Issue date: **September 2004**

NHS
National Institute for Clinical Excellence

Selective internal radiation therapy for colorectal metastases in the liver

1 Guidance

1.1 Current evidence on the safety of selective internal radiation therapy (SIRT) for colorectal metastases in the liver appears adequate. With regard to efficacy, the procedure may reduce tumour bulk, but there is a lack of evidence of symptom relief or increased survival, and combination with other treatments makes interpretation of the published literature difficult.

1.2 Clinicians wishing to undertake selective internal radiation therapy for colorectal metastases in the liver should take the following actions.

- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having selective internal radiation therapy for colorectal metastases in the liver.

1.3 Publication of research studies with outcome measures which include survival will be useful in reducing the current uncertainty about the efficacy of the procedure. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Colorectal cancer arises in the colon or rectum. It is the second most common cancer in women and the third most common cancer in men in the UK. Colorectal cancer will recur in around 50% of patients within 5 years of initial diagnosis, the liver being the most common site for metastatic disease. SIRT is used to treat non-resectable liver metastases secondary to colorectal cancer, usually in combination with hepatic arterial chemotherapy.

2.1.2 The standard method of treatment for patients with colorectal metastases in the liver is surgical resection, but fewer than 10% of patients are suitable for this operation because of the number and distribution of tumours and/or the presence of other disease. For patients with non-resectable metastases in the liver, treatment options include systemic chemotherapy, radiotherapy, radiofrequency ablation, cryotherapy, alcohol injection and laser photocoagulation.

2.2 Outline of the procedure

2.2.1 Radioactive spheres are injected using a syringe into the hepatic artery via a transfemoral catheter or a permanently implanted port with a catheter to the hepatic artery. For the placement of this access port, patients may need to undergo a laparotomy.

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2.3 Efficacy

2.3.1 In a randomised controlled trial (RCT) of SIRT in combination with hepatic artery chemotherapy, patients receiving SIRT had improved response rates compared with patients receiving chemotherapy alone. Response rates were measured by tumour area and volume, and carcinoembryonic antigen levels. Evidence on survival indicated no statistically significant difference in the outcomes of patients receiving SIRT compared with those treated with chemotherapy alone. The RCT, however, was stopped early and was therefore insufficiently powered to detect the level of increase in overall survival, which was the original aim of the study. For more details, refer to the Sources of evidence (see right).

2.3.2 Reported survival from time of treatment in the uncontrolled studies ranged from 9.8 to 12 months. In many of these studies, it was not possible to determine whether survival was measured from time of diagnosis or of treatment.

2.3.3 The opinions of the Specialist Advisors were divided about the efficacy of SIRT. One Advisor thought that increased survival could result for patients treated with SIRT, whereas another Advisor considered that efficacy was still unproven and better-quality studies were needed.

2.4 Safety

2.4.1 In the summary of adverse effects from case series in a systematic review, major complications included fatal radiation hepatitis 0.6% (2/363), gastrointestinal ulceration 3.6% (13/363), gastrointestinal haemorrhage 0.8% (3/363) and radiation pneumonitis 1.4% (5/363). In an RCT of SIRT in combination with chemotherapy and chemotherapy alone, the number of more serious (grades 3 and 4) toxicity-related events was similar for both groups. For more details, refer to the Sources of evidence (see right).

2.4.2 The Specialist Advisors listed potential complications as radiation injury to biliary structures, severe abdominal pain, nausea and pyrexia.

2.5 Other comments

2.5.1 This procedure is likely to be used in patients for whom other treatments are unsuitable.

3 Further information

3.1 The Institute has published cancer service guidance called *Improving Outcomes in Colorectal Cancers*, and published safety and efficacy guidance on radiofrequency ablation of colorectal liver metastases (IPG092).

3.2 The Institute has also published technology appraisal guidance called *Colorectal cancer – capecitabine and tegafur uracil* (TA61) and *Colorectal cancer – laparoscopic surgery* (TA17). For details of all of the Institute's guidance, visit www.nice.org.uk

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September 2004

Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG093publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of selective internal radiation therapy for the treatment of colorectal metastases in the liver, August 2003

Available from: www.nice.org.uk/ip228overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0708. *Information for the Public* can be obtained by quoting reference number N0709 for the English version and N0710 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at www.nice.org.uk/IPG093distributionlist

Published by the National Institute for Clinical Excellence, September 2004 ISBN: 1-84257-776-X

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N0708 1P 20k Sep 04 (ABA)