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CASE SERIES

Excisional Goniotomy in Latino Patients with Open-Angle Glaucoma: Outcomes Through 24 Months

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Purpose: To characterize the efficacy of combined phacoemulsification and excisional goniotomy with the Kahook Dual Blade (KDB-phaco) in eyes of Latino adults with cataract and open-angle glaucoma (OAG).

Methods: Health records of consecutive Latino patients undergoing KDB-phaco were retrospectively reviewed. Intraocular pressure (IOP) and IOP-lowering medication use were recorded at baseline and each postoperative visit through up to 24 months. Primary outcomes were reductions in IOP and medication use from baseline; secondary outcomes were the proportions of eyes achieving IOP reductions of ≥20% and medication reductions ≥1 medication from baseline. Subgroup analysis was conducted in eyes with high and low baseline IOP.

Results: Data from 44 eyes of 32 Latino patients with OAG were analyzed. Mean IOP was 17.8 (0.7) mmHg at baseline and postoperatively ranged from 12.4 to 13.8 mmHg ($p \geq 0.0003$), representing mean IOP reductions of 4.2–4.6 mmHg (19.7–23.1%). Mean medication was 1.5 (0.2) medications per eye at baseline and postoperatively ranged from 0.2 to 1.0 ($p \geq 0.0061$), representing mean medication reductions of 0.7–1.2 medications per eye (47.1–87.2%). In the low baseline IOP group (<18 mmHg), mean IOP was significantly reduced through Month 24 and medications through Month 12; in the high baseline IOP group (≥18 mmHg), IOP and medications were significantly reduced through Month 24. From Months 1–24, IOP reductions of ≥20% were achieved by 48.4–56.2% of eyes in the full cohort, by 20.0–33.3% in the low IOP group, and by 66.7–100% in the high IOP group; medication reductions of ≥1 medication were achieved by 72.0–95.6%, 64.7–94.2%, and 87.5–100% of eyes, respectively.

Conclusion: Combined KDB-phaco in eyes of Latino patients with glaucoma and cataract significantly lowers IOP and the need for IOP-lowering medications for up to 24 months and should be considered for such patients who warrant IOP reduction, medication reduction, or both.

Keywords: glaucoma, intraocular pressure, excisional goniotomy, Kahook Dual Blade, Latino

Introduction

The prevalence of primary open-angle glaucoma (POAG) in Latino adults is approximately twice that of white adults in every decade of life, and its prevalence increases faster with age in Latinos than in any other ethnic group.[1] Among Latinos aged 40 years or older in the Los Angeles Latino Eye Study, 4.74% were found to have POAG overall, increasing from 1.32% in those aged 40–49 years to 21.76% in

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those 80 years or older.[2] Further, the 4-year incidence of newly-diagnosed POAG is 2.3% and of ocular hypertension (OHTN) is 3.5%.[3] Glaucoma is also a leading cause of blindness in Latinos.[4]

Little is known regarding treatment patterns or responses to therapy in Latinos with glaucoma. Overall, Latinos with glaucoma are less likely to be treated than whites,[5] and are less likely to undergo visual field or ocular imaging assessments than other ethnicities.[6] The Registry in Glaucoma Outcomes Research (RiGOR) study, no ethnicity-based differences were observed in responses to medical, laser, or surgical interventions for glaucoma.[7] An uncontrolled series of Latinos with glaucoma undergoing phacoemulsification, trabeculectomy, or phacotrabeculectomy demonstrated intraocular pressure (IOP) and IOP-lowering medication reductions consistent with those reported in white patients,[8] while several other studies have found Latino ethnicity to be a risk factor for surgical success following trabeculectomy[9,10] and tube-shunt implantation.[11] Regarding minimally invasive glaucoma surgeries, a series of Latinos undergoing combined phacoemulsification and trabecular microbypass implantation manifested IOP and medication reductions consistent with those reported in studies with primarily white patient samples,[12] and Latino ethnicity was a positive prognostic factor for success of trabecular ablation.[13]

In this paper, we report the outcomes of excisional goniotomy using the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) combined with phacoemulsification in Latino patients with glaucoma and visually significant cataract.

Methods

This was a retrospective analysis of data drawn from the medical records of Latino patients undergoing excisional goniotomy using the Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) combined with phacoemulsification (KDB-phaco) by a single surgeon in the United States. The study protocol was reviewed and approved by the Surgical Center of El Paso Executive Committee (El Paso, TX) in February 2019 (and revised to permit longer term data collection in June 2020) and a waiver of consent was granted and all data accessed complied with relevant patient data protection and privacy regulations. Reasonable requests for data sharing submitted to the authors will be considered.

