

Primary Outcomes of combined cataract extraction technique with ab-interno trabeculectomy Dual-Blade and Endoscopic cyclophotocoagulation in patients with primary open angle glaucoma

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Abstract

Purpose: To provide an update of primary outcomes of combined phacoemulsification technique with ab-interno trabeculectomy Dual Blade and Endoscopic cyclophotocoagulation (ECP) in patients with primary open angle glaucoma. **Methods:** Retrospective case series comprised 27 consecutive eyes, with open-angle glaucoma (POAG) and cataract with combined phacoemulsification, ab-interno trabeculectomy-Kahook Dual Blade and Endocyclophotocoagulation at Instituto de ojos Oftalmosalud, Lima, Perú, between April 2017 and May 2017. Inclusion criteria were Glaucoma patients with POAG from mild to severe, according to Glaucoma Grading Scale (HODAPP), cataract condition, treatment with two or more glaucoma medications and visual field defects continued worsen. Intraocular pressure (IOP), Best corrected visual acuity (BCVA) logMAR, and number of glaucoma medications were recorded before, and 1 day, 1 week, and 1, 3, 6 and 9 months after surgery. Defining succes as IOP <14 mmHg with or without medications. **Results:** A total of 27 cases of glaucoma eyes were included. The mean IOP was 17.0 ± 3.7 mmHg preoperatively, 11.6 ± 1.9 mmHg at 6 months, and 11.4 ± 1.8 mmHg at 9 months ($P < 0.001$). There was a corresponding drop in glaucoma medications from 1.9 ± 1.41 at mean to 0.56 ± 1.05 at 9 months ($P < 0.001$). Preoperative best corrected visual acuity (BCVA) showed and improvement preoperative value from 0.4 ± 0.4 LogMAR ($p = 0.001$) to 0.2 ± 0.4 logMAR at 9 months. The main complication was blood reflux intraoperatively (66.7%), resolved within a few days. The mean IOP was reduce 32.9% from baseline and the qualifed succes was 92.6% at 9 months. **Conclusions:** Cataract extraction with phacoemulsification combined with ab-interno trabeculectomy Dual Blade and endoscopic Cyclophotocoagulation effectively lowered IOP and dependence on glaucoma medications.

Background

In the elderly it is common to find in the same patient cataract and glaucoma, both of which can be treated at the same time with a combined surgical treatment that consists of phacoemulsification and glaucoma surgery to improve vision and avoid progression while improving cost-effectiveness¹.

In the pathophysiology of open angle glaucoma is described a resistance of the outflow of aqueous humour, which is mainly in the juxtacanalicular portion of the trabecular meshwork; by performing an ab-interno trabeculectomy that disease portion is removed and the conventional outflow pathway is enhanced with posterior reduction of intraocular pressure (IOP)²⁻⁵.

Endoscopic cyclophotocoagulation is one of the safest armamentarium therapies for glaucoma; the ciliary processes are visualized directly and using diode laser energy treated precisely until shrinkage and whitening, this cause a reduction of aqueous humour production which decreases IOP effectively without the complications described for cycloablative procedures such as persistent hypotony, phthisis, inflammation or visual loss⁶⁻⁷.

Gold standard filtering surgery is associated with high rate of immediate and late complications as reported in the TVT study, for this reason, there is a trend to treat glaucoma patients with minimally

invasive procedures when maximal tolerated medical therapy fails to control visual field loss in initial or moderate glaucoma.

In this study a combined treatment of Phacoemulsification, ab-interno trabeculectomy and ECP was performed to treat uncontrolled POAG, with this combined glaucoma procedures double mechanism for reducing IOP is expected, the former increases aqueous outflow and the second reduces aqueous production; an update of the technique, reduction of IOP, glaucoma medications and visual acuity is evaluated.

Methods

This retrospective case series comprised 27 eyes of 21 patients, with uncontrolled open-angle glaucoma (POAG) and cataract, having combined phacoemulsification, ab-interno trabeculectomy with Kahook Dual Blade (New World Medical Inc., Rancho Cucamonga, CA, USA), and ECP, at Instituto de ojos Oftalmosalud, Lima, Peru, between April 2017 and May 2017. The ab-interno trabeculectomy was performed 90-120 degrees, and Endoscopic cyclophotocoagulation was performed 360 degrees through 2 site corneal incisions. The mean duration of the follow-up period was 9 months.

The Institutional Review Board of Instituto de Ojos Oftalmosalud in accordance with Declaration of Helsinki approved this retrospective study. We also obtained an informed consent from all patients after an explanation of the procedures to be used.

Inclusion Criteria: Glaucoma patients with uncontrolled POAG from mild to advanced, according to Glaucoma Grading Scale (HODAPP), cataract condition, treatment with two or more glaucoma medications; uncontrolled was defined as progression in at least 2 visual fields and/ or retinal nerve fibre layer thinning in spectral domain optical coherence tomography (sdOCT)

Exclusion Criteria: history of glaucoma surgery, any subsequent glaucoma surgery in the follow-up period, narrow angles or closed angle glaucoma, neovascular, uveitic or other secondary glaucoma, retinal or neurophthalmic diseases.

The intraocular pressure (IOP), best corrected visual acuity (BCVA) LogMAR, and number of glaucoma medications were recorded before and at 1 day, 1 week, and 1, 3, 6 and 9 months after surgery. At each visit, the IOP was measured with a Goldmann applanation tonometer. The intra and postoperative complications were recorded. Qualified Success was defined as IOP <14 mmHg with or without glaucoma medication.

Surgical modified Technique

All procedures were performed by the same surgeon (JCI). First, Phacoemulsification and IOL implantation was performed using 2,2mm keratome and 1.20 mm side-port blade, the anterior chamber

was filled with preservative-free lidocaine 1%, and an ophthalmic viscosurgical device (OVD) (Healon GV; Abbott Medical Optics, Santa Ana, CA, USA). Continuous curvilinear capsulorhexis (CCC) was created with a capsulorhexis fórceps. Lens segmentation was performed using a stop and chop technique. Surgery was then completed followed by intraocular lens (IOL) implantation in the capsular bag after successful removal of the lens cortex.

Secondarily, ECP (Endo Optiks® E2 Ophthalmic Laser Endoscopy System, Beaver-Visitec International, Inc. USA) containing an endoscope, an illumination source, the diode LASER (810 nm) and a helium-neon aiming beam, was inserted into the anterior chamber via the main corneal incision. Once the intraocular lens (IOL) is positioned in the bag, viscoelastic is injected to expand the sulcus behind the iris, and the diode laser ablation of the ciliary processes is performed under direct visualization via a 20G endoscope. In order to reach 360 degrees of the ciliary processes, a second incision 180 degrees away from the initial incision was made. The physical goals of treatment are to whiten the ciliary processes and cause visible shrinkage of the tissue, avoiding explosion. With 2 site corneal incisions 360 degrees were treated successfully with 0.2W energy on continues mode (Figure 1).

Finally, a 2.2 mm wide iris planar clear corneal incision is fashioned approximately 2 mm anterior to the surgical limbus. Viscoelastic is used in the anterior chamber. The patient's head is rotated 40 degrees away from the surgeon, and the microscope is tilted in the opposite direction. Gonioscopic visualization, with the goniolens (AVG; Surgical Gonio Lens, Volk Alcon, Mentor, OH, USA). The Trypan blue was use to stain the TM. The Kahook dual-blade (KDB; New World Medical, Rancho Cucamonga, CA, USA) is engaged in the TM just anterior to the scleral spur for a more pointed entry into the meshwork, then it's advanced 90 degrees parallel toward the wall of the canal. Intracameral dexamethasone 0.8 mg/0.2 ml was administered to all patients in addition to standard cataract antibiotic prophylaxis (intracameral cefuroxime 1.0 mg/0.1 ml). The corneal incisions were then closed with 10-0 nylon (Figure 2).

Postoperative care routinely included tobramycin 3mg/ml and dexamethasone 1mg/ml (Trazidex, Sophia, México) 6 times daily tapered over 1 week, and pilocarpine 1% (Pil, Sophia, México) 3 to 4 times daily tapered over 4 weeks. In all cases, the glaucoma medication was discontinued at the time of surgery and restarted in selected cases according to IOP.

Statistical Analysis

To compare the changes in IOP, according to the observation period, we used the non-parametric Friedman test, followed by a post-hoc multiple comparison test. For change in the number of glaucoma medications, the signed test for paired samples was used. The statistical tests we considered significant if p value was less than 0.05. The analysis was done with statistical software R, versión 3.4.3 (<https://www.r-project.org/>).

Results

This study included 27 eyes from 21 patients who underwent the combined surgical procedure and followed for at least 9 months. Mean age was 69.1 ± 8.09 (range: 53- 85) years old. A total of 16 females (59.2%) and 11 males (40.7%), 10 (37%) right eyes and 17 (62.9%) left eyes were analysed.

All eyes with POAG were classified into 3 groups according to Glaucoma Grading Scale (HODAPP): 10 (37%) eyes were mild, 10 (37%) eyes moderate, and 7 (25.9%) eyes advanced. All 3 categories had a reduction in IOP at 9 months follow-up, but multiple comparisons with Nemenyi test after Friedman test showed a statistically significant improvement from the third month ($p=0.010$) in the mild glaucoma group, from the nine month for the moderate glaucoma group ($p=0.031$) and without statistically significant improvement in the advanced glaucoma group in any follow-up time, this can be attributed for the smaller sample size of this group. The IOP in the mild glaucoma group reduced 7.1 mmHg, in the moderate glaucoma group the reduction was 4.2 mmHg, and in the advanced glaucoma group the reduction was 6.6 mmHg at 9 months (Figure 3).

Intraocular pressure

The mean preoperative IOP was 17.0 mmHg [± 3.7], postoperative IOP was 15.0 mmHg [± 5.3], 13.4 mmHg [± 4.1], 12.1 mmHg [± 1.9], 11.6 mmHg [± 1.9], 11.4 mmHg [± 1.8] at 1 week, 1, 3, 6, and 9 month respectively, ($p<0.001$). The mean IOP was reduced by 32.9% from baseline and the qualified success was 77.8% in the first month and 92.6% at 9 months follow-up (Figure 4).

Medication outcomes

The number of glaucoma medications preoperative was 1.9 [± 1.41], and postoperatively was 0.56 [± 1.05] at 9 months. The number of postoperative glaucoma medication was significantly reduced, 19 (70.3%) eyes were without glaucoma medication, 4 (14.8%) eyes with 1 medication, 4 (7.4%) eyes with 2 medications, 1 (3.7%) eye with 3 medications and 1 (3.7%) eye with 4 medications at 9 months ($P<0.001$). (Figure 5).

Visual acuity outcomes

Preoperative best corrected visual acuity (BCVA) showed and improvement from 0.4 ± 0.4 LogMAR to 0.2 ± 0.4 LogMAR at 9 months with no statistically significant differences.

Postoperative Complications

The most common complications include: 1) hyphema (66,7%), found during the first week which resolved spontaneously in all cases at one month of follow up. 2) Intraoperative reflux bleeding was observed in all cases, but stopped by the time the surgery was completed. 3) corneal edema (7.4%). 4) Transient hypotony (3,7%). 5) Temporary IOP spike (6%). Complications such as iris injury, corneal descompensation, corneal injury, cyclodialysis, choroidal hemorrhage or endophthalmitis were not found.

Discussion

This retrospective study of patients with uncontrolled POAG at different stages of the disease, showed a reduction of IOP, glaucoma medication with stable best corrected visual acuity at 9 months follow-up when a combined minimally invasive procedure consisting in phaco, ab-interno trabeculectomy and ECP is performed.

Cataract extraction as a stand alone procedure don't provide a significant reduction of IOP in patients with primary open angle glaucoma¹, therefore a combined treatment with a glaucoma surgery is almost always the choice for adequate control of the intraocular pressure. The available evidence suggests at most a modest reduction in IOP from cataract extraction around 1.5-3 mmHg⁹ possibly via decompression or mechanical stretch of the TM and Schlemm's canal⁷. Siegel et al. demonstrated a statistically significant difference between the combined phaco-ECP group versus phaco alone¹⁰.

The combination of ECP with phacoemulsification and ab-interno trabeculectomy with phacoemulsification has been studied¹¹. Kaplowitz K. Et all, described ECP used for POAG decreases IOP by 8%–47%, to a final average near 15 mm Hg¹². Clement et al. combining phaco-ECP observed IOP reductions up to 69%, the mean reduction of 23.9% 12 months after treatment^{7,13}.

A trial by Berke et al. compared 626 eyes treated with phacoemulsification/ECP and 81 eyes underwent phacoemulsification alone. The follow-up period ranged from 6 months to 5.5 years. In the phacoemulsification/ECP group, mean IOP decreased 3.4 mm Hg, from 19.1 to 15.7 mm Hg. In the control group, mean IOP increased 0.7 mm Hg, from 18.9 to 18.2 mm Hg. More significantly, the number of preoperative glaucoma medications decreased from a mean of 1.53 to 0.65 at the end of the follow-up period in the phacoemulsification/ECP group. There was no visual loss or significant adverse events postoperatively⁶. In our study the preoperative best corrected visual acuity (BCVA) showed and improvement from preoperative value of 0.4[± 0.4] LogMAR to 0.2 [± 0.4] LogMAR at 9 months (p=> 0.001).

In our combined study, the mean IOP was reduced 32.9% from baseline and the qualified success was 92.6% at 9 months. Morales et al., with Phaco/ECP reported the results obtained for IOP lowering to 15 mmHg and report an absolute success of 11.9% and a qualified success of 72.3%¹⁴. A retrospective Brazilian study on 247 patients, defined success based on IOP 21mm Hg, with 3 years of follow-up reported the corresponding rates were 55.7% for absolute success and 90.7% for qualified success¹⁵.

