NICE guidance

Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis

Interventional procedures guidance
Published: 1 February 2010
nice.org.uk/guidance/ipg331

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. However, 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.

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.

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.

This guidance replaces IPG116.

1 Guidance

This guidance replaces previous guidance on complete cytoreduction and heated intraoperative intraperitoneal chemotherapy (Sugarbaker technique) for peritoneal carcinomatosis (interventional procedure guidance 116).

1.1 Current evidence on the efficacy of cytoreduction surgery (CRS) followed by hyperthermic intraoperative peritoneal chemotherapy (HIPEC) for peritoneal carcinomatosis shows some improvement in survival for selected patients with colorectal metastases, but evidence is limited for other types of cancer. The evidence on safety shows significant risks of morbidity and mortality which need to be balanced against the perceived benefit for each patient. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake CRS followed by HIPEC for peritoneal carcinomatosis should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy in relation to the potential morbidity and mortality and the prolonged recovery period, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having CRS followed by HIPEC for peritoneal carcinomatosis (see section 3.1).

1.3 Patient selection and treatment should be carried out in the context of a multidisciplinary team, including oncologists and surgeons with experience in this operation.

1.4 NICE encourages further research into this procedure which should take the form of randomised controlled trials (RCTs) with clear descriptions of patient selection criteria and the types of cancer being treated. The chemotherapy regimens used should be well defined. Outcome measures should include survival and quality of life.

2 The procedure

2.1 Indications and current treatments

2.1.1 Peritoneal carcinomatosis is advanced cancer associated with short survival and poor quality of life.

2.1.2 Current treatments include systemic chemotherapy with the aim of prolonging survival, and/or surgery for short-term palliation of complications such as bowel obstruction.

2.2 Outline of the procedure

2.2.1 Cytoreduction surgery aims to remove all macroscopic tumours. Intraoperative intraperitoneal administration of chemotherapy aims to distribute the drug uniformly to all surfaces of the abdomen and pelvis.

2.2.2 With the patient under general anaesthesia, appropriate CRS is carried out, followed by perfusion of the abdomen with heated chemotherapy solution (heating increases penetration and cytotoxic effects). The abdomen is drained prior to closure. A further course of systemic or early postoperative intraperitoneal chemotherapy (EPIC) may be administered.

> 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 Efficacy

2.3.1 A systematic review of 4500 patients with peritoneal carcinomatosis of colorectal origin reported an overall median 5-year survival of 19% (16 studies).

2.3.2 A non-randomised comparative study of 506 patients with peritoneal carcinomatosis of colorectal origin comparing CRS and HIPEC (271 patients) with CRS and EPIC (123 patients) and CRS and HIPEC plus EPIC (112 patients) reported no significant difference in median survival between the groups (19.2 months, 19.2 months and 21.6 months respectively) ($p = 0.61$).

2.3.3 A case series of 96 patients with peritoneal carcinomatosis of varying primary tumour origin treated by CRS and HIPEC reported a significant improvement in quality of life (using the Short Form-36 questionnaire), with an increase in mean score from 69.5 to 80 at 6-month follow-up (significance not stated).

2.3.4 The Specialist Advisers listed key efficacy outcomes as survival, quality of life, symptom palliation, recurrence rate and return to work and recreational activities.

2.4 Safety

2.4.1 A meta-analysis of 4 comparative studies included in the systematic review of 4500 patients reported a 3-year survival hazard ratio of 0.55 (95% confidence interval: 0.4–0.75), indicating that patients were more likely to survive if they received CRS plus HIPEC or EPIC (total number of patients not stated).

2.4.2 The systematic review of 4500 patients reported a mortality range of 0–12% (27 studies) (follow-up not stated). A postoperative mortality rate of 4% (20/506) was reported in the non-randomised comparative study of 506 patients. Deaths were attributed to the following causes: septic shock (9), respiratory complications (5), pulmonary embolus (1), stroke (1), peritonitis (1), acute renal failure (1), aplasia (not otherwise described) (1) and unknown causes (1) (timing of events not stated). In an RCT of 105 patients (CRS, HIPEC and systemic chemotherapy group), 3 patients died from abdominal sepsis (2 within 40 days, 1 more than 3 months after the procedure) and 1 patient died of pulmonary embolism more than 3 months after the procedure.

2.4.3 Myocardial necrosis and myocardial infarction were reported in 1 patient each in case series of 207 and 122 patients (varying tumour origin; timing of events not stated).

2.4.4 Acute renal failure was reported in 3% (2/59) (successfully treated by medical therapy) and 1% (1/140) (requiring dialysis in intensive care) of patients in case series of 59 and 140 patients respectively (varying tumour origin). Haemolytic–uraemic syndrome occurred in 1 patient in the case series of 122 patients.

2.4.5 The Specialist Advisers listed possible adverse events as bowel obstruction, bleeding, abdominal pain, eating disturbances, vascular, ureteric and bile duct injury, liver dysfunction and failure, neuropathy and anaphylaxis.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed audit support (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 116.

This guidance has been incorporated into the NICE pathway on colorectal cancer, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

5 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation