NICE guidance

Extracorporeal shockwave therapy for Peyronie's disease

Interventional procedures guidance
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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.

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 NICE'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 extracorporeal shockwave therapy (ESWT) were the alleviation of pain and reduction of angulation of the penis. In 1 comparative study, 50% of patients (10 out of 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, see the overview.

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, see the overview.

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.

3 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.