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NHS
National Institute for Health and Clinical Excellence

Trabecular stent bypass microsurgery for open angle glaucoma

1 Guidance

1.1 Current evidence on trabecular stent bypass microsurgery for open angle glaucoma raises no major safety concerns. There is evidence of efficacy in the short term but this is based on small numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake trabecular stent bypass microsurgery for open angle glaucoma should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from **www.nice.org.uk/guidance/IPG396/publicinfo**).
- Audit and review clinical outcomes of all patients having trabecular stent bypass microsurgery for open angle glaucoma (see section 3.1).

1.3 Trabecular stent bypass microsurgery for open angle glaucoma should only be carried out by clinicians with specific training in the procedure.

1.4 NICE encourages the publication of further evidence on long-term efficacy and any occurrence of device extrusion.

2 The procedure

2.1 Indications and current treatments

2.1.1 Open angle glaucoma is a chronic condition associated with elevated intraocular pressure (IOP). Early stages are usually asymptomatic but as the condition progresses it leads to visual impairment and, if untreated, blindness.

2.1.2 Treatment usually involves eye drops containing different pharmacological agents that reduce the production or increase the absorption of aqueous humour. Surgical procedures such as trabeculectomy, deep sclerectomy and viscocanalostomy, or laser trabeculoplasty may also be used.

2.2 Outline of the procedure

2.2.1 Trabecular stent bypass microsurgery aims to reduce IOP by creating a bypass channel between the anterior chamber and Schlemm's canal to improve drainage of aqueous humour.

2.2.2 This procedure is often combined with phacoemulsification and intraocular lens insertion for the concomitant treatment of cataracts. With the patient under local anaesthesia, a small corneal incision is made and viscoelastic is inserted into the anterior chamber. Under gonioscopic guidance and using a special applicator, an L-shaped stent is slid through the trabecular meshwork (a small slit may be necessary) and into Schlemm's canal. The position of the stent is verified, the viscoelastic is removed, and the applicator withdrawn.

2.2.3 More than one stent may be inserted during the same procedure.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at **www.nice.org.uk/guidance/IP/854/overview**

Interventional procedure guidance 396

This 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.

This guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by NHS QIS for implementation by NHSScotland.

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2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 240 patients treated by phacoemulsification and trabecular stent bypass microsurgery or by phacoemulsification alone reported normal IOP values of 21 mmHg or less in 72% (84/117) and 50% (61/123) of patients respectively at 1-year follow-up ($p < 0.001$). In the same study, the proportion of patients whose IOP was reduced by more than 20% was higher following the combined procedure than following phacoemulsification alone (66% [77/117)] vs 48% [59/123]; $p < 0.003$) at 1-year follow-up.

2.3.2 The RCT of 240 patients treated by phacoemulsification and trabecular stent bypass microsurgery or by phacoemulsification alone reported that 15% and 35% of patients respectively required glaucoma medication at 1-year follow-up ($p = 0.001$) (number of patients not stated).

2.3.3 An RCT of 36 patients treated by phacoemulsification and trabecular stent bypass microsurgery or by phacoemulsification alone reported that glaucoma medication was not required in 67% (8/12) and 24% (5/12) of patients respectively at 15-month follow-up ($p = 0.027$).

2.3.4 The Specialist Advisers considered the key efficacy outcome to be long-term IOP reduction.

2.4 Safety

2.4.1 The RCT of 240 patients reported that of the 117 patients undergoing phacoemulsification and trabecular stent bypass microsurgery, incorrect placement of the stent into the anterior chamber and stent malpositioning occurred in 1 patient each (both required a second stent insertion). Stent malpositioning (not requiring surgery) was reported in 17% (2/12) of patients treated by phacoemulsification and trabecular stent bypass microsurgery in the RCT of 36 patients. Stent malpositioning that required surgery was reported in 5% (3/58) of patients treated by phacoemulsification and trabecular stent bypass microsurgery in the case series of 58 patients.

2.4.2 Paracentesis for elevated IOP was required in 28% (31/111) of patients following phacoemulsification and trabecular stent bypass microsurgery and in 27% (33/122) following phacoemulsification alone in the RCT of 240 patients at 12-month follow-up.

2.4.3 Visual disturbance (not otherwise described) occurred in 1% (1/111) of patients after phacoemulsification and trabecular stent bypass microsurgery and in 5% (6/122) of patients after phacoemulsification alone at 12-week follow-up in the RCT of 240 patients (significance not stated).

2.4.4 The RCT of 240 patients reported stent obstruction in 4% (4/111) of patients in the phacoemulsification and trabecular stent bypass microsurgery group at 12-month follow-up.

2.4.5 The Specialist Advisers listed anecdotal adverse events as infection, stent blockage and stent displacement into the anterior chamber.

2.5 Other comments

2.5.1 The Committee noted that compliance with glaucoma medication is often poor and that the usual surgical treatment is trabeculectomy. The Committee was advised that efficacious alternatives could therefore be useful for selected patients. Trabecular stent bypass microsurgery may be done at the same time as cataract surgery, enabling cataracts and glaucoma to be treated simultaneously.

2.5.2 The Committee noted concerns about the possibility of stent occlusion or extrusion in the longer term but was advised that these would not preclude further surgical treatment.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), available from **www.nice.org.uk/guidance/IPG396**

3.2 For related NICE guidance see **www.nice.org.uk**

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. See **www.nice.org.uk/guidance/IPG396/publicinfo**

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2549 for this guidance, N2550 for the 'Understanding NICE guidance' or N2551 for the large print version of the 'Understanding NICE guidance'.

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