ORIGINAL RESEARCH

Postoperative Management of Kahook Dual Blade Goniotomy with Phacoemulsification Cataract Extraction

Faith Birnbaum[1], Susan Wakil[2], Daniel M Vu[3], Shan McBurney-Lin[4], Mohammed ElMallah[5], Henry Tseng[6]

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Abstract

Aim: To review the efficacy and safety of two common postoperative regimens following Kahook Dual Blade goniotomy with phacoemulsification cataract extraction (KDB-CE).

Materials and methods: This is a retrospective review of eyes undergoing KDB-CE from May 2016 to 2018 by a single surgeon. Almost 12-month follow-up data were assessed for two common postop regimens—treatment with (1) topical prednisolone acetate 1% with pilocarpine 1% (pred-pilo) or (2) difluprednate 0.05% postoperatively. Postoperative results were compared to each respective baseline intraocular pressure (IOP) levels.

Results: There were 53 eyes in the difluprednate group and 25 eyes in the pred-pilo group. In the difluprednate group, the IOP decreased at postoperative day 1 (POD1) [16 ± 5 baseline vs 15 ± 5 POD1, mean ± standard deviation (SD) in mm Hg, and $p = 0.321$], but increased at postoperative week 1 (POW1) due to a 15% rate of IOP-spikes (19 ± 9, $p = 0.099$). The number of IOP-lowering drops decreased from baseline (2 ± 1 drops) to 1 ± 1 drops at POD1 ($p < 0.0001$), and remained at 1 ± 1 drops through postoperative month 12 (POM12) ($p < 0.0001$). In the pred-pilo group, there was a statistically significant decrease in mean IOP at POW1 (16 ± 4 POW1 vs 18 ± 6 baseline, $p = 0.044$), which persisted through POM6. The number of IOP-lowering drops was not statistically significantly lower from baseline at POM3 (2 ± 1 at POM3, $p = 0.188$). Spikes in IOP, corneal edema, and hyphema were the most common complications.

Conclusion: Both postoperative regimens were effective following KDB-CE at reducing IOP at 12 months. The difluprednate group was likely to experience an IOP-spike at POW1 but used fewer IOP-lowering drops 12 months after KDB goniotomy. In the pred-pilo group, the number of IOP-lowering drops was equivalent to baseline levels at POM3. Aside from IOP spikes, there were similar complication rates observed between the two postoperative regimens. Due to demographic differences, it was not possible to compare relative IOP-lowering efficacy between the two postoperative regimens.

Clinical significance: It is efficacious and safe to use either postoperative regimen following KBD-CE. Postoperative trajectories may differ with respect to the postoperative regimen, but further randomized controlled trials are needed to compare various topical steroid medications for postoperative regimens following KDB-CE.

Keywords: Cohort study, Kahook Dual Blade, Minimally invasive glaucoma surgery.

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Introduction

Kahook Dual Blade (KDB) goniotomy (KDB, New World Medical, Rancho Cucamonga, California) has been shown to be an effective surgical option for glaucoma with and without phacoemulsification.[1–3] During the postoperative course following goniotomy surgery, it is important to minimize transient intraocular pressure (IOP) elevation, hyphema, inflammation, and peripheral anterior synechiae (PAS) formation. These complications could diminish KDB efficacy at reducing IOP and the number of glaucoma medications. Furthermore, inflammation and synechiae formation could decrease the success of subsequent glaucoma surgeries such as trabeculectomy or glaucoma tube shunts.

Presently, there is no standardized postoperative drop regimen after KDB with cataract extraction (KDB-CE) and to date there have been limited observational studies performed. Some authors reported using a postoperative regimen associated with standalone CE consisting of a strong topical steroid medication, such as difluprednate, to minimize inflammation and synechiae formation.[2,4] However, the use of difluprednate has been associated with more transient IOP spikes or persistent IOP elevations.[5,6] As an alternative, other reports described using a milder steroid in conjunction with pilocarpine to minimize synechiae formation, through contraction of the ciliary body, and creation of tension on the scleral spur to open the trabecular meshwork (TM).[1,7] The postoperative outcomes and complications of these two postoperative regimens are unclear.

We therefore performed a retrospective study to investigate the efficacy and side effect profiles of these two postoperative eyedrop regimens. Specifically, the purpose of this retrospective study is to review the outcomes of these two commonly used postoperative

[1–4,6]Department of Ophthalmology, Duke Eye Center, Durham, North Carolina, United States

[5]Ocala Eye, Ocala, Florida, United States

Corresponding Author: Faith Birnbaum, Duke Eye Center, Durham, North Carolina, United States, Phone: +19196813937, e-mail: faithbirnbaum88@gmail.com

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regimens, prednisolone 1% with pilocarpine 1% (pred-pilo) and difluprednate 0.05% in eyes undergoing KDB-CE over a 12-month postoperative period. Because these postoperative regimens are significantly different, it is not possible to compare them to determine which steroid medication is superior. Rather, the intention of this study was to compare the postoperative outcome to the preoperative IOP of each regimen independently.

Materials and Methods

Data Collection

This study was approved by the institutional review board of Duke University Medical Center and adhered to the tenets of the Declaration of Helsinki. This was a retrospective chart review of all patients undergoing KDB-CE. Data was collected from the electronic medical records of patients who underwent surgery with subsequent follow-ups at the Ocala Eye Clinic between May 2016 and 2018. Patients were identified through the goniotomy-current procedural terminology (CPT) code (65820) and then included if they had KDB-CE performed. Patients were excluded if they underwent any other surgical procedure at the time of the goniotomy other than CE. They were also excluded if they were <18 years old or had a history of uveitic glaucoma or steroid-induced glaucoma. International Statistical Classification of Diseases and Related Health Problems, Ninth Revision criteria were used to grade glaucoma disease severity.

Baseline data were collected from a preoperative visit within 8 weeks from the time of surgery. Collected data included: demographics, use of systemic anticoagulants, glaucoma disease type and severity, prior ocular surgical history (trabeculectomy, glaucoma drainage device, selective/argon laser trabeculoplasty, other minimally invasive glaucoma surgery), best-corrected visual acuity (BCVA), IOP, and the number of IOP-lowering medications.

Postoperative data were collected at postoperative day 1 (POD1), postoperative week 1 (POW1), and postoperative months 1 (POM1), 3, 6, and 12 (POD1, POW1, POM1, POM3, POM6, POM12, respectively). Postoperative complications included IOP spike, hyphema, loss of BCVA of more than two lines, corneal edema, posterior capsular opacification (PCO), PAS, cystoid macular edema (CME), epiretinal membrane (ERM), retinal detachment (RD), retinal vein occlusion (RVO), and need of additional surgery. An IOP spike was defined as an increase of ≥10 mm Hg from baseline; such increases in IOP were confirmed with two different readings by the technician and physician. Hyphema was defined as any microhyphema or layering of blood within the anterior chamber noted on postoperative visits.

Surgical Technique

The surgery was performed by a single well-experienced surgeon Mohammed K. ElMallah. KDB goniotomy was performed after completion of an uncomplicated phacoemulsification CE with posterior chamber intraocular lens implantation using the clear corneal incision as the entry point. The patient's head was rotated 30–45° away from the surgeon. The KDB was then inserted through the main temporal corneal incision and advanced toward the nasal TM. Under direct visualization, using a Swan Jacobs gonioprism, the distal tip of the KDB then pierced the TM and was seated against the anterior wall of Schlemm's canal allowing its advancement along the canal for approximately 3–5 clock hours. The dual blades of the device create parallel incisions allowing the excision of TM. The blade was then removed from the eye and irrigation and aspiration were used to remove any remaining viscoelastic. All wounds were hydrated and checked to ensure water-tight closure.

