# Impact of initial topical medical therapy on short-term quality of life in newly diagnosed patients with primary glaucoma

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Purpose: To evaluate the impact of initial topical medical therapy on newly diagnosed glaucoma patients using the Indian Vision Function Questionnaire (IND-VFQ33). Patients and Methods: The IND-VFQ33 was used to evaluate the quality of life (QoL) in 62 newly diagnosed patients with moderate to severe primary glaucoma and 60 healthy controls. IND-VFQ33 is a 33 item QoL assessment tool with three domains: General functioning, psychosocial impact and visual symptoms. The glaucoma patients were started on medical therapy and the QoL assessment was repeated after 3 months. Results: Glaucoma patients (mean age:  $55.6 \pm 9.6$  years, range 40–77 years) and controls (mean age:  $54.9 \pm 6.7$  years, 42-73 years) were matched with respect to age (P = 0.72), gender (P = 0.91) and literacy (P = 0.18). Glaucoma patients had significantly worse QoL as compared to controls at baseline across all the three domains (P < 0.001). 3 months after initiation of treatment, the overall QoL life significantly worsened from baseline with a decrease in general functioning (P < 0.001) and psychosocial impact (P = 0.041). Visual acuity in better eye significantly co-related to poor QoL at baseline (P < 0.001) and at 3 months (P = 0.04). In addition, the use of >2 topical medications significantly co-related to poor QoL at 3 months (P = 0.01). Conclusions: Evaluation using the IND-VFQ33 revealed that newly diagnosed glaucoma patients have a significant worsening of QoL after initiation of topical ocular hypotensive therapy. This should be an important consideration when educating patients about the disease and its therapy.



Key words: Indian Vision Function Questionnaire, primary glaucoma, quality of life

Glaucoma is a heterogeneous group of diseases that results in typical changes in optic disc morphology and visual field.<sup>[1]</sup> Glaucoma is the leading cause of irreversible blindness in the world and has serious implications on the quality of life (QoL) in affected patients.<sup>[2,3]</sup> Visual impairment caused by the disease has been shown to have negative effects on health-related QoL and a significant impact on daily functioning.<sup>[4,5]</sup> social activities;<sup>[6,7]</sup> and emotional functioning of the patients.<sup>[8]</sup>

Among the available generic and vision-specific instruments available, popular QoL measuring tools have included the Short Form-36 (SF-36),<sup>[9]</sup> the 25 - Item National Eye Institute Visual Function Questionnaire (NEI VFQ-25),<sup>[10]</sup> the Visual Activities Questionnaire,<sup>[11,12]</sup> the Activities of Daily Vision Scale,<sup>[13]</sup> and the visual function index.<sup>[14]</sup> However, out of the numerous generic and disease-specific QoL tools available none was validated for people living in developing countries.<sup>[15]</sup> Murthy *et al.* developed the vision related Indian Vision Function Questionnaire (IND-VFQ-33) to elicit problem statements describing the consequences of vision impairment in the Indian population.<sup>[16]</sup> The questionnaire has been previously validated and tested for reliability.<sup>[17]</sup>

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This study was conducted to evaluate the QoL and the impact of initial medical therapy on newly diagnosed glaucoma patients using the IND-VFQ-33 questionnaire.

# **Patients and Methods**

The study was approved by the Institutional Review Board. 62 newly diagnosed cases of moderate to severe primary glaucoma were recruited from the Out-patient Department and Glaucoma Clinics of a Tertiary Care Center in New Delhi, India. Patients with characteristic changes in the optic nerve head and corresponding glaucomatous visual field defects on standard automated perimetry were included in the study. All patients had best corrected visual acuity of at least 20/200 in the better eye, were over 40 years of age and were conversant in Hindi or English. Exclusion criteria included subjects with history of previous treatment for glaucoma; vision <20/200 in better eye; presence of other comorbid ocular conditions, e.g., age-related macular degeneration, cataract, optic neuropathy other than glaucoma, that could potentially contribute to visual loss; chronic systemic diseases that could significantly affect QoL, e.g., diabetes, arthritis, coronary artery diseases, cerebrovascular diseases, collagen vascular disorders, history of any ocular surgery in previous 3 months; deaf or communication impaired; and physically disabled individuals.

