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The Royal College of Radiologists

Interventional oncology: guidance for service delivery
Second edition

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Contents

Foreword

In 2012, The Royal College of Radiologists (RCR) recognised that the term 'interventional oncologist' had begun to appear in medical literature. Our predecessors, Dr Diana Tait, Vice-President, Clinical Oncology, and Dr Pete Cavanagh, Vice-President, Clinical Radiology, established and led a working party, which defined the best practice for delivery of interventional oncology services and associated practice guidelines. We remain grateful to them, and the members of that working party, for their enthusiasm and commitment which resulted in the first edition of this guidance.

When the guidance was first published, the College accepted that it was a fast-developing field, and the guidance would require further updating. As a result, Dr Catherine Coyle and Dr Tze Wah were asked to review and update the document to ensure its on-going currency and we are grateful to them for the changes which have resulted in this second edition.

Much of the original content remains relevant and unchanged, which is a testament to the work of the original working party. However, we hope that colleagues will find this revised and updated version helpful and supportive.

As with all the College's guidance, this publication will be kept under review to ensure that it remains up to date and fit for purpose.

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1. Introduction

Purpose

The purpose of this guidance is to identify best practice in interventional oncology. The guidance does not cover diagnostic procedures, although it is recognised that these are widely used in oncology practice. It looks at current models of practice and ensures that areas of clinical responsibility are clear and that interventional radiology procedures are part of the overall multidisciplinary care pathway. Where therapeutic agents, such as chemotherapy or radiotherapy are administered, it recommends strict protocols for the prescribing and administration of these agents, and for the care of the patient before, during and after the procedure.

The guidelines do not relate to specific procedures, but provide generic best practice around provision of a safe, high-quality service, including data collection, outcome measures and quality assurance. The role of research, both in contributing to the defined standards and in developing this area of expertise, is incorporated.

Background

The patient should always be at the centre of any healthcare service. Patient safety, experience and wellbeing that should be the main drivers in designing the patient pathway. Nowhere is this more important than when new services or treatments are developed. Interventional radiology (IR) is a developing field of practice, which has an impact across diagnostics and therapeutics in virtually all branches of medicine and surgery and to this end it has been recognised formally as a subspecialty of clinical radiology.

The term ‘interventional oncology’ appears in medical literature when referring to interventional radiological techniques used in the diagnosis, treatment or palliation of patients with cancer. The RCR acknowledges that this is a misnomer as there are many established interventions provided by other specialties (for example, through surgery, radiotherapy and chemotherapy). We use the term ‘interventional oncology’ within this document to relate exclusively to interventions involving IR procedures.

However, the RCR is clear that the term ‘interventional oncologist’ should not be used, as the skills and competencies required to provide a safe and effective patient-centred service reside in a whole multidisciplinary team of healthcare professionals and not just with a single individual.

Interventional radiology plays an ever-increasing and important role in the management of cancer patients but, because of the relatively recent introduction of many techniques and the dependency on availability of local skills, its application is not entirely uniform throughout different cancer services and practices.

The RCR’s Clinical Oncology and Clinical Radiology Faculties are uniquely placed to define standards for the incorporation of IR procedures into the management of cancer patients. It is, therefore, entirely appropriate that the RCR should publish a second edition of this guidance to ensure that cancer patients have access to best interventional practice, appropriately incorporated into their multidisciplinary care.

A key component of any interventional oncology service is data collection as it is essential that there is clarity on the effectiveness and safety of such procedures when compared with more established practices.

A vital member of the team approach is the patient. In producing this guidance, we have sought the input of lay members working on our boards who have considered this guidance and we would like to acknowledge their input along with members of the working group.

2. Interventional oncology procedure categorisation

Interventional procedures undertaken in cancer patients can be considered under two main headings according to their primary intent. The following provides an indication of the types of procedures which may be undertaken. This is not intended to be an exhaustive list and will clearly continue to evolve as new interventions come to the fore.

