NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

High-intensity focused ultrasound for glaucoma

Glaucoma is usually caused by an increase in the pressure of the fluid that fills the inside of the eye. This damages the nerve that connects the eye to the brain (optic nerve) and can gradually lead to permanent loss of sight.

In this procedure, a device uses high-intensity focused ultrasound to destroy a small amount of the tissue that produces the fluid. The aim is to reduce the amount of fluid released into the eyeball, to reduce the pressure. Reduced eye pressure may slow or stop further damage to vision.

NICE is looking at high-intensity focused ultrasound for glaucoma.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 June 2019

Target date for publication of guidance: September 2019

1 Draft recommendations

1.1 Evidence on the safety and efficacy of high-intensity focused ultrasound for glaucoma is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

1.2 Research should ideally take the form of randomised controlled trials comparing this procedure with standard therapies and should report safety events and long-term outcomes.

1.3 NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Glaucoma is usually a chronic condition associated with elevated intraocular pressure. The most common type of glaucoma in the UK is primary open-angle glaucoma, also known as chronic open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness.

Current treatments

2.2 NICE's guideline on glaucoma describes its diagnosis and management. Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

The procedure

2.3 This procedure uses high-intensity focused ultrasound (HIFU) to partially destroy the ciliary body to reduce the production of aqueous humor (fluid) and thereby decrease the intraocular pressure.

2.4 The procedure can be done under regional, general or topical anaesthesia. One device available for this procedure consists of a compact operator console and a disposable probe (which includes a coupling cone and a therapy probe that generates the ultrasound beams). The coupling cone is placed directly on the centre of the patient's cornea and held in place by a low-vacuum suction ring. A ring-shaped therapy probe (connected to the console) that generates ultrasound beams is inserted into the cone. The space between the eye, cone and the probe is filled with saline solution to ensure dissemination of ultrasound energy. By pressing the foot switch, miniature transducers in the ring-shaped probe are sequentially activated to deliver HIFU beams directly into the ciliary body. These beams pass through the scleral tissue without disruption of ocular tissue to reach the ciliary body. The ultrasound heats and inactivates tissue within the ciliary body to decrease the production of aqueous humor.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 1 meta-analysis and 6 case series (2 of which were also included in the meta-analysis). It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in intraocular pressure, reduced use of medication and preservation of visual fields, in the long-term.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: hypotony, pain and macular oedema.

Committee comments

3.4 The committee noted that the technology is evolving.

3.5 The committee noted that in the context of such a common condition, there was a lack of controlled studies of sufficient statistical power, and this underpinned their recommendation for further research.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
May 2019

ISBN: