EE401

Cost-effectiveness of the OMNI® Surgical System versus iStent Inject® for the Treatment of Primary Open-angle Glaucoma in the United States

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INTRODUCTION

First-line treatment of primary open-angle glaucoma (POAG) usually comprises topical intraocular pressure (IOP) lowering medication. However, patient adherence and local adverse effects (AEs) to topical medications can be problematic. If topical IOP lowering medications are contraindicated or if medication does not sufficiently reduce IOP, laser therapy (e.g., selective laser trabeculoplasty) and surgical procedures (minimally invasive glaucoma surgery (MIGS) or conventional surgery) may be used.[1]

The OMNI® Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with POAG. The iStent inject Trabecular MicroBypass System (with two heparin coated stents) is intended to reduce intraocular pressure in adult patients diagnosed with mild to moderate POAG currently treated with ocular hypotensive medication.

The OMNI® Surgical System has demonstrated in clinical trials a reduction in IOP both as a standalone procedure or combined with cataract surgery in eyes with mild to moderate POAG.

Clinical data on efficacy and safety of OMNI® are published in the literature; however, the cost-effectiveness of OMNI® has not been studied.

Selection of iStent inject as the sole comparator for the cost-effectiveness analysis is due to iStent being the market leader among MIGS in combination with cataract. iStent inject is indicated only in combination with cataract; whereas, OMNI® is indicated in combination with cataract and as a standalone procedure.

OBJECTIVE

This analysis aimed to estimate the cost-effectiveness of the OMNI® Surgical System versus iStent inject for the treatment of primary open-angle glaucoma (POAG) in combination with cataract surgery.

METHODS

A cost-effectiveness model was developed in Microsoft Excel following principles of good practices as outlined in ISPOR guidelines.[2]

The base-case analysis included a baseline age of 65 years, according to Medicare eligibility criteria. Lifetime and 5-year time horizons were used with a 6-month Markov cycle based on typical treatment monitoring.

Health states were defined by POAG severity[3] (mild, moderate, advanced, severe) and death (Figure 1).

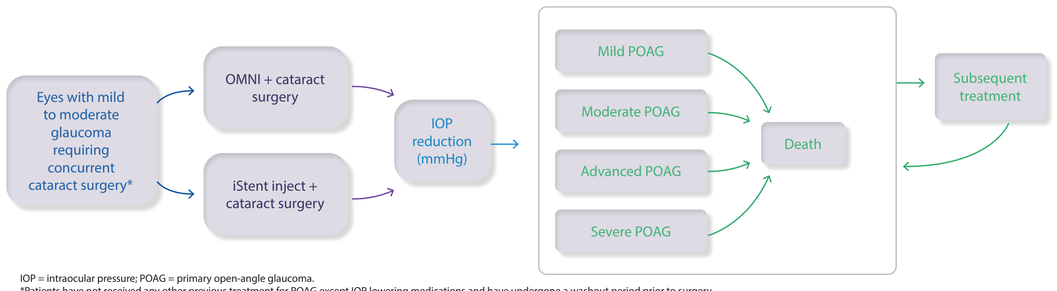
Transition probabilities were estimated using clinical trial data[4,5] and an adaptation of the calculations performed in a Canadian health technology assessment report (Table 2).[6]

Utility values by health state decreased with increased POAG severity and were sourced from published literature. Utility weights for patients with mild, moderate, advanced, and severe POAG were 0.902, 0.800, 0.722, and 0.502, respectively.[7]

Model outcomes included total quality-adjusted life-years (QALYs), total health care costs, net monetary benefit (NMB), and incremental cost-effectiveness ratio (ICER).

Probability of secondary intervention was 2.7% for patients receiving iStent and 0% for patients receiving OMNI®.[4,5] Patients undergoing a secondary intervention (tube/trabeculectomy) experienced a disutility of -0.007.[8]

Figure 1: Model Structure



IOP = intraocular pressure; POAG = primary open-angle glaucoma.
*Patients have not received any other previous treatment for POAG except IOP lowering medications and have undergone a washout period prior to surgery.

Table 1: Model Specifications

Specification	Description
Perspective	Medicare
Population	Patients with mild to moderate POAG
Time Horizon	Given that POAG is a chronic disease, the model adopts a lifetime time horizon as base case
Cycle Length	6-month cycles based on typical treatment monitoring
Discount Rate	3% (costs and outcomes)
Intervention	OMNI® Surgical System
Comparator	iStent inject
Design	Markov model

POAG = primary open-angle glaucoma.

Table 2: Transition Probabilities

OMNI®	Mild	Moderate	Advanced	Severe	Death
Mild	98.627% - p(age)	1.37%	0%	0%	p(age)
Moderate	0%	98.949% - p(age)	1.05%	0%	p(age)
Advanced	0%	0%	99.106% - p(age)	0.89%	p(age)
Severe	0%	0%	0%	100% - p(age)	p(age)
Death	0%	0%	0%	0%	100%
iStent Inject	**Mild**	**Moderate**	**Advanced**	**Severe**	**Death**
Mild	98.690% - p(age)	1.31%	0%	0%	p(age)
Moderate	0%	98.997% - p(age)	1.00%	0%	p(age)
Advanced	0%	0%	99.147% - p(age)	0.85%	p(age)
Severe	0%	0%	0%	100% - p(age)	p(age)
Death	0%	0%	0%	0%	100%

Table 3: Procedure Costs[9]

Intervention	ASC tariffs	Hospital Outpatient tariffs	Physician fees
OMNI®	$1,917	$4,000	$761
iStent inject	$3,245	$4,251	$683
Tube	$2,581	$4,000	$1,142
Trabeculectomy	$1,062	$2,121	$1,096
SLT	$137	$514	$203
Cataract*	$531	$0†	$272

ASC = ambulatory surgery center; SLT = selective laser trabeculoplasty.
*When combined with MIGS procedures, the payment receives a 50% reduction due to multiple procedure reduction rules. The amount displayed is the discounted figure; †Cataract surgery hospital outpatient payment is equal to $0 due to comprehensive Ambulatory Payment Classification (APC).