Eligible patients underwent a thorough history and ocular examination including evaluation of visual acuity; slit lamp biomicroscopy, intraocular pressure (IOP) assessment with Goldmann applanation tonometer; gonioscopy using Goldmann two-mirror gonioscope; and optic nerve head evaluation using a 90 D lens. Visual fields examination was performed using the Humphrey Visual Field Analyzer (Humphrey Instruments Inc., Allergan Humphrey, San Leandro, CA) using the Swedish Interactive Threshold Algorithm 30–2. The patients were categorized with respect to the severity of glaucoma according to the Hodapp–Parrish–Anderson Classification.<sup>[18]</sup>

Sixty healthy control subjects with no ocular or systemic disease visiting the hospital for refractive error were included. The controls were age-matched with the glaucoma cases and were evaluated in a similar manner. All patients were explained about the disease, its prognosis and cost of therapy. A written informed consent was obtained from all subjects included in the study.

#### Quality of life assessment

The IND VFQ33<sup>[16]</sup> is a 33-item questionnaire comprising of 33 items in three domains (Annexure). The general functioning elicited items related to distance vision, near vision, ambulation, night vision, dark adaptation, color vision, depth perception. The psychosocial impact domain related to the feelings of the patient related to low vision, e.g., whether the subject feared going out at night, was he/she a burden on their family or fear of losing the remaining vision. Finally, visual symptoms domain described most common visual symptoms like glare, discomfort, and blurring.

General functioning (Domain 1) had 21 items (Q1-Q21), a range of response varied from 1 to 5 giving a total range for domain 1 (21–105). Psychosocial Impact (Domain 2) and visual symptoms (domain 3) had 5 items (Q22-Q26) and 7 items (Q27-Q33), respectively. Domain 2 and domain 3 had 1–4 as the range of response with a total score of responses varying from 5 to 20 in psychosocial impact and 1–28 in visual symptoms domain. The summary scores from each domain were added to give a total QoL score with a minimum score of 33 and maximum 153. The higher the score, the worse the QoL. The mean total QoL score of controls and glaucoma patients at each visit was divided into quartiles viz. no difficulty (<25%), mild difficulty (25% – 50%), moderate difficulty (>50–75%) and severe difficulty (>75%) with cut-off score of 33–38, 38–44, 44–73 and >73 respectively.

The questions were translated and back-translated to the native language, Hindi, for standardization. The IND-VFQ33 questionnaire across the three domains was administered to the subjects, by a single investigator (VA) in the native language. The average time for the completion of the questionnaire was  $22 \pm 3.7$  min.

#### Follow-up visit

Patients were reassessed at 3 months following the start of the ocular hypotensive therapy. The evaluation included ophthalmological work-up including visual acuity assessment, slit lamp biomicroscopy, measurement of IOP, optic disc assessment and repeat visual field testing using the same algorithm. QoL assessment was repeated using IND-VFQ33 questionnaire, this being administered by the same investigator (VA) in same language as done at the initial visit.

#### **Statistical analysis**

The responses were entered into Microsoft Excel 2007<sup>®</sup> data sheet and statistical analysis was done using STATA 11<sup>®</sup> 1985–2011 StataCorp LP (Stata Press, Texas, USA). The mean QoL scores of glaucoma patients obtained were compared with that of controls using the unpaired *t*-test. Treatment

outcomes were compared using the paired *t*-test. One-way ANOVA was used for comparing more than 3 means. Two-way scatter was used to get correlation value between various parameters.

Multiple linear regression was used to assess significant factors affecting the QoL at baseline and 3 months after treatment. Factors like age, sex, visual acuity in the better eye, IOP in the better eye, glaucoma severity and number of medications used were included as these may affect the QoL of the patient.

Correlation values between visual acuity in the better eye, presenting IOP, glaucoma severity and total QoL score were obtained at baseline and at 3 months. The number of medications used was also correlated to the total QoL score.

# Results

Table 1 lists the baseline characteristics of the study population. The glaucoma subjects and the control population were well matched for age, gender and literacy rates (P = 0.71, 0.91 and 0.18 respectively). Better eye LogMAR visual acuity was 0.35 ± 0.25 and 0.08 ± 0.11 in glaucoma patients and controls respectively (P < 0.001). Glaucoma subjects had significantly higher baseline IOP in the better eye than the control population (25.4 ± 6.6 vs. 11.6 ± 2.1 mm of Hg respectively, P < 0.001).

A comparison of IND-VFQ33 total and domain wise scores is provided in Table 2. There was a significant difference between the two groups with respect to the mean total QoL scores, general functioning domain, psychosocial impact and visual symptoms (P < 0.001). As shown in Table 3, the total mean score increased from 74.8 to 78.3 (P < 0.001) on repeating the assessment 3 months after initiating the anti-glaucoma therapy suggesting worsening of QoL. Significant worsening was also noted in the general functioning and psychosocial impact domains.

Multiple linear regression analysis was used to assess the effect of various factors on the QoL as assessed with the IND-VFQ33 questionnaire [Table 4]. Better eye visual acuity was found to have a significant contribution to the QoL scores, both at baseline and after 3 months of starting ocular hypotensive therapy (P < 0.001 and < 0.05 respectively). It was also noted that the use of more than two ocular hypotensive medications was significantly related to poor QoL at 3 months assessment (P < 0.05).

Table 5 gives a list of items and response scores that were significantly different between the glaucoma and control subjects. The general functioning domain showed that most of the glaucoma patients had significant difficulty in ambulation, night vision, recognition, and dark adaptation as compared to controls. Most glaucoma patients were frightened to go out at night and were worried that they may lose their remaining vision. Problems of glare and low vision were also significantly higher in glaucoma patients than controls.

Table 6 elaborates the patient parameters and QOL scores across the primary open-angle glaucoma (POAG) and primary angle closure glaucoma (PACG) population as included in the study. These groups differed significantly in the visual acuity at baseline and at 3 months, being worse in the PACG population (P < 0.001). The mean IOP and mean glaucoma severity as seen by the visual field mean deviation scores were

# Table 1: Demographic characteristics of glaucoma patients and controls

	Glaucoma ( <i>n</i> =62) (%)	Controls ( <i>n</i> =60) (%)	Р
Age years (mean±SD)	55.6±9.6	54.9±6.7	0.72
Gender			
Male	33 (53.2)	32 (53.3)	0.91
Female	29 (46.8)	28 (46.7)	
Literacy			
Literate	40 (64.5)	38 (63.3)	0.18
Illiterate	22 (35.5)	22 (36.7)	

Literacy, as defined in census operations, is the ability to read and write with understanding in any language (http://lawmin.nic.in/ncrwc/finalreport/v2b1-5. html, accessed on October 6, 2013). SD: Standard deviation

comparable across the two groups. PACG patients had worse QoL scores than the POAG population both at baseline and at 3 months after initiating ocular hypotensive medications (P = 0.12 and 0.09 respectively), however, the difference did not reach statistical significance.

# Discussion

This is the first study that evaluates the vision related QoL in newly diagnosed glaucoma patients using a questionnaire developed and validated specifically for the population of the Indian subcontinent. Finger *et al.* have earlier validated this questionnaire for vision related QoL in 273 cataract patients in southern parts of India.<sup>[19]</sup> They noted that patients with severe visual impairment and blindness reported significantly worse vision-specific mobility and activity limitation (mean change –18.82, *P* = 0.007 and –29.48, *P* < 0.001 respectively) compared to those with no visual impairment. Nelson *et al.* have developed a glaucoma specific GQL-15 scale, and defined

## Table 2: Comparison of baseline QoL scores in glaucoma patients and controls

	Mean±SD (range; 95% CI)		Р
	Glaucoma ( <i>n</i> =62)	Controls ( <i>n</i> =60)	
Total QoL score	74.8±19.4 (42-122; 69.9-79.8)	38.1±0.4 (35-44; 37.2-38.8)	<0.01
General functioning	43.7±12.3 (25-74; 40.5-46.8)	22.9±1.2 (21-25; 22.4-23.3)	<0.01
Psychosocial impact	12.6±4.2 (5-20; 11.4-13.5)	5.5±0.6 (5-7; 5.1-5.6)	<0.01
visual symptoms	10.7±4.2 (11-20, 17.0-19.7)	9.0±0.3 (7-13, 9.3-10.3)	<0.01