Postoperative Regimen

Postoperatively, patients were started on either (1) topical pred-pilo or (2) difluprednate 0.05%. These regimens were chosen as they were two common regimens being used at the time. Patients were started on either regimen at the surgeon's discretion. Topical steroids and pilocarpine, if included, were both generally prescribed four times a day for 2 weeks, then tapered to twice a day for 1 week, daily for 1 week, and discontinued. In addition, all patients in both groups were prescribed moxifloxacin 0.5% four times a day and a nonsteroidal agent such as ketorolac 0.5% or bromfenac 0.07%.

Statistical Analysis

Paired *t*-tests were used to compare postoperative data of IOP and number of IOP-lowering drops to the baseline visit. Pilocarpine was not counted as an IOP-lowering medication for analysis. Regimens were not directly compared with each other because of the disparate regimens, the difference in sample sizes, and the lack of standardized criteria for randomization. Data were analyzed in R statistical software (version 3.5.1) and Microsoft Excel (version 16.54).

Results

There were 53 eyes included in the difluprednate group and 25 eyes in the pred-pilo group. The baseline demographics of the two groups are presented in Table 1. Both groups included patients in their 7th decade on average. They were comprised of a majority of women (67% female in difluprednate and 52% female in pred-pilo) and of white individuals (82% white in difluprednate and 66% white in pred-pilo). Approximately 40% were on anticoagulation at the time of surgery in both groups. The glaucoma history is presented in Table 2. There were 63% of eyes with moderate or severe glaucoma in the difluprednate group and 88% of eyes in the pred-pilo group included in the study. None of the eyes had glaucoma surgery prior to undergoing KDB-CE.

Table 1: Demographics of subjects undergoing KDB-CE. Categorical values were compared using Chi-squared tests. Continuous values were compared using unpaired two-sample *t*-tests

Demographics of subjects undergoing Kahook Dual Blade with CE		
	Difluprednate	*Prednisolone and pilocarpine*
Age (mean ± SD)	79.8 ± 6.9	75.8 ± 7.8
Gender		
Female	30 (67%)	11 (52%)
Male	15 (33%)	10 (48%)
Race		
White	37 (82%)	14 (66%)
Black	5 (11%)	0
Asian	1 (2%)	0
Hispanic	1 (2%)	0
Unknown	1 (2%)	7 (33%)
On anticoagulation	19 (42%)	9 (43%)
Type II diabetes	8 (18%)	6 (29%)
Family history of glaucoma	14 (31%)	10 (48%)

Table 2: Baseline ocular characteristics of eyes undergoing KDB-CE. Categorical values were compared using Chi-squared tests. Continuous values were compared using unpaired two-sample *t*-tests

Ocular characteristics of subjects undergoing Kahook Dual Blade with CE		
	Difluprednate	*Prednisolone and pilocarpine*
Number of eyes	53	25
Prior MIGS	0	0
Prior glaucoma drainage device	0	0
Prior trabeculectomy	0	0
Prior SLT*	24 (45%)	7 (28%)
CCT°	552	554
Glaucoma type*		
POAG	36 (68%)	19 (76%)
PEX	7 (13%)	2 (8%)
Mixed mechanism	7 (13%)	4 (16%)
Pigment dispersion	0	1 (4%)
NTG	3 (6%)	0
CACG	1 (2%)	0
Glaucoma severity*		
Mild	16 (30%)	3 (12%)
Moderate	20 (38%)	12 (48%)
Severe	13 (25%)	10 (40%)
Unclassified	5 (9%)	1 (4%)
Preoperative mean best corrected Snellen visual acuity (LogMAR)°	20/38 (0.278)	20/49 (0.392)

CACG, chronic angle closure glaucoma; CCT, central corneal thickness; LogMAR, logarithm of the minimal angle of resolution; MIGS, minimally invasive glaucoma surgery; NTG, normal tension glaucoma; PEX, pseudoexfoliation glaucoma; POAG, primary open-angle glaucoma; SLT, selective laser trabeculoplasty

The mean IOP at each postoperative visit is presented in Figure 1. Within the difluprednate group, no statistically significant change was observed in mean IOP from baseline to POD1 [16 ± 5 baseline vs 15 ± 5 POD1, mean ± standard deviation (SD) in mm Hg, and $p = 0.321$]. However, an increase in IOP from baseline occurred at POW1, which almost reached statistical significance (19 ± 9 POW1 vs 16 ± 5 baseline, $p = 0.099$). The IOP then became statistically significantly lower from baseline at POM1 (14 ± 3 POM1 vs 16 ± 5 baseline, $p = 0.003$) and remained as such throughout subsequent visits.

