2019 Health Technology Reassessment Report

Safety and Effectiveness Reassessment of Glaucoma Aqueous Tube Insertion

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Summary (English)

□ Background

Glaucoma aqueous tube insertion is used to regulate intraocular pressure by inserting Ex-PRESS^{TM} between the anterior chamber and sclera to drain aqueous humor. The technology underwent New Health Technology Assessment (nHTA) in 2009.

The Korea Ministry of Health and Welfare is in the process of transitioning the coverage status of each of 485 health technologies currently not covered by the national health insurance to a benefit item. The technology is one of the items that was planned for coverage status change in 2020 and had previously undergone a New Health Technology Assessment research. As part of the Health Technology Reassessment Project (NR19-001, principal investigator: In Soon Choi), evidence regarding the technology was updated.

□ Subcommittee operation

The 5-member Subcommittee made assessment on this procedure in accordance with the literary grounds through operation of the Subcommittee 3 times over a period of approximately 4 months from April and July 2019, and submitted the results of the review.

☐ Purposes and Methods

This study was conducted to update the outcomes of the using systematic review and reassess the safety and effectiveness of glaucoma aqueous tube insertion. The publication year was restricted such that the starting year would overlap by one year with the literature search performed for the New Health Technology Assessment research. Consequently, the literature published from 2009 to the date of literature search for this study were included. To assess the safety and effectiveness of the said technology, a systematic review was performed. Methods details were determined by

the “Subcommittee for the Safety and Effectiveness Assessment of Glaucoma Aqueous Tube Insertion" .

□ Results

1. Selected articles

A total of 21 articles were finally selected. Grouped by study design, 11 articles were randomized controlled clinical trials (RCT) and 10 were cohort studies. One of the articles had been included in the New Health Technology Assessment research in 2009.

2. Effectiveness

Effectiveness of Glaucoma Aqueous Tube Insertion as assessed by ocular pressure, the number of anti-glaucoma medications, (complete, partial) success rate, failure rate, and visual acuity on the basis of total of 21 literature.

In the RCTs, ocular pressure, the number of anti-glaucoma medications, partial success rate, and visual acuity were not significantly different in the Ex-PRESS and trabeculectomy groups. The complete success rate was higher in the Ex-PRESS group (RR 1.20, 95% CI 1.03,1.41).

In the cohort studies, the effectiveness outcomes of the Ex-PRESS and trabeculectomy groups were not significantly different.

3. Safety

Safety of Glaucoma Aqueous Tube Insertion was assessed by categorizing safety issues into aqueous tube insertion related complications, apparatus related complications and other complications following the surgery on the basis of total of 10 literatures.

Shallow anterior chamber, flat anterior chamber, bleb drainage, choroidal detachment, choroidal exudation, low-pressure macular degeneration, and low ocular pressure were evaluated as drainage-related complications. Cornea-device contact, iris-device contact, blocked tube, device dislocation, and change in corneal epithelial cells were evaluated as device-related complications. Other complications evaluated

include hyphema, a rapid increase in ocular pressure, intraocular inflammation, Tenon's capsule fibrosis, and conjunctival erosion.

In the RCTs, the Ex-PRESS and trabeculectomy groups showed significantly different changes in corneal epithelial cells, hyphema, and overall complications.

In the cohort studies, the Ex-PRESS and trabeculectomy groups showed significant differences in choroidal detachment, changes in corneal epithelial cells, and hyphema.

4. Quality of the evidence

The quality of the evidence was considered based on the study design, risk of bias, inconsistency, imprecision, and other considerations of the finally selected articles. The evidence quality grading was limited to those outcome variables for which the level of importance was "critical" or "important but not critical."

In the RCTs and cohort studies, all outcome variables for which the level of importance was "critical" (namely, ocular pressure, complete success rate, partial success rate) were graded to be of "low" quality. In addition, all outcome variables for which the level of importance was "important but not critical" (namely, change in corneal epithelial cells, shallow anterior chamber, flat anterior chamber, choroidal detachment, low-pressure macular degeneration, hyphema, and intraocular inflammation) were graded to be of "low" quality as well.

□ Conclusion

The Sub-committee made the following conclusions on “Glaucoma Aqueous Tube Insertion” on the basis of currently available literatures.

In comparison to trabeculectomy, glaucoma aqueous tube insertion showed similar or fewer complications in patients with open-angle glaucoma, pseudoexfoliation glaucoma, and pigmentary glaucoma (types of glaucoma that cannot be controlled by medications). Additionally, glaucoma aqueous tube insertion showed similar effectiveness in regulating ocular pressure regulation, reducing the use of anti-glaucoma medications, and improving visual acuity; they also showed greater complete success rates. Accordingly, the subcommittee assessed that glaucoma aqueous tube insertion is safe and effective.

Health Technology Reassessment Committee made the following deliberations on “Glaucoma Aqueous Tube Insertion” on the basis of the results of review by the Sub-committee (December 13, 2019).

The Health Technology Reassessment Committee considered that the subcommittee's assessment is reasonable. They considered glaucoma aqueous tube insertion as safe and effective given that it had similar or fewer complications than trabeculectomy and was similarly effective in regulating ocular pressure, reducing the use of anti-glaucoma medications, and improving visual acuity in patients with open-angle glaucoma, pseudoexfoliation glaucoma, and pigmentary glaucoma (conditions not controlled with drug therapy). However, the quality of the evidence is low. Accordingly, the committee determined that an additional review would be necessary in the future.