By the other side, The Kahook dual-blade shows promise as a refined and economical device for the treatment of glaucoma³. Salinas et al. studied 53 eyes and the mean IOP decreased from 18.4±6.1 mm Hg at baseline to 13.9±3.5 mm Hg at 6 months follow-up (23.9% reduction, $p < 0.001$); At 6 months, 63.5% achieved an IOP ≤ 14 mmHg and the mean number of glaucoma medications was reduced 1.2±1.3 compared to baseline ($P < 0.001$), a reduction of 36.6% was found¹⁶. In our study with the combined procedures the mean IOP decreased from 17.0±3.7 mmHg at baseline to 11.6±1.9mmHg at 6 months (31.7% reduction, $P < 0.001$), and an IOP of 11.4±1.8 mmHg at 9 months (32.9% reduction, $P < 0.001$). The IOP was significantly reduced ($P < 0.001$). The mean number of glaucoma medications was reduced 0.56±1.05 (29.5% reduction) from baseline to 9 months statistically significant ($P < 0.001$).

SooHoo et al., in a preclinical study of human donor of corneo-scleral rims; the dual blade device was used to incise TM and then compared with trabectome. Dual-blade showed more complete TM tissue removal and no significant damage to adjacent tissues³. Seibol et al., at the laboratory evaluation in a human eye perfusion model, demonstrated that trabectome treatment across 117.5 ± 12.6 degrees resulted in a decrease of IOP from 18.8 ± 1.7 mm Hg to 11.3 ± 1.0 mm Hg ($P < .01$) and with Dual-blade device treatment across 157.5 ± 26.3 degrees resulted in a decrease of IOP from 18.3 ± 3.0 mm Hg to 11.0 ± 2.2 mmHg ($p < 0.01$). The novel dual-blade device demonstrated a more complete removal of TM without residual TM leaflets or damage to surrounding tissues and significantly reduced IOP¹⁷.

Kaplowitz et al., showed that ab-interno trabeculectomy can be expected to lower the IOP by approximately 36% to a final mean IOP around 16 mmHg while decreasing the number of medications by less than one¹². Fallano et al. used a combined treatment of phaco-trabectome with 18% reduction in IOP². The cases of Trabectome combined with phacoemulsification showed a decrease in IOP from a preoperative mean of 20.0 ± 6.2 mmHg to a mean of 15.9 ± 3.3 mmHg at 12 months (n = 45), a decrease of 18%³. Francis et al. studied 304 patients treated with combined phaco-trabectome surgery, the mean IOP fell from 20.0±6.3 mmHg to 14.8±3.5 mmHg at 6 months and 15.5±2.9 mmHg at one year. The mean number of glaucoma medications was reduced from 2.65 ± 1.13 to 1.76 ± 1.25 at 6 months and 1.44 ± 1.29 at 1 year.¹

Dang et al. combined trabectome and phaco-trabectome and divided the patients into 4 groups depending on glaucoma severity. The group with the higher glaucoma severity index (GI) has an IOP reduction of 2.34±0.19 mmHg more than the group with lower glaucoma severity index¹⁸. In our study, all subcategories showed a significant reduction in IOP 9 months after combined surgery. The mild group drop the IOP from 18.9 to 11.8mmHg, the moderate group from 15.3 to 11.1 mmHg, and advanced group from 17.4 to 10.8 mmHg.

The review and meta-analysis of Phaco/ECP from Kaplowitz et al., shows the most common complication is hyphema similar to the present study, the second most common complication was peripheral anterior synechiae in 24% of the patients. The most serious complication was hypotony 0.09% of all reposted cases¹². SooHoo et al., with the use of Trabectome, all patients had transitory hyphema

that resolved after 6.4 days.³ In our study, the most common complications include hyphema 18 (66.7%), intraoperative bleeding was observed in all cases, corneal edema (7.4%), transient hypotony (3,7%) and temporary IOP spike (6%) with no vision sequelae and no need for reoperations.

The main weakness of the study was the retrospective nature, low sample included and no control group.

Conclusions

Cataract extraction with phacoemulsification combined with ab interno trabeculectomy and endoscopic cyclophotocoagulation effectively reduced IOP and dependence on glaucoma medication with a very safety profile and stable best corrected visual acuity in patients with uncontrolled open angle glaucoma. Further study is needed comparing this combination treatment with the gold standard filtration surgery.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board Statement, the patient consented the publication of the case in writing. This report does not contain any personal information that could lead to the identification of the patient.

Consent for publication

We obtained a consent for data publication from all patients.

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare to have no competing interests: JCI; LCR; JMS; NA; BRL.

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Author's Contributions

JCI; Sustancial contributions to the conception and desing of the work. LCR; Data acquisition and analysis. JMS; Interpretation of data and substantively revised the work. NA; Have drafted the work or substantively revised it. BRL; Have drafted the work or substantively revised it. All authors read and approved the final manuscript.

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