

The Long-Term Efficacy and Safety of the Glaukos iStent Implant in Open Angle Glaucoma (OAG)

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Project Summary

The iStent is a minimally invasive surgically implanted device to reduce the intra-ocular pressure in patients with glaucoma and thus reduce the risk of optic nerve damage. The long-term efficacy and safety of this device remains unknown. My impact project involved performing a retrospective, observational study to evaluate efficacy and safety outcomes in patients with open angle glaucoma who underwent iStent implantation in conjunction with phacoemulsification (cataract surgery) compared with phacoemulsification alone, as cataract extraction alone has been shown to reduce intra-ocular pressure.

Action Items/Outcome

Retrospective chart review of data from January 2012-April 2017 was conducted for iStent (n=30) and control (n=46) groups. Outcomes include efficacy measures: IOP and number of antiglaucoma medications, and safety measures: post-operative pressure spikes and complications. Data were collected both pre-operatively and post-operatively at day 1, weeks 1-2, months 1, 2, 3-4, 5-8, and years 1, 2, 3, and 4. For the iStent and control groups, differences between IOP and the number of medications between the pre-operative timepoint and each subsequent post-operative timepoint were calculated. The iStent and control groups were compared using the non-parametric Wilcoxon rank sum test.

Efficacy Outcomes:

At 1 year post-op, the mean IOP was 13.7 ± 3.6 mmHg in the control group compared to 15.7 ± 4.6 mmHg at baseline; in the iStent group, 15.0 ± 2.0 mmHg compared to 15.9 ± 3.2 mmHg at baseline ($p=0.50$). Long-term post-operative IOP at 3-4 years was 13.8 ± 4.8 mmHg in the control group, a decrease of 1.9 mmHg from baseline; and 14.4 ± 2.1 mmHg in the iStent group, a decrease of 1.4 mmHg from baseline ($p=0.78$).

At 1 year post-op, the mean number of medications in the control group was 1.3 ± 1.2 compared to 1.3 ± 1.2 at baseline; in the iStent group, 1.2 ± 1.5 compared to 1.7 ± 1.3 at baseline ($p=0.08$). Long-term post-operative number of medications at 3-4 years was 1.5 ± 1.1 in the control group, an increase of 0.2 from baseline, and 1.3 ± 0.9 in the iStent group, a decrease of 0.4 from baseline ($p=0.04$).

Safety Outcomes:

41.5% patients in the control group had an IOP spike at post-op day 1 compared to 21.4% in the iStent group. Complications occurring in the iStent group included n=2 hyphema, n=1 PAS obstructing iStent, and n=1 iStent malposition.

Conclusion/Reflection

Long-term post-operative IOP decreases compared to baseline are similar between patients with OAG who undergo iStent implantation and control groups, but iStent patients are on significantly fewer medications compared to their pre-operative baseline than control patients. The safety profile for iStent is favorable with a lower rate of post-operative IOP spikes compared to control patients.