Primary open-angle glaucoma is a progressive condition that causes long-term increase of pressure within the eye. This damages the nerve that connects the eye to the brain (optic nerve) and may gradually lead to permanent loss of sight. In this procedure a tiny tube (stent) is inserted just below the surface of the eye, to create a drainage channel for excess fluid. The procedure is usually done during surgery for cataracts. The aim is to reduce pressure in the eye.

The National Institute for Health and Care Excellence (NICE) is looking at ab interno supraciliary microstent insertion with phacoemulsification for primary open-angle glaucoma. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE’s guidance on using the procedure in the NHS.
Draft recommendations

1.1 The evidence on ab interno supraciliary microstent insertion with phacoemulsification for primary open-angle glaucoma shows no major safety concerns. Current evidence on the safety and efficacy of the procedure is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 The procedure should only be done by clinicians with experience of intraoperative gonioscopy and with specific training in the procedure.
2 The condition, current treatments and procedure

The condition

2.1 Open-angle glaucoma is a chronic condition associated with elevated intraocular pressure. 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 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 Ab interno supraciliary microstent insertion for primary open-angle glaucoma aims to increase outflow using the suprachoroidal space, without manipulateing the conjunctiva and sclera or creating a filtering bleb. It is usually done at the same time as phacoemulsification cataract surgery.

2.4 Using local anaesthesia, a small incision is made in the cornea. For the phacoemulsification, a small probe that emits ultrasound waves is inserted into the eye to break the lens into pieces. The pieces are removed and a small plastic lens is inserted. For the supraciliary microstent insertion, the anterior chamber of the eye is deepened using viscoelastic. Intraoperative gonioscopy is used to visualise
angle structures. A tiny stent is put into the supraciliary space, between the ciliary body and the sclera.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 4 case series, and is presented in table 2 of the interventional procedure overview. Other relevant literature is in appendix A of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in intraoperative pressure that persists long-term, reduction in glaucoma medications, and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: hypotony and loss of vision.

Committee comments

3.4 The committee noted that the evidence they reviewed was based on a single device.

3.5 The committee noted that the procedure can be done without concomitant cataract surgery, but this guidance only covers the use of this procedure with phacoemulsification.
Tom Clutton-Brock
Chairman, interventional procedures advisory committee
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