Data from the medical records of consecutive adult self-identified Latino subjects with open-angle glaucoma and visually significant cataract undergoing elective KDB-phaco between 9 June 2016 and 8 May 2019 were included. Subjects were included with all stages of glaucoma severity, on any number of topical IOP-lowering medications (including none), and irrespective of any prior laser or incisional glaucoma procedures.

The KDB-phaco procedure has been described in detail.[14–25] Phacoemulsification and intraocular lens implantation were performed in standard fashion. The KDB was then introduced into the anterior chamber through the phacoemulsification incision and advanced to the nasal angle. Its tip was used to pierce the trabecular meshwork, and advanced to position the instrument's heel against the anterior (outer) wall of Schlemm canal and the ramp and blades approximating the posterior (inner) wall. The instrument was then advanced along the canal to excise a strip of TM extended through 3–4 clock hours, which was removed using forceps. Standard antimicrobial and anti-inflammatory therapy were prescribed for postoperative use.

In addition to demographic and baseline glaucoma characteristics, data extracted from the records included best-corrected visual acuity (BCVA), IOP, and the number of IOP-lowering medications at every postoperative visit. Intraoperative and postoperative adverse events were also recorded. Visual acuity was measured using the Snellen chart and converted to logMAR for analysis. Goldmann tonometry was used for IOP measurement. Medications were counted by the number of active ingredients in the formulation.

The primary outcomes of this analysis were the reductions from baseline in IOP and IOP medications at each postoperative time point (IOP beginning on postoperative Day 1 to reflect acute extremes of IOP, and medications beginning at Month 1 once variable postoperative medication use stabilized). These outcomes were assessed using two-sided paired t-tests, with the level of significance taken as $p=0.05$. Secondary outcomes included the proportion of eyes achieving IOP reductions of $\geq$20% and medication reductions $\geq$1 medication (the latter evaluated only in eyes on $\geq$1 medication at baseline) at each time point from Month 1 onward, after postoperative stabilization; these outcomes were evaluated using descriptive statistics. Subgroup analysis was undertaken in patients with high and low baseline IOP; the groups were defined by baseline IOP above or below the full cohort's mean baseline IOP. The purpose of this analysis was to evaluate outcomes based on likely individual surgical goals, with the assumption that eyes

with lower baseline IOP underwent surgery primarily to reduce the medication burden and eyes with higher baseline IOP primarily to reduce IOP. Safety analysis consisted of descriptive analysis of the nature and incidence of adverse events. Means are reported with standard errors. As no specific hypotheses were being tested, formal power/sample size analysis was not undertaken.

Results

Data from 44 eyes of 32 patients were included in this analysis. Demographic and baseline glaucoma status data are given in Table 1. All subjects were Latino, their average age was 69.8 (2.6) years, and most (65.6%) were female. Most (84.1%) had primary open-angle glaucoma, with the balance having pseudoexfoliation glaucoma. Mild, moderate, and severe cases of glaucoma were roughly equally represented, roughly one-third were using 2 or more IOP-lowering medications, and 15.9% had undergone prior laser or incisional glaucoma procedures. Mean follow-up was 19.6 (7.5) months; 72.7% of eyes (32/44) were seen at Month 24.

Table 1 Demographic and Baseline Glaucoma Status of the Study Participants

Subject-Level Variables	**n=32**
Age (yr), mean (SE)	69.8 (2.6)
Gender, n (%)	
Male	11 (34.4)
Female	21 (65.6)
Ethnicity, n (%)	
Latino	32 (100)
Eye-Level Variables	**n=44 eyes**
Diagnosis, n (%)	
POAG	37 (84.1)
Pseudoexfoliation OAG	7 (15.9)
Glaucoma severity, n (%)	
Mild	12 (27.3)
Moderate	17 (38.6)
Severe	15 (34.1)
Cup-disc ratio, mean (SE)	0.7 (0.25)
Medications at baseline, mean (SE)	1.5 (0.2)
Number of medications at baseline, n (%)	
0	14 (31.8)
1	14 (31.8)
2	2 (4.6)
3	10 (22.7)
≥4	4 (9.1)
Prior glaucoma interventions, n (%)	
Selective laser trabeculoplasty	2 (4.5)
Trabeculectomy	2 (4.5)
Tube-shunt	3 (6.8)
Study Eye, n (%)	
Right Eye	23 (52.3)
Left Eye	21 (47.7)

