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Comparing Three Post-Op Regiments for Management of Inflammation Post Uncomplicated Cataract Surgery. "Are Steroids Really Necessary?"

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Abstract

Purpose: To compare intraocular pressure (IOP) differences; degrees of anterior chamber inflammation and macular edema between three different treatments.

Setting: Single center, private, teaching practice in Las Vegas, Nevada.

Methods: Prospective, randomized, single-blind study. Patients in the Control group received gatifloxacin 0.3%, prednisolone acetate 1%, and bromfenac 0.09%; Group #I received gatifloxacin and bromfenac; and Group #II was given one intraoperative steroid (Triamcinolone) injection and gatifloxacin and bromfenac in the post-operative period.

Pre-operative evaluation included a comprehensive ophthalmic exam and baseline macular optical coherence tomography (OCT). Post-operative data collected included IOP and direct visual anterior segment cell count at the one-day, one-week, and one-month post-surgery. Macular OCTs were performed at 1-week and 1-month post-operative.

Results: Elevated IOPs were noted on post-operative day one but were statistically insignificant (p = 0.15). The elevated IOPs were statistically significant for the glaucoma patients (p = 0.004). All IOPs returned to baseline after 1 week.

The degree of anterior segment inflammation was not statistically significant (p = 0.39) between the studied populations.

The foveal thickness (FT) was used to determine the degree of macula inflammation. The degree of macula inflammation was not statistically significant between the three groups (p = 0.82).

Conclusions: This study demonstrated efficacy between the three regimens in decreasing and resolving anterior chamber inflammation and preventing the development of macular edema. The intraocular spikes although more significant on post-operative day 1, returned to baseline by the one week post-surgery visit.

Introduction

The study was designed to evaluate and compare three clinical variables: intraocular pressure (IOP) spikes, degrees of anterior chamber inflammation and macula edema among three different pharmaceutical regimens employed post cataract surgery: control group (topical steroid); Group I (nonsteroidal anti-inflammatory drugs [NSAIDs] only); Group II (intraoperative steroid injection and topical NSAIDs).

Background

Cataract is the leading cause of blindness worldwide and cataract extraction is the treatment of choice leading to the improvement in the quality of life [1], cognitive function [2], and productivity as reported by multiple published studies. To maximize the outcome of cataract surgery, post-operative treatments of uncomplicated cataract extraction include three topical pharmaceutical agents: an antimicrobial, a potent corticosteroid and a non-steroidal anti-inflammatory drug (NSAID) [3]. Studies have shown the importance of antimicrobial prophylaxis in reducing ocular infection and endophthalmitis with the use of newer generation fluoroquinolones [4-6] along with the usage of topical corticosteroids and NSAIDs to reduce and prevent anterior chamber inflammation and macular edema respectively [7]. The regimen, however, varies among ophthalmologists due to a lack of published data establishing the optimal regimen; therefore it is the decision of the individual ophthalmologist to employ a regimen best suited for his/her cataract patients.

Method

This was a comparative, prospective, single-masked study

conducted at a single center, private, teaching, multi-specialty practice in Las Vegas, Nevada. The study began on 3 May 2010 and ended on 17 September 2010. There were a total of 137 eyes (patients) enrolled with 111 completing the study. Medications were provided for all the patients throughout the study period and none of the patients in study incurred any cost relating to medications in the post-operative period.

Patient selection and treatment group

Patients with visually significant cataract that have consented to cataract surgery were informed of the study. Consenting subjects were enrolled and randomized into three groups: Control (steroid – [Gatifloxacin 0.3% {Allergan Inc. PO Box 19534, Irvine, CA 92623}, Prednisolone Acetate 1% {Allergan Inc. PO Box 19534, Irvine, CA 92623}, and Bromfenac 0.09% {Ista Pharmaceuticals, 50 Technology Drive, Irvine, CA 92618}]); Group I (NSAIDs – [Gatifloxacin and bromfenac]); and Group II (Steroid injection – [one intraoperative