Within the pred-pilo group, the IOP at POD1 was not statistically lower from baseline (18 ± 6 baseline vs 17 ± 6 POD1, $p = 0.486$). There was a statistically significant decrease in mean IOP starting at POW1 (16 ± 4 POW1 vs 18 ± 6 baseline, $p = 0.044$). The mean IOP was further lowered at POM1 (15 ± 4, $p = 0.002$), and again at POM6 (14 ± 4, $p = 0.016$). There were not enough eyes for statistical analysis at POM12, but the average was consistent with the prior postoperative visit (14 ± 1).

The number of IOP-lowering drops at each postoperative visit is presented in Figure 2. The mean number of IOP-lowering drops was significantly lower in the difluprednate group at all postoperative visits when compared to baseline. The number of IOP-lowering drops decreased from baseline (2 ± 1 drops) to 1 ± 1 drops at POD1 ($p < 0.0001$) and remained at 1 ± 1 drops at all visits through POM12 ($p < 0.0001$).

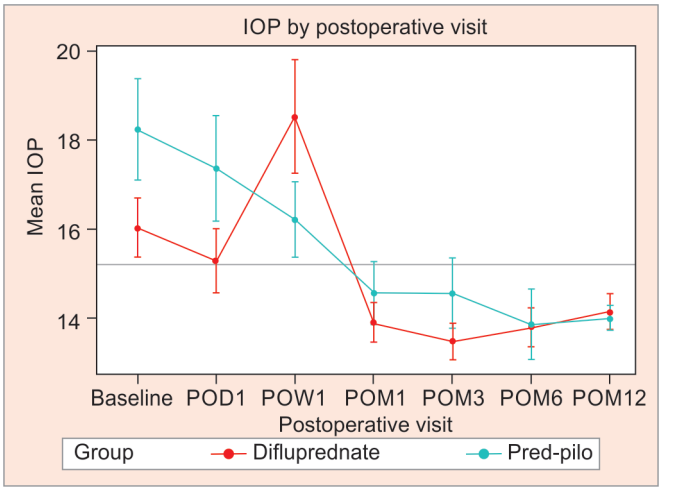

Fig. 1: Line graph depicting the mean IOP of difluprednate and pred-pilo groups at each postoperative visit with standard error bars

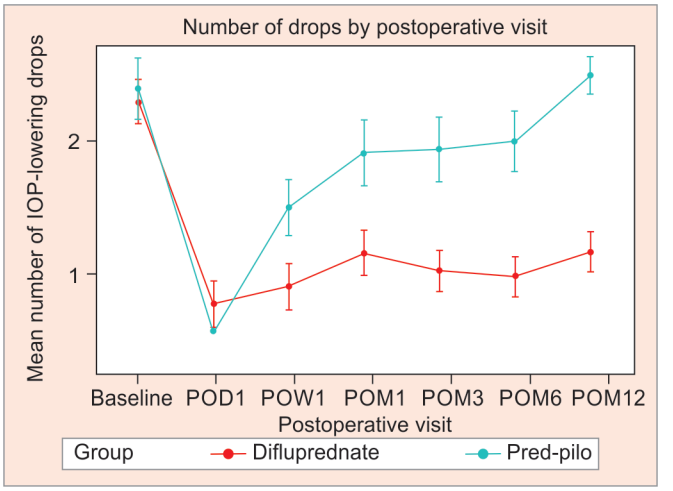

Fig. 2: Line graph depicting the mean number of IOP lowering drops of difluprednate and pred-pilo groups at each postoperative visit with standard error bars

