

# Real-World Treatment and Outcomes Following Trabeculectomy in US Clinical Practice: An Analysis of the AAO IRIS Registry

Davinder Grover,<sup>1</sup> Joanna Campbell,<sup>2</sup> Inder Paul Singh,<sup>3</sup> Rupali Naik,<sup>4</sup> Flora Lum,<sup>5</sup> Bhavya Burugapalli,<sup>6</sup> Arsham Sheybani<sup>7</sup>

<sup>1</sup>Glaucoma Associates of Texas, Dallas, TX, USA; <sup>2</sup>Allergan plc, Irvine, CA, USA; <sup>3</sup>Eye Centers of Racine & Kenosha, Racine, WI, USA; <sup>4</sup>Noesis Healthcare Technologies, Inc., Redwood City, CA, USA; <sup>5</sup>American Academy of Ophthalmology, San Francisco, CA, USA; <sup>6</sup>Verana Health, Inc., San Francisco, CA, USA; <sup>7</sup>Washington University School of Medicine, St. Louis, MO, USA

## CONCLUSIONS



In one of the largest real-world cohorts of patients with OAG/OHT undergoing trabeculectomy in US clinical practice assessed to date, the observed reduction in IOP was 8.3 mm Hg and 8.7 mm Hg at 12 and 24 months post-procedure. However, IOP reductions should be considered in the context of resource utilization observed in this study



This analysis was the first phase to assess treatment and outcomes in patients with OAG/OHT undergoing trabeculectomy. Additional analyses are ongoing to assess complication rates and the contribution of subsequent surgical treatments and/or use of adjunctive medications in trabeculectomy



While trabeculectomy currently represents the gold standard for surgical lowering of IOP in OAG, there nevertheless is a need for surgical options that could lead to less intensive patient monitoring

## RESULTS

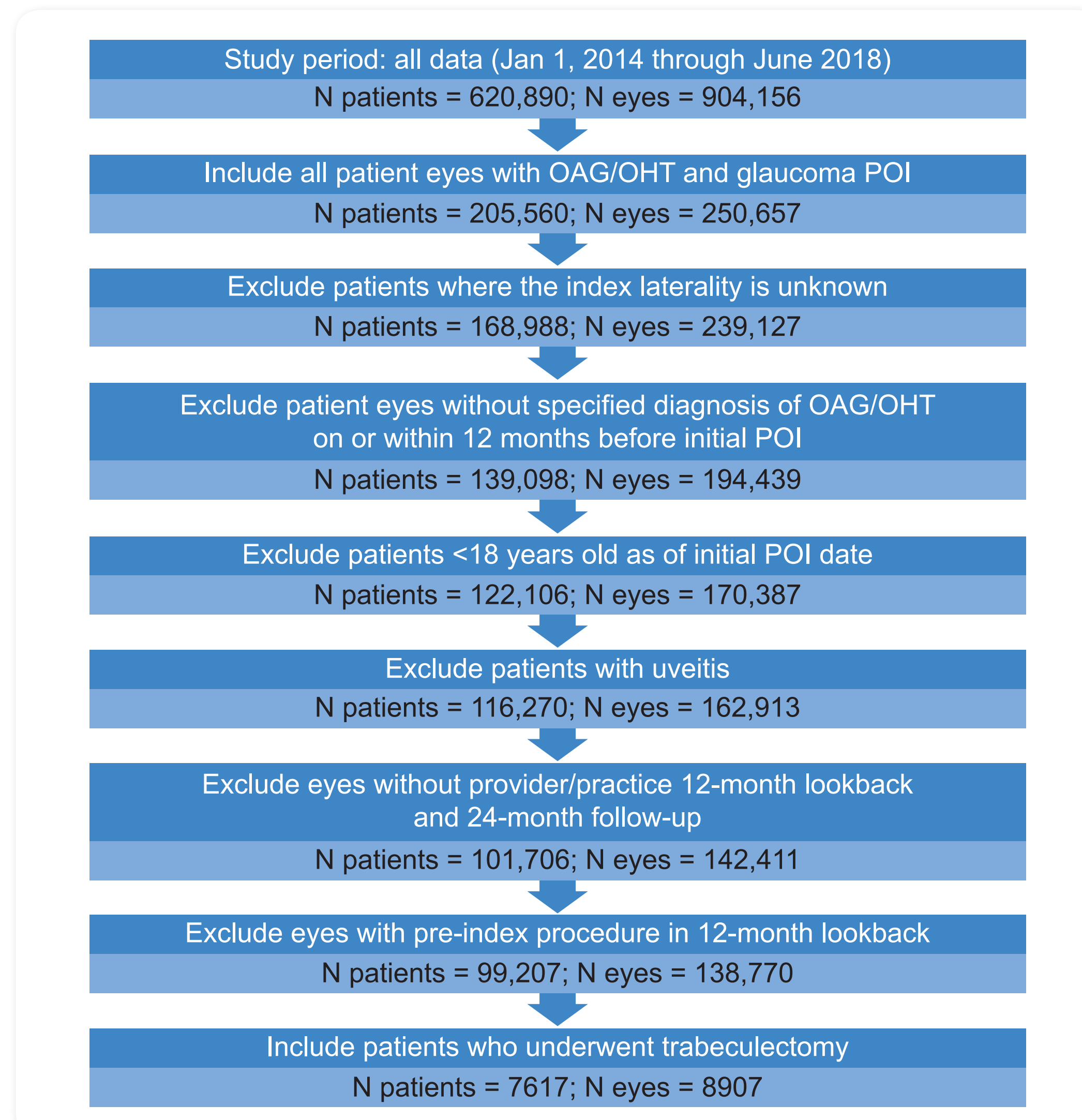
• **Figure 1** depicts the attrition table for the overall study sample used for assessing treatment and outcomes following glaucoma procedures of interest (POI) in OAG/OHT patients

• After applying inclusion/exclusion criteria, 101,706 OAG/OHT patients who received a glaucoma procedure during the index period contributed to the study sample. Of these, 7617 (7.68%) OAG/OHT patients who underwent trabeculectomy in 8907 eyes and had no surgery in the prior 12 months have been used for the analyses reported here

### Demographic Characteristics

- Of the 7617 patients who underwent trabeculectomy, 3889 (51.1%) were female and 5681 (74.6%) were ≥65 years of age, with mean (SD) age 71.2 (11.1) years
- Of the 8907 eyes undergoing trabeculectomy, a majority were in patients reporting their race as white (66.5%) and with Medicare/Medicaid insurance coverage (57.3%)

**Figure 1. Study Sample**



OAG, open-angle glaucoma; OHT, ocular hypertension; POI, procedure of interest

### Glaucoma-Related Health Care Utilization

#### Physician Office Visits

- During the 12-month pre-index period, patients had a mean (SD) of 5.78 (4.18) glaucoma-related physician office visits. Following the trabeculectomy procedure, the mean (SD) number of physician office visits for glaucoma-related care increased to 12.24 (7.56) visits over 12 months and 16.64 (11.01) visits over 24 months (**Table 1**)

**Table 1. Glaucoma-Related Health Care Utilization: Physician Office Visits**

Time Point	N	Physician Office Visits	
		Mean	SD
Baseline (–365 to 0 days)	7615	5.78	4.18
Over 12 months	7484	12.24	7.56
Over 24 months	7513	16.64	11.01

SD, standard deviation

#### Glaucoma Monitoring Tests

- In eyes undergoing trabeculectomy, mean (SD) numbers of gonioscopy and optic nerve optical coherence tomography (OCT)/Heidelberg retinal tomography (HRT) tests were similar at baseline, 12, and 24 months. Mean (SD) gonioscopy tests: 1.13 (0.42); 1.14 (0.47); 1.35 (0.65) at baseline, 12, and 24 months, respectively. Similarly, mean (SD) numbers of optic nerve OCT/HRT tests were 1.12 (0.37) at baseline, 1.08 (0.33) over 12 months, and 1.45 (0.68) over 24 months (**Table 2**)
- In eyes undergoing trabeculectomy, the mean (SD) number of IOP/tonometry tests increased from 4.30 (3.43) at baseline to 10.40 (5.83) over 12 months, and 13.65 (8.34) over 24 months (**Table 2**)

**Table 2. Glaucoma-Related Health Care Utilization: Glaucoma Monitoring Tests**

Time Point	Gonioscopy			Optic Nerve OCT/HRT			IOP/Tonometry		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Baseline (–365 to 0 days)	4768	1.13	0.42	5012	1.12	0.37	6721	4.30	3.43
Over 12 months	986	1.14	0.47	2727	1.08	0.33	7036	10.40	5.83
Over 24 months	1749	1.35	0.65	4699	1.45	0.68	7184	13.65	8.34

HRT, Heidelberg retinal tomography; IOP, intraocular pressure; OCT, optical coherence tomography; SD, standard deviation

## INTRODUCTION

- Trabeculectomy is the mainstay surgery for patients with advanced glaucoma who have failed initial topical and laser therapies.<sup>1</sup> However, there are limited data on post-trabeculectomy clinical outcomes and health care resource utilization in US clinical practice
- The objective of this study was to assess real-world clinical outcomes and health care resource utilization after trabeculectomy in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG) in US clinical practice, using the American Academy of Ophthalmology (AAO) IRIS Registry

## METHODS

### Study Design

- An observational, noninterventional, retrospective cohort study of treatments and outcomes following trabeculectomy was conducted as part of a larger-scale study of glaucoma procedures in US clinical practice using the AAO IRIS Registry
- The AAO IRIS Registry is an electronic health record (EHR)-based comprehensive eye disease clinical registry in the US, including 15,149 physicians from 3147 practices, providing data on 221 million patient visits from 52 million unique patients (as of September 1, 2018)
- Patients who underwent trabeculectomy were identified using *International Classification of Diseases, Ninth Revision (ICD-9)* and/or *Tenth Revision, Clinical Modification (ICD-10-CM)* diagnosis codes for OHT, OAG unspecified, primary OAG, low-tension OAG, pigmentary glaucoma, pseudoexfoliation glaucoma, and residual-stage OAG, as well as Current Procedural Terminology specific codes for trabeculectomy

### Patient Selection

- Patients were included if they were 18 years of age or older as of the index date, underwent trabeculectomy between January 2015 and June 2016 (index period), were in a practice contributing data to the registry for 12 months pre- and 24 months after the index procedure, and had no glaucoma surgery in the 12 months pre-index
- Patients were excluded if laterality of the index procedure was unknown, if they had uveitis, or if there were data quality issues

### Outcomes Assessed

- Intraocular pressure (IOP) was evaluated at baseline and at multiple time points over 24 months post-index. Eyes contributed to a given assessment if observed in the relevant visit window
- Glaucoma-related health care resource utilization (physician office visits and glaucoma monitoring tests) was assessed over 12 months pre-index and over 12 and 24 months post-index

### Treatment Outcomes

- Observed baseline and follow-up IOP measurements are reported in **Table 3**; eyes were not censored if additional surgical procedures were required or drop medications were increased
  - In eyes undergoing trabeculectomy, mean (SD) IOP at baseline (–60 to 0 days) was 22.37 (9.21) mm Hg. The mean (SD) observed IOP change from baseline was –9.19 (9.75) mm Hg at 6 months ± 4 weeks; –8.30 (9.46) mm Hg at 12 months ± 8 weeks; and –8.66 (9.60) mm Hg at 24 months ± 8 weeks (**Table 4**)

**Table 3. Observed Mean IOP at Baseline and Follow-up**

Time Point	N	Observed Mean IOP (mm Hg)*	SD
Baseline (–60 to 0 days)	5936	22.37	9.21
Month 6 (±4 weeks)	2529	12.84	5.32
Month 12 (±8 weeks)	2780	13.14	5.28
Month 24 (±8 weeks)	2070	13.14	5.29

\*Observed IOP; not censored if additional surgical procedures were required or drop medications were increased IOP, intraocular pressure; SD, standard deviation

**Table 4. Observed Mean Change in IOP From Baseline**

Time Point	N	Observed Mean IOP Change From Baseline (mm Hg)*	SD
Month 6 (±4 weeks)	2529	–9.19	9.75
Month 12 (±8 weeks)	2780	–8.30	9.46
Month 24 (±8 weeks)	2070	–8.66	9.60

\*Observed IOP; not censored if additional surgical procedures were required or drop medications were increased IOP, intraocular pressure; SD, standard deviation

### Discussion

- On average, patients in this study achieved an observed reduction in IOP of 8.3 mm Hg and 8.7 mm Hg at 12 and 24 months post-trabeculectomy. These results are lower than the IOP reductions reported at 3 years in the tube versus trabeculectomy (TVT) study.<sup>2</sup> In the TVT study, mean (SD) IOP reduction from baseline was 11.4 (8.9) mm Hg at 3 years in the trabeculectomy group. Mean (SD) baseline IOP was 25.6 (5.3) mm Hg in the trabeculectomy group in the TVT study compared with 22.4 (9.2) mm Hg in this study<sup>2</sup>
  - It is important to note that, while patients who underwent additional glaucoma surgery were censored in the TVT study,<sup>2</sup> no censoring was done in our study if additional surgical procedures were required or drop medications were increased
  - Additional analyses censoring for failure to achieve IOP goals and increase in drops or surgery are ongoing
- Significant health care resource utilization was reported over 12 and 24 months post-trabeculectomy, with a mean of 12 and 17 physician office visits, respectively

### Strengths

- Results of this study are based on the largest real-world US study cohort assessed to date
- With data from 3147 practices and 52 million patients, these results represent data from a geographically and sociodemographically diverse population

### Limitations

- Results of this study should be interpreted in light of the limitation that retrospective EHR data quality is dependent on the completeness, accuracy, comprehensiveness, and timeliness of data records
- With >3000 practices contributing to the IRIS dataset, it is important to note that there may be inconsistencies in the ICD-9/10 or Current Procedural Terminology codes used, which might impact the study results

## DISCLOSURES

The authors thank the patients and investigators who participated in this study.

This study was sponsored by Allergan plc, Dublin, Ireland. Editorial assistance was provided to the authors by Evidence Scientific Solutions, Inc (Philadelphia, PA) and funded by Allergan plc. All authors met the ICMJE authorship criteria. Neither honoraria nor payments were made for authorship. Financial arrangements of the authors with companies whose products may be related to the present report are listed below, as declared by the authors.

DG has received consultancy fees from Allergan, New World Medical, Reichert, and Shire; speaker fees from Allergan, Bausch & Lomb, New World Medical, and Reichert; research support from Alcon and Allergan; and advisory board fees from MicroOptx. JC is an employee of Allergan plc. IPS has received speaker and consultancy fees from Alcon, Allergan, Aerie, Bausch & Lomb, Ellex, EyePoint, EyeVance, Glaukos, Iantech, Ivantis, Katena, New World Medical, Shire, and Zeiss. RN is an employee of Noesis Healthcare Technologies, Inc. FL is an employee of the American Academy of Ophthalmology. BB is an employee of Verana Health, Inc. AS has received consultancy fees from Allergan.

### References

1. European Glaucoma Society Terminology and Guidelines for Glaucoma, 4th edition. *Br J Ophthalmol*. 2017;101:130–195.
2. Gedde SJ et al. *Am J Ophthalmol*. 2009;148:670–684.



To obtain a PDF of this poster:  
• Scan the QR code  
OR  
• Visit [www.allergancongressposters.com/148551](http://www.allergancongressposters.com/148551)  
Charges may apply.  
No personal information is stored.

