

Arteriovenous crossing sheathotomy for branch retinal vein occlusion

This document replaces previous guidance on arteriovenous sheathotomy for branch retinal vein occlusion (interventional procedure guidance 72).

1 Guidance

- 1.1 Current evidence on the efficacy and safety of arteriovenous crossing sheathotomy for branch retinal vein occlusion (BRVO) is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.
- 1.2 Research should take the form of controlled trials and should clearly define patient selection, the timing of treatment in relation to venous occlusion, and details of other treatment modalities used. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Branch retinal vein occlusions typically occur at arteriovenous crossings, where the artery and vein share a common membranous sheath. Degenerative changes can cause hardening of the retinal arteries which can lead to compression of companion retinal veins. This compression obstructs blood flow in the vein, leading to thrombosis, macular oedema and decreased visual acuity.
- 2.1.2 The natural history of BRVO is variable. It is usually managed by observation, and decisions about intervention are based on several factors, including the development of neovascularisation and the persistence of macular oedema and reduced visual acuity. Current treatments include grid laser photocoagulation of the macula, intravitreal injection of triamcinolone or an anti-vascular

endothelial growth factor agent, or surgery in the form of pars plana vitrectomy (surgical removal of the vitreous) without sheathotomy.

2.2 Outline of the procedure

- 2.2.1 Arteriovenous crossing sheathotomy for BRVO involves cutting the sheath surrounding the artery and the vein and separating them at the site where they cross, with the aim of restoring venous drainage.
- 2.2.2 The procedure may be carried out with the patient under general or local anaesthesia. A pars plana vitrectomy is usually performed before identification of the affected arteriovenous crossing and incision of the membranous sheath. A blade is used to separate adhesions holding the artery to the vein and the artery is then lifted away from the vein.

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/IP222aoverview

2.3 Efficacy

- 2.3.1 In a randomised controlled trial (RCT) of 40 patients treated by intravitreal injection or sheathotomy, mean improvement in best corrected visual acuity (BCVA) score (measured

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

on the early treatment diabetic retinopathy study scores chart by the number of letters patients could read from the chart, with correction for individual refractive errors) was greater in the intravitreal injection group (12.2 ± 12.3) than in the sheathotomy group (4.4 ± 8.9) at 1-month follow-up ($p = 0.026$). Improvements in outcome scores were not significantly different between the groups at any other follow-up interval, up to 6 months. An RCT of 36 patients treated by sheathotomy or vitrectomy reported that both groups showed significant improvement in BCVA from baseline, but there was no significant difference between the groups at 31-month follow-up (0.014 logMAR and 0.08 logMAR respectively) ($p = 0.25$).

- 2.3.2 A non-randomised controlled study of 68 patients reported a change in mean BCVA in patients treated by sheathotomy (from 0.16 ± 0.12 to 0.35 ± 0.25) and in those who declined surgery (from 0.23 ± 0.12 to 0.22 ± 0.16) at 6-week follow-up (significance not stated).
- 2.3.3 A non-randomised controlled study of 40 patients reported that the mean number of lines of BCVA gained at 14-month follow-up in patients treated by sheathotomy (4.55 lines) was significantly greater than in patients in the control group who were followed up to 19 months (either no surgery or grid laser photocoagulation) (1.55 lines) ($p = 0.023$).
- 2.3.4 A non-randomised controlled study of 36 patients reported that there was no significant difference in the mean change in BCVA from baseline in the sheathotomy group ($0.29 \text{ logMAR} \pm 0.35$) compared with the group treated by vitrectomy alone ($0.30 \text{ logMAR} \pm 0.22$) at 1-year follow-up ($p = 0.71$).
- 2.3.5 A case series of 60 patients treated by sheathotomy for BRVO with macular oedema reported recurrence of macular oedema in 3% (2/60) of patients at 12- to 16-month follow-up.
- 2.3.6 The Specialist Advisers listed key efficacy outcomes as improved blood flow (on fluorescein angiography), resolution of macular oedema and/or reduced macular thickness, and improvement in BCVA.

2.4 Safety

- 2.4.1 Intraoperative haemorrhage caused by retinal vascular damage (controlled by increasing intraocular pressure by high pressure perfusion) was reported in 6% (1/18) of patients in the sheathotomy group of the RCT of 36 patients. Vitreous haemorrhage which resolved spontaneously was reported in 10% (2/20) of patients in the sheathotomy group of the non-randomised controlled study of 36 patients (timing of event and follow-up not stated).
- 2.4.2 Cataract development was reported in 15% (3/20) of patients in the non-randomised controlled study of 40 patients (sheathotomy group), and in 10% (2/20) of patients in the sheathotomy group compared with 6% (1/16) of patients in the vitrectomy group of the non-randomised controlled study of 36 patients (significance and follow-ups not stated). The RCT of 40 patients reported that the mean increase in grade of cataracts was not significantly different between patients treated by sheathotomy or by intravitreal injection ($p = 0.382$) (absolute figures and length of follow-up not stated).
- 2.4.3 The non-randomised controlled study of 68 patients reported that 2% (1/43) of patients in the sheathotomy group and 36% (9/25) of patients in the no surgery group lost 2 or more BCVA lines at 6-week follow-up.
- 2.4.4 The Specialist Advisers listed adverse events reported in the literature as arterial or venous haemorrhage and retinal detachment. They cited recurrent BRVO as an anecdotal adverse event, and considered theoretical adverse events to include endophthalmitis and/or ophthalmitis, and glaucoma. In particular, there was a concern that sheathotomy used in combination with vitrectomy may confer additional risks without evidence of additional benefit.

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/IPG334/publicinfo A large print version is also available.

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2118 for this guidance, N2119 for the 'Understanding NICE guidance' or N2126 for the large print version of 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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