In the pred-pilo group, there was also a significant decrease in the mean number of IOP-lowering drops from baseline to POD1 (2 ± 1 baseline vs 1 ± 1 POD1, $p < 0.001$). The number of drops increased to 1.5 ± 1 at POW1 but was still significantly lower than baseline ($p < 0.001$). The number of drops continued to increase at POM1 to 2 ± 1, yet still, this was statistically significantly lower than baseline ($p = 0.01$). However, by POM3 the number of drops was no longer statistically significantly lower from baseline (2 ± 1 at POM3, $p = 0.188$), and remained close to this level at POM6 (2 ± 1, $p = 0.604$) The sample size was not large enough at POM12 to make a statistical comparison IOP-lowering drops, but the average number of IOP-lowering drops continued to increase at POM12 (3 ± 1). The aforementioned data are summarized in Table 3.

A study dropout analysis was performed to determine if patients who did not follow-up had a different IOP than patients who followed up. In the difluprednate group, eight patients presented for the POM6 visit but not the POM12 visit. The Welch's *t*-test was used to compare the IOP of those eight patients to the rest of the study patients at POM6, and no statistical difference was found ($p = 0.118$). In the pred-pilo group, seven patients presented

Table 3: Mean IOP and number of IOP-lowering drops among eyes after KDB-CE in the difluprednate group and the pred-pilo group. Groups are compared to each other using unpaired two-sample tests and postoperative visits are compared to baseline using paired two-sample *t*-tests. *p*-values < 0.05 are in bold

Mean IOP and number of IOP-lowering drops among eyes after Kahook Dual Blade with CE								
		Baseline	*POD1*	*POW1*	*POM1*	*POM3*	*POM6*	*POM12*
	N	53	52	50	51	48	47	42
IOP (mean ± SD)	Difluprednate	16.04 ± 4.83	15.29 ± 5.18	18.52 ± 9.17	13.9 ± 3.24	13.9 ± 3.24	13.79 ± 3.16	14.14 ± 2.93
	Comparison to baseline (*p*-value)*	–	0.321	0.099	0.003	0.0004	0.0014	0.028
	N	25	25	23	23	16	7	2
	Prednisolone and pilocarpine	18.24 ± 5.67	17.36 ± 5.89	16.22 ± 4.21	14.57 ± 3.53	14.56 ± 3.92	13.86 ± 3.93	14 ± 1.41
	Comparison to baseline (*p*-value)*	-	0.486	0.044	0.002	0.001	0.016	–
Number of IOP-lowering drops (mean ± SD)	Difluprednate	2.3 ± 1.2	0.77 ± 1.28	0.9 ± 1.27	1.16 ± 1.25	1.02 ± 1.12	0.98 ± 1.09	1.16 ± 1.10
	Comparison to baseline (*p*-value)*	–	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
	Prednisolone and pilocarpine	2.4 ± 1.15	0.56 ± 1.04	1.5 ± 1.06	1.91 ± 1.24	1.94 ± 1.24	0.604	2.5 ± 0.71
	Comparison to baseline (*p*-value)*	–	<0.001	<0.001	0.011	0.188	0.604	–

*Paired two-sample *t*-test. POD, postoperative day; POM, postoperative month; POW, postoperative week

Table 4: Frequency of cumulative postoperative adverse events in the difluprednate and pred-pilo groups

Frequency of postoperative adverse events		
Adverse event	*Difluprednate (n = 53)*	*Prednisolone and pilocarpine (n = 25)*
Corneal edema	10 (19%)	3 (12%)
IOP spike ≥ 10 mm Hg from baseline	8 (15%)	3 (12%)
BCVA loss ≥ 2 lines	7 (13%)	4 (16%)
Hyphema	7 (13%)	2 (8%)
Descemet tear	1 (1.9%)	0
PAS	0	0
CME	2 (3.8%)	2 (8%)
ERM	1 (1.9 %)	2 (8%)
RD	0	1 (4%)
RVO	2 (3.8%)	0
Additional glaucoma surgery	0	1 (4%)

