

Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma

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NICE has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'. More information on accreditation can be viewed at www.nice.org.uk/accreditation



1 Guidance

- 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 audit or research. Patient selection is particularly important.
- 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 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. 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 a clinician 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.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 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.
- 2.1.2 Current treatments for BCC and SCC include surgical excision and radiotherapy, and less commonly curettage, cryotherapy and chemotherapy.

2.2 Outline of the procedure

- 2.2.1 Electrochemotherapy is a local treatment that aims to enhance the effects of chemotherapy and can be performed as an outpatient procedure.
- 2.2.2 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).

Sections 2.3 and 2.4 describe efficacy and 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](#).

2.3 Efficacy

- 2.3.1 A non-randomised comparative study of 113 patients (85 BCC and 28 SCC) compared 2 different electric pulse sequences for electrochemotherapy of stage I (T1N0M0) BCC and SCC tumours. The complete response rate was 100% initially (not otherwise defined) and 83% at 12 months.
- 2.3.2 A non-randomised comparative study of 34 patients comparing electrochemotherapy with intratumoural bleomycin 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% (51/54) 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).
- 2.3.3 The study of 113 patients (85 BCC and 28 SCC tumours) with an initial 100% complete response reported that 14% (16/113) of tumours recurred between 2 and 6 months after treatment (no further details reported).
- 2.3.4 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.
- 2.3.5 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).
- 2.3.6 The Specialist Advisers listed additional key efficacy outcomes as quality of life, control of bleeding and reduction of odour from fungating tumours.

2.4 Safety

- 2.4.1 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.
- 2.4.2 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.
- 2.4.3 Slight burning of the skin was reported in 87% (7/8) of patients on whom the plate electrodes were used in the study of 34 patients. This healed within 6–8 weeks. No further details were reported.
- 2.4.4 Erythema and oedema 72 hours after treatment were reported in the case series of 24 patients. No further details were reported.
- 2.4.5 Superficial leukonecrosis in large tumours in which the skin was altered before electrochemotherapy was reported in the case series of 50 patients. No further details were reported.
- 2.4.6 Increased tear production was reported in 2 patients who received treatment 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.
- 2.4.7 Post-treatment pain was described as 'moderate' and was managed with paracetamol and diclofenac for 5–7 days in the case series of 6 patients.
- 2.4.8 Other side effects attributed to the chemotherapy agent such as slight nausea and allergic reactions were also reported.
- 2.4.9 The Specialist Advisers listed additional key safety outcomes as increase in wound exudate after the procedure and chemotherapy toxicity, specifically pulmonary fibrosis.

2.5 Other comments

- 2.5.1 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 the management of carefully selected patients who have inaccessible or otherwise difficult-to-treat primary BCCs and SCCs.
- 2.5.2 The Committee noted that patients may experience pain and ulceration following treatment.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), which will be available when the guidance is published.
- 3.2 For related NICE guidance see [the NICE website](#).

Information for patients

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

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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