Original Article

Intraocular Pressure Changes after Water Drinking Test in Surgically Treated Primary Congenital Glaucoma

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Abstract

Purpose: To assess intraocular pressure (IOP) changes after the water drinking test (WDT) in patients with primary congenital glaucoma (PCG).
Methods: In this prospective interventional study, 20 eyes of 20 patients with PCG were included. All patients had undergone trabeculotomy. Six out of twenty eyes had received a glaucoma drainage device (GDD) implantation. IOP was measured using an air-puff tonometer at baseline, and 15, 30, 45, and 60 min after WDT. The repeated-measures analysis of variance test was used to compare the mean IOPs at different time points.
Results: The mean (± standard deviation) of participants' age was 9.9 ± 2.7 years (range, 6 to 16 years), and 8 (40%) participants were male. The mean IOPs at baseline and 15, 30, 45, and 60 minutes after the WDT were 15.8 ± 3.7, 18.6 ± 3.4, 19.0 ± 3.8, 17.9 ± 3.8, and 16.9 ± 3.5 mmHg, respectively ($P < 0.001$). Pairwise comparisons revealed that the mean IOPs after 15 and 30 min were significantly greater than the baseline IOP ($P < 0.001$ and $P = 0.002$, respectively); however, the difference in mean IOPs after 45 and 60 min were not statistically significant from the baseline IOP. The averages of IOP peak and IOP fluctuation after the WDT were 20.0 ± 3.5 and 4.2 ± 2.9 mmHg, respectively. IOP fluctuation in those who underwent trabeculotomy alone was twice that of those with GDDs, but the difference was not statistically significant (5.0 vs 2.5 mmHg; $P = 0.08$).
Conclusions: In patients with PCG, WDT induced significant IOP elevation 15 and 30 min after the test, which returned to pre-test values after 45 min.

Keywords: Glaucoma Drainage Device; Intraocular Pressure; Primary Congenital Glaucoma; Trabeculotomy; Water Drinking Test

J Ophthalmic Vis Res 2020; 15 (3): 318–325

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Received: 14-04-2019 Accepted: 03-04-2020

Access this article online:

Website:
https://knepublishing.com/index.php/JOVR

DOI:
10.18502/jovr.v15i3.7450

INTRODUCTION

Primary congenital glaucoma (PCG) is the most common hereditary type of glaucoma in

How to cite this article: Razeghinejad R, Tajbakhsh Z, Masoumpour MB, Nowroozzadeh MH. Intraocular Pressure Changes after Water Drinking Test in Surgically Treated Primary Congenital Glaucoma. J Ophthalmic Vis Res 2020;15:318–325.

childhood.[1] Several mechanisms have been suggested for the development of PCG, which result in angle dysgenesis and compromise outflow through the trabecular meshwork. Goniotomy and trabeculotomy have been recommended as the initial procedures to improve outflow by removing the abnormal trabecular tissue and making a direct connection between the anterior chamber and the Schlemm's canal. Trabeculectomy and glaucoma drainage device (GDD) implantation are employed if the intraocular pressure (IOP) cannot be controlled with the aforementioned procedures or glaucoma medications.[2] The goal of glaucoma medical and surgical interventions is to keep the IOP at a specific level in order to halt or slow down glaucoma progression.[3]

IOP is a dynamic parameter with an individual circadian rhythm. Currently, management of glaucoma include IOP measurements during clinic hours performed a few times a year. A diurnal curve may be used to evaluate glaucoma progression in a patient when the office IOP is within an acceptable range. The most common methods for assessing the diurnal curve in glaucoma patients are IOP readings at different time points during clinic hours and hospitalization in a sleep laboratory; both are cumbersome and costly. The Water Drinking Test (WDT) has been suggested as a practical and easy-to-perform test to estimate the diurnal IOP profile in a more feasible and controlled fashion.[4, 5]

IOP changes after WDT have been evaluated in adult patients with various types of glaucoma,[6, 7] but not in children with PCG. Previous studies also evaluated the WDT-IOP profile of adult glaucoma patients who were taking glaucoma medications or had undergone trabeculectomy, deep sclerectomy, and GDD implantation.[8–11] However, there is no study in patients with PCG with prior trabeculotomy or GDD implantation.

The main objective of the present study was to evaluate the IOP changes after WDT in patients with PCG and to compare the IOP changes in those with the history of trabeculotomy and those who underwent trabeculotomy followed by GDD surgery.

METHODS

This prospective interventional study was conducted in a tertiary eye care hospital after getting approval from the local Ethics Committee. The study followed the principles of the Declaration of Helsinki, and informed consent was obtained from the parents of all participants. All enrolled patients underwent a complete ophthalmological examination, which included checking visual acuity, IOP measurement, and a dilated stereoscopic fundus examination to assess the amount of optic nerve head damage using Disc Damage Likelihood Scale.[12] Subsequently, those who met the eligibility criteria were included. The average thickness of the peripapillary retinal nerve fiber layer (using optical coherent tomography) and the central corneal thickness were also recorded.

At our center, all congenital glaucoma patients undergo trabeculotomy at the superonasal and inferotemporal sites in one session, and if the IOP cannot be controlled using medications, Ahmed Glaucoma Valve (FP7, New World Medical, Rancho Cucamonga, LA, USA) is implanted in the superotemporal quadrant. We do not perform trabeculectomy because of the high chance of failure. Therefore, all patients in the current study had the history of trabeculotomy procedure as the first line treatment. The inclusion criterion was having a controlled PCG with office IOP equal to or under 22 mmHg with or without medication. The exclusion criteria were the presence of ocular infection, corneal opacity, or scar preventing reliable IOP measurements; active heart or renal diseases; and refusal of parents to enroll their children in the study.

Water drinking test

Subjects were instructed to refrain from food and fluid intake 3 hours preceding the WDT. After checking the baseline IOP, patients drank 15 mL/kg of bottled water in five minutes. Subsequently, IOP was measured every 15 min for 1 hour. The IOP was measured five times (baseline, 15, 30, 45, and 60 min after drinking water). One examiner measured the IOP using a non-contact tonometer (CT80; Topcon Co., Tokyo, Japan). The average of three measurements was recorded and the measurements were repeated if the differences between the three measurements were greater than 3 mmHg. The following parameters were assessed: IOP trough (lowest IOP after drinking water), IOP peak (highest IOP after drinking water), IOP mean (the mean of the four IOPs after drinking water), IOP fluctuation (difference between peak IOP and baseline), IOP range (difference between peak IOP and lowest IOP reading after drinking water), and end-pressure difference (IOP at 60 min versus baseline).

Statistical analysis

The IOP of both eyes was measured, but one eye was randomly selected (using a randomization chart generated by a randomization software) for inclusion in the study. All data were analyzed using IBM SPSS Statistics software version 21 (SPSS Inc., Chicago, IL) and MedCalc version 12.2.1 (*MedCalc* Software, Mariakerke, Belgium). Descriptive results were presented as the mean ± standard deviation (SD). A *P*-value < 0.05 was considered to be statistically significant.

RESULTS

Patients' baseline characteristics are presented in Table 1. Of the 20 studied patients, 17 (85%) had no associated systemic disease. Cardiac disease (repaired ventricular septal defect), phenylketonuria, and glucose-6-phosphate dehydrogenase deficiency were each found in one patient. However, no subject was on systemic medications, and no patient was prohibited from undergoing the WDT by the pediatrician.

The mean IOPs at baseline, and 15, 30, 45, and 60 min after WDT were 15.8 ± 3.7, 18.6 ± 3.4, 19.0 ± 3.8, 17.9 ± 3.8, and 16.9 ± 3.5 mm Hg, respectively ($P < 0.001$, repeated-measures analysis of variance (ANOVA); Figure 1). Pairwise comparisons using Bonferroni correction revealed that the mean IOPs 15 and 30 min after WDT were significantly greater than the baseline IOP ($P < 0.001$ and $P = 0.002$, respectively), however, the mean IOPs after 45 and 60 min were not ($P = 0.062$ and $P = 1$, respectively). The IOP after 60 min was significantly lower than the IOP after 30 min ($P = 0.03$).

The values of different WDT-IOP parameters were as following: IOP trough, 16.2 ± 3.2 (range, 10.0 to 22.0) mm Hg; IOP peak, 20.0 ± 3.5 (13.0 to 25.0); IOP mean, 18.1 ± 3.3 (12.0 to 23.3); IOP fluctuation, 4.2 ± 2.9 (0.0 to 11.0); IOP range, 3.8 ± 1.8 (1.0 to 7.0); and end-pressure difference, 1.1 ± 3.1 (–4.0 to 7.0). The first time-point to show an IOP peak was 15 min in nine patients (45%), 30 min in six (30%) patients, 45 min in three (15%) patients, and 60 min in two (10%) patients.

Linear regression analysis revealed the IOP baseline to be the only statistically significant determinant of the IOP peak ($R^2 = 0.463$; $P = 0.001$; Figure 2A). The use of a higher number of topical medications was also associated with a trend toward higher IOP peak values ($R^2 = 0.170$; $P = 0.071$). IOP fluctuation was significantly associated with the IOP baseline ($R^2 = 0.216$; $P = 0.039$; Figure 2B); and it was lower in the GDD group compared with the trabeculotomy group ($R^2 = 0.158$; $P = 0.082$).

Figure 2C and Table 2 summarize the results of WDT in the GDD group and trabeculotomy alone group. The repeated measures analysis of covariance (assuming age, gender, body mass index (BMI), and number of topical medications as possible covariates) revealed no significant difference in WDT-IOP changes between the two surgical groups ($P = 0.46$; Figure 2C). Similarly, with the exception of the IOP fluctuation, which was marginally greater in the trabeculotomy alone group than in the GDD group (5.0 vs 2.5 mm Hg; $P = 0.08$; Table 2), the WDT-IOP parameters were not significantly different. However, because of the small sample size of the groups, the possibility of a type 2 error should be considered while interpreting the insignificant *P*-values.

Figure 2D shows the WDT-IOP changes in eyes that underwent trabeculotomy with and without adjunctive topical antiglaucoma medications.

DISCUSSION

Previous studies evaluated the WDT response in medically treated glaucoma and in adults who underwent trabeculectomy or GDD implantation.[9, 11] In our study involving PCG patients, the mean IOPs 15 and 30 min, but not 45 and 60 min, after WDT were significantly greater than the baseline IOP. The highest mean IOP was observed after 30 min. In the study by Martinez et al,[11] comparing the results of the WDT in 40 eyes of 34 primary open angle glaucoma (POAG) patients who underwent trabeculectomy or GDD implantation, the highest mean IOP in both groups was observed 30 min after WDT. Similarly, 20 eyes from 20 POAG or ocular hypertension patients had the highest mean IOP after WDT 30 min following selective laser trabeculoplasty; however, before the laser procedure the highest mean IOP was observed after 45 min.[13] In the study by Mansouri et al[14] involving normal subjects, the highest mean IOP was detected 15 min after the WDT. The ability of the outflow pathway to handle the load after WDT may have affected the time at which the highest mean IOP was detected. In normal adults with normal outflow facility, the highest IOP was observed after 15 min; however, in adult patients who underwent trabeculectomy or GDD implantation and in our patients, the highest IOP was observed after 30 min.[11, 14]

In our study the IOP fluctuation in all patients (GDD plus trabeculectomy), and in each of the trabeculectomy, and GDD groups were 4.2, 5.0,

Table 1. Baseline characteristics of patients with primary congenital glaucoma

Characteristic	Value
Age, year(s)	9.9 ± 2.7 (6 to 16)[a]
Gender, (Male/Female)	8/12
Eye, (Right/Left)	12/8
Weight, kg	30.3 ± 12.2 (14 to 53)[a]
Height, cm	134 ± 17 (104 to 169)[a]
Body Mass Index, kg/m^2	16.1 ± 3.4 (12.9 to 23.0)[a]
Spherical Equivalent Refraction, Diopter(s)	−2.7 ± 4.7 (−17.5 to +1.3)[a]
Astigmatism, Diopter(s)	−1.1 ± 1.1 (−4.5 to 0.0)[a]
Central Corneal Thickness, µm	582 ± 47 (488 to 653)[a]
Cup-to-Disc ratio, %	48 ± 24 (10 to 80)[a]
Average Retinal Nerve Fiber Layer Thickness, µm	92 ± 23 (51 to 140)[a]
Number of Topical Medications	1.4 ± 1.1 (0 to 3)[a]
Lens status, n (%)	Phakic: 20 (100)
Operation, n (%)	Trabeculotomy only: 14 (70) GDD 6 (30)
Baseline Intraocular Pressure, mm Hg	15.8 ± 3.7 (8.5 to 21.0)[a]