Supportive/symptomatic procedures

Supportive procedures support the provision of definitive treatment but are not in themselves directed at treating the tumour or its effects; that is, adjuncts to enable chemotherapy, radiotherapy or surgery. Symptomatic procedures provide relief from tumour-related symptoms but do not necessarily modify the underlying malignant disease process. Procedures can be both supportive and symptom-relieving and are, therefore, considered together:

- Image-guided biopsy
- Central venous access
- Enteral tube placement such as radiologically inserted gastrostomy (RIG)
- Image-guided aspiration; for example, pleural, ascitic
- Image-guided drainage such as pleural, ascitic, collections
- Vena caval filtration
- Biliary drainage and stenting
- Image-guided insertion of markers; for example, fiducials for stereotactic radiotherapy
- Nephrostomy and ureteric stenting
- Neo-adjuvant embolisation such as portal vein embolisation
- Ascitic diversion; for example, peritoneo-venous or peritoneo-cystic shunt/pump
- Vena caval stenting
- Gastrointestinal stenting
- Image-guided ablation
- Embolisation (such as pre-hepatic resection)
- Insertion of fiducial markers for stereotactic ablative radiotherapy (SABR) or other forms of image-guided radiotherapy.

Disease-modifying procedures

Disease-modifying procedures are those where the intent is to modify malignant progression and/or to modify the prognosis such as:

- Image-guided ablation
- Image-guided brachytherapy; for example, for prostate cancer
- Embolisation
- Transarterial chemoembolisation (TACE)

- Selective internal radiation therapy (SIRT)
- Isolated perfusion chemotherapy.

3. Patient selection and the role of multidisciplinary teams (MDTs) and MDT meetings (MDTMs)

It is considered essential that interventional oncology is practised within a team setting. However, it will not be practical for every procedure to be determined through an MDTM.

Patients may be suitable for a range of therapeutic options for example SABR, radiofrequency ablation (RFA), microwave ablation (MWA), irreversible electroporation (IRE), cryotherapy (CRYO) or SIRT for liver metastases. The MDMT should document the options with justification for recommendations to permit meaningful audit and outcome collection.

The interventional radiology procedures listed in Section 2 should form part of the pathway of cancer care for patients, with formal links to the relevant MDTs in place.

The interventional radiologist should, wherever possible, be a core member of the relevant MDT. In some clinical settings where complex interventional oncology procedures are frequently employed, an interventional radiologist should have a regular, active role in the MDTM.

Pathways which include interventional radiology procedures should be reviewed formally on a regular basis and should also sit within the local guidelines.

Patients being offered interventional radiology procedures should be discussed at an appropriate MDTM, unless clinical needs necessitate urgent intervention.

Referrals for interventional radiology procedures should be made to the interventional radiologist who is a member of the MDT, in the knowledge of the consultant in overall charge of the patient's care, unless clinical needs necessitate urgent intervention.

There may be circumstances in which onward referral to another provider may be necessary and appropriate.

Referrals from another provider/network for an interventional radiology procedure should be considered at the MDTM in the hospital where the procedure will be carried out.

Where clinical needs necessitate intervention before MDT discussion, the patient should be discussed at the earliest opportunity at the MDTM following the procedure.

Procedures which would not normally be discussed by the MDT (either within or outside the MDTM) are included in this guidance (see Section 2, supportive/symptomatic procedures). This is because important decisions around such procedures sometimes have to be made and because an MDT member might, in certain cases, have good reason to request that such procedures be discussed by the team.

4. Defining the patient pathway for interventional procedures

Patient referral

A patient with cancer should only be referred for an interventional procedure after appropriate clinical discussion between the referring clinician and the interventional radiologist.

If the referring clinician is not the oncologist looking after the patient, but there is an oncologist involved in the patient's care, the patient's oncologist should be informed. This is

to ensure that decisions are made in the context of the overall treatment plan, considering other potential options for the future and the impact of previous treatments. In the acute setting, additional oncology support may be provided by local acute oncology teams.

The case should normally be discussed at the appropriate MDTM (see Section 3).

The consultant(s) responsible for the patient during their admission for the interventional procedure should be clearly stated. This may be the referring clinician, the interventional radiologist or 'joint care'.

A cancer nurse specialist (CNS) already linked to the patient should be involved in the patient pathway. While it is acknowledged that some centres do not have CNSs, it is good practice to have their involvement as they provide a useful bridge between the clinical oncologist and the interventional radiologist.

