NICE National Institute for Health and Care Excellence

NICE guidance

Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma

HealthTech guidance
Published: 25 April 2018

www.nice.org.uk/guidance/htg470

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.

Contents

This guidance replaces IPG612.

1 Recommendations

1.1 Evidence on the safety and efficacy of microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear information to support shared decision-making. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma. NICE has identified relevant audit criteria and has developed NICE's interventional procedure outcomes audit tool.

1.3 NICE encourages further research into microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma, including randomised studies. Further research should include details of patient selection and long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Open-angle glaucoma is a chronic condition associated with increased intraocular pressure, which 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, inserting drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

The procedure

2.3 Microinvasive insertion of a trans-scleral gelatin stent via the ab interno approach (placed surgically from the anterior chamber, outwards to the subconjunctival space) for treating open-angle glaucoma is a minimally invasive procedure. It involves implanting a gelatin stent, a collagen-derived drainage device, to reduce intraocular pressure. The collagen is derived from animal sources. The procedure creates an artificial bypass channel and drainage pathway from the anterior chamber into the non-dissected tissue of the subconjunctival space to improve drainage and outflow of aqueous humor.

2.4 This procedure can be done at the same time as phacoemulsification and intraocular lens insertion for treating cataracts.

2.5 Under local or topical anaesthesia, a small incision is made in the cornea, and the anterior chamber is filled with viscoelastic. A preloaded implant injector is then advanced through the same corneal incision and directed towards the scleral spur. The injector needle is directed through the sclera to emerge under the conjunctiva, approximately 2 mm to 3 mm behind the limbus. The soft and permanent gelatin stent is then injected, to traverse the anterior chamber, sclera and conjunctival space. After placement is checked (using a gonioscopy mirror) the viscoelastic is exchanged for a balanced salt solution and the injector is withdrawn. The corneal incision is usually self-sealing but is sometimes sutured. Subconjunctival injection of mitomycin-C may be done during the procedure.

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 11 sources, which was discussed by the committee. The evidence included 1 retrospective comparative case series, 7 case series and 3 case reports, and 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 and reduction in glaucoma specific medication.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: hypotony, loss of visual acuity and infection.

3.4 One commentary was received from a patient who had experience of this procedure, and was discussed by the committee.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 612 has been migrated to HealthTech guidance 470. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-2898-9

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.