

One Year Evaluation of iStent Inject® Trabecular Micro-Bypass Stent Implantation with Phacoemulsification

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Introduction

A randomised pivotal trial demonstrated the effectiveness and safety of implanting iStent inject® second generation trabecular micro-bypass stents in conjunction with cataract surgery in patients with mild to moderate POAG and cataract. (1)

The Early Manifest Glaucoma Trial estimated a 10% lower risk of progression for each 1 mmHg reduction in IOP. Likewise, the Advanced Glaucoma Intervention Study (AGIS) demonstrated that eyes with IOP <18 mmHg in 100% of visits during follow-up demonstrated no average change on visual fields, as measured by standard automated perimetry (SAP). (2)

Combined iStent inject with phacoemulsification is a relatively low risk surgical procedure compared to ab externo filtering procedures. Moreover this combination procedure lends itself to significantly less theatre time and rigorous follow up.(3-4) Hence it was proposed to look for evidence whether this procedure would either delay or avoid Trabeculectomy in the short to medium term.

This is an unmasked prospective case series by a single surgeon (AD) in patients with moderate to advanced glaucoma undergoing combined phacoemulsification with iStent inject.

Aims

- The primary outcome is an intraocular pressure (IOP) drop of ≥20% versus preoperative values (adequate drop) and IOP maintenance between 6 and 18 mmHg (adequate range).
- To evaluate the side effect profile.

Methods

- Prospective audit of patients’ cases that underwent combined cataract surgery and iStent inject procedure from February 2019 to March 2020 in University Hospital Hairmyres.
- Data logged prospectively are V/A, IOP and number of ocular hypotensives.

Demographics

| | | |
|-------------------------------|------------------------|-------------------|
| Number of Eyes | 26 Eyes (25 subjects) | |
| Male /Female | 14/11 | |
| Race | Caucasian | 100% (n=25) |
| Age | Mean ± SD | 73 ± 8.7 |
| Number of Pre-Op Medications | Mean ± SD | 2.27 ± 0.8 |
| Number of Post-Op Medications | Mean ± SD | 2.27 ± 0.8 |
| Pre-op medicated IOP | Mean ± SD | 19.3 ± 4.9 |
| Post-op medicated IOP | Mean ± SD | 13.4 ± 3 |
| Follow up | Range (Average) | 1 – 12 months (7) |