[a]Scalar data are presented as mean ± standard deviation (range)

Table 2. Comparison of WDT-IOP parameters between the GDD (n = 6) and the trabeculotomy (n = 14) group

Parameter (mmHg)	Operation		P-value[b]
	Trabeculotomy[a]	GDD[a]	
IOP Trough	16.0 ± 2.9	16.7 ± 4.1	0.66
IOP Peak	20.1 ± 3.4	19.6 ± 4.1	0.75
IOP Mean	18.0 ± 3.2	18.3 ± 3.9	0.86
IOP Fluctuation	5.0 ± 2.6	2.5 ± 3.1	0.08
IOP Range	4.2 ± 1.8	2.9 ± 1.6	0.14
End Pressure Difference	1.5 ± 3.1	0.3 ± 2.9	0.41

[a]All data are presented as mean ± standard deviation; [b]Calculated with Independent Samples *T*-test; all measurements passed the Shapiro–Wilk test of normality
IOP, intraocular pressure; GDD, glaucoma drainage device; WDT, water drinking test

and 2.5 mmHg, respectively. The reported IOP fluctuation in adult glaucoma patients managed medically ranged from 4.3 to 8.4 mmHg.[8–10, 15, 16] The reported IOP fluctuations in eyes that underwent trabeculectomy ranged from 1.6 to 3.95 (Table 3).[8, 10, 11]

A study on GDDs reported an IOP fluctuation of 3.6 mmHg.[11] The IOP fluctuation in our trabeculotomy group (4.2 mmHg) was greater than the values reported in trabeculectomy (3.95 mmHg) and GDD (3.6 mmHg) groups in previous studies. However, the IOP fluctuation in our GDD group (2.5 mmHg) was lower than the value in POAG patients with GDD (3.6 mmHg).[11]

Several studies have suggested that IOP fluctuation is an important contributor to the risk of glaucoma progression.[8, 17] The Early Manifest Glaucoma Trial showed that even a 1 mmHg increase in IOP was associated with an 11% increase in the hazard ratio for glaucoma progression.[18] The Advanced Glaucoma Intervention Study Group suggested that IOP peaks should be below 18 mmHg to prevent visual-field deterioration in patients with moderate- or advanced-stage glaucoma.[19] As glaucoma progression is correlated with IOP peaks and fluctuations,[20] accurate identification of at-risk patients has become imperative as the first step

Table 3. The results of the water drinking test in normal subjects, primary open angle glaucoma, ocular hypertension, and pseudoexfoliation syndrome

Authors	Diagnosis	Management of glaucoma	Average age of patients (years)	IOP baseline (mmHg)	IOP peak (mmHg)	IOP fluctuation (mmHg)
Ozyol et al[15]	XFS (34)	No treatment		16.3	18.1	1.8
	XFG(30)	Medical therapy	65.6	19.7	26.9	7.2
De Moraes et al[16]	POAG (22)	Medical therapy	54.3	12.4	20.00	7.6
Danesh-Meyers et al[29]	POAG	Trabeculectomy	70	10.4	11.7	1.3
		Medical therapy	68	11.4	17.3	5.9
Mansouri et al[8]	POAG	Trabeculectomy	67.1	10.1	12.5	2.4
		Deep Sclerectomy	72.5	13.8	17.6	3.8
		Latanoprost	71.2	15.9	21.1	5.2
Mansouri et al[14]	Normal subjects (25)	No treatment	35.6	14.9	16.8	1.9
Guedes RA et al[10]	Normal subjects (20)	No treatment	58.9	13.9	15.8	1.9
	Glaucoma subjects (21)	No treatment		17.5	26	8.4
	Glaucoma subjects (21)	Dorzolamide-timolol		14.2	18.6	4.3
	Glaucoma subjects (15)	Deep sclerectomy		12.3	14.1	1.7
	Glaucoma subjects (21)	Trabeculectomy		10	11.6	1.6
Kocabeyoglu et al[30]	Normal subjects (20)	No treatment	64.4	14	15.5	1.5
	XFS (20)	No treatment	66.1	15	17.2	2.2
Kerr et al[13]	POAG and OHTN	Before SLT	73	16.9	21	4.1
		After SLT		14.2	16.5	2.3
Martinez et al[11]	POAG	Trabeculectomy (20)	67.9	12.3	16.25	3.95
		GDD (20)	66.2	12.5	16.15	3.6

XFS, pseudoexfoliation syndrome; XFG, pseudoexfoliative glaucoma; POAG, primary open angle glaucoma; OHTN, ocular hypertension; SLT, selective laser trabeculoplasty

in preventing further irreversible glaucomatous damage.[21] It has been shown that, in two-thirds of glaucoma patients, the highest IOP values occur outside regular clinic hours, frequently during the nocturnal/sleep period.[22] Therefore, significant IOP fluctuation may be missed if relying only on clinic IOP measurements. Twenty-four hour IOP monitoring and provocative tests such as WDT were suggested as viable options for identifying a greater number of patients with poorly controlled glaucoma. A group of normal tension glaucoma patients underwent several clinical tests for predicting the progression of visual field loss, and the WDT was the most useful clinical predictor for visual field progression.[5] The IOP peak occurred during home tonometry in approximately 30% of patients with progressive visual field loss while it occurred during home tonometry in 5% of patients with stable visual fields.[23] After drinking water, the ability of the outflow system to modulate the stress of an IOP rise is the only mechanism that can control the IOP. Interventions that improve outflow facility can be expected to induce fewer changes in the IOP after WDT.

