

Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma

Interventional procedures guidance

Published: 26 February 2014

www.nice.org.uk/guidance/ipg478

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.

This guidance replaces IPG447.

1 Recommendations

- 1.1 Current evidence on the safety of electrochemotherapy for primary basal cell carcinoma (BCC) and primary squamous cell carcinoma (SCC) raises no major concerns. Evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and local audit, and with submission of data to a register (see recommendation 1.5).
- 1.2 Clinicians wishing to undertake electrochemotherapy for treating primary BCC and primary SCC should take the following actions:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and why it is being offered as an alternative to other established methods of treatment, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 Patient selection should be carried out by a specialist skin cancer multidisciplinary team. Patient selection is particularly important because the cure rates for established treatments in accessible sites are very high. Careful consideration should be given to the reasons for offering electrochemotherapy,

especially in the context of treating primary BCC and SCC with curative intent.

- 1.4 This procedure should only be carried out by clinicians with specific training in the technique.
- 1.5 Clinicians should submit data on all patients undergoing electrochemotherapy (including details of case selection, methods of follow-up and outcomes) to the [InspECT register](#), an international register dedicated to electrochemotherapy, and review clinical outcomes locally. Entry into research trials should also be considered, with a view to providing data about cure and about recurrence rates, compared with other forms of treatment.

2 Indications and current treatments

- 2.1 Basal cell carcinoma (BCC) is the most common type of skin cancer in the UK. It is generally a slow-growing, locally invasive epidermal skin tumour that rarely spreads to other parts of the body. Although it is not usually life-threatening, the tumour can cause extensive tissue destruction if it is not treated. Squamous cell carcinoma (SCC) is the second most common type of skin cancer in the UK. It may spread into local lymph nodes and metastasise to other parts of the body.
- 2.2 Current treatments for BCC and SCC include surgical excision and radiotherapy, and less commonly curettage, cryotherapy and chemotherapy.

3 The procedure

- 3.1 Electrochemotherapy is a local treatment that aims to enhance the effects of chemotherapy.
- 3.2 The procedure is performed with the patient under general or local anaesthesia with or without sedation. Chemotherapy drugs are given first, either intravenously or directly into the tumour. Drug dose is individualised based on either body surface area or tumour volume. Shortly after drug administration, brief and intense electric pulses are delivered around or directly into the tumour using

either surface plates or needle electrodes. This makes the cell membranes more permeable to the chemotherapy drugs so that their cytotoxic effect is increased. Different-shaped plates or electrodes are used depending on the tumour size, extent, shape and location. Treatment duration may vary depending on the number and size of tumours. Larger tumours may need several applications to cover the entire surface. Repeated treatments can be performed if necessary (within the lifetime dose limits of the chemotherapy drugs).

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 4.1 A non-randomised comparative study of 113 patients (85 basal cell carcinoma [BCC] and 28 squamous cell carcinoma [SCC]) compared 2 different electric pulse sequences for electrochemotherapy of stage I (T1N0M0) BCC and SCC tumours. The complete response rate was 83% at 12 months.
- 4.2 A non-randomised comparative study of 34 patients comparing electrochemotherapy against either intratumoural bleomycin alone or electric pulse therapy included 21 patients with BCC or SCC (66 tumours). The study reported an objective response rate of 100% and a complete response of 94% (51 out of 54) in BCC primary tumours treated with electrochemotherapy at 12 weeks. The 1 SCC tumour treated with electrochemotherapy had a partial response. There were no complete responses in the 11 BCC tumours treated with either intratumoural bleomycin alone (8 tumours) or electric pulse therapy alone (3 tumours).
- 4.3 The study of 113 patients (85 BCC and 28 SCC tumours) with an initial 100% complete response reported that 14% (16 out of 113) of tumours recurred between 2 and 6 months after treatment (no further details reported).
- 4.4 A case series of 6 patients (3 BCC and 3 SCC tumours) reported no damage to nerve or ocular function after electrochemotherapy in 4 patients with tumours close to the facial nerve or eye muscles.

- 4.5 The case series of 6 patients (3 BCC and 3 SCC tumours) reported a 'very satisfactory' cosmetic outcome at between 6 and 12 months after electrochemotherapy (no further details reported).
- 4.6 The specialist advisers listed additional key efficacy outcomes as quality of life, control of bleeding and reduction of odour from fungating tumours.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 5.1 Localised involuntary muscle contractions and a sensation of a jolt or shock associated with the electric pulses were reported in the study of 34 patients and 3 case series of 50, 24 and 15 patients. They stopped immediately when the electric pulses were discontinued.
- 5.2 A septal cartilage perforation was reported in 1 patient receiving treatment in the right nasal vestibule in the case series of 6 patients. This occurred after a biopsy performed 8 weeks after treatment. No further details were reported.
- 5.3 Slight burning of the skin was reported in 87% (7 out of 8) of patients on whom the plate electrodes were used in the study of 34 patients. This healed within 6 to 8 weeks. No further details were reported.
- 5.4 Erythema and oedema 72 hours after treatment were reported in the case series of 24 patients. No further details were reported.
- 5.5 Increased tear production in the ipsilateral eye was reported in 2 patients who received treatment for tumours in the medial canthus in the case series of 6 patients. This caused no visual impairment and resolved within 2 months. No further details were reported.
- 5.6 Post-treatment pain was described as 'moderate' and was managed with paracetamol and diclofenac for 5 to 7 days in the case series of 6 patients.

- 5.7 Other side effects attributed to the chemotherapy agent such as slight nausea and allergic reactions were also reported.
- 5.8 The specialist advisers listed additional key safety outcomes as increase in wound exudate after the procedure and chemotherapy toxicity, specifically pulmonary fibrosis as a result of chemotherapy (bleomycin).

6 Committee comments

- 6.1 The Committee was advised that there are well-established methods for treating basal and squamous cell cancers of the skin with curative intent. It noted that this procedure may be useful in managing inaccessible or otherwise difficult-to-treat primary basal cell carcinomas and squamous cell carcinomas in carefully selected patients.
- 6.2 The Committee noted that patients may experience pain and ulceration after treatment.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-0430-3

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).