NICE National Institute for Health and Care Excellence

NICE guidance

Selective internal radiation therapy for primary hepatocellular carcinoma

HealthTech guidance
Published: 23 July 2013

www.nice.org.uk/guidance/htg314

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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG460.

This guidance should be read in conjunction with TA688 and HTG489.

1 Recommendations

1.1 Current evidence on the efficacy and safety of selective internal radiation therapy (SIRT) for primary hepatocellular carcinoma is adequate for use with normal arrangements for clinical governance, consent and audit. Uncertainties remain about its comparative effectiveness, and clinicians are encouraged to enter eligible patients into trials comparing the procedure against other forms of treatment.

1.2 Patients with primary hepatocellular carcinoma should be selected for treatment by SIRT or for entry into trials by a multidisciplinary hepatobiliary cancer team.

1.3 SIRT should only be carried out by clinicians with specific training in its use and in techniques to minimise the risk of side effects from the procedure.

1.4 Clinicians should enter details about all patients undergoing SIRT for primary hepatocellular carcinoma onto the UK SIRT register. They should audit and review clinical outcomes locally and should document them and consider their relationship to patient characteristics.

2 The procedure

2.1 Indications and current treatments

2.1.1 Hepatocellular carcinoma is the most common type of primary liver cancer.

2.1.2 The choice of treatment for primary hepatocellular carcinoma depends on a number of factors, including the exact location and stage of the cancer, and the patient's liver function. The aim of treatment is normally to slow progression with a view to improving quality of life and prolonging survival. In some patients, surgical removal with curative intent may be possible: this may sometimes be achieved by downstaging the tumour using other treatment modalities first. Treatment options include chemotherapy (intravenous or by hepatic artery infusion), surgical excision, transarterial chemo-embolisation (TACE) and radiofrequency ablation.

2.2 Outline of the procedure

2.2.1 Selective internal radiation therapy (SIRT) for primary hepatocellular carcinoma involves infusion of microspheres loaded with yttrium-90, which aims to deliver radiation directly into the tumour, minimising the risk of radiation damage to healthy surrounding tissues.

2.2.2 Before undertaking the treatment, a nuclear medicine liver-to-lung shunt study is carried out to assess the risk of radioactive microspheres causing lung damage. Radiographic imaging and selective coil embolisation of arteries to the stomach and duodenum are also commonly carried out.

2.2.3 Using local anaesthesia, radioactive microspheres that are designed to lodge in the small arteries are injected into branches of the hepatic artery, usually by a percutaneous femoral approach.

2.2.4 The procedure may be repeated depending on the response.

2.3 Efficacy

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.

2.3.1 A non-randomised comparative study of 86 patients, with 43 treated by SIRT and 43 treated by TACE, reported overall median survival of 42 months in the SIRT group compared with 19 months in the TACE group (p=0.008). A case series of 325 patients reported overall median survival was 12.8 months; this varied significantly by disease stage (Barcelona Clinic Liver Cancer [BCLC] stage A: 24.4 months; BCLC stage B: 16.9 months; BCLC stage C: 10 months).

2.3.2 The non-randomised comparative study of 86 patients reported a partial response (assessed using World Health Organization [WHO] criteria) in 61% (26 out of 43) of patients treated by SIRT (median follow-up 34 months) and 37% (13 out of 35) of patients treated by TACE (median follow-up 52 months). This difference was not significant (p=0.07).

2.3.3 A non-randomised comparative study of 245 patients, with 123 treated by SIRT and 122 treated by TACE, reported an overall response rate (assessed using WHO criteria) in 49% (60 out of 123) of patients treated by SIRT (median follow-up 23 months) and 36% (44 out of 122) of patients treated by TACE (median follow-up 33 months; p=0.05).

2.3.4 The non-randomised comparative study of 86 patients reported downstaging from stage T3 to stage T2 in 58% (25 out of 43) of patients in the SIRT group and 31% (11 out of 35) of patients in the TACE group at a 'median time to downstaging was within 6 months' (p=0.02).

2.3.5 A case series of 291 patients treated by SIRT reported that 12% (34 out of 291) of patients underwent treatment with curative intent: 32 went on to have liver transplants and 2 had resection of their tumours (median follow-up 31 months).

2.3.6 A case series of 35 patients treated by SIRT reported that 8 patients were downstaged and underwent liver transplantation (timing ranged from 12 days to 210 months after treatment).

2.3.7 The non-randomised comparative study of 245 patients reported a significantly longer median time to progression of 13.3 months in patients treated by SIRT compared against 8.4 months in patients treated by TACE (p=0.05).

2.3.8 A non-randomised comparative study of 28 patients, with 14 treated by SIRT and 14 treated by cisplatin, reported health-related quality of life measured on the Functional Assessment of Cancer Therapy – Hepatobiliary (FACT-Hep) questionnaire (scored on a scale of 0 to 4; higher score indicating better quality of life or fewer symptoms). The overall health-related quality of life score was 47 for the SIRT group (n=9) and 52 for the cisplatin group (n=5) at 6-month follow-up. This difference was reported as not significant (p value not reported).

2.3.9 The Specialist Advisers listed efficacy outcomes as tumour response, overall survival, quality of life, increased time to progression, downsizing or downstaging to potentially curative treatments, and bridging to liver transplantation.

2.4 Safety

2.4.1 Death within 30 days was reported in 7% (2 out of 27) of patients treated by SIRT and in 9% (4 out of 44) of patients treated by chemo-embolisation in a non-randomised comparative study of 71 patients.

2.4.2 Radiation pneumonitis was reported in 4 patients between 1 and 6 months after treatment by SIRT (a scan to determine lung shunting had been performed before SIRT) in a case series of 80 patients. All patients were treated by steroids. Three patients died of progressive respiratory failure and 1 from progressive cancer.

2.4.3 Ulceration caused by radiation was reported in 11% (3 out of 27) of patients who were treated by SIRT (after prophylactic coil embolisation of the gastroduodenal arteries) and gastritis and/or temporary ulceration was reported in 20% (9 out of 44) of patients treated by chemo-embolisation in the non-randomised comparative study of 71 patients. Two patients in the SIRT group were treated by subtotal gastrectomy; there were no further details on the other patient (median follow-up 6 months).

2.4.4 Cholecystitis reported as 'possibly related to treatment' occurred in 2 patients in

the case series of 80 patients treated by SIRT (both treated by emergency cholecystectomy 21 and 243 days after treatment).

2.4.5 Radiation-induced biliary stricture was described in a case report. The patient became progressively jaundiced and fatigued, with mild or moderate bilirubin toxicity (timing not reported).

2.4.6 Bone marrow suppression resulting in transient thrombocytopenia was reported 1 month after SIRT in a case report.

2.4.7 Post-embolisation syndrome was reported in 60% of patients in both the SIRT and TACE groups (absolute numbers not reported) in the non-randomised comparative study of 86 patients. The symptoms (fatigue and transient non-specific flu-like symptoms) lasted 7 to 10 days in the SIRT group (no further details).

2.4.8 The Specialist Advisers listed additional anecdotal adverse events as fibrosis and skin ulceration; and additional theoretical adverse events as liver failure, portal hypertension, and radiation-induced liver disease.

2.5 Other comments

2.5.1 The Committee noted wide variation in the published evidence about prior and adjunctive treatments that patients received. This made interpretation of the effect of SIRT difficult.

2.5.2 The Committee noted that safety outcomes from older published studies may not reflect current practice in which prophylactic coil embolisation is used.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 460 has been migrated to HealthTech guidance 314. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8860-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.