NICE guidance

Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg681

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.

1 Recommendations

1.1 Evidence on the safety of pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis shows that this procedure can cause serious but well-recognised side effects. Evidence on its efficacy is inadequate in quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE website.

1.2 Further research should be in the form of randomised controlled trials comparing pressurised intraperitoneal aerosol chemotherapy with standard care. Studies should report details of patient selection including type of tumour, the chemotherapy drugs used, survival 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 that is usually done using 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 using a closed extraction system. The trocars are removed, and the 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 8 sources, which was discussed by the committee. The evidence included 4 systematic

reviews, 3 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 One patient commentary from a patient who had experience of this procedure was received, which was discussed by the committee.

Committee comments

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

3.6 The committee noted that several different chemotherapy drugs have been used in this procedure and that the toxicity profile and efficacy for each of these may be different.

3.7 There is a potential risk that chemotherapy could be dispersed into the operating theatre environment. The committee were informed that this risk has been mitigated with robust safety measures.

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

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation