

Effect of Glaucoma Medications on Quality of Life Examined by Generic and Vision Specific Instruments

Gemma Caterina Maria Rossi^{1*}, Gian Maria Pasinetti², Aba Briola³ and Paolo Emilio Bianchi¹

¹MD, Ophthalmologist, University Eye Clinic of Pavia, IRCCS Policlinico San Matteo Foundation, Pavia, Italy

²MD, Ophthalmologist, UO Oculistica, Istituto Beato Palazzolo, Bergamo, Italy

³Assistant Ophthalmologist, University Eye Clinic of Pavia, IRCCS Policlinico San Matteo Foundation, Pavia, Italy

Abstract

Purpose: To evaluate the relation between number of glaucomatous medications and Quality of Life (QL) in glaucoma patients.

Methods: The study was an observational cross-sectional study. 53 consecutive patients with early or suspect glaucoma, matched for age and gender, were selected from the Glaucoma service of the University Eye Clinic of Pavia. The patients were then divided into 3 groups on the basis of the therapy (group A= no therapy, B= one drug, C= two drugs). All subjects completed both the self-administered version of Medical Outcomes Study Short Form (MOS SF-36) and the Italian version of the National Eye Institute Visual Functioning Questionnaire 25-item (NEI-VFQ 25). Relation and differences between each scale of both questionnaires and group was studied applying the ANOVA Kruskal-Wallis test and the Mann-Whitney U test.

Results: Social functioning scale (SF36) was significantly altered in the three groups ($p < 0.02$). SF was statistically different between group A and B ($p = 0.04$) and between group A and C ($p = 0.011$) suggesting a positive effect of the therapy on QL.

The physical functioning subscale (SF-36) and the vision specific social functioning sub-scale (NEI-VFQ) recorded differences but not significant ($p = 0.088$ and $p = 0.052$, respectively).

Conclusions: Our results suggest that the number of glaucoma medications is not predictive of quality of life. In some patients the number of medications may improve their QL perception. Further clinical trials to verify and study these outcomes are required.

Keywords: Quality of life; NEI-VFQ; Glaucoma; Therapy; Medical treatment; Multiple glaucoma medication

Introduction

Glaucoma is a chronic disease and in the last years the vision related quality of life (VRQOL) has been considered a more and more important medical variable in the treatment of such patients [1].

Patients suffering from primary open angle glaucoma (POAG) are usually asymptomatic before diagnosis but become symptomatic after diagnosis (ocular side effects, frequent follow-up visits and test examinations).

The diagnosis may alter the patient's perception of his quality of life (QL) both by the anxiety elicited by diagnosis itself and by the number of medications and frequency of therapy necessary to control the disease [2-4]. Symptoms due to visual field status and acuity loss affect QL only at an advanced stage of the disease.

Outcomes of glaucoma treatment therefore should not only be measured by the level of intraocular pressure or visual field defect but also by the impact of "glaucoma" on the QL of patients [3].

The VRQOL of the glaucoma patients may be evaluated both by generic instruments like the Medical Outcomes study 36-item Short Form (SF-36) [5] and by more disease specific instruments like the National Eye Institute - Visual Functioning Questionnaire 25-item (NEI-VFQ 25) [6,7].

The aim of this study was to evaluate the relation between number of glaucoma medications and QL in glaucoma patients as well as in glaucoma suspects.

To our knowledge, few previous papers have addressed this

question and no investigators have demonstrated any relation between number of medical treatment and overall QL in patients with glaucoma [8-10].

Methods

53 consecutive early to moderate primary open angle glaucoma (POAG) or glaucoma suspect were selected from the glaucoma service at University Eye Clinic of Pavia and were included in this observational cross-sectional open label study.

The study was approved by the Institutional Review Board. The study was conducted in accordance with the Declaration of Helsinki and the appropriate International Conference on Harmonization guidelines.

