NHS
National Institute for Health and Clinical Excellence

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Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions)

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

Information about NICE Interventional Procedure Guidance 155

Ordering information

You can download the following documents from www.nice.org.uk/IPG155

- 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:

- N0981 (full guidance)
- N0982 (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 in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions) – see below for a list of conditions covered by this guidance. 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 (PDT for short) is safe enough and works well enough for it to be used routinely for the treatment of the following non-melanoma skin tumours: basal cell carcinoma, squamous cell carcinoma, Bowen's disease, and actinic (sometimes known as solar) keratosis.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of PDT for non-melanoma skin tumours 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 the procedure

The types of skin tumour that are covered by the NICE guidance are basal cell carcinoma, squamous cell carcinoma, Bowen's disease and actinic (sometimes known as solar) keratosis. Skin tumours happen when the cells that make up the skin start to grow and divide in an uncontrolled way and produce physical changes in the affected area of the skin – this area is also called a lesion. Without treatment, the lesion grows. As a lesion grows, it becomes more difficult to remove it completely, and a large area of skin may need to be removed. Also, certain types of lesion can become cancerous if allowed to develop.

The standard treatments for basal cell carcinoma are scraping off the skin in the lesion, surgically removing the affected skin, destroying the tumour cells in the lesion by applying chemotherapy or radiotherapy to the affected skin, or freezing the area (cryotherapy). Squamous cell carcinoma is usually removed surgically. Scraping off the affected skin, cryotherapy, or applying chemotherapy to the affected skin are the usual treatment options for Bowen's disease and actinic keratosis.

The new treatment NICE has looked at is called photodynamic therapy (or PDT for short) and uses what's known as a photosensitising agent. Before the agent is applied, any 'crust' or scale on top of the lesion is removed. Cream containing the photosensitising agent in an inactive form is then put on the lesion and on a small area of unaffected skin around it. (Occasionally, the photosensitising agent may be injected as a liquid into a blood vessel.) Light with a particular wavelength is then shone on the area, and this activates the photosensitising agent, destroying the tumour cells. More than one lesion can be treated in one session, and the treatment can be repeated.

How well the procedure works

What the studies said

One study compared PDT with surgical removal of the lesion in patients with basal cell carcinoma. The results achieved with the two procedures were similar (with no statistically significant difference between them): the lesion was removed completely in 48 out of 53 patients (91%, which means 91 out of 100) who had PDT and in 51 out of 52 patients (98%) who had their lesion removed surgically. In another study, 11 out of 44 patients (25%) who had PDT had tumour cells detected when the area of the original lesion was checked with a biopsy 1 year later (a biopsy is a sample of the affected area that is checked under a microscope for signs of unusual cells). As a comparison, 6 out of 39 patients (15%) who had the lesion treated with cryotherapy had tumour cells detected when checked with a biopsy 1 year later. The difference between these results was not statistically significant. In both these studies, the area ended up looking better after PDT than after either surgery or cryotherapy.

Two studies compared PDT with cryotherapy in patients with actinic keratosis. In one study, the results for successful removal of the lesion were roughly equal (69% with PDT and 75% with cryotherapy). But in the other study, the PDT results were better than the cryotherapy results (91% compared with 68% – a true difference when analysed with statistical tests). In both these studies, the area tended to look better after PDT than after cryotherapy.

In a study that followed what happened in 59 patients with basal cell carcinoma, 277 out of 350 lesions (79%) were said to be cured when they were checked roughly 3 years after the patient had had PDT.

What the experts said

The experts said that there were some concerns about the likelihood of the tumour returning after PDT. They also said that PDT might be more suitable for people with Bowen's disease, actinic keratosis or basal cell carcinoma where the lesions are large and have not penetrated deeply into the skin, or the person has several lesions and they would otherwise have to have a large area of skin removed surgically.

Risks and possible problems with the procedure

What the studies said

The main problems with PDT in the studies were short-lived skin reactions. The number of patients who had side effects ranged from 44 out of 102 (43%) in one study to 38 out of 42 (90%) in another study. The most common side effect was a burning sensation in the skin – this affected 16 out of 52 patients (31%) in one study and 27 out of 42 patients (64%) in another.

Ulcers are areas where the skin, or tissue beneath the skin, has broken down. Two studies reported how many patients had areas of ulceration after PDT. In one of these studies, none of the 20 patients had ulceration, whereas in the second study, 5 out of 42 patients (12%) had ulceration.

In another study that followed what happened after PDT, there were small changes in skin coloration in the area of 10 out of 483 lesions (2%). Light scarring was also seen in the area of 10 out of 483 lesions (2%) that had been treated with PDT. Other side effects reported in some patients included pain, reddening, crusting, itching, fluid build-up and blisters in the area of the lesion.

What the experts said

The experts said that PDT is generally safe and does not cause major problems. In theory, it could start off cancerous changes in the skin but the risk of this happening is low.

What has NICE decided?

NICE has considered the evidence on PDT for basal cell carcinoma, squamous cell carcinoma, Bowen's disease and actinic keratosis. It has recommended that when doctors use this procedure for people with basal cell carcinoma, Bowen's disease or actinic keratosis, they should be sure that:

- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has said that there is not much information available on how well the procedure works in people with squamous cell carcinoma. There is a relatively high chance that the carcinoma will return after treatment, and there is a risk that the carcinoma will spread and become more dangerous. NICE has said that patients need to understand these risks before they agree to have PDT. They also need to understand that further treatment may be necessary.

Other comments from NICE

The NICE guidance covers the use of PDT for basal cell carcinoma, squamous cell carcinoma, Bowen's disease and actinic keratosis. It does not cover the use of PDT for other benign skin tumours.

A number of different photosensitising agents and treatments are used in PDT, and the results achieved with PDT may depend on the type of skin tumour a person has.

What the decision means for you

Your doctor may have offered you PDT. NICE has considered this procedure because it is relatively new. NICE has decided that for people with basal cell carcinoma, Bowen's disease or actinic keratosis, the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of PDT before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has some concerns about the use of PDT for people with squamous cell carcinoma because the evidence showing how well it works is limited. There is a relatively high chance that the carcinoma will come back after the PDT, and there is a risk that the carcinoma could spread and become more dangerous. Your doctor should discuss these risks with you, and should explain that you might need more treatment some time after PDT if there are signs that the carcinoma has returned.

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 non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions) 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 some of the skin tumours described on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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