NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis

Peritoneal carcinomatosis is cancer that has spread inside the peritoneal cavity (the space between the 2 membranes that separate the organs in the abdomen from the abdominal wall). It can happen with cancers in the pelvis, such as ovarian cancer, or in the abdomen, such as bowel cancer, and occasionally with cancers elsewhere in the body. In this procedure, chemotherapy is sprayed inside the peritoneal cavity through a small tube inserted into the abdomen for several minutes. The aim is to apply the chemotherapy directly to the cancer.

NICE is looking at pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

Issue date: July 2019

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 August 2019

Target date for publication of guidance: November 2019

1 Draft recommendations

1.1 Evidence on the safety of pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis shows well-recognised, serious side effects. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

1.2 Further research should report details of patient selection, including type of tumour and quality-of-life outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer associated with short survival and poor quality of life. It may lead to bowel obstruction, fluid build-up in the peritoneal cavity and pain.

Current treatments

2.2 There is no curative treatment. Current standard treatment uses systemic chemotherapy or surgery for short-term palliation of complications such as bowel obstruction.

The procedure

2.3 Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis is a laparoscopic procedure usually done under general anaesthesia. The aim is to distribute the drug uniformly to all surfaces of the abdomen and pelvis.

2.4 Trocars are inserted and the abdomen insufflated with carbon dioxide. Peritoneal biopsies or local partial peritonectomy may be done at this time. The chemotherapy is delivered using an aerosol device containing normothermic chemotherapy solution. This device is connected to a high-pressure injector, which is inserted into the abdomen through an access port. For operator safety, the procedure takes place in an operating room with laminar air flow. Once in position, the device is operated remotely. A laparoscopic camera can be used to visualise the treatment. The chemotherapy is kept in the insufflated peritoneum for about 30 minutes. The chemotherapy aerosol is then exsufflated via a closed extraction system. Trocars are removed and laparoscopy completed. The procedure is usually repeated several weeks later. One standard course of treatment comprises 3 procedures, usually given 6 weeks apart, although the timing can vary.

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

5 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 2 case series and 1 case report. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improved quality of life and prolonged survival.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: peritoneal sclerosis, bowel damage and inadvertent leakage of chemotherapy agents into the environment.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that the intent of the procedure is palliation.

3.6 There is a potential risk that chemotherapy could be dispersed into the environment, which could be a hazard to operating theatre staff.

3.7 The committee noted that the procedure is usually used with intravenous chemotherapy.

3.8 The committee noted that the technology is evolving to include, for example, using electrostatic charge.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
July 2019