Case report

Delayed bilateral hypertensive crisis with CyPass Micro-stent – The highs and lows

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ABSTRACT

Purpose: Microinvasive glaucoma surgery and its associated devices remain a field of continued interest and innovation in the management of patients with glaucoma. While a range of outflow optimisation devices have been designed, the efficacy and safety and these devices remains to be proven, particularly in the long term.

Observations: The authors present the first reported case to our knowledge of bilateral hypertensive crisis associated with CyPass® Micro-stent insertion two months post-operation and its resultant management.

Conclusions and importance: Despite the recall of the CyPass Micro-stent (Alcon, Fort Worth, Texas, USA), further clinical experience in the use of these and similar stents is required. Possible hypotheses explaining this phenomenon are also presented, the most likely being sudden closure of the suprachoroidal space.

1. Introduction

Microinvasive glaucoma surgery can be described as a surgical procedure or device implantation, often employed using a self-sealing corneal incision accompanying cataract surgery,** that aims to decrease intraocular pressure with rapid clinical recovery. This surgical approach creates options that attempt to lessen risks and require minimal conjunctival dissection. Traditional surgical options such trabeculectomy have documented efficacy but these procedures are not without risks, such as cataract formation, hypotony, subconjunctival fibrosis, choroidal haemorrhage, bleb failure and bleb leakage.

The CyPass® Micro-stent (Alcon, Fort Worth, Texas, USA) was approved by the Food and Drug Administration for management of mild to moderate open-angle glaucoma in conjunction with cataract surgery, following the results of the COMPASS two-year randomised control trial, which evaluated microstent insertion in conjunction with cataract extraction and intraocular lens insertion.1 COMPASS demonstrated early and sustained intraocular pressure reduction (> 20% of total, without medication) and a 2 mmHg reduction in favour of stent insertion compared to cataract surgery alone. The CyPass Micro-stent was recently recalled following an observed reduction in endothelial cell counts at the 5-year review of the COMPASS patient cohort.2

Some studies comment on raised intraocular pressure as a possible adverse event, which was reported as transient and usually self-limiting in the acute setting. We report the first case to our knowledge of bilateral hypertensive crisis associated with CyPass insertion 2-months post operation with reduction of visual acuity.

2. Case report

A 55-year-old female had a past ocular history of congenital nystagmus and myopic astigmatism, managed at the same practice for 14 years. Her medical history included a cervical disc fusion (C5-6) at age 37, epilepsy and olecranon bursitis of her right arm. Her medications included sodium valproate 700mg twice daily and supplemental calcium and vitamin D. In 2004, she presented with raised intraocular pressure at 40 mmHg in the right eye and 27 mmHg in the left (measured with Goldmann applanation tonometry).

Her visual acuity has never been measured as better than 6/12 bilaterally. Her cup-to-disc ratios were 0.7 in the left eye and 0.8 in the right, with open angles on gonioscopy. Her central corneal thickness on optical coherence tomography was 578 μm in the right eye and 584 μm in the left. Examination a demonstrated bilateral inferior scotoma; this did not progress during treatment. She was commenced on Timolol 0.5% BD; until 2018, her pressures were maintained close to the target pressure of 20 mmHg on timolol 0.5% BD.

Obtained in 2014, her Ocular coherence tomography (Stratus OCT, Carl Zeiss Meditec) at presentation demonstrated a retinal nerve fibre layer thickness of 64 μm in the right eye and 46 μm in the left with optic nerve head rim areas of 0.88 and 0.90 mm², respectively (Fig. 1).

In 2018 the patient developed visually significant cataracts with...
reduction in visual acuity to 6/18 bilaterally with no evidence progression of progression of glaucomatous optic neuropathy. At this her pressures were 30 mmHg in the left eye and 33 mmHg in the right eye. A change to combination latanoprost 0.005% and timolol 0.5% eye drops resulted in pressure reduction to 15–24 mmHg bilaterally during observation. Latanoprost was not well tolerated (ocular discomfort) and the decrease in vision was associated with cataract with no associated glaucomatous progress. (Figs. 2 and 3):

A decision with the patient was made to undertake CyPass insertion in conjunction with cataract extraction. Her preoperative spherical equivalent refraction was −6.50 D in both eyes, with axial lengths of 25.2mm in the right eye and 24.9mm in the left.

The patient was scheduled for CyPass insertion in conjunction with cataract extraction and insertion of intraocular lens of her left eye (26/3/18) and her right eye two-weeks later (9/4/18). There were no intraoperative or postoperative complications; the patient was commenced on ciprofloxacin 0.3% and dexamethasone 0.1% drops TDS and nepafenac 0.1% daily for three weeks and ceased her glaucoma medications. Her systemic medications remained unchanged. At serial one-day and one-week reviews the patient achieved a best corrected visual acuity of 6/12 in both eyes – at both visits her intraocular pressures remained between 10 and 14 mmHg bilaterally. At one-month review, the patient maintained a best-corrected visual acuity of 6/12 in both eyes, noting intraocular pressures of 14 mmHg on right and 13 mmHg on the left.