Eligible patients required the following: POAG diagnosis, age > 30 years, IOP < 18 mmHg on stable topical therapy (the same therapy from at least 6 months), best corrected visual acuity > 0.7 decimals, early to moderate visual field defect (MD < 10 dB, Glaucoma Staging

***Corresponding author:** Gemma Cm Rossi, Ophthalmologist, University Eye Clinic of Pavia, IRCCS Policlinico San Matteo Foundation, Pavia, Italy, E-mail: gemma.rossi.md@gmail.com

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System GSS S1-S2) [11], stable systemic therapies from at least six months. Eligible glaucoma suspects presented IOP > 21 mmHg without medical treatment, best corrected visual acuity > 0.7 decimals, GSS S0 or Borderline. All recruited patients were followed by Glaucoma Service from at least two years and submitted to regular control visits and visual field examinations every 4-6 months.

POAG was defined as the presence of glaucomatous visual field defect, glaucomatous optic nerve head (ONH) damage and/or retinal nerve fiber layer (RNFL) changes associated to elevated untreated IOP (IOP>21 mmHg); glaucoma suspects were characterized by elevated IOP but suspect visual field and/or ONH/RNFL.

Exclusion criteria were: any other ocular disease, secondary intraocular hypertension; previous intraocular surgery (cataract surgery included); argon laser trabeculoplasty within the past three months. Patients in waiting of laser or incisional therapy were excluded too.

All subjects were divided into three groups by the number of drugs used: group A = suspect glaucoma-none topical therapy; group B = POAG in therapy with one drug; group C = POAG in therapy with two drugs.

All participants underwent a complete clinical evaluation determining visual acuity, IOP, dilated fundus examination, visual field. All patients completed the Italian version of two QL questionnaires, the "general" Medical Outcomes Short Form 36 (SF-36) [12] and the "vision specific" Italian version of the National Eye Institute-Visual Functioning Questionnaire 25 item (NEI-VFQ 25) [13].

Participants were asked to complete the self-administered version of both questionnaires. Subjects were given verbal instructions prior to filling out the questionnaires. If a patient asked for help, the research interviewer was instructed to read each question verbatim and to record the responses. Four patients required assistance in filling out the surveys.

The SF 36 is a generic health related quality of life (HRQL) measure. It includes 8 subscales: general health (GH), physical function (PF), role limitations due to physical (RP) and mental (RE) disability, mental health (MH), social function (SF), vitality (V) and bodily pain (BP) (Table 1).

Each of the subscales is scored on a 0 to 100 scale, in which 100 indicates the best possible score on a specific subscale and 0 indicates the worst function. The SF-36 is one of the most widely used measures in health services research.

The NEI-VFQ 25 is the short form version of the 51-item NEI-VFQ; it takes 10 minutes on average to complete. It generates subscales for the following 12 dimensions of vision-targeted HRQL: overall health (OH), overall vision (OV), difficulty with near vision activities (NA), difficulty with distance vision activities (DA), limitations in social functioning due to vision (VSSF), role limitations due to vision (VSRD), dependency due to vision (VSD), mental health symptoms due to vision (VSMH), driving difficulties (D), limitations with peripheral (PV) and colour vision (CV) and pain or discomfort in or around the eyes (OP) (Table 2). Subscales are scored on a 0 to 100 point scale in which 100 indicates the best possible score on the measure and 0 indicates the worst.

Statistical Analysis

Data were not normally distributed, so median and Interquartile Range (IQR: 25° and 75° percentile) were used to summarize data

and non-parametric tests were employed in the statistical analysis; for each subscale the ANOVA Kruskal-Wallis test was used to analyze differences between three groups and the Mann-Whitney U (test) was used to analyze differences between two groups. A p value of less than 0.05 was considered to indicate statistical significance; all tests were two-sided. Analyses were performed with Statistica for Windows software (StatSoft Inc. 2004, Tulsa, OK, US).

Results

The glaucoma suspects were 10 (18.8%), 21 (39.6%) POAG were on therapy with one and 22 (41.5%) with two topical medications.

Age ranged from 25 to 88 years with a mean of 63 years and a standard deviation of 12 years. 5 patients were less than 50 years old (9.4%), 25 were between 50 and 60 years old (47%), 23 were older than 60 years. 31 of the enrollers were women, 22 men.

Intra-ocular pressure ranged from 10 to 25 mmHg (mean of 17 mmHg±3, 2).

