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## Hypotony in Patients with Uveitis: The Multicenter Uveitis Steroid Treatment (MUST) Trial

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### Abstract

**Purpose**—To assess the prevalence of hypotony in patients with severe forms of uveitis.

**Methods**—The Multicenter Uveitis Steroid Treatment (MUST) Trial, a randomized study, enrolled 255 patients. Patients with hypotony at the baseline visit were identified.

**Results**—Twenty (8.3%) of 240 patients with sufficient data had hypotony. Hypotony was more common in patients with uveitis 5 years duration (odds ratio [OR] = 5.0;  $p < .01$ ), and in eyes with a history of ocular surgery (vitrectomy vs. none, OR = 3.1;  $p = .03$ ). Hypotony was less in patients with older age of uveitis onset (>51 years vs. <51 years, OR = 0.1;  $p = .02$ ), in Caucasian patients (OR = 0.1;  $p < .01$ ) compared to African American patients. Hypotonous eyes were more likely to have visual impairment (OR = 22.9;  $p < .01$ ).

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**Conclusions**—Hypotony is an important complication of uveitis and more commonly affects African-American patients, those with uveitis onset at a younger age, and those with longer disease duration. It is associated with visual impairment.

### Keywords

hypotony; multicenter uveitis steroid treatment trial; uveitis; visual impairment; visual loss

Ocular hypotony is a well-recognized complication of uveitis that is associated with substantial visual loss. The definition of ocular hypotony has varied from an intraocular pressure (IOP) <6 to <8 mm Hg with most of the deleterious effects occurring at an IOP of <4 mm Hg.<sup>1</sup> In addition to chronic uveitis, hypotony can occur secondary to vitreoretinal or filtering surgery, trauma, or chronic retinal detachment.<sup>1,2</sup> Acute hypotony associated with acute intraocular inflammation is believed to be secondary to decreased ciliary body secretion or increased uveoscleral outflow, and typically is reversible.<sup>3</sup> Chronic hypotony, however, often is irreversible and may be due to atrophy of ciliary processes, resulting in decreased aqueous production, or cyclitic membranes, leading to ciliary body detachment or tractional cyclodialysis and thereby increasing outflow. Hypotony can be associated with structural complications such as hypotony maculopathy, optic nerve edema, and choroidal folds and often is associated with poor prognosis, ultimately leading to phthisis bulbi.<sup>4,5</sup>

Hypotony is an uncommon complication of uveitis, but its prevalence has been reported to be as high as 10%, and it may be more common in childhood uveitis, especially in juvenile idiopathic arthritis (JIA)-associated uveitis.<sup>6–10</sup> Chronic uveitic hypotony has been associated with poor visual outcomes both in children and adults.<sup>10,11</sup> Various surgical and medical treatment methods have been employed in an attempt to reverse chronic hypotony, most with transitory effect and modest success. These treatments include topical ibopamine (a dopaminergic agonist), intravitreal injection of corticosteroids or viscoelastic material, and surgical measures, such as pars plana vitrectomy with ciliary membrane removal and intraocular gas or silicone oil use.<sup>12–20</sup> Because therapeutic options are limited, prevention of hypotony and recognizing associated risk factors are important. Despite the difficulty of its treatment and its serious visual consequences, there are limited data on the risk factors associated with hypotony in patients with uveitis.

## MATERIALS AND METHODS

### The MUST Trial

The MUST Trial is a randomized, clinical trial comparing the fluocinolone acetonide intraocular implant with standard systemic therapy (systemic corticosteroids and immunosuppressive medications) for the treatment of noninfectious, recently active intermediate, posterior, or panuveitis. The methods for the MUST Trial have been published elsewhere.<sup>21</sup> At baseline, each study subject's uveitis was classified by type according to SUN criteria<sup>22</sup> as intermediate, posterior, or panuveitis; visual acuity, intraocular pressure, complete ophthalmic examination, and a detailed ocular and medical history were recorded. The study enrolled 255 patients at 23 clinical centers in the United States (21 centers), United Kingdom, and Australia.