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sub-tenon steroid {Triamcinolone [Bristol-Myers Squibb Company, Princeton, NJ 08543]} injection and Gatifloxacin and Bromfenac]) in the post-operative period. The standard dispensing protocol was followed. Exclusion criteria included those with proliferative diabetic retinopathy, epiretinal membrane (ERM), preexisting anterior uveitis, and exudative macular degeneration. None of the patients in the study had previous cataract surgery. This criterion was implemented to negate potential confusion with respect to the medications prescribed from previous cataract surgery. Patients were removed from the study if they 1) were seen and examined by any other ophthalmologists in the practice not directly involved with this study or returned to their primary ophthalmologist after the one week evaluation; 2) inadvertently instilled topical steroid and or a different NSAIDs; and 3) missed an IOP measurement or OCT scan during the study period and finally.

Pre-operative evaluation

Pre-operative data collected included a baseline intraocular pressure measurement by Goldmann's applanation and a macular optical coherence tomography (Stratus-OCT 4, Carl Zeiss Ophthalmic System, Inc.). Throughout the entire study period, all the IOP measurements were obtained by one certified ophthalmic tech. All the patients were instructed to instill gatifloxacin and bromfenac three days before surgery in accordance to the dispensing protocol. All surgeries were performed by one experienced ophthalmic surgeon at one surgery center and all post-operative visits were examined by one doctor of optometry.

Study standardization

The variables measured, intraocular pressure and degree of anterior chamber inflammation, were obtained at the 1-day; 1-week; and 1-month visits. Intraocular pressures were compared between the studied population and among those diagnosed with glaucoma.

The methodology for evaluating anterior chamber inflammation was used in accordance with the Standardization of Uveitis Nomenclature (SUN) Working Group Grading Scheme for Anterior Chamber Cells and Flare for reporting clinical data [8]. The values, cells and flares, obtained clinically were summed giving rise to the Summed Ocular Inflammation Score (SOIS) which were used to statistically assess the degrees of inflammation [9]. To standardize the clinical findings, the anterior segment examination was performed using one slit-lamp (Haag Streit) where the light source was angled at 45-degrees, the light beam set to 1mm x 3mm and the magnification set to high (25x). Unsuccessful attempts were made to obtain a laser cells and flare instruments.

Patients in Group I (NSAIDs) and II (steroid injection) were given rescue-medication, i.e., topical steroid, if the degree of anterior chamber inflammation did not improved clinically or the SOIS remained the same in subsequent clinic visit.

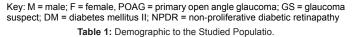
The macular OCTs were obtained at the 1-week and 1-month (30 days \pm 2 days post surgery) visits. In this study, the foveal thickness (FT): the mean thickness within the central 1000 micron diameter area of the fovea was used to determine the degree of macula inflammation [10]. Specific to this study, post-operative macular changes falling outside of one-standard deviation was considered to be cystoid macular edema suspect (CME suspect) and those outside of two-standard deviation was considered to have CME by OCT [11]. The study included evaluating the date for the entire population; diabetics with and without non-proliferative diabetic retinopathy. All the macular OCTs were performed by one certified ophthalmic technician to remove inconsistencies (techniques and applications) and ensuring repeatability and reproducibility [12].

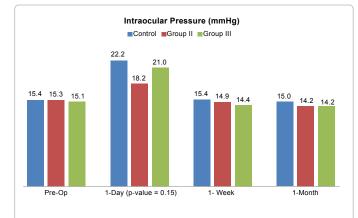
To reduce undue bias, the examining physician was blinded throughout the study, while the ophthalmic technicians were responsible for ensuring that all the medications were properly dosed and all patients were instilling the proper medication as dictated by the group they were randomized to. We would like to caution the readers to this aspect: all surgeries were performed by one surgeon with 30 years of cataract surgery experiences. The average surgery time, beginning with wound construction to the closure of the wound (by which ever means) is less than 10 minutes (mean = 7.4 minutes \pm 1.2) with an average phacoemulsification time less than one minute (mean = 27.5 seconds \pm 5.1).

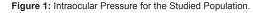
Statistical analysis

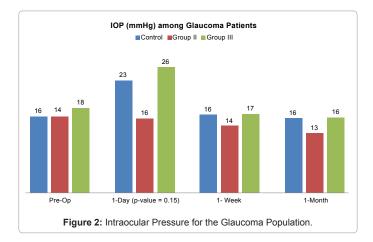
Results were recorded as mean and standard deviation. Excel spreadsheet (Microsoft Inc.) was used to analyze means for statistical significance. Variables (IOP, anterior chamber inflammation, and OCT) differences between and within the treatment groups were tested

	Total/Final	Eye	Sex	Age (years)	PAOG / GS	DM	DM with NPDR
Control	49/41	OD = 17 OS = 24		69.4 ± 11.3	10	9	3
Group I	48/40	OD = 24 OS = 16	MF = 15 F = 25	70.1 ± 12.4	8	11	4
Group II	40/30	OD = 17 OS = 13		69.8 ± 11.6	6	6	5









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	Intraocular pressure (mmHg)				AC Inflammation (SOIS)				ΟCT(μm)		
	Pre	1-day	1-wk	1-mth	F	Pre 1-day	1-wk	1-mth	Pre	1-wk	1-mth
Control	15.4±3.2	22.2±8.1	15.4±3.2	15.0±3.7	0	2.1±0.4	0.80±0.4	0	200±21	204±20	201±21
Group I	15.3±2.7	18.2±5.5	14.9±2.5	14.2±2.5	0	2.2±0.4	0.79±0.4	0	203±25	205±23	205±23
Group II	15.1±2.7	21.0±8.3	14.4±2.7	14.2±3.0	0	2.2±0.5	0.88±0.4	0	199±25	207±23	201±24
p-value between groups = 0.15						0.	39	0.82			
p-value within groups = 0.12						0.43			0.06		

Key: SOIS = summed ocular inflammatory score

Table 2: Pre-operative & Post-operative Variable Data.

Effect-IOP	Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noucent. Parameter	Observed Power ^b
Pillai's Trace	.089	1.667	6.000	214.000	.130	.045	10.003	.629
Wilk's Lambda	.911	1680ª	6.000	212.000	.127	.045	10.079	.633
Hotelling's Trace	.097	1.692	6.000	210.000	.124	.046	10.152	.636
Roy's Largest Root	.089	3.185°	3.000	107.000	.027	.082	9.555	.722

a = Exact statistic; b = computed using alpha =0.05; c = The statistic is an upper bound on F that yields a lower bound on the significance level; d = Design: intercept + group **Table 3:** Multivariate Tests - Power Analysis for Intraocular Pressure.

Effect	Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power ^b
Pillars Trace	.080	2.243	4.000	216.000	.065	.040	8.972	.651
Wilk's Lambda	.920	2.269ª	4.000	214.000	.063	.041	9.078	.657
Hotelling's Trace	.087	2.295	4.000	212.000	.060	.042	9.180	.662
Roy's Largest Root	.086	4.654°	2.000	108.000	.012	.079	9.307	.773

a = Exact statistic; b = computed using alpha =0.05; c = The statistic is an upper bound on F that yields a lower bound on the significance level; d = Design: intercept + group **Table 4:** Multivariate Tests - Power Analysis for Macular Edema and Foveal Thickness.

		Diabetic with NPDR				
	Pre	1 -wk	1-mth	Pre	1 -wk	1-mth
Control	196±17	196±17	196±16	204±17	202±17	199±6
Group I	205±23	211±2	207±25	206±23	207±22	202±29
Group II	195±18	203±17	195±19	199±19	205±16	203±18
	p-valu	0.77				
	p-va	0.85				

Key: NPDR = non-proliferative diabetic retinopathy

 Table 5: Optical Coherence Tomography Data among Diabetics with and without NPDR.

using the repeated measures ANOVA (MANOVA) test (SAS-JMP 9 software [SAS Campus Drive, Building S, Cary, NC 27513]). A *p*-value equal to 0.05 or less was regarded statistically significant. Due to size of our population, a power-analysis was also performed to determine if there is indeed sufficient power and detect any differences between the studied groups. An observed power of 0.4 or greater is significant.