Two months post-operation, the patients presented with an acute bilateral ocular hypertensive crisis: measured intraocular pressures were 83 mmHg in the right eye and 56 mmHg in the left. Best-corrected visual acuity was also reduced to 6/60 in the right eye and 6/15 in the left.

Clinical examination revealed microcystic oedema with a hazy cornea in both eyes. Her anterior chamber was deep and quiet. Gonioscopy demonstrated open angles and a well-positioned CyPass implant. There was no visible evidence of luminal occlusion in either eye. The microcystic oedema and haze was very mild and did not preclude accurate anterior chamber and examination and cleared.
within 24 hours. The following day examination findings were repeated and confirmed.

The patient was given oral acetazolamide, apraclonidine 0.5% and travaprost 0.04%/timolol 0.5% drops. With minimal intraocular pressure change over 2 h, she underwent a paracentesis in the right eye which reduced the intraocular pressure to 11 mmHg. She was then discharged on travaprost 0.04%/timolol 0.5%, brimonidine tartrate 0.2%/brinzolamide 1% and acetazolamide 250mg four times a day.

Over the course of a week, with intraocular pressure readings within 6 mmHg of the above, the patient was weaned to 250mg of acetazolamide daily. At 1-week post presentation, pressures were measured at 16 mmHg in the right eye and 25 mmHg in left eye with reduced vision to 6/30 in the right eye and 6/30 in the left eye. Clinical examination revealed a shallow anterior chamber and open angles. A small, inferior choroidal effusion and hypotonic maculopathy was also identified in the right eye.

Acetazolamide and brimonidine tartrate 0.2%/brinzolamide 1% were discontinued. The patient’s intraocular pressure subsequently stabilised and the choroidal effusion and hypotonic maculopathy resolved. Bilateral posterior chamber opacifications were identified 3-months post-op and received bilateral YAG laser capsulotomy was performed at nine-months post-op with no complications. At one year post-presentation, the patient demonstrated intraocular pressures of 13 mmHg in right eye and 24 mmHg in left eye whilst on travoprost 0.04%/timolol 0.5%. Best-corrected visual acuity in the right eye was 6/12 bilaterally; deep anterior chambers with well positioned CyPass stents were noted on examination bilaterally. Visual field tests were repeated, which demonstrated no progression no new field defects or glaucoma progression.

3. Discussion

The authors present the first case, to our knowledge, of bilateral hypertensive crisis associated with CyPass insertion two-months post-operatively with reduced visual acuity. The patient’s intraocular pressure subsequently stabilised and the choroidal effusion and hypotonic maculopathy resolved. Bilateral posterior chamber opacifications were identified 3-months post-op and received bilateral YAG laser capsulotomy was performed at nine-months post-op with no complications. At one year post-presentation, the patient demonstrated intraocular pressures of 13 mmHg in right eye and 24 mmHg in left eye whilst on travoprost 0.04%/timolol 0.5%. Best-corrected visual acuity in the right eye was 6/12 bilaterally; deep anterior chambers with well positioned CyPass stents were noted on examination bilaterally. Visual field tests were repeated, which demonstrated no progression no new field defects or glaucoma progression.

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The two-year COMPASS trial results revealed 16 patients (4.3%) having IOP > 10 mmHg, however, this was transient and did not affect
Complications of CyPass included best-corrected visual acuity loss (> 10 letters) in 33 patients (8.8%), iritis in 32 patients (8.6%), hypotony (intraocular pressure < 6 mmHg) in 11 patients (2.9%) and hyphema 10 patients (2.7%). Similar complication rates were seen in the 12-month post-insertion analysis performed by Hoeh et al. More recently identified in the COMPASS-XT trial was an increase in corneal endothelial cell loss. Similarly, the DUETTE trial, reviewing microstent insertion as a standalone therapy, demonstrated that 10 of 65 eyes (15%) developed intraocular pressure changes 10 mmHg above pre-insertion readings or greater than 30 mmHg within twelve months but did not comment on the timeframe or severity of the increase. Five cases were treated medically while the others underwent an additional glaucoma procedures such as laser trabeculoplasty, second microstent insertion or trabeculectomy. Hoeh et al. reported in a cohort of 167 eyes, 3 cases (1.2%) of intraocular pressures > 30 mmHg and 10 mmHg above baseline within one month of insertion (40% of overall intraocular pressure spikes in their cohort), as well as 23 cases (14%) of hypotony. The authors suggested cases of transient ocular hypertension may be associated with concurrent phacoemulsification, microstent insertion and/or the cessation of glaucoma medications prior to surgery.

The authors’ hypothesis of the nature of the intraocular pressure elevation in the presented case is a sudden closure of the suprachoroidal space combined with a possible underlying longer-term increase in trabecular meshwork resistance. This may have resulted in a sudden surge of intraocular pressure analogous to the sudden closure of a cyclodialysis cleft.

