NICE guidance

Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions)

Interventional procedures guidance
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nice.org.uk/guidance/ipg155

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. However, 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.

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.

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 Guidance

1.1 Current evidence suggests that there are no major safety concerns associated with photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions).

1.2 Evidence of efficacy of this procedure for the treatment of basal cell carcinoma, Bowen's disease and actinic (solar) keratosis is adequate to support its use for these conditions, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.3 Evidence is limited on the efficacy of this procedure for the treatment of invasive squamous cell carcinoma. Recurrence rates are high and there is a risk of metastasis. Clinicians should ensure that patients understand these risks and that retreatment may be necessary. In addition, use of the Institute's information for the public is recommended.

2 The procedure

2.1 Indications

2.1.1 Non-melanoma skin tumours include basal cell carcinoma, squamous cell carcinoma, Bowen's disease and actinic (or solar) keratosis.

2.1.2 Basal cell carcinoma is the most common form of skin cancer. It is generally a slow-growing, locally invasive epidermal skin tumour that rarely spreads to other distant parts of the body. Although it is not usually life threatening, the tumour can cause extensive tissue destruction if it is not treated adequately. Squamous cell carcinoma is the second most common type of skin cancer in the UK. It arises from cells in the epidermis and spreads into the surrounding skin. It can also spread to nearby lymph nodes and may be life threatening in rare cases. Bowen's disease is an early form of non-melanoma skin cancer. If untreated, it can progress to invasive squamous cell carcinoma. Actinic keratoses are small lumps of hard skin that are usually harmless but have the potential to develop into squamous cell carcinoma.

2.1.3 Current treatments for basal cell carcinoma include topical chemotherapy, curettage, surgical excision, cryotherapy and radiotherapy. Squamous cell carcinoma is usually removed surgically. Bowen's disease and actinic keratoses are usually treated with curettage, cryotherapy or topical chemotherapy.

2.2 Outline of the procedure

2.2.1 In photodynamic therapy (PDT), the lesion is prepared by removing overlying crust and scale. A photosensitising agent is applied to the lesion and a margin of surrounding skin. The lesion is illuminated by light of an appropriate wavelength to activate the photosensitiser, producing targeted tumour destruction. Occasionally, the photosensitising agent may be given intravenously. More than one lesion may be treated in a session and the treatment can be repeated.

2.3 Efficacy

2.3.1 One randomised controlled trial (RCT) of patients with basal cell carcinoma reported that there was no statistically significant difference in lesion clearance between PDT and surgery (91% [48/53] and 98% [51/52] of patients, respectively). Another RCT reported that 25% (11/44) of patients had a positive biopsy at 12 months after PDT compared with 15% (6/39) of patients after cryotherapy ($p > 0.05$). Both of these studies reported statistically significantly better cosmetic outcomes after PDT than after the comparator.

2.3.2 Two RCTs compared PDT and cryotherapy in patients with actinic keratosis. One reported a similar lesion clearance rate for PDT and cryotherapy (69% [252/367] and 75% [250/332], respectively) whereas the other reported a clearance rate of 91% (267/295) for lesions treated with PDT at 3 months, compared with 68% (278/407) of lesions treated with cryotherapy ($p < 0.001$). Both studies reported that cosmetic outcomes were good or excellent in a significantly higher proportion of patients after PDT.

2.3.3 A case series of 59 patients with basal cell carcinoma reported that the overall cure rate was 79% (277/350) of lesions after a mean follow-up of 35 months. For more details refer to the Sources of evidence.

2.3.4 The Specialist Advisors stated that there were some concerns about recurrence rates and that the treatment may be more appropriate for large, superficial lesions of Bowen's disease, actinic keratosis and basal cell carcinoma, especially where there are multiple lesions and where repair would otherwise require extensive surgery.

2.4 Safety

2.4.1 Adverse events were mainly transient local reactions. Three studies reported that the total rate of adverse events ranged from 43% (44/102) to 90% (38/42) of patients. The most common complication was a burning sensation of the skin, and this affected between 31% (16/52) and 64% (27/42) of patients. Two studies reported ulceration rates of 0% (0/20) and 12% (5/42), respectively. One large case series reported minor pigmentary changes and superficial scarring each in 2% (10/483) of lesions. Other adverse events included pain, erythema, crusting, itching, oedema and blisters. For more details refer to the sources of evidence.

2.4.2 The Specialist Advisors stated that the procedure is generally safe and well tolerated. It is theoretically possible that the treatment could induce carcinogenicity but this is likely to be a low risk.

2.5 Other comments

2.5.1 It was noted that there is a large variety of benign skin tumours and the guidance refers only to those mentioned in section 2.1.1.

2.5.2 It was noted that a variety of agents and treatments are used.

2.5.3 It was also noted that results may vary depending on the conditions being treated, and that a Cochrane review is being developed on photodynamic therapy for localised squamous cell carcinoma of the skin and its precursors.

Andrew Dillon
Chief Executive
February 2006

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions', April 2005.

Information for patients

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

4 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 procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

20 January 2012: minor maintenance.

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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 avoid unlawful discrimination and to have

regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.