

Complete cytoreduction and heated intraoperative intraperitoneal chemotherapy (Sugarbaker technique) for peritoneal carcinomatosis

1 Guidance

- 1.1 Current evidence on the safety and efficacy of complete cytoreduction and heated intraoperative intraperitoneal chemotherapy (the Sugarbaker technique) for peritoneal carcinomatosis does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake complete cytoreduction and heated intraoperative intraperitoneal chemotherapy for peritoneal carcinomatosis should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure 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 quality of life and clinical outcomes of all patients with peritoneal carcinomatosis who have complete cytoreduction and heated intraoperative intraperitoneal chemotherapy.
- 1.3 Patient selection for this procedure is important and should involve a multidisciplinary team. The procedure should be performed by surgical oncology teams experienced in the technique.
- 1.4 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty, and clinicians are encouraged to collect quality of life as well as survival data. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer that may lead to bowel obstruction, ascites and pain. It is associated with short survival and poor quality of life.
- 2.1.2 There is no curative treatment. Systemic chemotherapy and/or surgery are currently the standard options for the short-term palliation of complications such as bowel obstruction.

2.2 Outline of the procedure

- 2.2.1 The procedure combines complete surgical tumour removal (complete cytoreduction) with intraoperative heated chemotherapy, and is followed by postoperative intraperitoneal chemotherapy. The operation takes around 10 hours and involves:
 - removal of the right hemicolon, spleen, gallbladder, greater omentum and lesser omentum
 - stripping of the peritoneum from the pelvis and diaphragm
 - stripping of the tumour from the surface of the liver
 - removal of the uterus and ovaries in women
 - removal of the rectum in some cases.

Interventional Procedure Guidance 116

This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

2.3 Efficacy

- 2.3.1 In one randomised controlled trial of 105 patients, 54 patients treated with this procedure had a significantly longer median survival than 51 patients treated with systemic chemotherapy with or without surgery (22.4 months compared with 12.6 months respectively; $p = 0.03$). Survival was lower among patients with extensive residual disease after surgery, 30% (3/10) compared with 94% (17/18) in those with complete resection. In one non-randomised controlled study, 48 patients treated with surgery and intraoperative heated chemotherapy had a significantly better survival rate (25% at 8 years) than 18 control patients treated with surgery and chemotherapy (0% at 16 months; $p < 0.01$). In a retrospective, non-randomised controlled trial, there was no significant difference in survival between 27 patients treated with this procedure and 37 patients treated with surgery and unheated intraperitoneal chemotherapy at 5-year follow-up.
- 2.3.2 The reported survival based on a case series of 109 patients varied according to the site of the primary cancer. Patients with peritoneal carcinomatosis arising from stomach cancer had a median survival of 10 months after the procedure, compared with 63 months for patients with their appendix as the primary site. Overall survival at 1 year was 61%. Overall 5-year survival following the procedure was reported in three studies: it ranged from 16% ($n = 49$) to 31% ($n = 48$). The stomach was the primary site of cancer in the studies with the highest and lowest 5-year results. For more details, refer to the Sources of evidence.
- 2.3.3 The Specialist Advisors noted that the published efficacy results apply to a highly selected group of patients, and only a small proportion of patients with carcinomatosis may be suitable for the procedure.

2.4 Safety

- 2.4.1 The postoperative mortality rate ranged from 4% (2/49) to 12% (9/77). The most commonly reported specific complication was gastrointestinal fistula, affecting between 4% (2/49) and 18% (5/27) of patients. Other complications included leukopenia

(17%; 8/48), haemorrhage (12.5%; 6/48), heart failure (12.5%; 6/48), pulmonary embolism (4%; 2/48) and pleural effusion (2%; 1/48). Four studies reported haematological complications, with 7% (2/27) to 21% (23/109) of patients being affected. For more details, refer to the Sources of evidence.

- 2.4.2 The Specialist Advisors noted the potential for serious morbidity associated with this major surgery, including infection, perforation of viscera, and respiratory and cardiac complications.

2.5 Other comments

- 2.5.1 It was noted that the site and nature of the primary tumour influence the outcome of the procedure.

3 Further information

- 3.1 The Institute has issued guidance on complete cytoreduction for pseudomyxoma peritonei (Sugarbaker technique), www.nice.org.uk/IPG056guidance

Andrew Dillon
Chief Executive
March 2005

Information for the public

NICE 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/IPG116publicinfo.

Sources of evidence

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

Interventional procedure overview of complete cytoreduction and heated intraoperative intraperitoneal chemotherapy (Sugarbaker technique) for peritoneal carcinomatosis, July 2004.

Available from: www.nice.org.uk/ip256overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0842. *Information for the public* can be obtained by quoting reference number N0843 for the English version and N0844 for a version in English and Welsh.

The distribution list for this guidance is available at www.nice.org.uk/IPG116distributionlist

Published by the National Institute for Clinical Excellence, March 2005 ISBN: 1-84257-908-8

© National Institute for Clinical Excellence, March 2005. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the National Institute for Clinical Excellence.

National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

N0842 1P 20k Mar 05 (ABA)