

Extracorporeal shockwave therapy for Peyronie's disease

Interventional procedures guidance

Published: 17 December 2003

www.nice.org.uk/guidance/ipg29

1 Guidance

- 1.1 Current evidence on the safety of extracorporeal shockwave therapy (ESWT) for Peyronie's disease appears adequate. However, the evidence on the efficacy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake ESWT for Peyronie's disease should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its efficacy and should provide them with clear written information. Use of the Institute's [information for the public](#) is recommended. Clinicians should ensure appropriate arrangements are in place for audit or research. Publication of efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

2 The procedure

2.1 Indications

- 2.1.1 Peyronie's disease is a localised connective tissue disorder of unknown cause. It is characterised by the formation of inelastic fibrous plaques within the erectile tissue of the penis. The hardened plaque reduces flexibility, causing pain and causing the penis to bend or arc during erection.
- 2.1.2 For many patients, Peyronie's disease results in sexual problems because there is difficulty in attaining and/or maintaining erections.
- 2.1.3 Treatment options for Peyronie's disease include pharmacological interventions, radiation and surgery. They are designed to alleviate the symptoms rather than to cure the disease. A number of surgical techniques have been developed for patients with more severe symptoms and for patients who have been refractory to conservative treatment.

2.2 Outline of the procedure

- 2.2.1 The procedure involves the use of shockwave lithotripsy technology. Extracorporeal shockwaves are high-pressure, low-frequency sound waves, generated by a device outside the body and applied to the affected tissue in a site-specific manner. In Peyronie's disease, the penile plaque is the target of the shockwaves, and it is generally localised using an ultrasound scanner. The procedure can be performed with or without sedation.

2.3 Efficacy

- 2.3.1 From comparative studies, the main benefits of ESWT were the alleviation of pain and reduction of angulation of the penis. In one comparative study, 50% of patients (10/20) receiving ESWT experienced a decrease in curvature of at least 30%. Case series evidence also

suggested some improvement of sexual performance. For more details refer to the sources of evidence section.

- 2.3.2 The Specialist Advisors commented on the difficulty of evaluating efficacy, given the lack of controlled data and agreement regarding relevant endpoints. The Advisors also noted that placebo response, inter-patient variability, and the natural history of the disease were potential problems when evaluating the evidence.

2.4 Safety

- 2.4.1 In the studies identified, relatively few complications were reported. Complications were mostly of a transient nature and included urethral bleeding, bruising, skin discoloration due to petechiae, and haematoma. The relationship between the energy level used in the treatment and the reported complications is unclear. For more details refer to the sources of evidence section.
- 2.4.2 The Specialist Advisors did not note any particular safety concerns about this procedure. Superficial bruising and moderate local pain were noted as potential adverse events.

2.5 Other comments

- 2.5.1 Good comparative data would be useful in establishing the efficacy of this procedure.

Andrew Dillon
Chief Executive
December 2003

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 extracorporeal shockwave therapy for Peyronie's disease', March 2002.

Information for patients

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

4 Changes since publication

As part of NICE's work programme, the current guidance was considered for review but did not meet the review criteria as set out in the IP process guide. This guidance therefore remains current.

30 January 2012: minor maintenance.

5 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.

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 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](#).