BCVA, best corrected visual acuity; CME, cystoid macular edema; ERM, epiretinal membrane; IOP, intraocular pressure; PAS, peripheral anterior synechiae; RD, retinal detachment; RVO, retinal vein occlusion

to the POM1 but not the POM3, eight patients presented to the POM3 but not the POM6, and five patients presented to the POM6 but not the POM12 visit. When patients who presented to their last visit were compared to the rest of the study population for each of these visits, there were no statistical differences in IOP at any visit (POM1 $p = 0.95$, POM3 $p = 0.373$, and POM6 $p = 0.895$).

The total number of postoperative complications in the two groups is similar and depicted in Table 4. In the difluprednate group, the most common complications were—corneal edema (19%, $n = 10/53$), BCVA decrease of ≥2 Snellen lines (13%, $n = 7/53$), hyphema (13%, $n = 7/53$), and IOP spike (15%, $n = 8/53$). In the pred-pilo group, the most common complications were—BCVA decrease of ≥2 Snellen lines (16%, $n = 4/25$), corneal edema (12%, $n = 3/25$), hyphema (8%, $n = 2/25$), and IOP spike (12%, $n = 3/25$). In both groups, the corneal edema was resolved in all eyes by POW1. In the difluprednate group, all eyes with BCVA loss of ≥ two lines were also resolved by POW1. In the pred-pilo group, late onset of BCVA loss of ≥ two lines occurred in four patients; one was due to ERM and posterior capsule opacification, one was due to high IOP eventually requiring additional surgery, and two were due to CME occurring at POM1. All but two hyphemas were resolved by POW1; of the two that did not resolve by then, one was resolved by POM1, and one was resolved by POM3. There was one RD that occurred in the pred-pilo group at POM1.

Discussion

Efficacy

Our retrospective study demonstrates that following KDB-CE, both difluprednate and the pred-pilo groups achieved significantly

lower postoperative IOPs compared to their preoperative baseline. As such, surgeons who perform KDB goniotomy can use either postoperative regimen at their discretion and differences in insurance coverage of medications.

Patients on the difluprednate regimen experienced an increased IOP at POW1, followed by a steady decline over the 12-month period. This increase in IOP can be attributed to the significant proportion of IOP spikes (15%). These IOP spikes resolved and the IOP plateaued around POM1, decreasing approximately 13% (16–14 mm Hg). Patients maintained using one IOP-lowering drop less from baseline though POM12.

In the pred-pilo group, patients experienced a steady decline in IOP starting at POD1, which also plateaued around POM1 to achieve approximately 22% in IOP reduction (18–14 mm Hg). In order to maintain this IOP effect, patients in the pred-pilo group needed a higher number of IOP-lowering drops which became equivalent to baseline levels at POM3. However, even with an equivalent number of IOP-lowering drops to baseline, the IOP was still lower at POM6 and likely would have been lower at POM12 as well if there were sufficient numbers in the study for analysis.

These results are consistent with prior literature published on KBD goniotomy with phacoemulsification.[1] Other studies have reported a significantly lower IOP starting at POD1.[2,3] In all studies, including ours, the IOP lowering effect was maintained up until the end of the studies at POM12.[1–3]

Our results suggest the IOP and number of IOP-lowering drops may follow different postoperative trajectories with different postoperative regimens. Direct comparisons between the groups could be misleading because it cannot be determined if differences seen in this study are attributed to a difference in steroid potency or the cholinergic miotic. To our knowledge, there are no published reports comparing postoperative steroids following goniotomy procedures. A study evaluating postoperative use of pilocarpine following standalone Trabectome surgery (NeoMedix, Tustin, California, United States of America) found no significant difference in IOP at any postoperative visit with or without pilocarpine,[8] suggesting that pilocarpine might not be superior in IOP-lowering after angle surgery. Our study supports the Trabectome study in that we found early postoperative pilocarpine use did not lead to fewer IOP-lowering drops long-term, although IOP was significantly lowered.

