

## INTRODUCTION:

The Guidelines for Rehabilitation in Patients with Cardiovascular Disease recommends convalescent cardiac rehabilitation (CR) as the standard treatment for patients with ST elevation myocardial infarction (STEMI) (class I, evidence level B) (1). However, health economic evaluation of cardiac rehabilitation (CR) is limited.

## METHODS:

This systematic review, meta-analysis study elucidated the cost-effectiveness of CR in the short term. The target population in this study included convalescent and comprehensive CR patients with coronary artery disease (CAD), most with myocardial infarction (MI). We used mortality, life years (LY, expected life years), medical costs, and cost-effectiveness as the evaluation parameters in this analysis. We set medical costs in the analysis associated with testing, diagnosis, and treatment during the observation period related to CR. For cost-effectiveness analysis, we analyzed medical cost per LY. We examined the differences in effects for two comparisons (CR versus Usual Care, UC) using the Risk Ratio (RR) and Standardized Mean Difference (SMD). We assumed the standard deviation (SD) of cost effectiveness in this study by applying the error propagation.

## RESULTS:

We reviewed fifty-nine studies and identified three that matched our selection criteria. The studies had the following characteristics: two randomized clinical trials and one systematic review/meta-analysis; a control that does not include exercise in patients with CAD; an observation period longer than 1 year; adapting medical costs, LY, cost/LY, and mortality as the evaluation index. In total, 129,272 patients were included. Meta-analysis results revealed that the CR arm significantly improved LY (SMD: -.78, 95 percent Confidence Interval (CI): -1.37, -.19) compared with UC. Similar to LY, the CR arm significantly improved the mortality (SMD: .57, 95 percent CI: .22, 1.47) compared with UC arm. Since medical costs showed a high tendency (SMD:.02, 95 percent CI: -.08, .13), cost/LY demonstrated no improvement (SMD: .00; 95 percent CI: -.17, .18). Substantial statistical heterogeneity was observed between the studies with respect to LY and cost/LY.

## CONCLUSIONS:

While sufficient evidence to conclude health economic efficiency is not available at present, these results suggest that CR is not potentially cost-effective in the short term.

## REFERENCES:

1. JCS Joint Working Group. Guidelines for rehabilitation in patients with cardiovascular disease (JCS 2012). *Circ J.* 2014;78(8):2022-2093.

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## 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.

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## 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 contribute to patient access harmonization efforts with a holistic approach.

### RESULTS:

Historically, health authorities play defensive strategies by delaying the adoption of new and innovative medical devices and implementing certain periods (that is, 2 to 5 years) for a patient's out-of-pocket payment scheme. It is well illustrated with the statistic that only twenty-nine percent of new and innovative medical technologies which have successfully gone through the nHTA process were determined for reimbursement coverage in the past 7 years.

The survey by the medical device industry to determine the patient access lead-time of innovative medical devices with a holistic perspective indicated significantly delayed patient access even considerably exceeding the legally required decision-making lead time. The in-depth case studies with two innovative devices indicated the disadvantageous patient access processes to the innovator in terms of both final approval timing and the price level.

### CONCLUSIONS:

The concurrent review process for reimbursement coverage decision making for medical procedures, medical devices and reimbursement coverage payment guidelines committed within the Health Insurance Review and Assessment Service shall be created. New programs to deal with uncertainty in reimbursement coverage decision making shall be considered such as coverage with evidence development,