SD: Standard deviation, CI: Confidence interval, QoL: Quality of life

#### Table 3: QoL scores of glaucoma patients at baseline and 3 months

	Mean±SD (ra	ange; 95% CI)	Р
	At baseline	At 3 months	
Total QoL score	74.8±19.4 (42-122; 69.9-79.8)	78.3±18.3 (43-127; 73.7-83.1)	0.01
General functioning	43.7±12.3 (25-74; 40.5-46.8)	46.2±11.8 (27-79; 43.2-49.2)	0.01
Psychosocial impact	12.6±4.2 (5-20; 11.4-13.5)	13.0±3.9 (5-20; 12.1-13.9)	0.041
Visual symptoms	18.7±4.2 (11-28; 17.6-19.7)	19.1±3.8 (11-28; 18.1-20.1)	0.08

SD: Standard deviation, CI: Confidence interval, QoL: Quality of life

# Table 4: Multiple regression analysis showing the correlation of factors and QoL among glaucoma subjects

Variable	At baseline	At 3 months	<b>P</b> *	Coefficients	95% CI	<b>P</b> *
	Coefficients	95% CI				
Age	-0.1	-0.3-0.3	0.99	0.1	-0.2-0.7	0.26
Sex	0.2	-4.3-4.8	0.91	6.6	-1.6-15.1	0.11
Visual acuity in better eye	30.5	17.5-43.5	0.0001	18.3	0.7-36.0	0.04
POAG	12.1	-0.9-25.2	0.1	0.7	-7.9-9.5	0.86
PACG	13.6	-0.03-27.7	0.07	1.5	-3.7-8.2	0.75
IOP in better eye	0.3	-0.2-0.9	0.59	0.4	-0.90-1.7	0.51
Moderate glaucoma	1.6	-9.6-12.9	0.77	2.3	-11.2-15.9	0.72
Severe glaucoma	4.8	-7.16-16.6	0.42	-1.1	-15.5-13.2	0.87
Use of 2 medication				8.7	-1.9-19.3	0.17
Use of >2 medications				18.9	3.8–34.1	0.01

\*P<0.05. Coefficients indicate a unit increase in value of variable leads to change in the QoL score. QoL: Quality of life, CI: Confidence interval, POAG: Primary open-angle glaucoma, PACG: Primary angle closure glaucoma, IOP: Intraocular pressure

Questionnaire reported symptom	Score (mean±SD)		Р
	Controls ( <i>n</i> =60)	Glaucoma patients ( <i>n</i> =62)	
Making out the bumps and holes in the road when walking	1.13±0.06	2.38±0.13	<0.0001
Going out at night	1.03±0.03	3.19±0.14	<0.0001
Recognizing people from distance	1.13±0.06	2.77±0.14	<0.0001
Seeing outside in bright sunlight	1.07±0.03	2.89±0.13	<0.0001
Seeing when coming into the house after being in the sunlight	1.3±0.03	3.16±0.13	<0.0001
Frightened to go out at night	1.07±0.05	2.78±0.13	<0.0001
May lose your remaining vision	1.2±0.07	3.14±0.10	<0.0001
Reduced vision	1.33±0.08	2.93±0.11	<0.0001
Dazzled in bright light	1.13±0.06	2.93±0.11	<0.0001
Vision blurred in sunlight	1.06±0.05	2.58±0.10	<0.0001
Bright light hurt your eyes	1.83±0.14	2.68±0.10	<0.0001

# Table 5: A comparison of commonly reported problems in glaucoma patients and their statistical significance as compared to control subjects

SD: Standard deviation, QoL: Quality of life

#### Table 6: Comparison of baseline parameters and QoL scores between PAOG and PACG patients

Variable	Mean±SD (95% CI)		Р
	POAG ( <i>n</i> =32)	PACG ( <i>n</i> =30)	
Vision better eye baseline (logMAR)	0.3±0.2 (0.2-0.3)	0.4±0.2 (0.3-0.5)	<0.001
Vision better eye at 3 months (logMAR)	0.3±0.26 (0.2-0.4)	0.4±0.2 (0.3-0.5)	<0.001
Intraocular pressure better eye baseline (in mmHg)	25.1±4.25 (23.6-26.6)	25.6±8.45 (22.4-28.8)	0.36
Intraocular pressure better eye at 3 months (in mmHg)	15.12±2.09 (14.4-15.9)	17.13±4.39 (15.5-18.8)	0.78
Mean deviation better eye at baseline in dB P<0.5%	-14.10±5.74 (-16.112)	-14.74±8.61 (-17.911.5)	0.73
Mean deviation better eye at 3 months (dB P<0.5%)	-15.30±6.06 (-17.6-13.1)	-15.82±8.05 (-18.812.8)	0.80
Total QoL at baseline	71.1±16.6 (65.2-77.1)	78.8±21.6 (70.7-86.8)	0.12
Total QoL score at 3 months after initiation of therapy	74.4±16.5 (68.5-80.3)	82.6±19.4 (75.4-89.9)	0.09

