Issue date March 2013

Information for the public

National Institute for Health and Clinical Excellence

Treating metastases in the skin from tumours of non-skin origin and melanoma using chemotherapy with electrical pulses

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how chemotherapy with electrical pulses can be used in the NHS to treat people with metastases in the skin from tumours of non-skin origin or melanoma. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This document is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe metastases in the skin or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document includes some questions you may want to

ask your doctor to help you reach a decision. Some sources of further information and support are on page 9.

What has NICE said?

This procedure can be offered routinely as a palliative treatment option for people with metastases in the skin from tumours of non-skin origin or melanoma provided that doctors are sure that:

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

(A palliative treatment aims to relieve the symptoms of a disease rather than curing it.)

An appropriate specialist healthcare team should decide which patients might benefit from the procedure. It should only be done by a clinician with specific training in the procedure.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the InspECT register (www.insp-ect.org). NICE is also asking doctors to check within their local area how well the procedure works.

Other comments from NICE

NICE said that the procedure may reduce symptoms and improve quality of life for people with disease that cannot be treated with, or doesn't respond to, other treatments.

NICE said that the procedure can cause pain and skin ulceration.

Treating metastases in the skin from tumours of non-skin origin and melanoma using electrical pulses with chemotherapy

This procedure may not be the only possible treatment for metastases in the skin. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is ‘electrochemotherapy’.

The procedure is not described in detail here – please talk to your specialist for a full description.

Cancer that starts in one part of the body (primary cancer) can spread (metastasise) and form secondary tumours on or below the skin elsewhere in the body. These skin tumours can cause problems such as bleeding, pain or ulceration.

Electrochemotherapy can be used to treat secondary skin tumours when surgery isn’t suitable, and radiotherapy and chemotherapy haven’t worked. The procedure is carried out with the patient under local or general anaesthesia. An anticancer (chemotherapy) drug is given by injection either into a vein or directly into a tumour. Short, powerful pulses of electricity are then applied to the tumour using either plate (flat) or needle electrodes. The electrical energy opens pores in the cells, allowing the anticancer drug to enter the tumour cells and have a more damaging effect.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS as a palliative treatment. If your doctor thinks it is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used in this way. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?

Summary of possible benefits and risks

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 13 studies on this procedure.

How well does the procedure work?

A study of 19 patients with melanoma metastases found that 13 out of 18 tumours treated with the procedure had a complete response (had disappeared completely) when checked at an average of 21 months after treatment. When compared with chemotherapy treatment alone, electrochemotherapy worked better: 64% of tumours treated with electrochemotherapy had an objective response (which means they either disappeared completely or shrank to less than half their original size) compared with 29% of the tumours treated with chemotherapy alone.

A study of 35 people with breast cancer metastases found a complete response in 54% of patients 2 months after treatment. Another study of 41 patients (with 171 tumours of different kinds) found that at an average of 133 days after the procedure 85% of tumours had an objective response, and 74% of tumours had a complete response.

A study of 52 patients with breast or melanoma metastases found that the smaller the tumour, the better the complete response. There was a complete response in 66% of tumours that were less than 1.5 cm in diameter, but in only 28% of tumours greater than 3 cm.

The same study found that melanoma metastases returned in areas treated with the procedure in 3 out of 34 patients, including 1 patient who had originally had a complete response. In another study of 6 people with breast cancer metastases who were followed up for 26 weeks, the effects of treatment lasted for an average of 10 weeks in

4 out of 12 tumours that had had a complete response, and for an average of 5 weeks in 8 out of 12 tumours that had had a partial response (had originally shrunk to less than half their original size).

In the study of 52 patients, 36 people completed a questionnaire on their quality of life before and after the procedure. Their average score (out of 60 where a higher score means a better quality of life) went up from 46 before the procedure to 55 at 2 months after the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the other main success factors were the number of procedures needed, control of bleeding and reduction of the smell of some tumours.

Risks and possible problems

In a study of 12 patients, 3 reported muscle spasms and twitching while the electric pulses were being given. These stopped as soon as the pulses stopped.

In the study of 19 patients, a reaction occurred in all the treated tumours which made the top layers of skin die and come off. This healed after 16 weeks.

In the study of 52 patients, 4 had a mild rash in the area where the anticancer drug had been injected. All 14 patients in a study had electrode marks and slight skin damage after the procedure, which healed within a month. In the same study, 3 people had redness and swelling that lasted a few days.

In the study of 6 patients, minimal scarring and depigmentation (loss of colour) of the treated area happened after the procedure and was still there when checked 26 weeks later.

Other side effects due to the chemotherapy drug such as slight nausea, short-lasting increase in heart rate and short-lasting breathlessness were also reported in the studies.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the other main safety outcomes are increases in fluid oozing out of the wound after treatment and reactions to the chemotherapy drugs, in particular scarring of the lungs.

More information about cancer

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on cancer, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This document is about 'Electrochemotherapy for metastases in the skin from tumours of non-skin origin and melanoma'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG305

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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ISBN 978-1-4731-8813-6
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