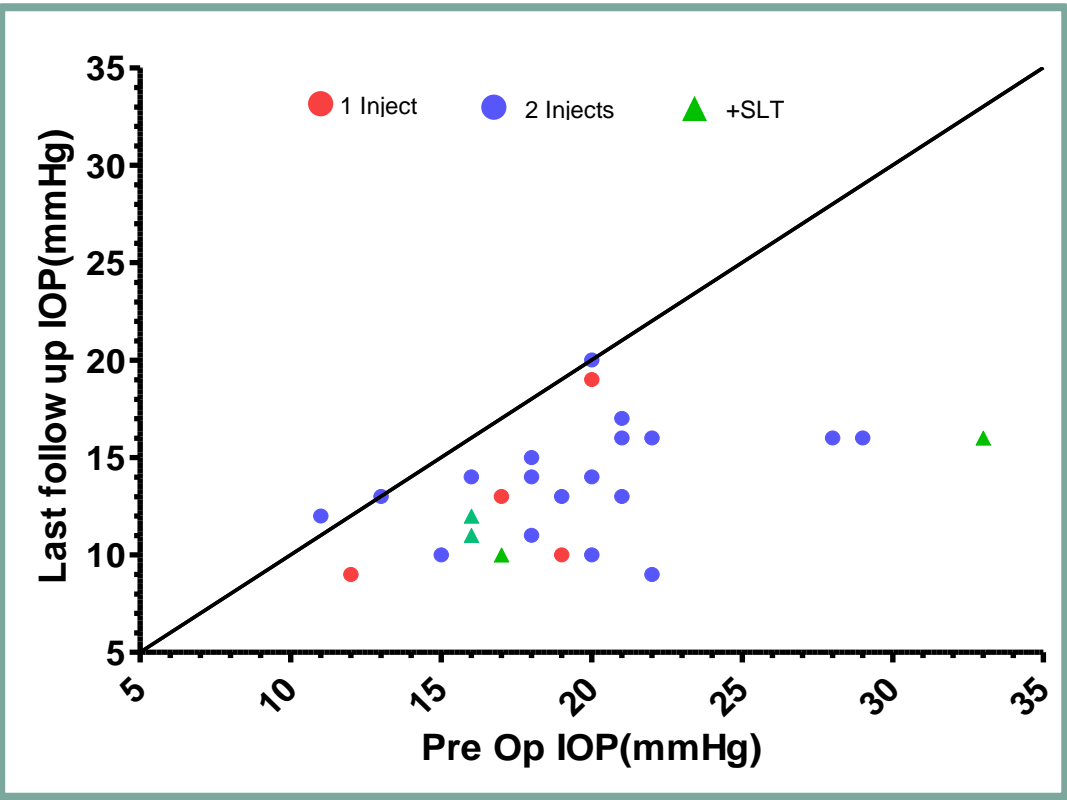


FIGURE 1: PRE-OP IOP VS Last Follow Up IOP (mmHg)

Results

- At last follow up, 24 eyes (92.3%) had IOP between 06-18 mmHg (adequate range) – No eyes had IOP higher than 20 mmHg post procedure (**Figure 1**).
- At last follow up, 69% of eyes achieved >20% IOP reduction (adequate drop) (**Figure 2**).
- Out of 26 eyes, 4 eyes had only 1 iStent inject (**Figure 1**).
- 4 eyes required further IOP lowering procedures in the form of SLT. (**Figure 1**).
- At 12 months’ follow up, mean IOP was 14mmHg, compared to 19.3 mmHg preoperatively (**Figure 3**).
- No significant changes are noted in visual acuity and ocular hypotensive use pre and post op.
- No short or long-term complications were noted.

Discussion

- None of the study subjects required Trabeculectomy or other ab externo filtering procedures in the short to medium term.
- SLT is the only additional procedure required in the study subjects.
- Limitations of the study design is unmasked evaluation, lack of control group, small number of subjects and single ethnic group.

Conclusion

- Combined cataract surgery and iStent inject procedure can be a useful temporising measure in short to medium term in moderate to advanced glaucoma.

