulations governing practice but attempt to define the aspects of radiological services and care which promote the provision of a high-quality service to patients.

Current standards documents

Standards for the introduction of new procedures and new devices

Standards for providing a 24-hour diagnostic radiology service

Standards for patient confidentiality and PACS

Standards for providing a 24-hour interventional radiology service

Standards for the communication of critical, urgent and unexpected significant radiological findings

Standards for Self-assessment of Performance

Standards for Radiology Discrepancy Meetings

Standards in Vascular Radiology

Standards for Ultrasound Equipment

Standards for Iodinated Intravascular Contrast Agent Administration To Adult Patients

Standards for Patient Consent Particular to Radiology

Standards for the Reporting and Interpretation of Imaging Investigations

Cancer Multidisciplinary Team Meetings – Standards for Clinical Radiologists

360° Appraisal – Good Practice for Radiologists

Individual Responsibilities – A Guide to Medical Practice for Radiologists

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Foreword

Radiofrequency ablation is a rapidly developing minimally invasive treatment for certain cancers of the lung, liver and kidney. It is also useful in certain bone tumours. Currently, equity of access to this important therapeutic option is poor but many NHS trusts are considering developing services. This standard was written in response to the current demand for guidance. Tumour ablation is a rapidly developing field with cryotherapy, microwave ablation and high intensity ultrasound all beginning to prove their effectiveness. These standards of practice should be applicable to all.

The Royal College of Radiologists is grateful to Drs Fergus Gleeson and Mark Anderson (Consultant Clinical Radiologists, Churchill Hospital, Oxford), Dr David Breen (Consultant Clinical Radiologist, Southampton University Hospital) and Mr Zahir Soonawalla (Consultant Hepatobiliary Surgeon) for writing the standards and Dr Rob Manns and the Standards Sub-Committee of The Royal College of Radiologists for their advice and help.

Dr Tony Nicholson

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The Royal College of Radiologists

Executive summary

Radiofrequency ablation (RFA) is now an accepted method of local tumour ablation, with published guidelines on its use by the National Institute for Health and Clinical Excellence (NICE), and has been shown to increase survival in appropriately selected patients. It is most commonly used to ablate liver and lung metastases and primary renal cell carcinoma. It is also used for primary (most commonly osteoid osteoma) and secondary bone malignancy, and soft tissue metastases. It requires reasonably simple and inexpensive equipment, but does require a moderately complex supporting infrastructure of experienced operators, appropriate case selection, deep conscious sedation or general anaesthesia, day-case beds or overnight ward facilities, therapy guidance using ultrasound and/or computed tomography (CT), and follow-up imaging. The number of patients that would benefit from RFA is expected to exceed 5,000 per annum in the UK and may be substantially greater than this if also used for debulking hepatic metastatic disease in colorectal cancer. This large workload will require appropriate resources and guidelines on:

- Patients suitable for therapy
- Post-procedure follow-up
- RFA centre infrastructure
- Operator and staff training
- Audit.

Introduction

There are numerous minimally invasive ablative therapies available, including radiofrequency ablation (RFA), microwave ablation, high-intensity focused ultrasound (HIFU), laser-induced interstitial thermotherapy (LITT), cryoablation and percutaneous ethanol injection. The most common ablative technique currently in use with the greatest numbers of procedures performed and related publications is RFA. It is most commonly performed in patients with primary and secondary liver tumours (particularly metastatic colorectal carcinoma), but also in those with renal cell carcinoma, and increasingly primary bronchogenic carcinoma or metastatic pulmonary disease. It may also be performed in patients with benign and metastatic bone tumours.

RFA may be performed by both radiologists and surgeons, either percutaneously (using ultrasound, CT or magnetic resonance imaging [MRI] guidance), or under direct vision (using intraoperative ultrasound during a laparotomy or laparoscopic surgery). Microwave ablation is perhaps the most promising new technique as it may be able to produce larger ablation volumes and at a greater rate than other techniques, but the experience and published evidence for microwave ablation is far less than with RFA.

As the evidence and experience is greatest for RFA, this technique will be used here as the model for service provision, but other techniques such as microwave ablation may be used in its place if and when evidence to support their use becomes available. There are now case series and a few prospective studies showing significantly increased survival in patients treated with RFA.