Pre-procedure patient information

The service should have patient information leaflets for all procedures.

Normally, the patient should be offered a hospital patient information leaflet specific to the procedure to be performed and, if appropriate, radiation protection should be discussed. For some complex procedures, the patient may benefit from consultation with the interventional radiologist and this should be during a clinic appointment for an elective procedure or on the ward for an urgent/emergency procedure.

The British Society of Interventional Radiology has produced a patient information leaflet on interventional radiology.[1] Information pertaining to SIRT and RFA is available from Oxford University Hospitals Trust and Cancer Research UK respectively.[2,3]

Consent

Informed consent, in line with local guidance, should be obtained either in the clinic or on the ward by the clinician performing the procedure or an appropriately trained and delegated healthcare professional who is part of the team responsible for the patient's care.

Prescription of therapeutic agents

A named medical practitioner will be responsible for the procedure.

All therapeutic agents should be prescribed and signed as per local written protocols by an appropriately trained medical practitioner.

Radioisotopes should be prescribed by Administration of Radioactive Substances Advisory Committee (ARSAC) licence holders.

Admission (day case or inpatient)

Consent should be confirmed.

Patients should be assessed for fitness to proceed by a member of the IR team, using a pro forma appropriate to the procedure.

Interventional procedure

The range of interventional procedures in the management of cancer patients is wide and varied. All procedures should be performed by a competent, appropriately trained interventional radiologist to the expected standard and there should be clear

documentation of the procedure that will facilitate data collection. The procedure should only be carried out in appropriately equipped, defined locations with appropriate team support for example, radiographers, scrub nurses and anaesthetists.

Recovery from procedure

Patients should recover on a ward where staff are familiar with the procedure and should be monitored according to written protocols.

Discharge should occur only after assessment by a healthcare professional familiar with the procedure.

Pathways should include clear links with appropriate support services including clinical services, for example, surgical and medical specialities to manage patients with potential complications, and also interventional radiology vascular service support for example, for embolic procedures.

5. Post-procedure follow-up

Multidisciplinary follow-up and continued aftercare are critical components of the appropriate care of any patient with cancer having an interventional procedure.

Local protocols should be in place for appropriate aftercare within the first few days of the procedure, for example, a chest X-ray (CXR) to check the position of a nasogastric tube or low molecular weight heparin (LMWH) for patients suffering immobilisation due to the procedure.

Local protocols should include prescription of analgesia and anti-emetics for certain procedures.

For inpatient procedures, ward protocols should be available for nursing staff, including guidance on radiation protection, where relevant, with awareness of the patient's location on the ward and appropriate induction for complex interventions (such as for those involving complex nursing or requiring close monitoring).

All patients need a personalised follow-up plan which should be based on an agreed protocol defined by the procedure performed and modified according to the individual's specific medical circumstances. There should be clear records as to what the follow-up plan is and auditable evidence of adherence to it.

It should be clear which clinician is primarily responsible for patient follow-up and it is the responsibility of that clinician to liaise with other members of the multidisciplinary team.

6. Outcome measures

Wherever feasible, new interventions should be developed within the context of well-designed clinical trials which establish the optimal use of the intervention within the patient pathway.[4]

Adequate resource needs to be allocated by healthcare organisations to allow effective collection of outcome data. Both oncologists and radiologists should be part of 'cancer peer review' which, if conducted correctly, improves standards. This can also contribute to benchmarking and support the development of appropriately resourced services or business cases for appropriate resources.

For new interventions, development of national registries should be encouraged to allow standardisation of procedures and pooling of follow-up and outcome data.

The efficacy of the intervention should be recorded in the patient's case notes with specific reference to the symptoms being relieved by the intervention and side-effects experienced. Wherever possible, validated symptom scales should be used to objectively record the degree of symptomatic improvement.

Audit data

For well-established interventions, follow-up data should be audited as an important means of quality control. For newer interventions where the evidence base is less well developed, audit data can contribute further evidence to justify the intervention.[5]

Minimum data set: three measures

Different procedures will require different outcome data, but there are three headings which need to be considered as the minimum data set.

