NICE guidance

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

Interventional procedures guidance
Published: 2 April 2024

www.nice.org.uk/guidance/ipg784

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 More research is needed on epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer.

1.2 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

1.3 More research is needed on:

- 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.

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 7 sources, which was discussed by the committee. The evidence included approximately 240 people from an interim analysis of 1 prospective single-arm trial, 1 prospective single-arm trial, 1 prospective single-arm pilot study and 5 retrospective case series. It is presented in the summary of key evidence section in the interventional procedures overview.

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 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 in the published studies.

ISBN: 978-1-4731-5703-3

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation