NICE guidance

Photodynamic therapy for bile duct cancer

Interventional procedures guidance
Published: 27 July 2005

www.nice.org.uk/guidance/ipg134

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 Current evidence on the safety and efficacy of photodynamic therapy (PDT) for bile duct cancer 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 PDT for bile duct cancer should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having PDT for bile duct cancer.

1.3 Publication of safety and efficacy outcomes will be useful. A randomised trial (PHOTOSTENT 2) is in progress and clinicians are encouraged to enter patients in this trial. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Bile duct cancer may prevent bile flowing from the liver to the intestine. Early

cancers are often asymptomatic, but as the disease advances patients may experience symptoms from biliary obstruction, such as jaundice, itchy skin, abdominal discomfort, loss of appetite, loss of weight and fever. PDT is a palliative treatment option for bile duct cancer.

2.1.2 Treatment options depend on the stage, size, position and type of tumour. Bile duct cancer is not usually diagnosed before the symptoms of biliary obstruction occur, by which time the cancer may be too advanced for curative surgical resection. Options for palliative treatment include surgical bypass of the bile duct or the insertion of a stent using surgical, endoscopic or percutaneous techniques. The benefits of other palliative treatments such as radiotherapy, chemotherapy and brachytherapy are still being investigated.

2.2 Outline of the procedure

2.2.1 PDT produces localised tissue necrosis. A photosensitising agent is applied that is absorbed into the tumour tissue. The area is then exposed to laser light of an appropriate wavelength.

2.2.2 PDT is usually administered in conjunction with a biliary stenting procedure. The photosensitising agent is injected intravenously and photoactivation is performed approximately 48 hours later. A laser is inserted through a translucent endoscopic catheter situated close to the tumour, or it is placed directly across the tumour. Radiological control is used to ensure correct positioning of the laser fibre. Patients remain in subdued lighting for about 3 days after injection to avoid skin photosensitivity and are then gradually readapted to light. The treatment can be repeated.

2.3 Efficacy

2.3.1 A randomised controlled study of 39 patients reported that those treated with PDT and biliary stenting had a significantly longer median survival time than patients treated with biliary stenting alone (493 days versus 98 days, $p<0.0001$). This study was terminated prematurely because PDT was so superior to stenting

alone. Several quality-of-life scores were significantly improved after PDT, including global quality of life, fatigue, itching and weight loss. No significant improvements in quality-of-life scores were reported for the patients receiving biliary stenting alone. A non-randomised study of 44 patients reported that the mean survival after PDT and biliary stenting was 16 months, compared with 12.5 months after biliary stenting alone. For more details, refer to the Sources of evidence.

2.3.2 The Specialist Advisors considered that there is not yet enough data to draw clear conclusions about the effect of PDT on survival. One Specialist Advisor stated that this procedure is only effective for tumours that are in visual proximity to the light source.

2.4 Safety

2.4.1 The most common complications were cholangitis, affecting between 15% (3/20) and 56% (13/23) of patients, and photosensitivity, which was reported in 0% (0/8) to 33% (2/6) of patients. Other reported complications included bilioma, cholecystitis, stenosis and haemobilia. For more details, refer to the Sources of evidence.

2.4.2 The Specialist Advisors stated that potential adverse effects of the procedure include cholangitis, photosensitivity, stenosis of the biliary tree, biliary perforation, acute pancreatitis, bleeding and pain.

2.5 Other comments

2.5.1 It was noted that efficacy may depend on the particular photosensitising agent used.

2.5.2 The initial evidence suggests that PDT may be an efficacious palliative technique in patients with bile duct cancer.

3 Further information

Sources of evidence

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

Information for patients

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

ISBN: 978-1-4731-6495-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.