NICE interventional procedures consultation document, August 2023

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer

Non-melanoma skin cancer develops slowly over months or years in the top (epidermal) layers of the skin. In this procedure, a protective foil is placed on the cancer. Then, radioactive paste (rhenium-188 paste) is spread on top of the foil to deliver radiation to the cancer (radiotherapy). The foil and paste are usually left in place for about 30 to 180 minutes. The aim is to destroy the cancer cells, which are slowly replaced with new healthy cells.

NICE is looking at epidermal radiotherapy using rhenium paste for non-melanoma skin cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Issue date: September 2023

NICE interventional procedures consultation document, August 2023

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 26 October 2023

Target date for publication of guidance: February 2024

1 Draft recommendations

1.1 Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should report:

- details of patient selection
- tumour histology
- the site and size of the tumour
- the dose and number of treatments
- the treatment margin around the tumour
- remission status
- patient-reported outcome measures, including cosmetic outcomes
- safety outcomes.

Why the committee made these recommendations

This procedure offers an additional non-surgical option for some people with non-melanoma skin cancer. The evidence shows there are no major safety concerns with this procedure and evidence on efficacy is promising. But, the evidence is limited because most of the studies are retrospective (a retrospective study looks back in time and assesses events that have already occurred), and are small, even though non-melanoma skin cancer is a common condition. Also, the calculation of how much rhenium-188 paste to use and the treatment margin around the tumour to use are not standardised for this procedure. It is also unclear how the procedure compares with other treatments. So, more research is needed.

2 The condition, current treatments and procedure

The condition

2.1 Non-melanoma skin cancer is the most common type of cancer. It affects the cells in the top layers of the skin. The most common types of non-melanoma skin cancer are basal cell carcinoma and squamous cell carcinoma. The main symptom is the appearance of lesions (lumps or discoloured patches) on the skin. The lesions are mostly found on skin that is regularly exposed to the sun.

Current treatments

2.2 Standard care depends on the initial presentation of non-melanoma skin cancer, such as the type, size, and location of the tumour. Surgery is the main treatment. Other treatment options include chemotherapy cream, immunotherapy creams, cryotherapy, brachytherapy, external beam radiotherapy and photodynamic therapy.

The procedure

2.3 The procedure is done without the need for anaesthesia or inpatient admission. It uses a beta-emitter radioisotope, rhenium-188, which can penetrate human tissue up to 3 mm deep. Rhenium-188 is bound to a matrix to form a paste and is applied using a specially designed applicator.

2.4 During the procedure, the area to be treated is protected from direct contact with the paste by a cream or sterile transparent foil. The paste is then applied over the area of the tumour using a safety margin, using a specially designed applicator. The treatment time is typically 30 to 180 minutes, and is calculated based on the target dose of radioactivity and the depth and size of the area to be

treated. The paste dries out during the treatment time and turns into a flexible film. The film is removed when the treatment is over. The dead cancer cells are gradually replaced with new healthy cells.

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 6 sources, which was discussed by the committee. The evidence included approximately 218 people from 1 prospective single arm trial and 5 retrospective case series. It is presented in the summary of key evidence section in the interventional procedures overview. The committee also considered safety data from 1 conference abstract.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: remission status and cosmesis (including the use of validated patient reported outcome measures), recurrence rate and long-term outcomes.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, oedema, redness and scarring.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The procedure should only be done in a unit with Radioactive Substance Advisory Committee approval for the use of radioisotopes, in line with the licence for treatment.

3.6 The procedure can be repeated and multiple lesions can be treated at the same time.

3.7 The committee was informed that the procedure may result in better cosmetic outcomes than surgery and some other treatments.

3.8 The committee was informed that the procedure is only for use in non-melanoma skin cancers up to 3 mm deep and with a maximum surface area of 8 to 9 cm^2. The procedure cannot be used safely on the upper eyelid because of potential damage to the cornea.

3.9 The committee was informed that there are uncertainties around the dose and safety margins used in this procedure and the long-term risk of secondary malignancy.

3.10 The committee was informed that there is an ongoing study that includes a larger sample of people with non-melanoma skin cancer than currently published studies.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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