- **Efficacy:** Did the procedure do what it was supposed to do; for example, unblock an obstruction? The treatment intent must be considered in evaluating the efficacy of the intervention. Time points of assessment also vary according to treatment intent and can be specific to interventions performed, such as instant symptom relief for a radiologist relieving an obstruction or validated response measurement for disease modifiers usually performed eight to 12 weeks from the procedure date.
- **Safety:** Was the procedure carried out such that it ensured avoidance of harm? Safety should be assessed by morbidity or mortality related to the procedure. This information should be recorded in institutional and regional audits, and in national registries where available.
- **Patient feedback:** Arrangements should be in place to ascertain the patient's experience of the pathway including, where possible, objective measurement of patient-reported outcomes.

Disease-modifying interventions

Interventional radiology input can be a single procedure (such as thermal for example, RFA, MWA and CRYO or non-thermal for example, irreversible electroporation ablation) or multiple sequenced events (for example, TACE). The multidisciplinary team should be responsible for follow-up of the patient, via one designated clinician, to assess the success or morbidity of the recommended treatment and to advise on expert aspects of assessing response.[6] For example, zones of thermal ablation within the liver parenchyma or the appearances of early radiation-induced liver disease (RILD) following SIRT may be misinterpreted by non-expert reporting radiologists as progressive disease or as alternative pathology.[7]

Assessment of response

Specialist multidisciplinary teams should define how they think response is best assessed (such as modality of scanning, time points of scans, Response Evaluation Criteria In Solid Tumors [RECIST][8] or alternative criteria, for example, potential pitfalls in interpretation) and should develop clear protocols specifying these factors for each intervention undertaken.

Multidisciplinary follow-up and continued aftercare is a critical component of the appropriate care of any patient with cancer having an interventional procedure.

Sustainable service delivery depends on accurate clinical coding and thus reimbursement for the procedure (including consumables), within national tariffs

7. Implications for training

Those performing interventional radiology procedures for cancer therapy need to develop an understanding of cancer biology, knowledge of the action of chemotherapeutic agents, their side-effects and interactions, management of side-effects and complications of cancer therapies relating to the specific cancer sites and treatments that they offer.[9]

Given that interventional radiologists are likely to have significant conversations with cancer patients, consideration also needs to be given to undertaking advanced communication skills training.

It is important that oncologists have a clear understanding of the potential role of interventional radiology procedures in the management of their patients, and these need to be included in training curricula.

In this evolving field, centres performing new interventional radiology procedures have a responsibility to educate other teams – both within the local network who may refer patients for procedures and at other centres who are developing their own service. This may include observation of procedures and sharing of protocols.[10]

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References

1. www.bsir.org/patients/patient-information-leaflets/ (last accessed 13/03/17)
2. www.ouh.nhs.uk/patient-guide/leaflets/files%5C120417spheres.pdf (last accessed 13/03/17)
3. www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/other/radiofrequency-ablation-rfa (last accessed 13/03/17)
4. National Institute for Health and Care Excellence. S*elective internal radiation therapy for non-resectable colorectal metastases in the liver.* London: NICE, 2013.
5. NHS England. *Interim clinical commissioning policy statement: selective internal radiotherapy (SIRT).* London: NHS England, 2013.
6. Kennedy A, Nag S, Salem R *et al*. Recommendations for radioembolization of hepatic malignancies using yttrium-90 microsphere brachytherapy: a consensus panel report from the radioembolization brachytherapy oncology consortium. *Int J Radiat Oncol Biol Phys* 2007; **68**(1): 13–23.
7. Sharma RA, Anthony S, Anderson EM. Clinical benefit and potential pitfalls in combining thermal ablation and radiation therapy to treat liver metastases. *J Clin Oncol* 2013; **31:** e404–e406.
8. www.irrecist.com/ (last accessed 13/03/17)
9. Nicolay NH, Berry DP, Sharma RA. Liver metastases from colorectal cancer: radioembolization with systemic therapy. *Nat Rev Clin Oncol* 2009 ; **6**(12): 687–697.
10. Department of Health. *Interventional radiology: guidance for service delivery. A report from the National Imaging Board.* London: Department of Health, 2010.

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