INAHTA Brief

Issue 2019/020

Title Optimal Use of Minimally Invasive Glaucoma Surgery: A Health Technology Assessment

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Reference Optimal use of minimally invasive glaucoma surgery: a health technology assessment. Ottawa: CADTH; 2019. (CADTH optimal use report; vol.8, no.1b).

Aim

The objective of this health technology assessment (HTA) was to inform the optimal use, including appropriate patient selection, of minimally invasive glaucoma surgery (MIGS) devices and procedures for adults with glaucoma, and whether MIGS devices and procedures should be funded by the public health care system. The HTA included an assessment of the clinical effectiveness and safety, cost-effectiveness, patients' and caregivers' perspectives and experiences, ethical issues, and implementation issues of MIGS for the treatment of adults with glaucoma.

Conclusions and Results

Overall, there was insufficient conclusive evidence to determine the comparative clinical effectiveness and safety of MIGS versus pharmacotherapy, laser therapy, different MIGS (i.e., one type of MIGS versus another), or filtration surgery. The clinical effectiveness of MIGS in combination with cataract surgery tended to be more favourable than cataract surgery alone in terms of intraocular pressure (IOP) and number of medications; however, findings for comparative safety were mixed. There was insufficient conclusive evidence to determine the comparative clinical effectiveness and safety of MIGS in combination with cataract surgery versus filtration surgery in combination with cataract surgery. The clinical effectiveness conclusions were based largely on indirect outcomes (i.e., IOP and number of medications as surrogates for visual field and quality of life, respectively).Particularly in the context of inconclusive clinical outcomes, increased attention to patient-important outcomes (e.g., health-related quality of life [HRQoL]) is imperative; although HRQoL data were limited and likewise inconclusive. Most adverse events (AEs) were considered minor; however, in the two studies in which major AEs occurred (e.g., failure of corneal graft, retinal detachment), between-group differences were not significant or unclear.

In terms of cost-effectiveness, MIGS seemed to offer more clinical benefit at a higher cost when compared with pharmacotherapy or when performed in combination with cataract surgery instead of cataract surgery alone. However, the findings were subject to a very high level of uncertainty; results were sensitive to costs associated with MIGS and the purported long-term benefits of MIGS.

Current treatments for glaucoma in the form of eye drops are highly disruptive for patients who welcome the opportunity to reduce or eliminate the need to use them. Patients' perceptions and experiences of glaucoma were highly shaped by societal understandings and awareness of glaucoma and of blindness, including vision changes as a normal part of aging and which may delay seeking treatment. While treatments may reduce IOP and slow the progression of their glaucoma, once diagnosed, patients move through the world with glaucoma as a chronic condition. Patient–provider relationships are central to patients' experiences with glaucoma treatment and provide an opportunity to assist patients to become acquainted with glaucoma, to improve adherence to treatment, and to adjust to vision changes.

Ethically and socially relevant issues include: the need for guidelines to help institutions and surgeons fairly allocate MIGS under conditions of scarcity; concerns about public coverage versus private payment for MIGS, as well as diverging views of MIGS as an "optional upgrade" or a medical need; and concerns about equitable access to MIGS for patients living in rural and remote locations and for patients from certain racialized groups. Ethical concerns related to the context of surgical innovation include conflicts of interest, assignment of responsibility for tracking and reporting outcomes of MIGS usage, and challenges defining and carrying out surgeons' responsibilities to enable informed patient consent in the potential use of MIGS.

Implementation of MIGS in Canada is a multi-factorial issue, including factors such as funding models, organization, and professional considerations. Currently, access is limited for many Canadians because of geography or setting, the restricted supply of the technology, or the slow uptake of the technology by providers.

Although MIGS are categorized as a particular class of intervention, each MIGS is unique in terms of its structure and mechanism of action, and may reasonably be anticipated to have different clinical effectiveness, safety, and cost-effectiveness profiles. There was insufficient evidence to offer specific conclusions regarding individual MIGS devices and procedures, and there was no definitive evidence regarding which MIGS might be preferable — either overall or for a subset of patients.

Recommendations

The Health Technology Expert Review Panel (HTERP) recommendations are, as follows:

1. HTERP considered that there is insufficient evidence at present to make recommendations specific to the optimal use and funding of MIGS.

2. HTERP suggests that there is a potential role for MIGS devices and procedures in the treatment of adult patients with glaucoma, if the choice of MIGS is presented to patients with full consideration and disclosure of relevant factors, including:
   - the diversity of MIGS options, and uncertainties and unknowns associated with their benefits and risks
   - individual patient factors bearing on the choice of treatment (e.g., vulnerabilities, geographical location, and financial considerations)
   - the surgeon's experience performing MIGS and potential conflicts of interest
   - alternative forms of treatment.
3. HTERP suggests that provinces and territories establish harmonized procedure codes for MIGS (to enable surveillance of access and treatment patterns) and document actual costs associated with MIGS and alternative treatments.
4. HTERP suggests that the optimal use, including funding, of individual MIGS be reassessed if further research is conducted that includes: detailed reporting of results stratified by patient characteristics; valid and reliable measures of direct, patient-important outcomes; and long-term evaluation of clinical effectiveness, adverse events, harms, and cost-effectiveness.

Methods

To assess the comparative clinical effectiveness and safety, a systematic review of primary studies was conducted. A Markov cohort model was constructed to examine the cost-effectiveness of MIGS, with or without cataract surgery, compared with alternative treatments during a patient's lifetime from a Canadian health care payer perspective. The perspectives and experiences of patients and caregivers were explored in a systematic review and thematic synthesis of primary qualitative research. Patients were engaged throughout the project in the form of conversations with three female patients with glaucoma, two of whom had undergone MIGS. The ethics analysis was informed by a literature search that included ethical, legal, and social issues, as well as research and commentary dealing with issues indirectly or analogously identified through expert recommendations and through a CADTH Environmental Scan entitled *Minimally Invasive Glaucoma Surgery: Implementation Considerations.* The implementation issues surrounding MIGS were likewise informed by the Environmental Scan, which comprised a narrative literature review and consultations with targeted key informants.

Further Research/Reviews Required

There is a need for detailed assessment, reporting and stratification of results by patient characteristics (e.g., type and severity of glaucoma); use of valid and reliable measures of direct patient-important outcomes (e.g., HRQoL); and systematic long-term evaluation of clinical effectiveness, harms, and cost-effectiveness. Documenting actual costs associated with MIGS and alternative treatments may allow for greater certainty in the true absolute and incremental costs of MIGS to better inform the potential economic value of MIGS. Implementation research regarding MIGS may also benefit from branching out into surveys involving more general ophthalmologists and cataract surgeons to gain their perspectives on the use of MIGS in Canada, as they may be able to perform MIGS in addition to surgical ophthalmologists. Further qualitative studies that focus on patients' and providers' perceptions and experiences with MIGS before and after surgery are needed. Two important areas for further research relevant to the ethical and social concerns are:

- knowledge of how glaucoma treatment in general and MIGS treatment options in particular intersect with racialized groups within Canada's demographic make-up
- whether and how specialists can reasonably incorporate patients' circumstantial details (e.g., financial means, geographical constraints) into informed-consent discussions around the potential choice of MIGS as a glaucoma treatment.

Written by

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