Mean IOP for the full cohort (Table 2) was 17.8 (0.7) mmHg at baseline and from Month 1 through up to Month 24 ranged from 12.4 to 13.8 mmHg ($p \geq 0.0003$), representing mean IOP reductions of 4.2–4.6 mmHg (19.7–23.1%). In the low IOP group (baseline IOP <18 mmHg), mean IOP was reduced from 14.8 (0.4) at baseline to 12.5–14.0 mmHg from Months 1–24 (mean IOP reductions of 0.9–2.4 mmHg [4.-5–15.3%]); these reductions were significant at Months 1, 3, and 24 ($p \leq 0.03$) but not at Months 6 or 12. In the high IOP group (baseline IOP ≥18 mmHg), mean IOP was reduced from 21.3 (0.9) mmHg to 11.8–14.6 mmHg at Months 1–24 (mean IOP reductions of 6.8–8.9 mmHg [28.7–42.3%]); these reductions were significant ($p \leq 0.0023$) at every time point. From Months 1–24, IOP reductions of ≥20% were achieved by 48.4–56.2% of eyes in the full cohort, by 20.0–-33.3% in the low IOP group, and by 66.7–100% in the high IOP group (Table 4).

Mean medication use for the full cohort (Table 3) was 1.5 (0.2) medications per eye at baseline and from Month 1 through up to Month 24 ranged from 0.2 to 1.0 ($p \geq 0.0061$), representing mean medication reductions of 0.7–1.2 medications per eye (47.1–87.2%). In the low IOP group, mean medication use was reduced from 1.1 (0.2) at baseline to 0.2–0.8 from Months 1–24 (mean reductions of 0.4–1.0 [46.1–90.7%]); these reductions were significant ($p \leq 0.0047$) at all time points except Month 24. In the high IOP group, mean medication use was reduced from 2.0 (0.4) to 0.3–1.3 at Months 1–24 (mean reductions of 1.1–1.6 [49.4–85.9%]); these reductions were significant ($p \leq 0.0379$) at every time point. From Months 1–24, medication reductions of ≥1 medication were achieved by 72.0–95.6% of eyes in the full cohort, by 64.7–94.2% in the low IOP group, and by 87.5–100% in the high IOP group (Table 4).

Safety outcomes are given in Table 5. The most common adverse events were transient IOP elevation seen in 8 eyes (18.2%) and corneal edema in 4 eyes (9.1%), the latter of which resolved within a one month in 3 cases. The one patient with persistent corneal edema through month 24 was absent from scheduled clinical exams following his one-month postoperative visit and did not

Table 2 Mean IOP and Changes from Baseline at Each Study Time Point

	All Eyes (N=44)					Baseline IOP < 18 mmHg (N=24)					Baseline IOP ≥ 18 mmHg (N=20)				
	n	Mean	Mean Change	Mean % Change	P value*	n	Mean	Mean Change	Mean % Change	P value*	n	Mean	Mean Change	Mean % Change	P value*
Baseline	44	17.8 (0.66)	–	–	–	24	14.8 (0.36)	–	–	–	20	21.3 (0.87)	–	–	–
Day 1	40	16.1 (1.38)	−1.57 (1.47)	−5.47 (8.31)	0.2923	22	14.5 (1.59)	−0.36 (1.66)	−0.69 (10.86)	0.8290	18	18 (2.34)	−3.05 (2.59)	−11.31 (13.03)	0.2537
Week 1	43	15.1 (0.95)	−2.67 (0.99)	−12.24 (5.33)	0.0104	24	14.2 (1.06)	−0.54 (1.06)	−2.96 (6.88)	0.6147	19	16.1 (1.70)	−5.37 (1.64)	−23.95 (7.75)	0.0043
Month 1	42	13.6 (0.81)	−4.19 (1.05)	−19.74 (5.23)	0.0003	23	12.7 (0.79)	−2 (0.86)	−12.37 (5.73)	0.0300	19	14.6 (1.52)	−6.84 (1.93)	−28.67 (9.00)	0.0023
Month 3	31	13.3 (0.66)	−4.58 (0.97)	−22.53 (4.22)	<0.0001	16	12.5 (0.50)	−2.37 (0.56)	−15.29 (3.34)	0.0007	15	14.2 (1.24)	−6.93 (1.75)	−30.26 (7.62)	0.0014
Month 6	37	13.8 (0.52)	−4.22 (0.96)	−18.69 (4.09)	0.0001	20	14 (0.48)	−0.85 (0.60)	−4.54 (3.83)	0.1754	17	13.6 (1)	−8.18 (1.50)	−35.34 (5.42)	<0.0001
Month 12	33	13.3 (0.51)	−4.39 (0.95)	−20.78 (4.19)	<0.0001	18	13.1 (0.66)	−1.44 (0.70)	−9.02 (4.93)	0.0565	15	13.5 (0.82)	−7.93 (1.46)	−34.90 (5.16)	<0.0001
Month 24	32	12.4 (0.51)	−4.31 (0.80)	−23.06 (3.82)	<0.0001	21	12.8 (0.64)	−1.91 (0.56)	−12.98 (3.70)	0.0027	11	11.8 (0.87)	−8.91 (1.19)	−4229 (4.81)	<0.0001

Note: *Significance for mean change from baseline.

Table 3 Mean Medications and Changes from Baseline at Each Study Time Point

	All Eyes (N=44)					Baseline IOP < 18 mmHg (N=24)					Baseline IOP ≥ 18 mmHg (N=20)				
	n	Mean	Mean Change	Mean % Change	P value*	n	Mean	Mean Change	Mean % Change	P value*	n	Mean	Mean Change	Mean % Change	P value*
Baseline	44	1.5 (0.22)	–	–	–	24	1.13 (0.20)	–	–	–	20	1.95 (0.41)	–	–	–
Month 1	42	0.26 (0.10)	−1.21 (0.21)	−87.1 (5.51)	<0.0001	24	0.17 (0.10)	−0.96 (0.20)	−90.74 (6.49)	<0.0001	18	0.39 (0.20)	−1.55 (0.40)	−80.67 (10.20)	0.0011
Month 3	32	0.44 (0.15)	−1.06 (0.20)	−82.2 (6.94)	<0.0001	16	0.31 (0.15)	−81 (0.24)	−87.18 (8.88)	0.0047	16	0.56 (0.27)	−1.31 (0.32)	−75.67 (11.20)	0.0011
Month 6	36	0.22 (0.09)	−1.14 (0.21)	−87.2 (5.43)	<0.0001	20	0.15 (0.11)	−0.75 (0.16)	−88.09 (8.27)	0.0002	16	0.31 (0.15)	−1.62 (0.42)	−85.92 (5.82)	0.0014
Month 12	33	0.82 (0.21)	−1 (0.22)	−58.4 (11.9)	<0.0001	18	0.61 (0.23)	−0.78 (0.22)	−59.37 (17.27)	0.0027	15	1.07 (0.37)	−1.27 (0.41)	−56.83 (15.53)	0.0077
Month 24	32	0.97 (0.22)	−0.66 (0.22)	−47.1 (13)	0.0061	21	0.81 (0.24)	−0.43 (0.23)	−46.08 (17.35)	0.0829	11	1.27 (0.45)	−1.09 (0.46)	−49.37 (18.70)	0.0379

Note: *Significance for mean change from baseline.

Table 4 Treatment Success at Each Study Time Point

	All Eyes			Baseline IOP < 18 mmHg			Baseline IOP ≥ 18 mmHg		
	IOP Reduction ≥ 20% (%)	Medication Reduction ≥ 1 (%)*		IOP Reduction ≥ 20% (%)	Medication Reduction ≥ 1 (%)*		IOP Reduction ≥ 20% (%)	Medication Reduction ≥ 1 (%)*	
Month 1	54.8	26	92.9	39.1	17	94.4	73.7	9	90
Month 3	48.4	21	91.3	31.2	12	92.3	66.7	9	90
Month 6	48.6	22	95.6	20.0	13	92.9	82.3	9	100
Month 12	51.5	22	84.6	27.8	13	81.2	80.0	9	90
Month 24	56.2	18	72.0	33.3	11	64.7	100.0	7	87.5

Note: *Among eyes on ≥1 medication at baseline.

Table 5 Adverse Events

Adverse Event	Incidence, n (%)
Intraocular pressure elevation	8 (18.2)
Corneal edema	4 (9.1)
Cystoid macular edema	1 (2.3)
Posterior capsule opacification	1 (2.3)
Epiretinal membrane	1 (2.3)
Branch retinal vein occlusion	1 (2.3)
Persistent hypotony	1 (2.3)

return for two years. The eye was hypotonous but associated with the self administration of four topical antiglauocma medications. Once mediations were discontinued, his intraocular pressure rose to target levels but the coreal edema persisted. Aside from the hypotony, most of the other ocular adverse events were not directly correlated to the surgery. Rather, predisposing co-morbidities were present in these subjects, which included uncontrolled diabetes mellitus and systemic hypertension. The subject with macular edema presenting at postoperative month 1 also had proliferative diabetic retinopathy. The vein occlusion occurred at postoperative year 1 and was not a manifestation of the surgery. The single case of persistent hypotony resolved without surgical intervention. Gonioscopic evaluation of the angle did not reveal iatrogenic cleft formation in this eye.

Three eyes required secondary glaucoma surgery: one eye failed at Month 3 and underwent diode cyclophotocoagulation, another developed a branch retinal vein occlusion and subsequent neovascular glaucoma unrelated to the procedure between Months 12–24 requiring a Baerveldt shunt, and one eye underwent selective laser trabeculoplasty at Month 24. Mean BCVA improved from 0.69 (0.10) at baseline to 0.45 (0.13) at Month 24 (p=0.0165); 13 eyes (29.5%) had BCVA of 20/200 or worse (including 6 with BCVA of counting fingers or worse) at baseline, of which 9 had BCVA of 20/200 or worse at last follow-up.

Discussion

In this analysis of Latino patients with cataract and glaucoma undergoing combined phacoemulsification and excisional goniotomy with the KDB, clinically and statistically significant reductions in both IOP (19–23%) and the need for IOP-lowering medications (47–87%) were achieved through up to 24 months of postoperative follow-up. The procedure was safe with few adverse events, most of which were self-limited.

This study demonstrates that KDB-phaco can provide long-term reductions in both IOP and medication use across the spectrum of baseline IOP. In eyes with low baseline IOP—many of which underwent surgery primarily to reduce the medication burden—mean IOP was significantly reduced at 24 months, and medications were significantly reduced at 12 but not 24 months. This group had a very low baseline IOP (14.8 mmHg), offering a narrow therapeutic window for IOP reduction; despite this, 33.3% achieved a ≥20% IOP reduction from baseline at Month 24, accomplished with concurrent reduction of the medication burden by ≥1 medication in 64.7%. In the high baseline IOP group, both IOP and medications were significantly reduced at all time points through Month 24; 100% of these eyes achieved a ≥20% IOP reduction and 87.5% a ≥1 medication reduction by Month 24.

These outcomes in Latino patients compare favorably to outcomes of similar studies in other populations, in which combined KDB-phaco lowered IOP 12–27% and medications by 21–71% in studies of 6–12 months in duration.[14–26] Of these studies, one is a randomized clinical trial comparing excisional goniotomy with the KDB to trabecular microbypass implantation (iStent, Glaukos,

San Clemente, CA) in combination with phacoemulsification in which 12-month IOP reductions were 15% and 11%, respectively (p=0.2903), and medication reductions were 79% and 71%, respectively (p=0.2707).[26] The safety profile characterized in the current study is also similar to that described in prior studies, with the exception of corneal edema, which occurred in 4 eyes (9.1%). Of note, 2 of these eyes had low vision (counting fingers and light perception) at baseline due both to advanced glaucoma and dense cataract requiring higher than typical ultrasound energy for extraction.

Outcomes of glaucoma surgery in Latinos—particularly in comparison to outcomes in other ethnicities—are incompletely characterized in the literature. Gallardo and Supnet reported IOP and medication outcomes 1 year following combined phacoemulsification and trabecular micro-bypass (iStent, Glaukos, San Clemente, CA) in a predominantly (76%) Latino population[12] that were similar to those reported in the device's first- and second-generation registry trials[27,28] and persisted through 3 years of follow-up.[29] Interestingly, Latino ethnicity was associated with lower failure rates than other ethnicities following trabecular ablation (Trabectome, Microsurgical Technology, Redmond, WA)[13] but higher failure rates for trabeculectomy.[30]

Strengths of this study include its focus on Latino patients, a group in whom glaucoma and blindness are highly prevalent and yet little is known about the efficacy and safety of modern glaucoma therapies. Also, the duration of follow-up—up to 24 months in the majority (73%) of eyes—is beneficial in characterizing longer-term outcomes given the chronic nature of glaucoma. The retrospective nature of data collection is a limitation of the study; the risk of selection bias was mitigated by including data from all Latino subjects undergoing the procedure within the data collection window. The lack of a control group is also a limitation that precludes benchmarking these outcomes against other procedures, although the similarity of the results in this series to published results of other studies—including comparative studies[16,18,20,21,25,26] supports the representative nature of these data. Also, as this was a retrospective study, there was no specific protocol for the addition or withdrawal of medications; instead, these decisions were made by the investigator on a case by case basis determined by clinical status, as reflects clinical practice.

In summary, combined KDB-phaco in eyes of Latino patients with glaucoma and cataract significantly lowers IOP and the need for IOP-lowering medications for up to 24 months. This procedure can be considered for such patients who warrant IOP reduction, medication reduction, or both.

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