

Extracorporeal shockwave therapy for Peyronie's disease

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.

2.1.2 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 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.

2.3 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 below.

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This guidance is written in the following context:

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

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 below.

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

Information for the Public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG029publicinfoenglish and in English and Welsh from www.nice.org.uk/IPG029publicinfowelsh.

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

Available from: www.nice.org.uk/IP182overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0388. *Information for the Public* can be obtained by quoting reference number N0389 for the English version and N0390 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG029distributionlist

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