SD: Standard deviation, QoL: Quality of life, CI: Confidence interval, POAG: Primary open-angle glaucoma, PACG: Primary angle closure glaucoma

the vision related problems perceived by glaucoma patients, e.g., peripheral field, color vision, glare, dark adaptation, which are well covered in the IND-VFQ33 questionnaire.<sup>[20]</sup>

This study shows that subjects with glaucoma had worse QoL as compared to control population. The fact that this further worsened after initiation of medical therapy has some pertinent implications. This highlights that the diagnosis of glaucoma, a chronic sight-threatening condition that may require life-long therapy, may have a significant psychological impact on a patient. This should be identified, acknowledged and managed by appropriate disease-related education and counseling. Our results are similar to those reported by Nelson et al. where they have noted a statistically significant decrease in performance-related QoL between normal subjects and all groups of glaucoma patients.<sup>[20]</sup> In another study, Goldberg et a1. also noted that patients with glaucoma had significantly poor QoL as compared to subjects without glaucoma.[21] We noted that in patients with worse visual acuity and those who had to be started on more than two medications, QoL further worsened after initiation of medical therapy. This in turn highlights the importance of educating the patients about the nature of the disease and ensuring drug compliance despite a perceived deterioration in symptoms after starting antiglaucoma medications. A comparison between POAG and

PACG subjects suggested a possible worse QoL in the latter. However, the results were not significant statistically.

A number of studies have elaborated on the significant problems encountered by subjects with glaucoma. Goldberg et al. reported that activities involving glare, dark adaptation, central and near vision, peripheral vision, and outdoor mobility were most problematic for patients with glaucoma.<sup>[21]</sup> In another study, McKean-Cowdin et al. noted that persons with visual field loss had the greatest difficulty with driving activities, dependency, mental health, distance vision, and peripheral vision.<sup>[22]</sup> Wu et al. reported that the presence of open-angle glaucoma was significantly associated with lower scores for distance activities, mental health, and color and peripheral vision.[23] The Collaborative Initial Glaucoma Treatment Study by Janz et al. showed that difficulty with bright lights, and with light and dark adaptation; were the most frequently reported symptoms related to visual function in glaucoma patients.<sup>[11]</sup> These findings are comparable to the results obtained in our study whereby glaucoma subjects were noted to have significant problems in activities which involved near and distance vision, night vision, ambulation, dark adaptation, color vision and glare.

Both worse eye and better eye visual acuity have been independently associated with poor QoL.<sup>[11]</sup> We noted that

the decrease in better eye visual acuity was associated with worse QoL at baseline and at 3 months. Janz *et al.* evaluated QoL in newly diagnosed glaucoma patients using multiple QoL instruments available.<sup>[11]</sup> They also noted that QoL had a significant correlation with better eye visual fields and visual acuity varied from -0.07 to -0.18, however that the strength of correlation was weaker as compared to our results. Van Gestel *et al.* found a significant relationship between QoL and IOP in the better eye (P < 0.001).<sup>[24]</sup> Lee *et al.* have published that both visual field index and visual acuity have a linear correlation with glaucoma-related QoL.<sup>[25]</sup>

Small subject population limits this study. However, to assess the QoL in patients with primary adult-onset glaucoma, all patients with secondary glaucoma were excluded. Also, the exclusion of patients with cataract attempted to remove the confounding of the results obtained. Second, the effects of economic factors, which are especially important for people residing in developing countries, were not included in the questionnaire. Nonetheless, this study shows the important implication of presence of glaucoma, suggesting that newly diagnosed patients may have manifested symptoms of the disease, and initiation of medical therapy may be associated with further worsening of QoL. Thus, eye care providers should take every opportunity to educate patients about the nature of disease. They should be encouraged to continue with therapy despite no apparent benefits or even worsening of their QoL at the outset.

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