PP031 iStent® For Open Angle Glaucoma: Standard Or Emerging Care ?

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INTRODUCTION:

Increased intraocular pressure (IOP) in open angle glaucoma (OAG) may lead to optic nerve damage due to progressive obstruction of aqueous humor drainage. Among surgery options, trabecular micro-bypass stent (iStent®) was recently introduced. This Health Technology Assessment (HTA) aimed to assess the effectiveness and safety of iStent®, combined or not with cataract surgery, in patients with mild-to-moderate OAG.

METHODS:

A systematic review (SR) was performed from 2000 to August 2016. Studies reporting data at three months or more on IOP and hypotensive medication use following iStent® implant were eligible. Governmental databases on safety issues were reviewed. The project involved an interdisciplinary group of experts.

RESULTS:

Two HTA reports, one SR, four randomized controlled trials (RCTs) and nine observational studies (OSs) were included. Compared to cataract surgery alone, implantation of iStent®combined with cataract surgery was associated with a decrease in IOP at 12 months in RCTs (-1.37 mmHg; 95 percent Confidence Interval, CI: - 2.76 to .03 mmHg, p = .055). Results from RCTs and OSs on the effect of iStent® combined or not with cataract surgery suggest also a 12-month positive effect on IOP (mean reduction: 1.5 to 9.5 mmHg) and on mean number of medications (reduction: .3 to 2.0) compared to baseline. Scattered results were found on the proportion of patients who no longer use glaucoma medications. Small sample size, short duration of follow-up, and potential conflicts of interest were among studies limitations. The most common adverse events reported were posterior capsular opacification, decrease in visual acuity, and stent obstruction or malposition.

CONCLUSIONS:

Appraisal of the effectiveness and safety suggests that iStent® implantation combined to cataract surgery in mild-to-moderate OAG is an emerging practice. Uncertainties related to clinical benefits, safety and care organization need to be clarified before an introduction as a standard of medical practice.

PP032 Holistic Patient Access Processes Of Medical Devices In South Korea

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INTRODUCTION:

Historically, patient access processes of new and innovative medical devices including *in-vitro* diagnostics are made in the sequence of regulatory approval, new Health Technology Assessment (nHTA) approval, reimbursement coverage and coding finally reaching the pricing approval stage in South Korea. Although the individual patient access process has its own distinct objective and perspective, there are still opportunities for the authorities or agencies in charge to streamline their processes by working together to promote earlier patient access of new and innovative medical devices to patients without impacting their own decision making.

METHODS:

This research examined and analyzed the current policies about: patient access processes with a holistic viewpoint, industry-wide survey about patient access practices; case studies of two innovative medical devices for patient access in South Korea and also proposed new or alternative programs which can

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