The procedure

RFA is a minimally invasive ablative treatment that produces cell death by coagulative necrosis using heat. The radiofrequency current is delivered through a probe, consisting of a partly insulated needle, with an active tip. The tip may be of variable length, and may either be a single straight tip or expandable, containing multiple prongs or tines that, when deployed, form an umbrella-like appearance where the active portion of the needle is positioned. After the procedure, the probes are removed, with the probe tracts being ablated (cauterised) as the needles are withdrawn, reducing the incidence of tumour seeding and haemorrhage. Adjunctive interventional manoeuvres such as hydrodissection, pre-embolisation or post-procedural chemoembolisation have extended the scope and applicability of these procedures. The procedure may be performed under deep conscious sedation or general anaesthetic and either as a day case or requiring an overnight admission (the most common practice in the UK) with discharge the following day. Antibiotic prophylaxis is routinely administered before the procedure and continued for a variable period of 24 to 72 hours afterwards. Analgesia is required during the recovery period but may be self-administered as an outpatient and the post-procedure pain is usually limited in severity and duration, commonly requiring only non-steroidal therapy.

There are recognised complications of the procedure, both generic and unique to the area being ablated – liver, lung or kidney. The risk of certain complications also varies according to the size and position of the lesion, its proximity to other structures, and the experience of the operator. For the most part, RFA is an extremely successful method of providing focal tumour ablation and in skilled hands has a low and acceptable rate of complications, with a significant morbidity and mortality of less than 2–5% and 0.5%.

Requirements

Equipment

RFA probes and a radiofrequency generator are required.

Staff support

There are significant numbers of staff required to provide a successful and busy RFA practice. The service is most likely to run efficiently and successfully if a team of individuals, both medical and non-medical are involved.

- Secretarial/clerical support: Necessary to liaise with patients and referring clinicians, request scans performed elsewhere, book scans, arrange patient anaesthetic pre-assessment, book theatre sessions, retrieve medical notes, and deal with correspondence. Facilities for the electronic transfer of images from referring centres will greatly aid the prompt initial assessment of tertiary referrals and accommodation into the local patient pathway.

- Nursing staff: As with any form of interventional procedure, nurses may help with patient queries about the procedure, and are essential to providing assistance during the procedure. They may be involved in significant periods of patient aftercare, including discharge and follow-up.

- Radiographers: Need to be familiar with both RFA and cross-sectional interventional procedures, particularly those performed with CT. They are essential to enable accurate probe localisation.

- Cross-sectional and interventional radiologists: Both subspecialists perform RFA. Independent of the subspecialisation, all individuals require adequate training. As far as possible, at least two consultants should be involved in service provision per centre. This enables joint discussion of more complex cases, and allows continuation of service during leave or illness.

- Anaesthetists and operating department assistants (ODAs): As procedures are performed under deep conscious sedation or general anaesthesia, an anaesthetist and an ODA are core team members. It is preferable to have a limited number of anaesthetists involved, so that they are familiar with the procedure, including patient positioning within CT or MRI, the potential complications, and the facilities available within the radiology department.

Sessional/logistic support

- Outpatients: Patients need to be seen as outpatients prior to the procedure either by the radiologist or a team member, to explain the risks and benefits and to discuss any patient concerns. This may provide an opportunity for further imaging and assessment within the department. In addition, patients require follow-up in outpatients.

- Anaesthetic pre-assessment: Patients requiring general anaesthesia will require an anaesthetic assessment. Access to pre-assessment clinics will greatly aid in the co-ordination of preoperative investigations and facilitate patient pathways, as day-case or overnight stay procedures.

- Day-case beds: The patients may be transferred after the procedure to a day-case bed – either within the radiology department or elsewhere within the hospital. Adequate day-case or overnight bed facilities are necessary, as are nursing staff familiar with potential interventional complications.

Time and support

- Case selection: Clear guidelines should be disseminated across the cancer network regarding the referral of cases for RFA to the tertiary centre. There is guidance available on the use of RFA for lung, renal, hepatocellular carcinoma and hepatic colorectal metastases on the NICE website for clinicians and the general public.

- Multidisciplinary team (MDT) meetings: It is essential that all these patients are discussed at a MDT meeting, even if it does not include all those involved in treating that particular tumour type. This is of critical importance in liver and lung RFA, as the role of chemotherapy, surgical resection and RFA frequently requires detailed discussion in relation to risks and benefits, the timing of intervention and the potential if necessary for combined surgical and interventional procedures.

- Outpatients: Patients require pre-procedural information and explanation and also require explanations or reassurance post-procedure. This can be done by a surgeon or oncologist but the radiologist is best placed to decide whether further RFA is required to achieve complete ablation of the area(s) treated.

Training

There are no formalised requirements for training, but it is recommended that a period of secondment at a unit providing the service occurs. This may be on a case-by-case basis if the trainee is a consultant at another institution, or may be for a block attachment at specialist registrar level.

Cancer Reform Strategy and extended waiting time standards

As of December 2008, the extended waiting time standards in the Cancer Reform Strategy came into force. For all subsequent treatments in patients with cancer, there is a 31-day deadline from the decision to treat and commencement of treatment. For RFA, most treatment decisions will be made at the MDT meeting and it is at this point that the 31-day clock will start.