The smoother WDT-IOP profile in our GDD group may have a protective effect on the damaged optic nerve. It is plausible that trabeculotomy increases aqueous outflow, but not as effective as GDD surgery, which bypasses the congenitally abnormal aqueous drainage pathway in PCG. The IOP fluctuation in the trabeculotomy group was two times greater than that in the GDD group (5.0 vs 2.5 mmHg; P = 0.08).

The IOP profile in the trabeculotomy group on glaucoma medications was greater, though not statistically significant, compared to the trabeculotomy group who were not on medication

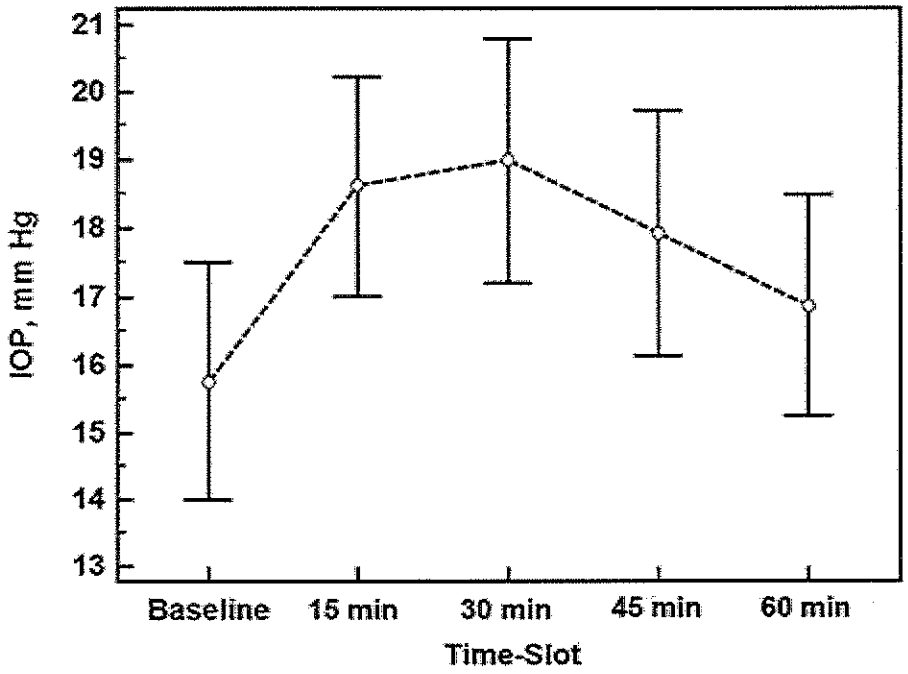

Figure 1. The average intraocular pressure at baseline and at each time-point after the water drinking test in patients with congenital glaucoma.

(Figure 2D). A trend toward a greater IOP peak was observed as the number of topical medications increased (R^2 = 0.170; P = 0.071). The use of glaucoma medications following the surgical procedure indicates insufficient IOP control and suggests the existence of increased resistance to the outflow. In other words, the higher number of medications may be an indirect measure of the increased resistance in the outflow pathway.

The baseline IOP was the only significant determinant of the IOP peak (R^2 = 0.463; P = 0.001). This is in line with the findings of previous studies in adult patients demonstrating that a higher IOP at baseline is associated with greater 24-hour IOP changes when measured in the seated position.[24] The rate of aqueous production is steady and the outflow facility is the only determinant factor of IOP. When the baseline IOP is low, the possibility of IOP fluctuation might be reduced because the outflow pathway can handle the load and vice versa.

IOP variation over time may be divided into diurnal, short-term, and long-term fluctuations. It is often difficult to get a true picture of a patient's IOP profile when it is measured only several times a year. The current method of IOP measurements is simply a snapshot of the real IOP over time and does not represent the actual IOP profile. The WDT is utilized as a provocative test to evaluate outflow capacitance and the effect of medical or surgical glaucoma treatments on the IOP peak and fluctuation.[19] Studies have shown that the WDT-IOP peak strongly correlates with the peak of shortened diurnal curves and the long-term IOP profile.[6, 16] The exact mechanism that underlies IOP elevation after water ingestion remains unclear. The proposed mechanisms include choroidal expansion, plasma hypo-osmolality-enhanced aqueous ultrafiltration, autonomic nervous system stimulation, and increased episcleral venous pressure.[7, 19] Compared to the 24-hour IOP curve measurement that requires the patient to stay in the hospital and involves the measurement of IOPs at night, the WDT could be an inexpensive and feasible alternative.

This study has several limitations including the small number of patients, especially in the GDD group, and the fact that the IOP was measured using an air-puff tonometer. In most studies that involved performing WDT in adult glaucoma patients, the number of participants was around 20–30 patients, and in some studies both

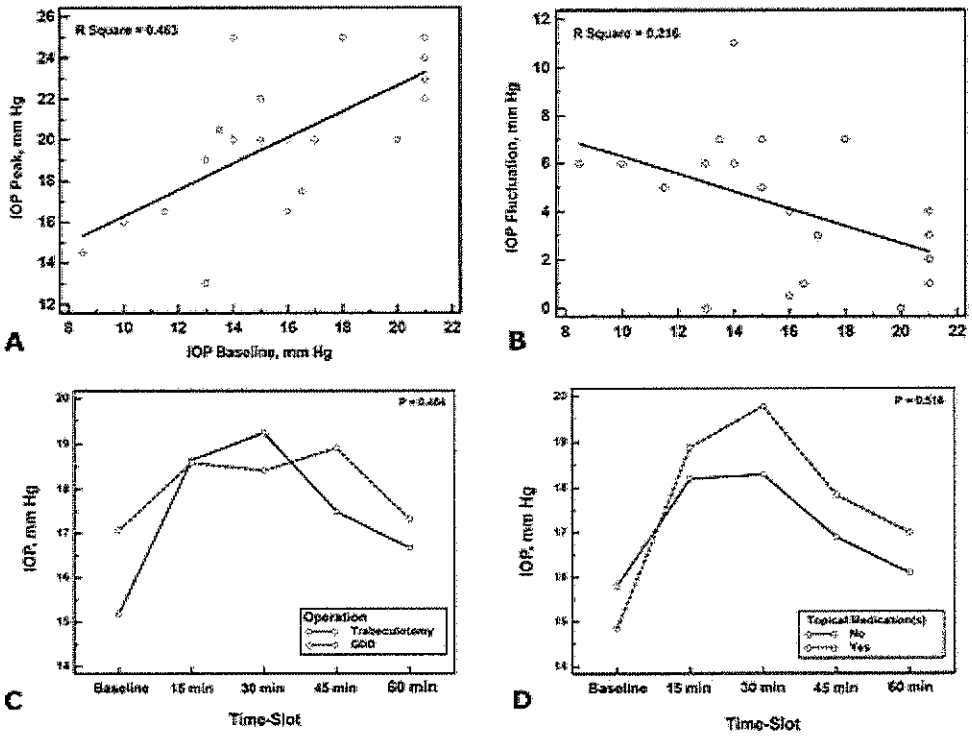

Figure 2. (A) The scatter diagram and regression line showing direct association between IOP baseline and IOP peak. (B) The scatter diagram and regression line showing reverse association between IOP baseline and IOP fluctuation. (C) The IOP profile after the water drinking test in the trabeculotomy and glaucoma drainage device implantation groups. (D) The IOP profile after the water drinking test in eyes that underwent trabeculotomy with and without adjunctive topical antiglaucoma medications.

eyes were included (Table 3). In this study, we included one eye from each patient. The global prevalence of glaucoma for the population aged 40–80 years is 3.54%, which is much greater than that for PCG (0.01–0.001%).[25, 26] The rarity of this disease makes recruiting PCG patients challenging. With respect to cooperation for IOP measurement, non-Goldmann tonometer are usually used for IOP measurement in pediatric patients. It has been shown that, in PCG patients, IOP values obtained using an air-puff tonometer are similar to those obtained using a Goldmann tonometer.[27] Additionally, in a recent meta-analysis that compared all available tonometers with the Goldmann applanation tonometer, air-puff tonometers yielded the least amount of variability in IOP values (mean difference of 0.2 mm Hg).[28]

In conclusion, the WDT induced significant IOP elevation 15 and 30 min after the test in patients with PCG. This increased IOP returned to pre-test values after 45 min. In eyes previously treated with trabeculotomy, the IOP fluctuation was greater, though not statistically significant.

Financial Support and Sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

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Record: 1

Title: The impact of primary open-angle glaucoma: Comparison of vision-specific (National Eye Institute Visual Function Questionnaire-25) and disease-specific (Glaucoma Quality of Life-15 and Viswanathan 10) patient-reported outcome (PRO) instruments.

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Source: Indian journal of ophthalmology [Indian J Ophthalmol] 2019 Jan; Vol. 67 (1), pp. 83-88.

Publication Type: Comparative Study; Journal Article

Language: English

Journal Info: *Publisher:* Medknow Publications *Country of Publication:* India *NLM ID:* 0405376 *Publication Model:* Print *Cited Medium:* Internet *ISSN:* 1998-3689 (Electronic) *Linking ISSN:* 03014738 *NLM ISO Abbreviation:* Indian J Ophthalmol *Subsets:* MEDLINE

Imprint Name(s): *Publication*: Mumbai : Medknow Publications
Original Publication: Bombay : All-India Ophthalmological Society

MeSH Terms: Patient Reported Outcome Measures*
Quality of Life*
Surveys and Questionnaires*
Visual Acuity*
Glaucoma, Open-Angle/*physiopathology
Vision Disorders/*etiology
Visual Fields/*physiology
Female ; Follow-Up Studies ; Glaucoma, Open-Angle/complications ; Humans ; Male ; Middle Aged ; National Eye Institute (U.S.) ; Prospective Studies ; Reproducibility of Results ; Sickness Impact Profile ; United States ; Vision Disorders/diagnosis ; Vision Disorders/physiopathology ; Visual Field Tests

Abstract: **Purpose:** To compare a general vision-specific patient-reported outcomes (PRO) instrument, National Eye Institute Visual Function Questionnaire-25 (NEIVFQ-25) with two disease-specific PRO instruments, Glaucoma Quality of Life-15 (GQL-15), and Viswanathan 10 in patients with varying severity of primary open angle glaucoma (POAG).

Methods: This hospital-based, prospective study enrolled 140 glaucoma patients. The patients were classified into mild, moderate, and severe glaucoma based on visual field defects. All these patients were administered the three PRO instruments and the results were statistically analyzed.

Results: All the three instruments showed high internal consistency (Cronbach's alpha for GQL-15, NEIVFQ-25, and Viswanathan 10 were 0.918, 0.937, and 0.929, respectively) There was a statistically significant difference between patients with mild, moderate, and severe POAG with all instruments ($P \leq 0.001$). The instruments correlated well across several parameters especially the peripheral vision and glare/dark adaptation. The disease-specific scales however are simpler and faster to administer.

Conclusion: All three instruments were reliable in assessment of mild, moderate, and severe glaucoma. They correlated strongly with each other in most of the related subscales, domains, and questions. NEIVFQ-25 additionally gave information regarding the general, psychological, and social effects of the disease.

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Contributed Indexing: *Keywords:* Glaucoma Quality of Life-15; Impact; National Eye Institute Visual Function Questionnaire-25; glaucoma; quality of life

Entry Date(s): *Date Created:* 20181222 *Date Completed:* 20190416 *Latest Revision:* 20200225

Update Code: 20210210

PubMed Central ID: PMC6324158

DOI: 10.4103/ijo.IJO_798_18

PMID: 30574899

Database: MEDLINE with Full Text

The impact of primary open-angle glaucoma: Comparison of vision-specific (National Eye Institute Visual Function Questionnaire-25) and disease-specific (Glaucoma Quality of Life-15 and Viswanathan 10) patient-reported outcome (PRO) instruments

Purpose: To compare a general vision-specific patient-reported outcomes (PRO) instrument, National Eye Institute Visual Function Questionnaire-25 (NEIVFQ-25) with two disease-specific PRO instruments, Glaucoma Quality of Life-15 (GQL-15), and Viswanathan 10 in patients with varying severity of primary open angle glaucoma (POAG). Methods: This hospital-based, prospective study enrolled 140 glaucoma patients. The patients were classified into mild, moderate, and severe glaucoma based on visual field defects. All these patients were administered the three PRO instruments and the results were statistically analyzed. Results: All the three instruments showed high internal consistency (Cronbach's alpha for GQL-15, NEIVFQ-25, and Viswanathan 10 were 0.918, 0.937, and 0.929, respectively) There was a statistically significant difference between patients with mild, moderate, and severe POAG with all instruments ($P \leq 0.001$). The instruments correlated well across several parameters especially the peripheral vision and glare/dark adaptation. The disease-specific scales however are simpler and faster to administer. Conclusion: All three instruments were reliable in assessment of mild, moderate, and severe glaucoma. They correlated strongly with each other in most of the related subscales, domains, and questions. NEIVFQ-25 additionally gave information regarding the general, psychological, and social effects of the disease.

Keywords: Impact; glaucoma; quality of life; National Eye Institute Visual Function Questionnaire-25; Glaucoma Quality of Life-15

From the patient's perspective, activities like reading, walking down the stairs, and recognizing people are more important than clinical endpoints like intraocular pressure (IOP) and visual fields (VFs).[1],[2] Therefore, currently there is a conscious shift on the part of clinician towards incorporation of patient centric outcomes rather than clinical outcomes to measure efficacy of treatment in glaucoma patients. Assessment of patient's perception-based QoL has become an integral part of overall evaluation and management of glaucoma patients.

Quality of life in glaucoma patients can be evaluated using various QoL instruments. A number of instruments have been developed and employed in the past decade. Currently, patient-reported outcomes (PROs) are being used to estimate functional status, disease status, or health-related QoL.[3] These PRO instruments are classified into three major categories that include instruments addressing functional status related to vision loss [Glaucoma Quality of Life 15 (GQL-15), Viswanathan 10 questionnaire, and Visual Activity Questionnaire], instruments addressing QoL [National Eye Institute Visual Function Questionnaire-51, NEIVFQ-51), the shorter version NEIVFQ-25, Vision Core Module 1, Quality of Life, and Visual Function Questionnaire], and instruments assessing other factors related to disease and treatment like symptoms, side effects, adherence, satisfaction, and self-efficacy (Treatment Satisfaction Survey for Intraocular Pressure, the Comparison of Ophthalmic Medication for Tolerability, and Eye Drop Satisfaction Questionnaire).[4],[5],[6],[7],[8]

Health-related or generic vision-related instruments are lengthy, difficult to use, and have complex scoring system and parochial bias. Instruments addressing health-related/generic QoL are also less accurate in picking up glaucoma patients, especially in early/mild stage of disease.[3] However disease-specific instruments act as great discriminator between glaucoma patients and controls as they have stronger correlation with clinical parameters like VF indices as compared to vision-specific instruments.[9] The ideal glaucoma PRO instrument should be easy to use, reproducible, have simple questions and easily understandable scoring system. Till date, no single questionnaire satisfies this definition of an ideal glaucoma PRO instrument.

The NEIVFQ-25 is most commonly employed vision-specific instrument for assessing QoL in glaucoma patients.[10] It is considered gold standard to assess QoL in glaucoma patients and all newer and disease-specific tools are compared to it. GQL-15, a disease-specific instrument, can evaluate the effect of binocular

VF loss on visual function.[4] As compared to NEIVFQ-25, GQL-15 is shorter, easier to use, and faster to administer.[4],[9],[2] Viswanathan and associates have designed a disease-specific 10-item PRO that directly target functions and activities influenced by glaucoma.[11]

A number of studies have found vision-specific instrument like NEIVFQ-25 to be useful in assessing QoL of glaucoma patients.[2],[9],[12] One study has compared vision-specific instrument, NEIVFQ-25 with disease-specific instrument GQL-15, and found GQL-15 to be better in terms of being quick and more user-friendly.[9] There is however still lack of literature regarding comparison of different instruments for assessing QoL in glaucoma patients. There is also lack of clarity as to which instrument is best for elucidating QoL amongst glaucoma patients. To the best of our knowledge, no study has simultaneously evaluated more than two instruments for assessing glaucoma patients. This study was designed to compare two disease-specific instruments (GQL-15 and Viswanathan 10) with one vision-specific instrument (NEIVFQ-25) for QoL assessment in Indian primary open angle glaucoma (POAG) patients.

Methods

Study design

The study was conducted as per the tenets of the Declaration of Helsinki after taking approval from the institutional ethics committee. It was a hospital-based, cross-sectional analytical study. All the subjects enrolled in the study gave a written informed consent before being included in the study. This was a pilot study, so a prior sample size calculation was not done. A total of 140 consecutive subjects visiting the outpatient services were enrolled in the study.

Comprehensive ocular examination

This included documentation of detailed ocular history, visual acuity testing with refraction, IOP testing, gonioscopy with four mirror lens, dilated fundus examination with stereoscopic biomicroscopy of the optic nerve head using slit-lamp, indirect ophthalmoscopy where indicated, and VF testing using 24-2 SITA FAST on Humphrey Field Analyser II. The Hodapp-Parrish-Anderson criteria were used to classify the cases into mild, moderate, and severe glaucoma, respectively, considering VF defects on HFA in the less severely affected eye.[13]

Patient selection

Inclusion criteria: Patients diagnosed with POAG with age 40 years or older and on medical therapy. POAG was diagnosed if the patient had evidence of optic nerve damage from either one or both of the following: glaucomatous optic disk or retinal nerve fiber layer abnormalities, reliable and reproducible glaucomatous VF abnormality, and open angles on gonioscopy.[14]

Exclusion criteria: In order to avoid factors that could preclude the patient from providing reliable and valid data, patients having preexisting visually significant cataract and history of cataract surgery in past 3 months were excluded from the study. Patients with neurological disease, diabetic retinopathy, hypertensive retinopathy, and age-related macular degeneration were also excluded from the study.

QoL assessment

The QoL instruments were orally administered by a single interviewer (Supplemental Material). The patient was conveyed the questions in their vernacular language by the interviewer. Over a course of two clinic visits

(a week apart), the patient was administered GQL-15 and Viswanathan 10 in the index visit and NEIVFQ-25 in the follow-up visit. In order to ensure compliance, the patients were contacted and reminded in case they missed a visit. The patients requiring any change in treatment between the two clinic visits were excluded from the study.

Statistical analysis

The data were recorded in a spreadsheet and QoL scoring was done as per standard recommended scoring algorithm for that questionnaire.[4],[11],[10],[15] Higher values of NEIVFQ-25 and Vishwanathan 10 scale indicate better QoL, while in GQL-15, higher values indicate a lower QoL. The data were then analyzed using IBM Statistical Package for Social Sciences (SPSS Version 21 for Windows, Armonk, NY: IBM Corp.). ANOVA was used to compare the QoL scores across various severity of glaucoma and Pearson's correlation coefficient was used to assess the correlation of the scores with each other. Cronbach's alpha was calculated to assess the internal reliability of the instruments.

Results

The mean QoL scores in mild, moderate, and severe glaucoma using NEIVFQ-25, GQL-15, and Viswanathan instruments are shown in [Figure 1] and [Figure 2]. All the three instruments showed statistically significant difference between mild, moderate, and severe grades of glaucoma (P values in [Table 1]). There was no statistically significant difference between the three groups based on age and gender ($P > 0.05$).{Figure 1} {Figure 2}{Table 1}

All the instruments showed good internal reliability. Cronbach's alpha for GQL-15, NEIVFQ-25, and Viswanathan 10 was 0.918, 0.937, and 0.929, respectively. Average time taken to administer the instruments was 5, 7, and 14 min for Viswanathan, GQL-15, and NEIVFQ-25, respectively.

Correlations:

NEIVFQ-25 and GQL-15: Correlation between NEIVFQ-25 and GQL 15 is shown in [Table 2]. The subscales of NEIVFQ-25 and domains of GQL-15 showed statistically significant correlation as shown in [Table 3]. Near activities subscale of NEIVFQ-25 correlated strongly with central and near vision domain of GQL 15 ($r = -0.672$). Peripheral vision subscale of NEIVFQ-25 correlated with outdoor mobility domain of GQL-15 ($r = -0.663$). Driving subscale of NEIVFQ-25 correlated with the peripheral and glare/dark adaptation domain of GQL-15 ($r = -635$ and -0.615, respectively)NEIVFQ-25 and Viswanathan 10: The subscales of NEIVFQ-25 and questions of Viswanathan 10 instrument showed statistically significant correlation as shown in [Table 4]. General health subscale of NEIVFQ-25 correlated strongly with the question, Do you have particular difficulty seeing after moving from a light to a dark room?; near vision subscale correlated with the question, Do you ever have trouble following a line of print or finding the next line when reading?; distance vision subscale with questions like Do you ever notice that parts of your field of vision are missing?, Have you noticed any deterioration in your sight over the last few years?, and Have you had to give up activities because of your sight?; the driving subscale correlated with questions like Do you ever notice that parts of your field of vision are missing?, Are you troubled by glare or dazzled on sunny days or in bright lighting?, and Do you have particular difficulty seeing after moving from a light to a dark room?GQL-15 and Viswanathan 10: The domains of GQL-15 instruments showed statistically significant correlation with relevant questions of Viswanathan 10 instrument as shown in [Table 5]. Central/Near domain correlated strongly with the question, Do you ever have trouble following a line of print or finding the next line when reading?; Peripheral domain with questions like Have you noticed any deterioration in your sight over the last few years? and Do you have difficulty finding

things that you have dropped?; glare/dark adaptation with questions like Have you had to give up activities because of your sight?, Are you troubled by glare or dazzled on sunny days or in bright lighting?, and Do you have particular difficulty seeing after moving from a light to a dark room?; and outdoor mobility with question like Have you had to give up activities because of your sight?{Table 2}{Table 3}{Table 4}{Table 5}

Discussion

PRO is a broad term comprising of health status of patients as perceived by them. Current day QoL instruments may provide important information regarding disease and its treatment aspects and form essential part of their management strategy. However, it is a challenge to the glaucoma specialist to select appropriate and most useful instrument for their patients. In this study, we have compared three instruments and tried to find the best-suited QoL instrument for our glaucoma patients.

Mean QoL scores for all instruments correlated well with the VF indices [Table 1]. Pourjawan et al. have found stronger correlation of NEIVFQ-25 scores with mean deviation, pattern SD as compared to GQL-15.[12] However, Mbadunga et al. showed results similar to our study.[9] Viswanathan questionnaire has also been shown to have strong correlation with VF indices similar to our study.[16]

There was statistically significant difference between mild, moderate, and severe glaucoma with all three instruments ($P < 0.001$). Goldberg used GQL-15 to differentiate mild, moderate, and severe glaucoma and reported similar findings as ours.[4] However, Nelson was not able to differentiate mild glaucoma from moderate glaucoma by using GQL-15 instrument.[15] In another study, the authors were not able to differentiate mild glaucoma from moderate glaucoma with NEIVFQ-25 and GQL-15 instrument.[9] These facts deviate from our findings but varied ways to grade disease severity in different studies may account for this difference.

NEIVFQ-25 (nonvisual subscales)

Nonvisual subscales of NEIVFQ-25 like general health, mental health, social function, and role limitation showed significant decrease in scores corresponding to increased severity of glaucoma [Table 5]. All these subscales were able to differentiate between mild, moderate, and severe glaucoma ($P < 0.001$).

These results demonstrate the importance of nonvisual or general health-related subscales while assessing QoL in glaucoma patients. Jung et al. have previously reported the higher levels of depression, anxiety, altered sleep, psychological stress, and suicidal ideation in patients with glaucoma when compared to controls.[17] These findings highlight the fact that glaucoma despite being an ocular disease has huge impact on general and psychological health-related QoL. Thus, nonvisual parameters like general health, psychological health, and social health form an integral part of any QoL instrument.