In order to further clarify a preferred postoperative regimen, a prospective trial comparing steroid potency after goniotomy is needed. Our study shows that KDB is an effective surgical approach to decreasing IOP using either postoperative regimens.

Safety

The difluprednate group had a relatively high rate of IOP spikes at POW1 (15%).

Difluprednate has been associated with IOP elevations in glaucomatous eyes.[6,9] In a retrospective review comparing the use of difluprednate 0.05% twice a day to prednisolone 1% four times a day after cataract surgery, authors reported a clinically significant increase in IOP occurring 5–10 days postoperatively with difluprednate use with the highest risk in glaucomatous eyes and in people over >75 years.[6] This timeline is consistent with our results and may explain the POW1 IOP spikes.

Our rate of IOP spikes in the pred-pilo group (three in 25 eyes, 12%) is similar to Sieck et al.,[1] who found a 10% rate at 1 week in 197 eyes after KDB with or without phacoemulsification. In their study, the postoperative regimen consisted of pred-pilo four times a day tapered over 4 weeks. Two other reviews of KDB with phacoemulsification reported lower rates of IOP spikes of 2.8 and 3.8%, however, the authors did not describe the postoperative regimen used.[2,3] All aforementioned studies also used IOP elevation ≥10 mm Hg as the definition of an IOP spike.

Beyond IOP spikes, KDB-CE appears relatively safe with similar complications observed between the two postoperative regimens. There were no eyes with PAS observed postoperatively, which is lower than other reported rates of PAS, ranging from 1.4 to 1.9%, although in those studies the postoperative regimen was not standardized.[2,3] It is notable that the rate of PAS was not higher in the pred-pilo group prednisolone's weaker potency in relation to difluprednate, as well as pilocarpine's induction of aqueous humor flare.[10,11]

The rate of hyphema among all eyes at 11.3% (nine of 80) in our study is similar to other studies, which have reported a rate ranging from 11 (six of 53) to 17.3% (34 of 197), mostly resolving by POW1.[1,12] A very rare complication is RD. One patient (3.8%) had an RD in the pred-pilo group which occurred around POM1. Although pilocarpine has been associated with RD in prior case reports, the causal relationship between pilocarpine and RD has not been definitively determined.[13,14]

Strengths and Limitations

A main strength of our work is that KDB goniotomy was performed by a single experienced surgeon who was fellowship-trained in glaucoma. The surgical procedure was performed in the same manner for each of the study patients. Differences in outcomes and complications are thus less attributable to surgical variation, which minimizes confounding factors.

A limitation of our study is the lack of direct comparisons of difluprednate to prednisolone alone. Our data suggest that postoperative regimens may play a role in long-term efficacy, and direct comparisons warrant future research in a prospective trial. Another limitation is a low follow-up rate at the POM 12 visit, particularly in the pred-pilo group. Patients were lost to follow-up or returned to their referring providers. However, the low follow-up rate at POM12 for pred-pilo group minimally affects our findings regarding postoperative complications and safety. As observed in prior reports and our current study, most complications occur within the first 3 months, a time period during which our follow-up rate was very high in our study.

Conclusion

In conclusion, we present postoperative outcomes for two common postoperative regimens following combined KDB goniotomy and phacoemulsification CE. Both regimens achieved a significant reduction in IOP postoperatively when compared to their respective preoperative baselines. Patients using difluprednate required less IOP-lowering medications but had short-term IOP spikes that did not persist. Further randomized controlled trials are warranted to directly compare various topical steroid medications following KDB goniotomy and other minimally invasive angle-based glaucoma surgeries.

Clinical Significance

Following KDB-CE, both difluprednate and the pred-pilo groups achieved significantly lower postoperative IOPs compared to their preoperative baseline. As such, surgeons who perform KDB goniotomy can use either postoperative regimen at their discretion and differences in insurance coverage of medications.

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