RESULTS

Total costs and QALYs were $11,178 and 8.950 for OMNI® versus $11,730 and 8.933 for iStent inject (Table 4).

OMNI® reduced health care costs by $552 with an incremental benefit of 0.017 QALYs when compared with iStent inject across a lifetime period (Table 4).

Over a 5-year time horizon, OMNI® reduced health care costs by $573 with an incremental benefit of 0.002 QALYs when compared with iStent inject.

The main cost-effectiveness drivers were a reduction in health care costs related to a less expensive tariff and similar progression through health states compared to iStent inject.

For OMNI®, a surgical reintervention related to device complications is not necessary (assumption based on clinical trial[4]), resulting in additional cost savings and QALY gains. Based on literature for iStent inject, surgical reintervention occurs in a few patients.

When compared with iStent inject, OMNI® has a hgher probability of being cost-effective (54.2%; Table 5) at the reference willingness-to-pay (WTP) threshold and across all WTP thresholds considered (Figure 3).

Table 5: Probabilistic Sensitivity Analysis Results

	Lifetime
Average incremental cost	-$573.00
Average incremental QALYs	0.331
Probability of cost-effectiveness	54.2%

QALY = quality-adjusted life-year.

Table 4: Results

OMNI® Surgical System

$11,178 Total costs
8.950 Total QALYs
-$552 Incremental cost
0.017 Incremental QALYs

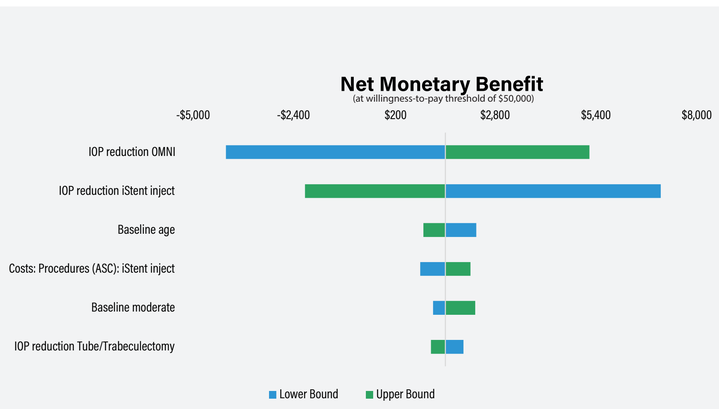
iStent Inject

$11,730 Total costs
8.933 Total QALYs

ICER: OMNI® dominates iStent inject

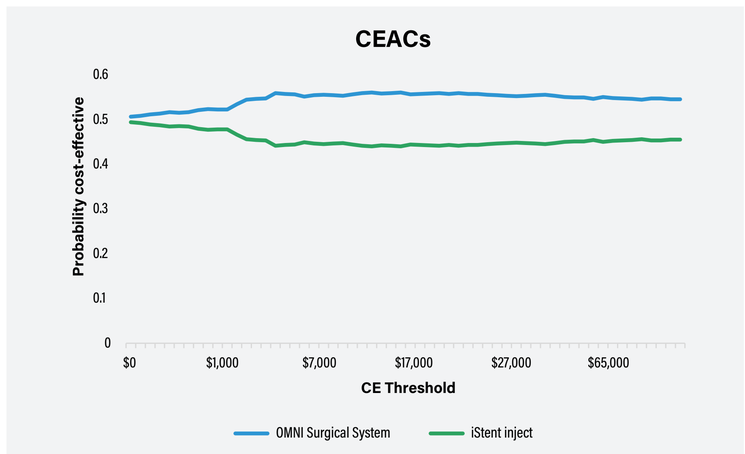
ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life-year.

Figure 2: One-way Sensitivity Analysis



ASC = ambulatory surgery center; IOP = intraocular pressure.

Figure 3: Cost-effectiveness Acceptability Results



CE = cost-effectiveness; CEAC = cost-effectiveness acceptability curves.

DISCUSSION

- The main limitation of the analysis was that efficacy had to be sourced from the most relevant clinical studies for the respective procedures, as there is no evidence for the comparative clinical effectiveness of OMNI® versus iStent inject.
- The model was built on several assumptions, and sensitivity analyses were conducted to address the potential impact of assumptions on the results.
- Modeling of disease progression and treatment was necessary to extrapolate long-term costs and consequences as clinical studies reported on IOP lowering over a shorter time period (12 months for OMNI®; 24 months for iStent inject). To address the uncertainty related to extrapolation, the model was also run over a shorter time horizon. The results of the 5-year model confirmed those of the lifetime model.

CONCLUSIONS

The OMNI® Surgical System for treatment of mild to moderate POAG in combination with cataract surgery is clinically superior based on QALY gains and cost-saving compared to iStent Inject. OMNI® is an appropriate treatment option in the treatment paradigm for mild to moderate POAG patients.

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