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Photodynamic therapy for bile duct cancer

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG134

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0891 (full guidance)
- N0892 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS. This guidance covers England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called photodynamic therapy for bile duct cancer. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether photodynamic therapy is safe enough and works well enough for it to be used routinely for the treatment of bile duct cancer.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of photodynamic therapy for bile duct cancer and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About photodynamic therapy for bile duct cancer

The bile ducts are tubes that connect the liver and gallbladder to the small intestine. They transport bile, which is made in the liver, stored in the gallbladder and used to help digest fats in the small intestine. If a cancer forms in a bile duct, it can block the flow of bile, and this can cause symptoms such as jaundice (in which the whites of the eyes and eventually the skin can become yellowy), itchy skin, loss of appetite, weight loss, abdominal pain or discomfort, and fever.

The treatment options for bile duct cancer depend on the type of cancer, how advanced it is, how big it is and where it is. If the cancer is advanced or there are other reasons why it can't be removed, the aim of treatment is to make the person feel more comfortable rather than cure them. The new procedure NICE has looked at, called photodynamic therapy, is one of these treatments.

Other treatments include surgery to bypass the blockage in the bile duct or to help to keep the bile duct open.

Photodynamic therapy aims to shrink the blockage so that bile can pass through the bile duct more easily. A couple of days before the procedure, the person has an injection of a special chemical called a photosensitising agent. Over the next 48 hours, this spreads throughout the body. A small laser is put either very close to the cancer or directly across it using special surgical equipment (the doctor uses images of the person's abdomen to make sure the laser is being put into place correctly). The laser is then used to activate the photosensitising agent in the cancer. The activated agent destroys some of the cancer and so shrinks the blockage.

Usually, the person also has a stent put in place. This is a strong tube that's put inside the bile duct to give it support and help it to stay open.

After the person has had the injection, he or she has to stay in subdued lighting for about 3 days because the photosensitising agent may become activated in the skin by normal light.

The procedure can be done more than once if necessary.

How well the procedure works

What the studies said

One study compared people who'd had photodynamic therapy and a stent with people who'd just had the stent (there were 39 people in the study in total). The people who'd had photodynamic therapy lived a significantly longer time after the procedure than those who didn't have it (an average of 493 days compared with 98 days for the people who just had the stent). In general, people who'd had the photodynamic therapy also seemed to feel better after the procedure. Some people said there were improvements in their general quality of life, and in their symptoms of tiredness, itching and/or weight loss. People who just had the stent didn't tend to have these types of improvement. The study was stopped early because the people who had had photodynamic therapy treatment seemed to be doing better than those who had had the stent treatment alone.

In another study, this time with 44 people, the group who had photodynamic therapy and a stent lived for an average of 16 months after the procedure compared with 12 and a half months for the group who just had a stent put in.

What the experts said

The experts didn't think there was enough information from studies to be clear about whether photodynamic therapy helped patients to live longer. One expert said photodynamic therapy only works if the doctor can see that the part of the cancer that's blocking the duct is close to the laser.

Risks and possible problems with the procedure

What the studies said

The most common problems after having photodynamic therapy were inflammation of the bile duct (which is called cholangitis) and sensitivity to light (photosensitivity). In one study 3 out of 20 people (15%) had inflammation, and 13 out of 23 people (56%) had it in another study. Light sensitivity affected 2 out of 6 people (33%) in one study, but no one in another study.

Other problems affecting people in the studies were:

- bilioma, which is the formation of a bile-filled sac (pouch)
- cholecystitis, which is inflammation of the gallbladder
- stenosis (narrowing of the bile duct) because of the effects of the procedure
- haemobilia, which is bleeding in or through the bile duct.

What the experts said

The experts outlined the possible problems as being cholangitis, photosensitivity, stenosis, damage to the bile duct, inflammation of the pancreas (pancreatitis), bleeding and pain.

What has NICE decided?

NICE has decided that if a doctor wants to carry out photodynamic therapy for bile duct cancer, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

NICE has said that further information on the safety of photodynamic therapy and how well it works will be helpful. It has encouraged doctors to think about taking part in a clinical trial looking at photodynamic therapy for bile duct cancer. NICE may look at this procedure again if more information becomes available.

Other comments from NICE

How well the procedure works may depend on which photosensitising agent is used. NICE noted that the early studies suggest that photodynamic therapy may work well for relieving the symptoms of bile duct cancer.

What the decision means for you

Your doctor may have offered you photodynamic therapy for bile duct cancer. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of photodynamic therapy for bile duct cancer which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on photodynamic therapy for bile duct cancer that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on cancer affecting the bile duct on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.



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