Results

Data collected include age, sex, and operating eye (Table 1: Demographic). The past medical history for our patients included hypertension, type-II diabetes, coronary artery diseases, chronic obstructive pulmonary disease, arrhythmias, hyperthyroidism and prostate cancer. Ocular history included glaucoma suspect (GS), primary open angle glaucoma (POAG), non-proliferative diabetic retinopathy (NPDR), non-exudative age-related macular degeneration (ARMD), posterior vitreous detachment (PVD), chronic blepharitis, ptosis and dermatochalasis.

Intraocular pressure between the studied populations (Figure 1, Table 2, Table 3)

The intraocular pressure had the greatest flux at the one-day postoperative period. The Control and Group II had a mean IOP elevation of 7 mmHg and 6 mmHg respectively compare to a 3 mmHg spike in Group I. Although there was a trend in IOP elevation, the differences in IOPs were not statistically significant between groups (*p*-value = 0.15 [F(2,108) = 1.955, p = 0.1465]) and within groups (*p*-value = 0.12). Statistically, the IOP elevation was not significant between groups (*p* = 0.20) when comparing non-glaucoma to the glaucomatous patients. The observed power between groups was 0.629.

Intraocular pressure within the glaucoma population (Figure 2)

In this study, we combined the glaucoma suspects (GS) and those with primary open angle glaucoma (POAG) into one group (Glaucoma group). There were a total of twenty-four patients (24/111 = 21.6 %) in the Glaucoma group (N = 10 [Control]; N = 8 [Group I]; N = 6 [Group II]). The greatest IOP flux was noted at the 1-day visit with a mean difference from baseline of 7mmHg (Control) and 8 mmHg (Group II). The flux was noticeably less for Group I (mean $\Delta = 2$ mmHg) and statistically significant (p = 0.004) between groups. The flux in IOP was not statistically significant within the respective groups (p = 0.27). All the IOPs returned to normal at the 1-week and 1-month visits.

Degrees of anterior chamber inflammation (Table 2)

The mean SOIS (degree of AC inflammation) when compared, showed no statistical differences between (p = 0.39) and within the groups (p = 0.43). The mean SOIS for all three groups was less than 1 at the one week visit and return to baseline at the 1-month visit (p > 0.05). Power analysis yielded an observed power of 0.245. No patients in Group I and Group III required rescue medication.

Macular edema by OCT between the studied populations (Table 2, Table 4)

The mean FT for entire studied population was $201 \pm 23 \ \mu\text{m}$. The mean FT for the Control, Group I and Group II in the pre-operative period was $200 \pm 21 \ \mu\text{m}$, $203 \pm 25 \ \mu\text{m}$ and $199 \pm 25 \ \mu\text{m}$. Comparing the FT at the 1-week and 1-month showed no statistical differences between the groups (p = 0.82) and within the groups (p = 0.06). The observed power between groups was 0.651. There was no evidence based on clinical examination toward the development of clinical or sub-clinical macular edema at the 1 month visit in any of our patients.

Macular edema by OCT within the diabetic population (Table 5)

In the Control group, nine patients (9/41 = 22%) had type II diabetes and 3 (3/41 = 7%) had non-proliferative diabetic retinopathy (NPDR) at the time of enrollment. In Group I, there was a total of 11 patients (11/40 = 28%) with type II diabetes and four (4/40 = 10%) with NPDR. Group II had six patients (6/30 = 20%) presented with type II diabetes and 5(5/30 = 17%) had NPDR at the time of surgery.

The degree of macular thickness within one-standard deviation of the mean among all diabetics between (p = 0.35) and within (p = 0.77) the three groups were not statistically significant from baseline to the termination of the study. Comparing diabetics with and without NPDR showed no statistical differences between (p = 0.45) and within (p = 0.85) the studied population. Similar to the studied population, our diabetic patients did not manifest any evidence of clinical or subclinical macular edema.

