PREFERRED PRACTICE PATTERN® CLINICAL QUESTIONS

















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American Academy of Ophthalmology P.O. Box 7424 San Francisco, California 94120-7424 415.561.8500 Preferred Practice Pattern® (PPP) Clinical Questions are evidence-based statements that guide clinicians in providing optimal patient care. PPP Clinical Questions answer specific questions in the "Patient, Intervention, Comparison, Outcome" (PICO) format.

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Methods and Key to Ratings

Preferred Practice Pattern Clinical Questions should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network (SIGN)¹ and the Grading of Recommendations Assessment, Development and Evaluation (GRADE)² group are used. All studies used to form a recommendation for care are graded for strength of evidence individually. To rate individual studies, a scale based on SIGN¹ is used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.³

SIGN¹ Study Rating Scale

I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias	
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias	
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias	
II++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal	
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal	
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal	
III	Nonanalytic studies (e.g., case reports, case series)	

GRADE² Quality Ratings

Good quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Insufficient quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate Any estimate of effect is very uncertain

GRADE² Key Recommendations for Care

Strong recommendation	Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not
Discretionary recommendation	Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced



TOPIC

Surgery for nonarteritic anterior ischemic optic neuropathy (NAION)

CLINICAL QUESTION

What is the safety and efficacy of optic nerve decompression surgery compared with other treatment or no treatment in people with NAION?

LITERATURE SEARCH

The PubMed portion of the literature search for the Cochrane Review was last updated May 23, 2013. None of the 28 new citations met the inclusion criteria of the review.

Literature search details

SYSTEMATIC REVIEW

Dickersin K, Manheimer E, Li T. <u>Surgery for nonarteritic anterior ischemic optic neuropathy.</u> Cochrane Database of Systematic Reviews. 2012, Issue 1. Art. No.: CD001538. DOI: 10.1002/14651858.CD001538.pub3.



Recommendations for Care

SUMMARY

Nonarteritic anterior ischemic optic neuropathy (NAION) is a common cause of acute optic nerve disease in the elderly, resulting in sudden vision loss. The etiology of NAION is unknown. Although various medical interventions have been used to treat NAION, no therapy to date has proven effective. It was proposed in the late 1980s⁴ that optic nerve decompression surgery might improve vision problems in NAION patients. The surgery entails making slits, or a 'window', in the tissue surrounding the optic nerve, allowing cerebrospinal fluid to escape thereby reducing the pressure surrounding the optic nerve. However, the safety and efficacy of this surgery compared with other treatment or no treatment in people with NAION remained in question.

The Cochrane Review authors identified one systematic review, which found one randomized controlled trial (RCT) comparing optic nerve decompression surgery plus follow-up against follow-up alone in patients with NAION. Enrollment in the Ischemic Optic Neuropathy Decompression Trial (IONDT)⁵ was stopped earlier than planned due to futility, as the study's Data and Safety Monitoring Committee (DSMC) determined that continued enrollment was unlikely to lend statistical support for optic nerve decompression surgery. The published results suggest no benefit and possible harms from the surgery.

(Study Rating Scale I-, Good Quality, Strong Recommendation)

DISCUSSION

Nonarteritic anterior ischemic optic neuropathy (NAION) is characterized by a sudden, painless loss of vision in one eye, accompanied by swelling of the optic disc. Some at risk patients experience new NAION in the fellow eye (~14.7%). In general, medical interventions have not proven effective in the treatment of NAION, i.e., corticosteroids or phenytoin sodium.

The Cochrane Review authors systematically reviewed the evidence for optic nerve decompression surgery for treatment in people with NAION. Studies included in the Cochrane review were RCTs where a) study participants consisted of people with NAION; b) surgical treatment for NAION was compared against any other treatment, including usual care; and c) the study had to report change in visual acuity (VA), change in visual field, NAION occurrence in the fellow eye, adverse events (including perioperative safety), or patient quality of life.

The Cochrane search identified one RCT that meet these inclusion criteria. The IONDT study⁵ compared optic nerve decompression surgery with careful follow-up observation against careful observation alone in 258 patients ages 50 years and older. The study subjects had all been diagnosed with NAION within the prior two weeks, and all had BCVA of 20/64 or worse at baseline. The follow-up intervention included an ophthalmologic exam and VA measurement at baseline, follow-up visits at one week, one month, three months, six months, and 12 months, and at six-month intervals thereafter, as well as visual field tests at 12 months and as needed.

Enrollment in the IONDT was stopped earlier than planned due to futility, as the study's DSMC determined that continued enrollment was unlikely to lend statistical support for surgery. At six months' follow-up, 32.0% of surgery patients had improved VA by three or more Snellen lines, compared to 42.6% in the careful follow-up group; at 24 months, 29.4% of surgery patients and 31.0% of follow-up patients had improved VA. These differences were not statistically significant. In a slightly higher proportion of surgery patients, vision worsened – i.e., loss of light perception and diplopia — at six months compared to follow-up patients, but this difference was not significant. One week after enrollment, 17% of surgery patients reported pain, and 8% of these patients reported diplopia; more serious adverse events in this group included central retinal artery occlusion (one patient), and loss of light perception and loss of vision persisting up to 12 months (two patients).

CONCLUSION

Although the systematic review identified only one RCT comparing optic nerve decompression surgery to careful follow-up observation in NAION patients, the RCT was rated highly in its quality and the strength of its evidence. The trial was stopped early due to futility and concerns regarding safety of the intervention. The published results fail to suggest a benefit from surgery (possibly harm). Participants who received surgery experienced both intraoperative and postoperative adverse events. Further, the review authors believe with reasonable certainty, that a clinically meaningful beneficial effect has not been established with surgical optic nerve decompression and outcomes, defined as an improvement in vision by three or more Snellen lines during a six month follow-up timeframe.

While it is difficult to discuss with a patient that there is no effective therapy for a potentially blinding disorder, the natural history for observation suggests that NAION may improve spontaneously. Therefore, there is no evidence supporting a role for optic nerve decompression surgery in the treatment of NAION, especially given the potential risks from the procedure. Currently, there is a lack of a clinically meaningful benefit from optic nerve decompression surgery and this should not be considered an effective treatment for NAION.



- 1. Scottish Intercollegiate Guidelines Network. Annex B: key to evidence statements and grades of recommendations. In: SIGN 50: A Guideline Developer's Handbook. Available at: www.sign.ac.uk/guidelines/fulltext/50/annexb.html. Accessed May 31, 2013.
- 2. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.
- 3. GRADE Working Group. Organizations that have endorsed or that are using GRADE. Available at: www.gradeworkinggroup.org/society/index.htm. Accessed May 12, 2013.
- 4. Sergott RC, Cohen MS, Bosley TM, Savino PJ. Optic nerve decompression may improve the progressive form of nonarteritic ischemic optic neuropathy. Arch Ophthalmol 1989;107:1743-54.
- Optic nerve decompression surgery for nonarteritic anterior ischemic optic neuropathy (NAION) is not effective and may be harmful. The Ischemic Optic Neuropathy Decompression Trial Research Group. JAMA 1995;273:625-32.