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Anterior Chamber Washout During Ahmed Valve Glaucoma Surgery Reduces the Incidence of Hypertensive Phase

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Abstract

Purpose—To characterize the incidence of postoperative hypertensive phase (HP) in patients receiving anterior chamber (AC) washout at the time of Ahmed glaucoma implant (AGI).

Patients and Methods—A total of 24 patients with medically refractory glaucoma who underwent AGI surgery at a tertiary academic medical center in Southern California from December 2018 through March 2021 were included in this retrospective comparative case series. Patients who received a pediatric implant, underwent concurrent intraocular surgery, or did not complete a minimum of 6 months follow-up were excluded. 9 patient eyes receiving AC washout and 15 controls that were analyzed through 6 months post-procedure. HP was defined as intraocular pressure (IOP) above 21mmHg within 6 months post-procedure with maximum tolerated medical therapy. AC washout was performed by irrigating the AC with 5 mL balanced salt solution (BSS) before placing the tube of the AGI into the anterior chamber. The rate of postoperative HP, defined as peak IOP >21mmHg, at 6 months follow up, was observed as the primary outcome measure.

Results—Patients included in the study had a high mean preoperative IOP ($\overline{X}$ = 44.11, SD=13.85). There were no baseline differences between washout and control groups. The odds of HP were significantly reduced (OR=0.050; 95% CI=[0.004, 0.706]; *P*=0.027) for patients who underwent intraoperative AC washout compared to those who did not. Bivariate analysis of subject baseline characteristics revealed that only washout status was significantly different in subjects with HP compared to subjects without HP (*P*=0.015). A multivariate logistic regression model using washout status and autoimmune conditions as covariates was significant in predicting HP ($X^2(2)=12.337$, *P*=0.002), with washout as a significant predictor when controlling for autoimmune comorbidities (*P*=0.027).

Meeting Presentation

This material is not under consideration at any scientific meetings.

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Ethics Statement

Informed consent was obtained from all patients under the University of California, Irvine IRB#20216593.

Conclusions—AC washout significantly decreases the odds of HP after AGI surgery. AC washout with BSS adds minimal time and risks to surgery and therefore may be an effective adjunct during AGI placement.

Précis

Intraoperative anterior chamber washout reduces the odds of hypertensive phase by 95% compared to those receiving control during Ahmed glaucoma implant, suggesting it may be effective prophylaxis for the postoperative hypertensive phase.

Keywords

trabecular meshwork; hypertensive phase; glaucoma drainage implant; Ahmed glaucoma implant; cytokines; anterior chamber washout

Introduction

Glaucoma drainage implants (GDIs) are used to surgically lower intraocular pressure (IOP) in patients with intractable glaucoma that cannot be managed with medications or laser procedures.[1] The Ahmed (AGI) and Baerveldt (BGI) glaucoma implants are two commonly used GDIs that differ in material and design. The AGI contains a pressure-sensitive valve, whereas the BGI is non-valved and needs to be ligated for several weeks prior to plate encapsulation to minimize hypotony. As such, implantation of the AGI allows for immediate and significant aqueous egress, while the BGI only allows for limited outflow in the early postoperative period if a fenestration is made.[2]

Both the AGI and BGI suffer from the potential complication of a hypertensive phase (HP), which is generally defined as treated IOP greater than 21 mmHg during the 6-month postoperative period that is not a result of tube obstruction, retraction, or malfunction.[3] HP is thought to stem from the mechanical and biochemical sequelae of subconjunctival bleb encapsulation, an important part of the healing process following device implantation. One hypothesis is that the aqueous of a hypertensive eye contains elevated proinflammatory cytokine levels and the immediate aqueous outflow associated with the AGI allows for surrounding tissue exposure to these cytokines. This process further generates cytokines that may lead to earlier bleb encapsulation and give rise to HP.[4] The tissue changes associated with HP are potentially of clinical significance for patients with late-stage glaucoma, as sustained elevations in IOP can worsen glaucomatous optic neuropathy.

The AGI is used frequently for patients presenting with medically refractory glaucoma and high preoperative IOP and is associated with a higher incidence of HP and implant failure than the BGI.[5] Previous studies have observed that HP occurs in more than 50% of patients undergoing AGI surgery compared to approximately 20-30% of patients undergoing BGI surgery.[2,6,7,8] This finding is consistent with the hypothesis that immediate aqueous outflow and release of proinflammatory cytokines to the surrounding episclera, as seen in non-ligated valved GDIs like the AGI, contributes to a response that increases hypertensive phase risk. To test this hypothesis, we evaluated whether AC washout with BSS during AGI placement reduces the risk of HP.

For AGI surgeries conducted at our tertiary academic medical center, some surgeons performed AC washout in all cases, while others only did so in the presence of hyphema. There were no significant differences in surgical techniques among the glaucoma surgeons at our institution. No anti-metabolites were administered intraoperatively. The primary objective of this study is to evaluate HP incidence among AGI patients who received AC washout compared to those who did not.

Methods

Study Design

Retrospective chart review was performed on patients who received AGI surgery at a tertiary academic medical center from December 1, 2018, through March 30, 2021. The study was approved by the institutional review board of the University of California, Irvine and the tenets of the Declaration of Helsinki were followed. All patients who underwent AGI surgery during this period were eligible for inclusion, regardless of glaucoma type or stage. Exclusion criteria included medical charting deficiencies and failure to complete follow up before 6 months after AGI surgery. Data collected included patient demographics such as age, gender, race/ethnicity, diabetes; pre-existing conditions such as diabetic retinopathy, autoimmune conditions (e.g. type I diabetes, rheumatoid arthritis), panuveitis, or human immunodeficiency virus; baseline IOP, baseline number of glaucoma medications, surgical technique, and outcomes. Outcomes of interest included IOP, glaucoma medication count, and HP incidence.

Informed Consent

Institutional Review Board (IRB) and Ethics Committee approval were obtained under the University of California, Irvine IRB#20216593.

Data Extraction

Patients who underwent AGI surgery were identified through a filtered search in the electronic medical record (EMR). All surgeries were performed by an attending glaucoma specialist (N=4) or glaucoma fellow (N=3). Other than the AC washout step, there were no major technical differences between surgeons performing AGI surgery. Patients who received AC washout were identified through further EMR review. Chart reviewers were trained to collect necessary data points from the EMR and utilized a standardized data collection form developed *a priori*. Chart reviewers were blinded to study endpoints and removed erroneous data or missing data points.

Subject Selection

Patients were included in the study if they met the following conditions: 1) received AGI surgery (model FP7) as noted in the surgical history page of their EMR; 2) completed a 6-month postoperative follow up appointment. Exclusion criteria included patients who received a referral for a pediatric Ahmed implant (model FP8), those with concurrent or additional ophthalmologic surgeries within the 6-month postoperative period, or those who did not complete postoperative follow-up visits in the analyzed time frame. Of the 51 patient charts that were accessed and reviewed, 24 patients (26 eyes) met the criteria

for postoperative analysis at 6 months. The majority of cases were performed to treat neovascular glaucoma secondary to uncontrolled proliferative diabetic retinopathy, with a minority being secondary to retinal vein occlusion. All surgeries were performed for the purpose of preserving vision; no surgeries were performed for bullous keratopathy or symptomatic relief. General criteria for patient inclusion included a failure to respond to medical management (3-4 glaucoma eye drops) and/or the presence of florid, uncontrolled neovascular glaucoma with dangerously high and vision-threatening IOP that necessitated urgent AGI placement.

Outcome Measures

Rates of postoperative HP, defined as peak IOP >21mmHg, at 6 months follow up.

Statistical Analyses

Data were analyzed using Microsoft Excel 2021 and SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp). Descriptive statistics were run to evaluate the baseline characteristics of subjects in AC washout and non-washout groups. Bivariate analysis of various demographic and clinical characteristics was used to determine the significance of their relationships to HP and multivariate logistic regression was used to determine which patient factors were most closely associated with HP. The existing literature supported examining autoimmune comorbidities as a covariate; therefore, we included them in our analysis.

Surgical Approach

All subjects underwent AGI surgery. The surgical site was prepared and draped in the usual sterile fashion. After sub-Tenon irrigation of 2 mL of 2% lidocaine for retrobulbar anesthesia, a superior temporal corneal traction suture was placed, and conjunctival and Tenon’s capsule incisions were created superiorly 4 mm posterior to the limbus from 4 to 9 o’clock. Blunt dissection was performed to expose the sclera and a muscle hook was used to clear adhesions between Tenon’s capsule and the superior and lateral rectus muscles. The AGI was sutured to sclera with 8-0 Vicryl through the two anterior plate islets 4-5 mm posterior to the limbus between the rectus muscles. A single paracentesis was made with an MVR blade. If AC washout was performed, a 5mL bolus of BSS was infused into the anterior chamber at this point by cannulating the paracentesis to allow for simultaneous irrigation and outflow. A scleral tunnel into the anterior chamber was then created with a 23-gauge needle and the AGI tube trimmed sharply so its point would reach approximately 2 mm into the mid-AC. An appropriately sized glycerin-preserved donor scleral patch graft (Corneagen, WA, USA) was fixed to the sclera with two interrupted 8-0 Vicryl sutures. Finally, the conjunctiva and Tenon’s capsule were closed in two layers in the usual running fashion, also with 8-0 Vicryl, followed by subconjunctival injections of cefazolin and methylprednisolone. Of note, a gonioscopic view of the AC angle was not consistently obtainable on every patient due to often-present corneal edema.

Results

51 patient eyes were retrospectively screened for eligibility for the analysis of HP at the 6-month postoperative period. 27 cases were excluded due to subsequent revision surgeries or ocular surgeries for indications other than glaucoma, failure to follow up within the 6-month postoperative period, inaccessible electronic medical records, or placement of BGI instead of AGI. Of these 16 were lost to follow up during the postoperative period, 6 were duplicate patients secondary to an institutional electronic medical record change, 3 received BGI, 1 required postoperative revision due to iris occlusion of the tube shunt, and 1 received pars plana vitrectomy and cataract surgery due to vitreous hemorrhage secondary to proliferative diabetic retinopathy. Of the remaining 24 (47%), 9 received AC washout, and 15 received standard of care (Figure 1).

Overall, the average age of study participants was 53.33 years with a standard deviation of 11.74. Most patients were white, with the second most common race being “other/mixed.” 46% of patients were male. Most patients had a primary ophthalmic diagnosis of neovascular glaucoma (67%, N=16), with the remaining having the following diagnoses: primary open-angle glaucoma (N=2), chronic angle closure glaucoma (N=2), phacomorphic glaucoma (N=2), and uveitic glaucoma (N=2). Patients included in the study had a high mean preoperative IOP ($\overline{X}$ = 44.11, SD=13.85). A small majority of the patients (63%) did not receive the extra AC washout step during AGI surgery. Of the eyes included in the study, 12 were phakic, 11 were pseudophakic, and 1 was aphakic (Table 1).

The washout and non-washout control groups were comparable in terms of demographic and preoperative clinical characteristics. There were no statistically significant differences in the baseline characteristics of age, race/ethnicity, sex, eye, autoimmune comorbidity, diabetes, diabetic retinopathy, preoperative IOP, and number of glaucoma medications between washout and non-washout control groups (Table 2).

A comparison of IOP measurements following AGI surgery showed a statistically significant difference in 1-week IOP (P=0.040) between washout and non-washout groups. Postoperative day 1 IOP, 3-month IOP, 6-month IOP, and number of meds taken at 6 months were not statistically significant between washout and non-washout groups (P=0.106, P=0.079, P=0.057, and P=0.562, respectively). Among patients who presented with HP in the first 6 months post procedure, the washout group had an average number of 21.75 days (SD=10.44) to the first occurrence of HP, compared to the control group average of 30.14 days (SD=22.23) (Table 3).

Bivariate analysis of subject baseline characteristics revealed that only washout status was significantly different in subjects with HP compared to subjects without HP (P=0.015; Table 4). Age, race/ethnicity, sex, eye, diabetes, diabetic retinopathy, number of glaucoma medications at baseline, and baseline IOP were not predictive of HP (P=0.574, P=0.544, P=0.357, P=1.000, P=0.129, P=0.341, P=0.946, and P=0.538, respectively). History of autoimmune comorbidities (P=0.129) was not predictive of HP, but was included in a separate multivariate analyses to examine the effect of autoimmune-related conditions (Table 5).

Overall, our general logistic regression model using washout status and autoimmune comorbidities as covariates was statistically significant ($X^2(2)=12.337$, $P=0.002$), explained 59.5% of the variance in NHP (Nagelkerke R^2), and correctly classified 87.5% of the HP cases (Table 5). In this model, AC washout had a significant negative association with HP incidence (OR=0.50, $P=0.027$). After controlling for autoimmune comorbidities, patients who received AC washout had 95% lower odds (95% CI [0.004, 0.706], $P=0.027$) of experiencing HP in the 6-month postoperative period compared to patients who did not receive washout. Conversely, after controlling for washout, the individual covariate of autoimmune comorbidities did not converge and was not significantly associated with HP incidence (Table 5).

A qualitative comparison of HP incidence during the 6-month follow-up period demonstrated that the washout group had a greater percentage of subjects without HP compared to the non-washout group. Interestingly, all patients without diabetes had HP, whereas some patients with diabetes did not have HP. The vast majority of patients with autoimmune comorbidities had HP by 6 months, whereas some patients without autoimmune comorbidities did not have HP (Figure 2).

Discussion

Our finding that intraoperative AC washout significantly reduces the odds of HP for patients with refractory glaucoma and high preoperative IOP ($\overline{X} = 44.11$, SD=3.85) who undergo AGI surgery offers clinical support to the hypothesis that immediate transport of proinflammatory cytokines through aqueous outflow to the episclera, as seen in non-ligated valved GDIs like the AGI, contributes to a proinflammatory response that increases HP risk. We are unaware of any other reports so far that demonstrate the mitigation of HP risk with AC washout.

Previous studies describe high myopia, high preoperative IOP, and young age as risk factors for HP after AGI surgery.[9,10] Our bivariate analysis found no statistically significant association between preoperative IOP, preoperative mean number of glaucoma medications, age, gender, or race/ethnicity and HP (Table 4). Studies of demographically diverse patient populations should be conducted in the future to better characterize the risk factors for HP and guide the clinical management of postoperative IOP.

Although the exact molecular mechanisms underlying HP have not been elucidated, one theory is that high IOP contributes to a proinflammatory and hypoxic milieu in the AC. AGI surgery can then yield circulating immune cells immediate access to the episclera and Tenon’s capsule, rendering a pro-fibrotic environment surrounding the AGI plate. Prior studies note a higher prevalence of autoimmune diseases in patients with primary open-angle glaucoma,[11] suggesting that abnormal conversion of the adaptive immune response plays a role in HP pathogenesis, perhaps through overstimulation by glaucomatous autoantigens in the AC. Indeed, experimental studies of plasma samples taken from patients with glaucoma report statistically significant increases in CD4+ T cell count and proinflammatory cytokine concentration.[12,13] Another study of tube implant expansion induced by administering a bolus of viscoelastic in the implants of patients who received glaucoma tube implant surgery

reported substantial reductions in postoperative IOP.[14] These findings suggest that dilution of proinflammatory factors in the AC may reduce the risk of HP.

There are animal studies reporting that adoptive transfer of immune cells from glaucomatous mice to healthy mice results in T-cell mediated glaucomatous derangements.[15] Moreover, pre-existing heart disease is associated with protection against HP after AGI surgery,[16] implicating that poor ocular perfusion may limit or withhold proinflammatory factor entry into the AC. Taken together, these findings suggest that proinflammatory cells and factors travel through the blood supply of the posterior segment and enter the AC to induce glaucomatous progression, and that AC washout may be an effective method of diluting or removing these factors.

In our study, a general logistic regression model found that AC washout at the time of the surgery has a significant association with reduced HP occurrence in patients after controlling for autoimmune comorbidities. While the individual covariate of autoimmune comorbidities did not converge in our model, our combined regression model did converge, supporting the theory that there may be an immunologic component to HP pathogenesis.

Our study is a retrospective single-center study with a small sample size, which may limit its generalizability. Our small sample size may also limit the ability of our regression model to detect significant associations between individual covariates and HP incidence. Additional studies that track patient outcomes beyond 6 months need to be performed to determine the long-term effects of HP and AC washout on IOP control and visual function. Moreover, many patients who receive AGI surgery take different glaucoma medications.

Furthermore, at our institution, the BGI is the default GDI of choice unless the presenting IOP is extremely high and a significant and immediate reduction of IOP is warranted, in which case an AGI is placed. This principle explains why, in our study population, the average preoperative IOP was above 40 mmHg and neovascular glaucoma was the most common glaucoma diagnosis. In all cases, patients were found to have a relatively acute presentation of IOP elevation. It is important to interpret our results with this potential selection bias in mind; namely, AC washout reduces the incidence of HP following AGI placement when preoperative IOP is extremely high. The results of our study do not determine if AC washout is protective against HP when preoperative IOP is mildly and more chronically elevated, as is commonly observed in primary open-angle glaucoma. This would be an interesting future direction to explore.

Overall, AC washout is significantly associated with a decrease in postoperative HP at 6 months, especially in patients with refractory neovascular glaucoma and high preoperative IOP. AC washout with BSS adds minimal surgical time, risks, and invasiveness, and our findings suggest it may be an effective adjunctive step during AGI placement.

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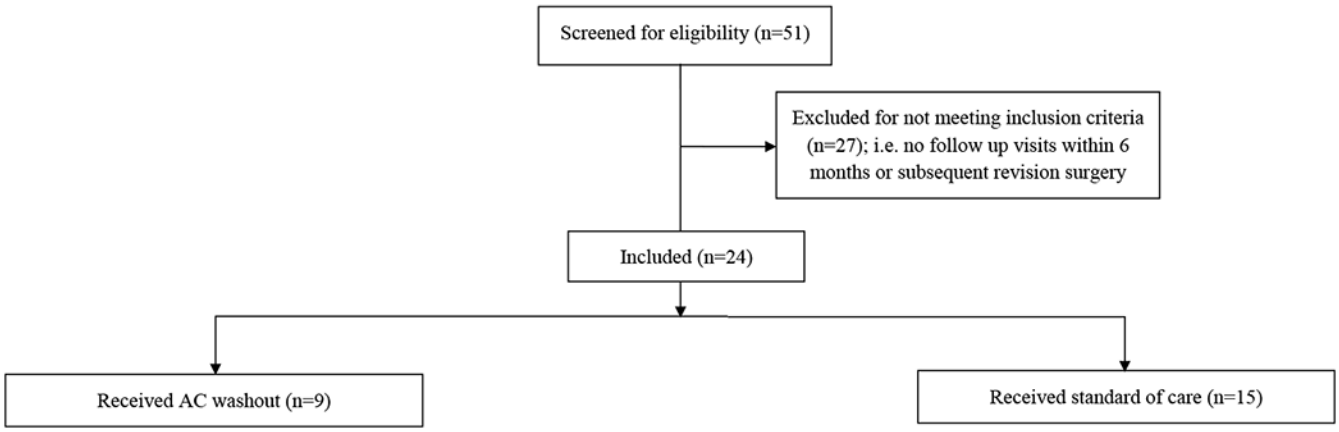

Figure 1.
Flowchart of subject screening and enrollment

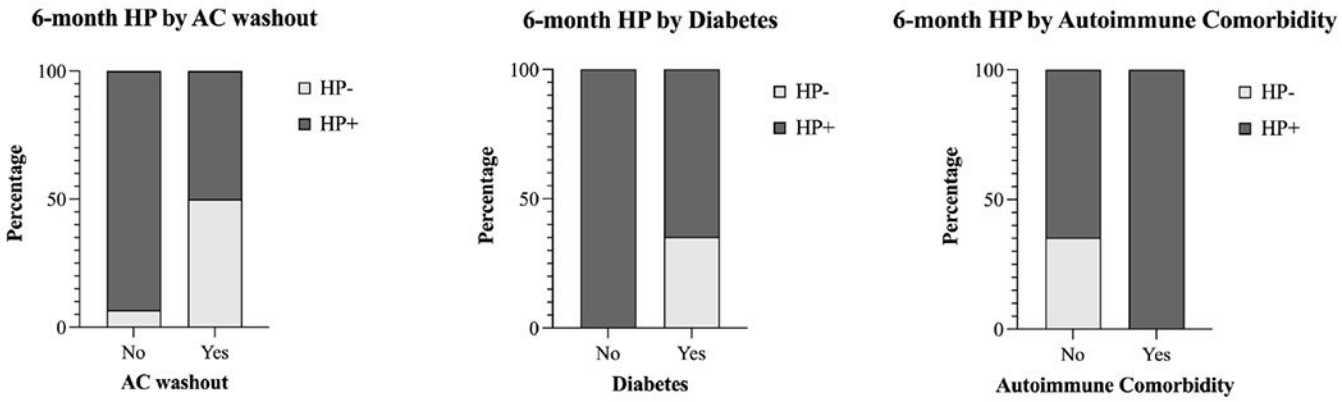

Figure 2.

Stacked bar charts of 6-month HP with AC washout, diabetes, and autoimmune comorbidities as covariates

Table 1.

Baseline demographic and clinical characteristics

	Descriptive Statistics (n=24)
Age (years)	
Mean	53.33
Standard deviation	11.74
Race/ethnicity	
White *	14 (58%)
Black	1 (4%)
Asian	3 (13%)
Other/“Mixed”	5 (21%)
Unknown	1 (4%)
Sex	
Male	11 (46%)
Female	13 (54%)
Washout	
No	15 (62.5%)
Yes	9 (37.5%)
HP at 6 months	
No	6 (25%)
Yes	18 (75%)
Primary glaucoma diagnosis	
Neovascular Glaucoma	16 (66.7%)
Other	8 (33.3%)
Lens status	
Phakic	12 (50%)
Pseudophakic	11 (45.8%)
Aphakic	1 (4.2%)

* Our electronic medical record does not differentiate between subgroups of “Whites”

Table 2.

Comparison of demographic and clinical characteristics of AC washout and control subjects

	Control group (n=15)	Washout group (n=9)	T-test statistic, X^2 value or Fisher's exact test statistic	*P* value
Age (years)				
Mean	53.40	53.22	0.035	0.972
Standard deviation	11.96	12.07		
Race/ethnicity				
White *	9 (64%)	5 (36%)		
Black	0 (0%)	1 (100%)		
Asian	3 (100%)	0 (0%)	4.641	0.303
Other/"Mixed"	3 (60%)	2 (40%)		
Unknown	0 (0%)	1 (100%)		
Sex				
Male	7 (63.6%)	4 (36.4%)	0.011	1.000
Female	8 (61.5%)	5 (38.5%)		
Eye				
Right eye (OD)	8 (61.5%)	5 (38.5%)	0.011	1.000
Left eye (OS)	7 (63.6%)	4 (36.4%)		
Autoimmune comorbidities				
No				
Yes	9 (56.3%)	7 (43.8%)	0.800	0.657
	6 (75%)	2 (25.0%)		
Diabetes (type 1 or 2)				
No	6 (85.7%)	1 (14.3%)	2.272	0.191
Yes	9 (52.9%)	8 (47.1%)		
Diabetic retinopathy				
No	8 (80%)	2 (20%)	2.240	0.210
Yes	7 (50%)	7 (50%)		
Pre-op IOP (mmHg)				
Mean	42.67	46.81	0.606	0.558
Standard deviation	9.10	19.28		
Number of pre-op glaucoma medications				
Mean	7.53	5.67	0.827	0.424
Standard deviation	4.00	6.02		

OD = oculus dexter; OS = oculus sinister; mmHg = millimeters mercury; IOP = intraocular pressure

* Our electronic medical record does not differentiate between subgroups of "Whites"

Table 3.

Measures of postoperative IOP management in AC washout and control groups.

	Non-washout group (n=15)	Washout Group (n=9)	T-test statistic	*P* value
Post-op IOP (mmHg)				
Mean	20.33	13.44	1.702	0.106
Standard deviation	14.69	4.25		
1WK IOP (mmHg)				
Mean	23.00	13.56	2.193	***0.040***
Standard deviation	14.25	6.71		
3M IOP (mmHg)				
Mean	21.20	16.67	1.877	0.079
Standard deviation	5.44	5.89		
6M IOP (mmHg)				
Mean	18.40	14.89	2.060	0.057
Standard deviation	3.66	4.26		
6M med count				
Mean	8.93	7.78	0.597	0.562
Standard deviation	3.17	5.26		
Number of post-op days to first HP				
Mean	30.14	21.75	1.062	0.310
Standard deviation	22.23	10.44		

mmHg = millimeters mercury; IOP = intraocular pressure; WK = week; M = month; HP = hypertensive phase

Table 4.

Bivariate analysis of patient factors in relation to HP

	No Hypertensive Phase	Hypertensive Phase	T-test statistic, X^2 value, or Fisher's exact test statistic	*P* value
Washout Status				
No	1 (6.7%)	14 (93%)	7.17	***0.015***
Yes	5 (55.6%)	4 (44.4%)		
Age (years)				
Mean	50.67	54.22	−0.588	0.574
Standard deviation	13.26	11.46		
Race/ethnicity				
White *	3 (21.4%)	11 (78.6%)	2.991	0.544
Black	0 (0%)	1 (100%)		
Asian	0 (0%)	3 (100%)		
Other/"Mixed"	3 (50%)	3 (50%)		
Sex				
Male	4 (36.4%)	7 (63.6%)	1.399	0.357
Female	2 (15.4%)	11 (84.6%)		
Eye				
Right eye (OD)	3 (23.1%)	10 (76.9%)	0.056	1.000
Left eye (OS)	3 (27.3%)	8 (72.7%)		
Autoimmune comorbidity				
No	6 (37.5%)	10 (62.5%)	4.000	***0.129***
Yes	0 (0%)	8 (100%)		
Diabetes (type 1 or 2)				
No	0 (0%)	7 (100%)	3.294	0.129
Yes	6 (35.3%)	11 (64.7%)		
Diabetic retinopathy				
No	1 (10%)	9 (90%)	2.057	0.341
Yes	5 (35.7%)	9 (64.3%)		
Number of pre-op glaucoma medications				
Mean	6.67	6.89	−0.071	0.946
Standard deviation	7.34	3.94		
Pre-op IOP (mmHg)				
Mean	47.08	40.94	0.650	0.538
Standard deviation	21.74	10.47		

OD = oculus dexter; OS = oculus sinister; mmHg = millimeters mercury; IOP = intraocular pressure; HP = hypertensive phase

* Our electronic medical record does not differentiate between subgroups of "Whites"

Table 5.

Multivariate logistic regression with AC washout and autoimmune comorbidities as covariates

	Beta	Exp(B)	95% CI	*P* value
Washout status	−2.996	0.050	[0.004, 0.706]	***0.027***
Comorbidity	20.657	935910421	[0.00, N/A]	0.999
Constant	2.079	8.000		***0.050***