Correlation of NEIVFQ-25 and GQL-15

The scores of different domain and subscales showed significant correlation in both the instruments [Table 2]. The near and peripheral vision subscales of NEIVFQ-25 correlated well with the near and peripheral vision domain of GQL 15. This is similar to the previously reported results.[9] We also found strongest correlation between the general health and peripheral vision subscale of NEIVFQ-25 and outdoor mobility domain of GQL-15. A significant correlation between the peripheral vision subscales of the NEIVFQ-25 with the outdoor mobility domains of the GQL-15 was demonstrated by Mbadugha et al. They however did not show correlation

with general health subscale which is in contrast to our findings. This correlation can be explained by the fact that any deterioration in general health will be reflected in decreased outdoor activities.

The driving subscale of NEIVFQ-25 in our study correlated best with the peripheral vision and glare/dark adaptation domain of GQL-15. Mbadugha et al. have previously shown that driving subscale of NEIVFQ-25 strongly correlated with the glare and dark adaptation but not with the peripheral vision domain of GQL-15.[9] Our findings again highlight the importance of peripheral vision while driving in daylight. We agree that glaucoma patients may also have difficulty in driving at night due to glare and poor dark adaptation. Previous studies have also shown that glare and dark adaptation were most disturbing problems especially during early stage of disease but get less problematic as disease progresses, probably because patients adapt to these problems over a period of time.[15],[18],[19] The inability to drive leads to decreased outdoor mobility and hence adversely affects the quality of life of these patients. The assessment of glare and dark adaptation is thus of paramount importance in the clinical management of all stages of glaucoma patients.

Correlation of NEIVFQ-25 subscales and Viswanathan 10

The scores of different subscales of NEIVFQ-25 and different questions of Viswanathan 10 showed significant correlation [Table 3]. In our study, the question, Do you ever notice that parts of your field of vision are missing? in Viswanathan 10 instrument, has strong correlation with general vision subscales of NEIVFQ-25. Near vision subscale of NEIVFQ-25 showed strong correlation with question, Do you ever have trouble following a line of print or finding the next line while reading? in Viswanathan 10 instrument. Color vision subscale of NEIVFQ-25 showed significant correlation with question, Do you notice variations in color intensity? of Viswanathan 10 instrument. All these facts highlight high degree of agreement between different subscales and related questions of these two instruments.

Driving subscales of NEIVFQ-25 showed strong correlation with questions, Do you ever notice that parts of your field of vision are missing? and Do you have particular difficulty seeing after moving from a light to a dark room?, and Are you troubled by glare or dazzled on sunny days or in bright lighting? of Viswanathan 10 instrument. So driving subscales of NEIVFQ-25 is strongly correlating with questions related to dark adaptation, glare as well as peripheral vision. The findings of these two instruments correlate well with the findings discussed previously, highlighting the importance of glare/dark adaptation and peripheral vision in activities like driving.

In our study, vision-related subscales of NEIVFQ-25 are strongly correlating with questions of Viswanathan 10 related to activities dependent on vision. Our findings are quite similar to those reported previously, which highlight the importance of questions relating to near and peripheral vision in assessment of progressive glaucomatous decrease in QoL.[11]

Correlation of GQL-15 and Viswanathan 10

The scores of different domains of GQL-15 and related questions of Viswanathan 10 instrument also showed significant correlation [Table 4]. In our study, the question, Do you ever have trouble following a line of print or finding the next line when reading of Viswanathan 10 correlated best with the central-near vision domain of GQL-15. Questions, Do you have difficulty finding things that you have dropped? and Have you noticed any deterioration in your sight over the last few years?, of Viswanathan 10 correlated best with the peripheral vision domain of GQL-15. The question, Have you had to give up activities because of your sight?, correlated best with the glare/dark adaptation and outdoor mobility domains. The questions, Are you troubled by glare or dazzled on sunny days or in bright lighting? and Do you have particular difficulty seeing after moving from a

light to a dark room?, also correlated best with the glare/dark adaptation and outdoor mobility domains of GQL-15.

In a previous study, the following questions of Viswanathan 10 instrument, Do you notice variations in color intensity?, Do you bump into things sometimes?, Do you trip on things or have difficulty with stairs?, and Do you have difficulty finding things that you have dropped?, were the most useful questions to evaluate patients' limitations due to glaucomatous damage.[16] In our study, the most useful question which strongly correlated with other instruments, Have you had to give up activities because of your sight?, correlated best with the glare/dark adaptation, and outdoor mobility domains, Are you troubled by glare or dazzled on sunny days or in bright lighting? and Do you have particular difficulty seeing after moving from a light to a dark room? also correlated best with the glare/dark adaptation and outdoor mobility domains. These findings highlight that both instruments have strong agreement between similar domains.

Our study however has its limitations. These limitations stem from the fact that this study is a clinic-based one. The study population is more male dominated and this may not be applicable to other centers having a different gender distribution. The analysis of the three instruments indicates that essentially all three are in good agreement while evaluating the functional impact of glaucoma on similar visual domains. Disease-specific instruments like GQL-15 and Viswanathan 10 have advantage of being shorter, less time-consuming, and are easy to administer as compared to NEIVFQ-25. NEIVFQ-25 provides additional information like general health, mental health, role limitation, and outdoor mobility that better indicate overall QoL. The inclusion of such parameters is vital for any PRO instrument design.

Conclusion

In our study, one vision-specific and both disease-specific instruments were able to differentiate between mild, moderate, and severe glaucoma. In pairwise comparison most subscales of NEIVFQ-25, domains of GQL-15 and questions of Viswanathan 10 strongly correlate. Most disease-specific instruments assess symptoms and their effects on various activities of patients but lack general health-related assessment. Vision-related instruments like NEIVFQ-25 assess overall QoL but are difficult to administer. We believe that with the current available tools, use of multiple instruments to assess QoL offers a more comprehensive assessment than using a single tool. More studies are required to develop a precise and user-friendly future instrument for QoL assessment in glaucoma patients after incorporating factors such as emotional concerns, financial impacts of medications, or other treatment-related issues.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Source: Indian journal of ophthalmology, 2019 Jan, Vol. 67 Issue 1, p83
Item: 30574899