Intraocular pressure spikes following cyclodialysis cleft closures have been previously reported. In Ionnidis et al.’s cohort of 17
patients undergoing cyclodialysis cleft closure with conventional or surgical cryopexy for clefts refractory to conventional therapy 12 patients had postoperative intraocular pressure rises of > 20 mmHg. Küchle and Naumann’s performed retrospective analysis of 29 patients who underwent consecutive direct surgical cyclopxe for hypotony secondary to cyclodialysis: 14 cases experienced reversible pressure spikes of up to 58 mmHg in the first post-operative days, though noted no secondary glaucoma persisted in follow-up. 

Pastor et al. performed a one-year analysis of patients following CyPass insertion. Performing ultrasound biomicroscopy at 2, 6 and 12 months post-insertion, the group evaluated the presence of suprachoroidal and peri-implant fluid; at two months all 24 eyes demonstrated fluid in the suprachoroidal space, with five patients demonstrating fluid in all four quadrants (as opposed to solely the quadrant where the CyPass was inserted). At six-months, only one eye demonstrated fluid in all four quadrants. The authors hypothesise the reduction in suprachoroidal fluid may be analogous to cleft closure and potentially trigger an intraocular pressure surge.

While fibrosis of the suprachoroidal space is a potential cause of delayed IOP elevation, the sudden surge in intraocular pressure seen in this patient (rather than a slow rise) suggested this aetiology was less likely. Other causes such as luminal occlusion, incorrect positioning, inflammatory and steroid sensitivity were clinically excluded in this patient. The authors reflect that similar patients may require reduced intervals between follow-up. Analysis of the structural changes in the suprachoroidal space could be monitored to potentially predict patients who may be susceptible to sudden intraocular pressure surges. If ultrasound biomicroscopy is available to cases with high intraocular pressure with similar devices in situ, it may prove useful in confirming this suggested mechanism by examining the depth of the suprachoroidal space and if this has acutely altered within the cohort, as seen in Pastor et al.’s analysis. The authors also suggest that the possible benefits of continuing glaucoma medication regimens following an implant insertion are worth further analysis and discussion.

4. Conclusions

While the Cypass implant has been recalled, lessons learned from its complications will remain relevant in current practice as a variety of other implants, past and present, have utilised a suprachoroidal outflow pathway. Previously used devices such as the Gold Micro-Shunt (SOLX Inc., Occulogix, Waltham, MA, USA), STARflo implant (ISTAR Medical, Isnes, Belgium), and iStent Supra (Glaukos, San Clemente, CA, USA) provide intraocular pressure reduction through suprachoroidal stenting. The suprachoroidal space is not traditionally targeted for intentional intraocular pressure reduction; if clinicians are to utilise surgical approaches to this space effectively in the future, there is a need to understand the potential complications that may ensue. Specifically, patients may need to be more closely monitored for delayed post-operative IOP spikes, as seen in this case.

Patient consent

The patient consented to publication of the case in writing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajo.2020.100635.

References

1. Vold S, Ahmed IIK, Craven ER, Mattus C, Stamper R, Packer M, et al. Two-year COMPASS trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. Ophthalmology. 2016;123(10):2103–2112.
2. A Study to Assess Long-Term Safety of the CyPass Micro-stent in Patients Completing the COMPASS Trial. https://ClinicalTrials.gov/show/NCT02700984.
3. Saheb H, Ianchulev T, Ahmed II. Optical coherence tomography of the suprachoroid microstent. J Ocul. Pharmacol. Therapeut.: ophthalmol. 2018;34(7):538–542.
4. García-Feijoo J, Hoh H, Uznov R, Dickerson Jr JE. Supraciliary microstent in refractory open-angle glaucoma: two-year outcomes from the DUETTE trial. J. Ocul. Pharmacol. Therapeut.: ophthalmol. 2013;39(7):538–542.
5. Hoeh H, Ahmed II, Grisanti S, Grabner G, Nguyen QH, et al. Early postoperative safety and surgical outcomes after implantation of a suprachoroidal micro-stent for the treatment of open-angle glaucoma. Br J Ophthalmol. 2014;98(1):19–23.
6. Garcia-Feijoo J, Hoh H, Uznov R, Dickerson Jr JE. Supraciliary microstent in refractory open-angle glaucoma: two-year outcomes from the DUETTE trial. J. Ocul. Pharmacol. Therapeut.: ophthalmol. 2013;39(7):538–542.
7. Ioannidis AS, Bunce C, Barton K. The evaluation and surgical management of cyclodialysis clefts that have failed to respond to conservative management. Br J Ophthalmol. 2014;98(4):544–549.
8. Kuchle M, Naumann GO. Direct cyclopxe for traumatic cyclodialysis with persisting hypotony. Report in 29 consecutive patients. Ophthalmology. 1995;102(2):322–333.
9. Pastor E, Bermudez M, Morales-Fernandez L, Martinez de la Casa J, García-Feijoo J. Ultrasound biomicroscopy findings after suprachoroidal cypass implant for glaucoma: one year follow-up. Invest Ophthalmol Vis Sci. 2013;54(15):4773.