Service provision

Referrals

Direct referrals may be from physicians, surgeons and oncologists following outpatient consultations; and referrals may also follow MDT discussion; GP referral, and direct patient referrals may all occur. All these referrals should be channelled via the appropriate MDT. Direct tertiary referrals to radiologists from other centres also occur and should be reviewed once again at the tertiary MDT meeting.

Numbers of patients

Hepatic tumours

It is likely that the numbers of patients that would benefit from ablation of hepatic metastases will exceed all other referrals. At present, it is estimated that up to 50% of patients with colorectal metastatic disease have liver-only metastases. Only about 10% of those with metastases undergo liver resection. A conservative estimate would suggest that another 10% of these cases may be suitable for ablative therapy often as an adjunct to chemotherapy. RFA is also being used in conjunction with resection to extend the number of patients treated with curative intent. Additionally, 50–60% of surgically treated patients will have disease relapse, with the majority of these being local hepatic relapse; these patients may also be suitable for RFA. Another consideration is the potential to retreat patients, further increasing the number requiring treatment. Perhaps the biggest potential increase in patients suitable for hepatic ablative therapy is due to the advent of the newer chemotherapeutic agents. These may make up to 30–40% of patients with organ-confined hepatic metastases previously thought untreatable for cure, suitable for either surgery or ablative therapy. The potential number of ablative therapies for hepatic disease alone is likely to be in the order of 3,000 to 5,000 patients annually. As the incidence of cirrhosis rises in the UK, the numbers developing hepatocellular carcinoma and those referred for RFA will increase.

Renal tumours

The number of patients suitable for renal ablation is also significant, with some centres increasingly ablating small renal tumours or those in patients unfit for surgical resection.

Lung tumours

It is also likely that the number of thoracic ablations is likely to increase significantly due to the increasingly aggressive treatment of oligometastatic disease and inoperable non-small cell lung cancer.

Bone metastases

A further increase is likely as the role of RFA in the palliation of bone metastases expands.

To treat this number of patients requires a significant expansion in both the numbers of centres providing ablative therapy and the numbers being performed in each centre. Each cancer network should be encouraged to identify patient pathways for RFA within each tumour type, and preferably develop RFA services within the network.

Baseline and follow-up imaging

Before treatment, each patient should have appropriate recent baseline imaging. Assuming the treatment is to be provided as a curative procedure, a multi-slice CT (MSCT) of the chest, abdomen and pelvis should be performed using an agreed scanning protocol. If this does not identify significant extra-hepatic metastases in patients for consideration of RFA for colorectal hepatic metastases, a PET-CT should be performed. This should also be considered in patients for pulmonary ablative therapy, but is unnecessary in patients with hepatocellular carcinoma and renal cancer. There is no defined accepted follow-up scanning protocol after RFA. A baseline scan performed shortly after the procedure is advisable and then scans at pre-agreed time intervals should be performed either at the referring institute or at the centre, dependent on local agreement and expected tumour biology. MR may play an increasing role in this context.

Patient information

Written and online information should be provided for each of the types of procedures to be performed. This should be available in outpatients, with referring clinicians and local radiologists familiar with the information included. Patients should have easy access to a key worker who they can contact with any queries or requests for further information. Patients who are discharged after the procedure should have clear guidance about possible problems, and what they should do in such a case.

Numbers of centres

The numbers of patients referred into each current unit currently providing RFA is unknown, as is the potential number of patients that might benefit from the procedure. It is suggested that RFA should be limited to centres that are designated for the specialist treatment of those tumours; that is, lung RFA should be undertaken only at centres that are designated for the treatment of lung tumours and have a lung MDT.

Audit and research

Audit

Each unit must regularly audit its own practice. The audit should include the number of patients considered for RFA and declined, as well as those accepted. The following parameters should be assessed:

- The patient pathway
- Complications – major and minor
- The incidence of incomplete treatment and local relapse
- Survival – disease-free and overall
- Patient satisfaction.

The results of these audits should be made available to referring clinicians, patients, and the trust clinical governance committees.

An audit template is in preparation and will be available on AuditLive on www.rcr.ac.uk

Research

There are a number of unresolved questions regarding the use of RFA. It would be desirable that large centres, performing more than one case per week, were involved in active research, with co-ordination between centres to further research goals. Serious consideration should be given to establishing large multicentre randomised clinical trials to assess the role of RFA in clinical scenarios where the evidence in literature at present is scanty and clinical equipoise exists. In future, participation of patients within such trials could be considered as an endpoint for audit.

Approved by the Board of the Faculty of Clinical Radiology: 19 June 2009

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