Discussion

Acquired cataract is the leading cause of blindness worldwide [13-16]. In the United States, cataract is the most common age-related eye disorder affecting approximately 22 million with a projected prevalence increasing to 30.1 million by the year 2020 [17,18]. Surgical intervention is the treatment of choice for those diagnosed visually significant cataract. Cataract surgery is the most frequently performed surgery in the US with a success rate of 95% or higher and a visual outcome of 20/40 or better. According to the 2007 study "Economic Impact of Vision Problems: The Toll of Major Adult Eye Disorders, Visual Impairment, and Blindness on the U.S. Economy" [17] funded by Prevent Blindness America, the cost is approximately 6.8 billion [18] and rising on direct cataract care: outpatient, inpatient, and prescription drugs.

Compliance is another factor associated with favorable therapeutic outcomes. Although there are no "standardized" post-operative regimens for uncomplicated cataract surgery, the common or prevailing therapeutic regimen is a three-drug combination: an antimicrobial, a topical steroid and topical NSAIDs. The reported efficacies associated with these chemical agents are well published. Although there are no published data directly comparing the compliance rate among the different post cataract regimen, we know from published data that the relationship between dosing and compliance is inversely proportional [19,20]. Another factor influencing compliance is cost²⁰ and the number of medications [21].

Although not statistically significant, the initial intraocular spike was seen at the one-day visit with Group I having the lowest spike. All the IOPs returned to baseline (pre-operative values) at one-week and one-month evaluations. The spikes in the Glaucoma groups mirror the studied population when compared within the respective group but between groups, the elevation in IOP was statistically significant. The transient IOP elevation, specifically the Control and Group II, is of interest since published data reported the onset of IOP elevation occurs one to four weeks and peaked at 6 weeks after steroid therapy [22,23].

We feel the initial spike maybe secondary to phacoemulsification secondary to dissipated ultrasound energy [24], i.e. controlled trauma with resulting trabeculitis (pseudo post-traumatic glaucoma). Another theory for the transient IOP elevation is the increased in humor protein concentration (increased hydrostatic pressure) which resulted from the disrupted blood-aqueous-barrier [25]. Other potential causes for IOP spike include lenticular debris [26] and retained viscoelastic material [27,28]. However, the most compelling fact remains: Group I (NSAIDs) had the lowest IOP spike and the only group in the study without any form of steroid in the treatment paradigm. This phenomenon may be due to the inherent biochemical and pharmacological properties associated with a non-steroidal anti-inflammatory agent which may elucidate with future studies.

The degrees of anterior chamber inflammation based on the SUN standardized protocol and SOIS for all three groups demonstrated no statistical differences in controlling and resolving post cataract inflammation. Each of the regimen demonstrated exceptional efficacy with respect to the inflammatory response.

Macular edema post cataract surgery can be protracted and visually debilitating ultimately decreasing the quality of life. Topical steroids, NSAIDs, and sub-tenon Triamcinolone acetate injection when used alone have shown to reduce or prevent macular edema [29-31]. The combination of a topical steroid and NSAIDs demonstrated significant decreased in macular edema [32]. The optical coherence tomography (OCT) is the instrument of choice use to detect and monitor macular edema [32,34]. The diagnosis of macular edema is made both clinically and with the use of the OCT and/or angiography [33]. Currently, there is no standardization in determining macular edema by OCT. Kim et al. [34] provided ophthalmologists with a guideline with respect to the degree of vision loss correlating that to the increased in thickness of the macular. Our study demonstrated that each of the respective regimens was efficacious in preventing macular edema and without significant changes in macular thickness.

Although macular edema was not statistically significant between the three groups, power analysis demonstrated that there was significant power within the study to elucidate any differences between groups. Based on the data, we can conclude that the efficacy in controlling/ preventing cystoid macular edema post cataract extraction between the three groups is similar.

Conclusion

This study demonstrated efficacy among the three regimens in decreasing and resolving anterior chamber inflammation and preventing the development of macular edema. The authors feel a more lengthy evaluation period and a larger population size is warranted.

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