Hypotony was defined as an eye with an IOP of  $\leq 7$  mm Hg at the baseline visit or an eye with a history of hypotony and an IOP  $\leq 9$  mm Hg at the baseline visit. Because the low IOP after glaucoma surgery often is directly related to the surgery, as opposed to the uveitis, and at times may be considered a good result, eyes with history of glaucoma surgery were excluded from this analysis.

## Measures

Best-corrected visual acuity was measured in standard letters using the Early Treatment for Diabetic Retinopathy Study (ETDRS) logarithmic charts.<sup>23</sup> Intraocular pressure was measured twice by certified study staff using Goldman applanation, and was repeated a third time if the two measurements differed by  $\geq 2$  mm Hg. Ophthalmic exam findings, including gonioscopy, slit-lamp exam (anterior chamber cells and flare, presence of posterior or anterior synechiae, iris abnormalities, inflammatory activity, lens status), dilated fundus exam (inflammatory activity, optic nerve abnormalities, structural complications such as macular edema, epiretinal membrane, and optic nerve edema) all were recorded at baseline according to standard study procedures. A detailed treatment history spanning 30 days prior to enrollment also was recorded.

## Analyses

Both person-specific and eye-specific analyses were performed on data collected as of 1 June 2010. For the person-level analysis, a participant was counted as having hypotony if either eye met the definition of hypotony as described above. The relationship between person-level demographic and clinical characteristics and hypotony was examined using univariate logistic regression, i.e., each characteristic was examined separately without control for other characteristics. For the eye-level characteristics, the relationship between the eye-specific clinical characteristics and hypotony in the eye was examined using logistic regression with generalized estimating equations (GEE) and robust variance estimation to account for potential within-person, between-eye correlations. Analyses were performed with SAS/STAT software, Version 9.2 of the SAS System for Windows (Copyright © 2002–2010 SAS Institute Inc, Cary, NC, USA). For both the person-specific and eye-specific analyses, multivariate models were not considered appropriate due to the small number of cases of hypotony and the co-linearity of the risk factors, and they were not performed.

## RESULTS

Among 255 patients enrolled in MUST Trial, 3 people were excluded from this analysis because the hypotony was in the nonuveitic eye, and 1 person was excluded because baseline IOP was not collected. Eleven patients were excluded because of a history of glaucoma surgery. Among 474 eyes (251 patients) with sufficient data, 441 eyes (220 patients) without history of glaucoma surgery were identified. Of these, 20 patients with hypotony were identified (8.3%); hypotony was bilateral in 3 patients (15%). There were 23 eyes (5.2%) with and 418 eyes without hypotony.

Characteristics of *persons* with hypotony are summarized in Table 1. Mean age at the time of randomization, smoking status, and laterality of uveitis were comparable between patients with and without hypotony. Older age at uveitis onset ( $> 51$  years) was associated with lower odds of having hypotony (odds ratio [OR] = 0.1; 95% confidence interval [CI], 0.0–0.6;  $p = .02$ ) compared to those with younger age at onset. Duration of uveitis  $\geq 5$  years prior to baseline as compared to shorter duration of uveitis was more likely to be associated with hypotony (OR = 5.0; 95% CI, 1.7–14.2;  $p < .01$ ). The odds of hypotony were lower among Caucasian patients (OR = 0.1; 95% CI, 0.1–0.4;  $p < .01$ ) and among patients of Hispanic or other ethnicity (OR = 0.2; 95% CI, 0.0–0.9;  $p = .04$ ) when compared with African-American patients. The stratum of uveitis type (intermediate vs. posterior/panuveitis) was not significantly different between patients with and without hypotony (Table 1).

Ocular characteristics of *eyes* with hypotony are shown in Table 2. Mean IOP was 4.6 mm Hg among eyes with hypotony and 14.8 mm Hg among eyes with no hypotony (median: 4.5

and 14.5 mm Hg, respectively). Prior history of ocular hypertension or overall disease activity at the baseline visit was not significantly different between hypotonous and nonhypotonous eyes. When the level of inflammation was evaluated separately in terms of aqueous cells or flare and vitreous cells or haze, the odds of hypotony were higher in eyes with anterior chamber flare of +1 or more (OR = 6.1; 95% CI, 1.8–20.8;  $p < .01$ ). Of the specific uveitis diagnoses, the odds of hypotony were higher in eyes with pars planitis (OR, 2.8; 95% CI, 1.1–7.2;  $p = .04$ ). In addition, presence of ocular features, such as angle closure, peripheral anterior synechiae, iris abnormalities (i.e., posterior synechiae, iris atrophy, iridocorneal touch), and pseudophakia or aphakia, were all associated with higher odds of hypotony ( $p = .02$ ). Choroidal folds or effusion were also significantly associated with hypotony (OR = 13.6; 95% CI, 2.7–69.6;  $p < .01$ ). There was no significant difference in the odds of hypotony in those eyes with and without macular edema as measured by OCT (OR = 0.7; 95% CI, 0.2–2.7;  $p = .70$ ).

Eyes with history of vitrectomy were more likely to have hypotony (OR = 3.1; 95% CI, 1.1–8.4;  $p = .03$ ). Eyes with hypotony were more likely to have visual acuity of 20/50 or worse (visual impairment) (OR = 22.9; 95% CI, 3.8–139.7;  $p < .01$ ).

## DISCUSSION

The reported prevalence of hypotony has ranged between 1.2 and 10% in patients with uveitis, and it varies based on the type of uveitis. Much of the information about the prevalence of hypotony comes from pediatric uveitis cohorts, where the prevalence is higher than in adults.<sup>6–11,24</sup> The lower estimate of the prevalence of hypotony of 1.2% was in an unselected cohort of patients with uveitis and may be more generalizable.<sup>24</sup> The baseline prevalence of 8.3% in the MUST Trial is among the higher estimates, but the trial enrolled patients at tertiary care referral centers for whom systemic corticosteroid therapy was indicated. This combination of potential referral and selection biases likely resulted in more severe cases being enrolled in the trial, thus leading to a higher proportion of patient with a low IOP.

Hypotony is believed to be a result of chronic, longstanding inflammation and is reported to be more common in childhood-onset uveitis.<sup>7–9,11</sup> Previous studies have shown higher rates of hypotony in children, particularly JIA-associated uveitis, which is typically an anterior uveitis.<sup>7–9,11</sup> However, the rate of hypotony has been reported to be much lower in anterior uveitis in adults compared to anterior uveitis in children.<sup>6,9,10</sup> The MUST Trial did not enroll patients with only anterior uveitis and thus had no data on the relative proportions of patients with hypotony between anterior and other anatomic locations of uveitis. In addition, there was no association of hypotony with the anatomical stratum of the uveitis; the proportions of eyes with intermediate, posterior or panuveitis in the hypotony and nonhypotony groups were comparable. Although only adolescent and adult patients were enrolled in the MUST Trial, younger age at onset still was associated with hypotony. Similarly, a longer duration of uveitis, which could be co-linear with younger age of onset and a potential confounder, was associated with hypotony. There were more women than men with hypotony, which was of borderline significance ( $p = .06$ ). Whether gender is associated with hypotony is unclear; some studies have reported a significant association between gender and structural complications or poor outcomes,<sup>6,25</sup> whereas others have found no significant difference.<sup>26,27</sup>

We found an association between hypotony and sarcoidosis in the African-American subset of patients. In one cohort of patients with sarcoidosis-associated uveitis, hypotony was seen in 1.2% at presentation.<sup>24</sup> In the present study, both sarcoidosis and African-American race were significantly associated with hypotony. Sarcoidosis has been reported to be three to

four times more common in African-Americans than in Caucasians,<sup>28</sup> and it also has been reported that African-American patients tend to have more severe sarcoidosis than do most Caucasian patients.<sup>29</sup> In the MUST Trial, all of the patients in the hypotony group with sarcoidosis were African-American. Due to the small number of patients and clustering we were unable to verify the role of sarcoidosis independent of race. Nevertheless, among the participants without sarcoidosis the proportion of eyes with hypotony was higher in the African American participants (16.0%) than among those from other races (4.3%).

Prior vitrectomy and cataract surgery (pseudophakia/aphakia) both were significantly associated with hypotony in our study. It is possible that the association with prior surgery is due to factors other than the surgery itself, and that prior surgery may be a marker for disease duration or severity. However, even among the subset of patients with longer disease duration, a history of vitrectomy or cataract surgery still was associated with higher likelihood of hypotony, suggesting that prior surgery is not a marker for disease duration. It remains possible that cataract surgery and vitrectomy are markers for more severe disease and may not be independent risk factors. Similarly, the fact that anterior and posterior segment structural changes (i.e., angle closure, peripheral anterior synechiae, iris abnormalities, choroidal folds or effusion) were more common in hypotonous eyes also is suggestive that hypotony is associated with more severe disease.

Visual impairment (acuity 20/50 or worse) was significantly and strongly associated with hypotony, with an odds ratio of nearly 23, and may be a result of the effects of hypotony or of the attendant ocular complications or a combination of these factors. Other studies also have suggested an association between hypotony and poor visual acuity,<sup>9-11</sup> making its prevention an important goal of therapy.

Evidence suggests that hypotony in uveitis is caused mainly by a decrease in aqueous production rather than an increase in outflow.<sup>4</sup> However, in experimental uveitis models increased levels of prostaglandins were associated with increased outflow and hypotony.<sup>30</sup> It is possible that sustained levels of prostaglandin in eyes with long-standing, poorly controlled inflammation may be contributing to hypotony by an increased outflow in addition to ciliary body damage. In patients with chronic uveitis, hypotony is seen much more often among those with long-standing disease and may represent the effects of past events, making it difficult to show an association between current inflammation and hypotony. As such, although some studies suggest that immunosuppressive drug therapy can reduce the risk of hypotony, there are no good data linking the severity of inflammation with the risk of hypotony.<sup>9,10</sup> Similarly, in our study, we were not able to demonstrate a statistically significant association between active inflammation (as assessed by intraocular cells or chorioretinal lesions) and hypotony. However, such relationships likely can only be assessed adequately by long-term follow-up studies with time-updated longitudinal data, integrating the effects of both severity and chronicity of the inflammation. Anterior chamber flare was associated with hypotony. Flare in an eye with hypotony may be the consequence of the low IOP and hydrostatic forces, particularly with acute disease, but it also can be a marker for chronic undertreated disease leading to vascular damage and subsequent hypotony. Although not evident directly from the current study, these data suggest the likely importance of aggressive treatment of chronic inflammation.

There are limitations to our study, and the results should be interpreted with caution. The MUST Trial is not a population-based study, and it included patients referred to selected tertiary care centers for a clinical trial. It enrolled only patients for whom systemic therapy might be indicated and did not enroll patients with isolated anterior uveitis. Therefore, the results are not generalizable to all patients with uveitis; however, the results are representative of patients with severe intermediate, posterior, or panuveitis for whom

systemic corticosteroid therapy is indicated. Although there are evident referral and selection biases compared to a population-based study, these biases may not affect substantially the evaluation of risk factors associated with hypotony among patients with severe uveitis. These data come from a cross-sectional analysis of baseline data and do not include longitudinal follow-up data. Risk factors identified are associations and do not prove causality. Most importantly, small numbers and the co-linearity of the factors in this cohort did not allow multivariate analyses, in which confounding factors could be accounted for and clearer associations could be drawn. We cannot exclude the fact that some of these associations may be driven by other unaccounted factors or by pure chance due to multiple comparisons. Although hypotony typically has been assessed as one of the structural complications in some cohort studies, there are few data on risk factors associated with hypotony. This study confirms many of the preexisting clinical suspicions about clinical findings associated with hypotony. It has been an impression among clinicians that hypotony is a consequence of severe and/or undertreated uveitis, and that patients need to be treated aggressively to prevent structural complications, such as hypotony, and the attendant poor vision.<sup>9,10</sup> Patients with the characteristics identified in this study may need to be treated more aggressively to prevent hypotony. Identification of risk factors for hypotony through longitudinal data is crucial for the development of better preventive or therapeutic approaches.

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**Other acknowledgments:** See the credit roster in the appendix.

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## APPENDIX: CREDIT ROSTER

### Participating Clinical Centers

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**National Eye Institute, Bethesda, MD:** Natalie Kurinij, PhD.

TABLE 1

Characteristics of persons with hypotony at baseline.

	Hypotony <sup>a</sup>		Odds ratio (95% CI) <sup>b</sup>	p value
	No N (%)	Yes N (%)		
Participants	220	20		
Age at randomization				
13–29	30 (14)	5 (25)	Reference	
30–50	93 (42)	7 (35)	0.5 (0.1, 1.5)	.20
51+	97 (44)	8 (40)	0.5 (0.2, 1.6)	.25
Gender				
Male	59 (27)	1 (5)	Reference	
Female	161 (73)	19 (95)	0.1 (0.0, 1.1)	.06
Race				
Black, not Hispanic	50 (23)	13 (65)	Reference	
White, not Hispanic	130 (59)	5 (25)	0.1 (0.1, 0.4)	<b>&lt;.01</b>
Hispanic or other	40 (18)	2 (10)	0.2 (0.0, 0.9)	<b>.04</b>
Smoking				
Never	97 (44)	10 (50)	Reference	
Ever	123 (56)	10 (50)	0.8 (0.3, 2.0)	.61
Age at uveitis onset				
13–19	11 (5)	3 (15)	Reference	
20–50	145 (66)	16 (80)	0.4 (0.1, 1.6)	.20
51+	62 (28)	1 (5)	0.1 (0.0, 0.6)	<b>.02</b>
Missing	2 (1)	0 (0)		
Uveitis onset 5 years before baseline				
No	136 (62)	5 (25)	Reference	
Yes	82 (37)	15 (75)	5.0 (1.7, 14.2)	<b>&lt;.01</b>
Missing	2 (1)	0 (0)		
Bilateral uveitis				
No	24 (11)	1 (5)	Reference	
Yes	196 (89)	19 (95)	2.3 (0.3, 18.2)	.42
Type of uveitis				
Intermediate	83 (38)	6 (30)	Reference	
Post/panuveitis	137 (62)	14 (70)	1.4 (0.5, 3.8)	.50
Sarcoidosis				
No	200 (91)	15 (75)	Reference	
Yes	20 (9)	5 (25)	3.3 (1.1, 10.1)	<b>.03</b>
Other associated systemic disease <sup>d</sup>				
No	196 (89)	20 (100)		
Yes	24 (11)	0 (0)		.23 <sup>c</sup>
Bilateral hypotony				

	<b>Hypotony<sup>a</sup></b>		<b>Odds ratio (95% CI)<sup>b</sup></b>	<b>p value</b>
	<b>No N (%)</b>	<b>Yes N (%)</b>		
No	218 (99)	12 (60)		
Yes	0 (0)	7 <sup>e</sup> (35)		
Missing	2 (1)	1 (5)		

<sup>a</sup>Hypotony: baseline IOP < 8 or baseline IOP < 10 with prior history of hypotony. Eyes with previous glaucoma surgery were excluded. Person-level hypotony was defined as hypotony in either eye.

<sup>b</sup>Odds ratios, confidence intervals, and *p* values calculated using univariate logistic regression.

<sup>c</sup>*p* values calculated using Fisher's exact test.

<sup>d</sup>Other associated systemic disease excluding sarcoidosis, i.e., diagnosis of Behcet disease, MS, familial systemic juvenile granulomatosis, or "other."

<sup>e</sup>Four of the bilateral hypotony cases had a history of glaucoma surgery in the other eye and, therefore, contributed only one eye with hypotony to eye level analysis.

TABLE 2

Characteristics of eyes with hypotony at baseline.

	Hypotony <sup>a</sup>		Odds ratio (95% CI) <sup>b</sup>	p value
	No N (%)	Yes N (%)		
Eyes	418	23		
Prior history of ocular hypertension				
No	361 (86)	20 (87)	Reference	
Yes	57 (14)	3 (13)	0.9 (0.2, 3.5)	.88
Specific uveitis diagnoses				
Retinal vasculitis				
No	380 (91)	21 (91)	Reference	
Yes	38 (9)	2 (9)	0.8 (0.1, 5.4)	.85
Multifocal choroidopathy <sup>c</sup>				
No	322 (77)	18 (78)	Reference	
Yes	96 (23)	5 (22)	0.9 (0.3, 2.5)	.91
Pars planitis/intermediate uveitis				
No	246 (59)	8 (35)	Reference	
Yes	172 (41)	15 (65)	2.8 (1.1, 7.2)	<b>.04</b>
Other uveitis diagnosis <sup>d</sup>				
No	355 (85)	20 (87)	Reference	
Yes	62 (15)	2 (9)	0.5 (0.1, 2.8)	.47
Missing	1 (0)	1 (4.4)		
Inflammation at baseline				
Anterior chamber inflammatory cells				
<1+	334 (80)	15 (65)	Reference	
1+	84 (20)	8 (35)	1.9 (0.7, 5.2)	.23
Aqueous flare				
<1+	225 (54)	3 (13)	Reference	
1+	193 (46)	20 (87)	6.1 (1.8, 20.8)	<b>&lt;.01</b>
Vitreous haze				
<1+	132 (32)	1 (4)	Reference	
1+	267 (64)	13 (57)	5.0 (0.9, 29.5)	.07
Missing	19 (5)	9 (39)		
Anterior vitreous cells				
<1+	165 (39)	5 (22)	Reference	
1+	238 (57)	11 (48)	1.4 (0.5, 3.9)	.58
Missing	15 (4)	7 (30)		
Angle closure				
Absent	388 (93)	14 (61)	Reference	
Present	29 (7)	9 (39)	7.8 (3.0, 20.5)	<b>&lt;.01</b>
Missing	1 (0)	0 (0)		

	Hypotony <sup>a</sup>		Odds ratio (95% CI) <sup>b</sup>	<i>p</i> value
	No <i>N</i> (%)	Yes <i>N</i> (%)		
Peripheral anterior synechiae				
No	287 (69)	9 (39)	Reference	
Yes	130 (31)	14 (61)	3.3 (1.2, 9.0)	<b>.02</b>
Missing	1 (0)	0 (0)		
Any iris abnormality				
No	284 (68)	2 (9)	Reference	
Yes	134 (32)	21 (91)	22.7 (5.4, 95.2)	<b>&lt;.01</b>
Lens status				
Phakic	259 (62)	6 (26)	Reference	
Pseudophakic/aphakic	159 (38)	17 (74)	3.9 (1.6, 9.2)	<b>&lt;.01</b>
History of vitrectomy				
No	381 (91)	18 (78)	Reference	
Yes	37 (9)	5 (22)	3.1 (1.1, 8.4)	<b>.03</b>
IOP lowering medications at baseline				
No	358 (86)	23 (100)		
Yes	60 (14)	0 (0)		.06 <sup>e</sup>
Best corrected VA 20/50 or worse				
No	235 (56)	1 (4)	Reference	
Yes	183 (44)	22 (96)	22.9 (3.8, 139.7)	<b>&lt;.01</b>
Macular edema from OCT				
No	255 (61)	8 (35)	Reference	
Yes	137 (33)	3 (13)	0.7 (0.2, 2.7)	.70
Missing	26 (6)	12 (52)		
Other ophthalmologic conditions				
Choroidal folds or effusion				
No	413 (99)	19 (83)	Reference	
Yes	5 (1)	4 (17)	13.6 (2.7, 69.6)	<b>&lt;.01</b>
Exudative retinal detachment				
No	404 (97)	22 (96)	Reference	
Yes	14 (3)	1 (4)	1.2 (0.2, 6.9)	.88
Other uveitic complications <sup>f</sup>				
No	231 (55)	12 (52)	Reference	
Yes	187 (45)	11 (48)	1.2 (0.6, 2.4)	.66

<sup>a</sup>Hypotony: baseline IOP < 8 or baseline IOP < 10 with prior history of hypotony. Eyes with previous glaucoma surgery were excluded.

<sup>b</sup>Odds ratios, confidence intervals, and *p* values calculated using univariate logistic regression with generalized estimating equations and robust variance estimation.

<sup>c</sup>Multifocal choroidopathies: birdshot chorioretinitis, serpiginous choroiditis, multifocal choroiditis with panuveitis, or punctate inner choroidopathy.

<sup>d</sup>Other uveitis diagnosis: Vogt-Koyanagi-Harada disease, sympathetic ophthalmia, "Other."

<sup>e</sup> $p$  value calculated using Fisher's exact test.

<sup>f</sup>Other ophthalmologic conditions: vitreous hemorrhage, choroidal neovascularization, or preretinal neovascularization, epiretinal membrane, or optic nerve edema.