

Cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg688

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.

This guidance replaces IPG331.

1 Recommendations

- 1.1 Evidence on the safety of cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis shows frequent and serious but well-recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website.
- 1.2 Clinicians wishing to do cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered

into [NICE's interventional procedures outcomes audit tool](#) (for use at local discretion).

- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by an experienced multidisciplinary team.

1.5 The procedure should only be done in highly specialised centres by clinicians with specialist expertise and specific training in cytoreduction surgery and hyperthermic intraoperative peritoneal chemotherapy.

1.6 NICE encourages further research in the form of randomised controlled trials. These should clearly describe the patient selection criteria, the types of cancer being treated and the chemotherapy regimens used. Outcomes should include survival, reduction in tumour burden and quality of life.

1.7 NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Peritoneal carcinomatosis is an advanced form of cancer resulting from the regional spread of gastrointestinal, gynaecological and other malignancies. It is associated with short survival and poor quality of life. It may lead to bowel obstruction, ascites and pain.

Current treatments

- 2.2 Current standard management includes treating complications such as bowel obstruction using systemic chemotherapy (alone or with surgery), closed peritoneal instillation of chemotherapy or surgery alone.

The procedure

- 2.3 Cytoreduction surgery is done to remove all macroscopic tumours within the abdominal cavity. Hyperthermic intraoperative peritoneal chemotherapy is then used to distribute a chemotherapeutic drug uniformly to all surfaces within the abdominal cavity and to increase drug penetration. This is done to treat any remaining microscopic traces of the cancer. The aim is to reduce symptoms, extend survival and improve quality of life.
- 2.4 Using general anaesthesia, a laparotomy is done and all macroscopic tumour is removed, with resection of involved organs and stripping of the tumour from the surface of some organs and peritoneum. The surgery is extensive and complex. It is followed by perfusion of the abdominal cavity with a heated (between 40 and 48°degrees Celsius) chemotherapy solution for 30 to 120 minutes, with the abdomen open or closed. The fluid is drained from the abdominal cavity before closure. A further course of systemic or early postoperative intraperitoneal chemotherapy may be administered.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 6 meta-analyses, 3 systematic reviews and 1 randomised controlled trial. It is presented in the [summary of key evidence section in the](#)

interventional procedures overview. Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: progression-free survival, disease-free survival, recurrence-free survival, overall survival and improvement in quality of life (physical and emotional).
- 3.3 The professional experts and the committee considered the key safety outcomes to be: postoperative haemorrhage, perioperative mortality, anastomotic leaks, sepsis, pain, stoma rate, readmission to an intensive care unit and the need for further surgery.
- 3.4 Two commentaries from patients who have had this procedure were discussed by the committee.

Committee comments

- 3.5 This procedure is unlikely to be curative and may be offered to patients for whom cure is not the intention. Therefore, it is important that patients are clearly informed that the procedure is associated with significant periprocedural morbidity including prolonged treatment in an intensive care unit and long-term postoperative recovery.
- 3.6 The resectability of the tumours is important in determining the outcome, but criteria for this have not been clearly established.
- 3.7 Hyperthermic intraoperative peritoneal chemotherapy has no standardised protocol, and protocols are continuing to evolve. Variations in the drug regimens include temperature, dose, duration of infusion time, and whether a drug is used on its own or in combination with other drugs.
- 3.8 There have been large improvements in survival and quality of life for patients with metastatic cancer in recent years because of advances in systemic chemotherapy. This made it difficult to assess the benefits of hyperthermic intraoperative peritoneal chemotherapy.

3.9 The outcomes are different depending on the type of tumour being treated.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).