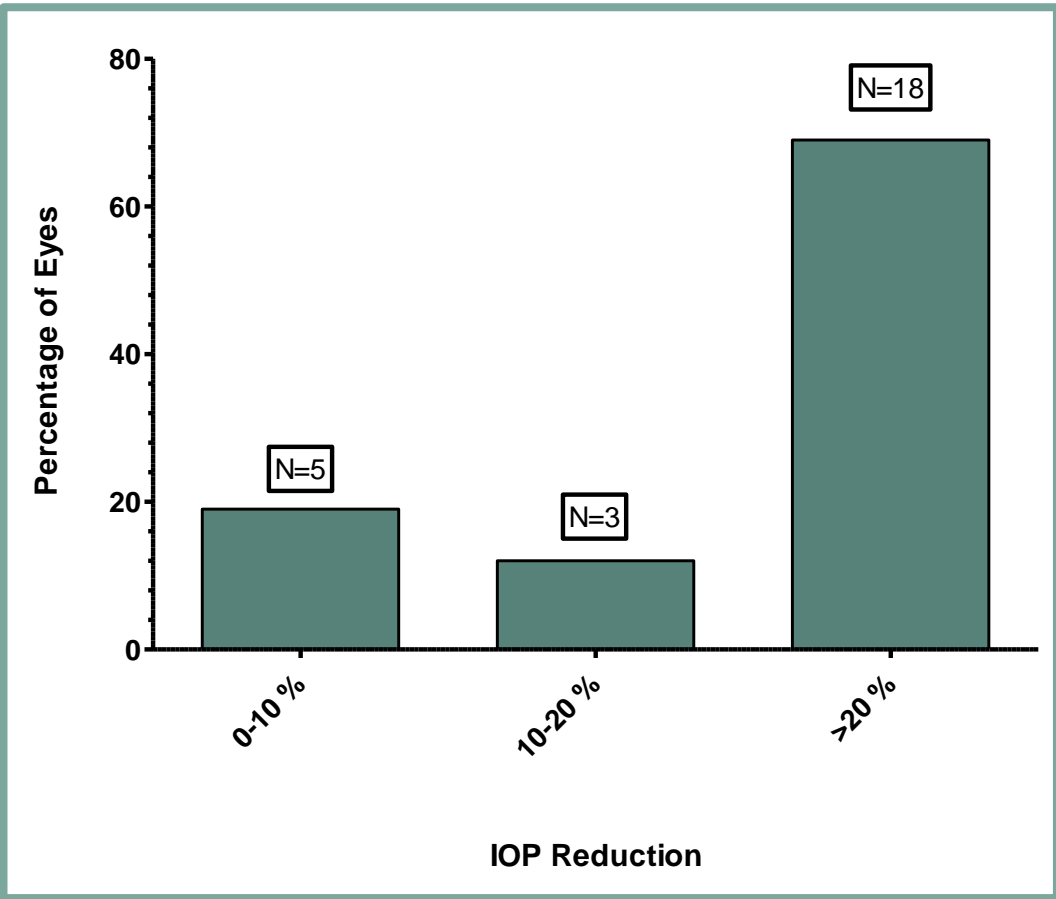


FIGURE 2: Proportional Analysis of POST-OP IOP Reduction

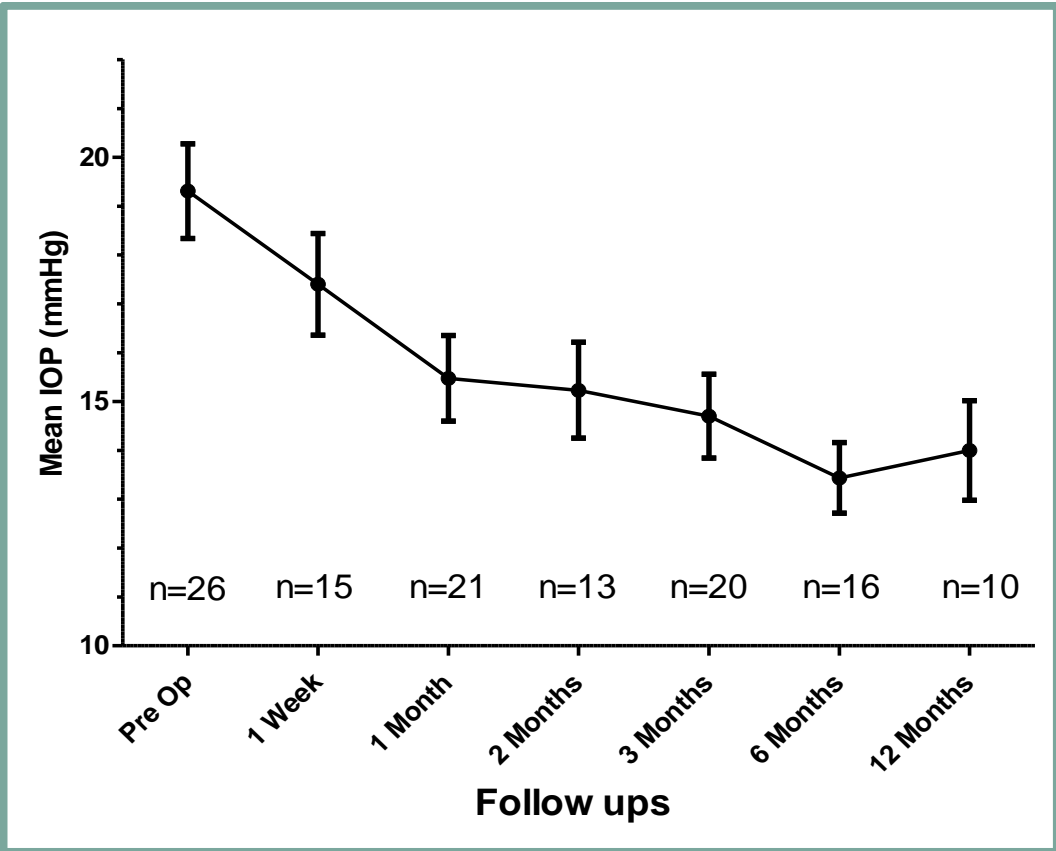


FIGURE 3: Mean IOP (mmHg) values VS Follow Up

References

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