24-2 SITA Standard was performed and classified by Brusini GSS as follows: Group A: 4 patients S0, 6 Borderline; group B: 14 S1 and 7 S2; group C: 12 S1 and 10 S2.

7 patients out of 21 (33, 3%) of group B were on prostaglandin analogues, 66, 6% on beta-blockers therapy; in group C, 9 out of 22 (40.9%) subjects instilled beta-blockers and prostaglandin analogues, 10 (45%) beta-blockers and topical carbonic anhydrase inhibitors (CAI) and 3 (13.6%) beta-blockers and alpha 2 agonists.

The statistical analysis pointed out that the quality of life is significantly influenced in all the groups only when considering the social functioning sub-scale (SF) of the SF-36 questionnaire (p<0.02). When compared each others, there were some differences among the three groups. SF was statistically different between group A and B (p=0.04) and between group A and C (p=0.011) but not between group B and C (Table 3).

Subscale name	No of items
1. Physical functioning (PF)	10
2. Role functioning physical (RP)	4
3. Bodily pain (BP)	2
4. General health (GH)	5
5. Vitality (V)	4
6. Social functioning (SF)	2
7. Role functioning emotional (RE)	3
8. Mental health (MH)	5

Table 1: Listing of SF-36 subscales.

Subscale name	No of items
1. General health (GH)	2
2. General vision (GV)	2
3. Ocular pain (OP)	2
4. Near activities (NA)	6
5. Distance activities (DA)	6
6. Vision specific social functioning (VSSF)	3
7. Vision specific mental health (VSMH)	5
8. Vision specific role difficulties (VSRD)	4
9. Vision specific dependency (VSD)	4
10. Driving (D)	3
11. Colour vision (CV)	1
12. Peripheral vision (PV)	1

Table 2: Listing of NEI-VFQ subscales (VFQ 25 + optional items).



	K-W	M-W		
		A versus B	A versus C	B versus C
SF36 PF	0.088	0.08		0.055
SF36: RP	0.90			
SF36:BP	0.90			
SF36: GH	0.27			
SF36: V	0.78			
SF36: SF	0.02	0.04	0.011	
SF36:RE	0.60			
SF36:MH	0.29			
NEI GH	0.14			
NEI GV	0.93			
NEI OP	0.11			
NEI NA	0.43			
NEI DA	0.77			
NEI VSSF	0.052	n.s	n.s.	n.s.
NEI VSMH	0.93			
NEI VSRD	0.16			
NEI VSD	0.38			
NEI D	0.23			
NEI CV	0.29			
NEI PV	0.24			

Table 3: Correlation between questionnaire sub-scales and groups. MW analysis.

	Group A			Group B			Group C		
	Median	IQR (25° - 75°)		Median	IQR (25° - 75°)		Median	IQR (25° - 75°)	
SF36 PF	75,0	60,0	80,0	90,0	80,0	95,0	75,0	60,0	90,0
SF36: RP	75,0	25,0	100,0	100,0	25,0	100,0	75,0	50,0	100,0
SF36:BP	62,0	41,0	100,0	62,0	41,0	74,0	61,0	32,0	100,0
SF36: GH	52,0	30,0	57,0	62,0	55,0	72,0	67,0	45,0	82,0
SF36: V	40,0	25,0	65,0	70,0	50,0	80,0	70,0	35,0	80,0
SF36: SF	62,5	37,0	75,0	87,5	75,0	87,5	100,0	75,0	100,0
SF36:RE	66,0	33,0	100,0	100,0	33,3	100,0	100,0	33,0	100,0
SF36:MH	60,0	40,0	76,0	76,0	60,0	84,0	68,0	56,0	80,0
NEI GH	47,5	37,5	60,0	62,5	37,5	65,0	47,5	37,5	70,0
NEI GV	65,0	55,0	85,0	65,0	50,0	75,0	70,0	50,0	75,0
NEI OP	75,0	50,0	75,0	75,0	62,5	87,5	93,8	50,0	100,0
NEI NA	91,6	83,3	91,6	89,6	83,3	95,8	91,6	79,1	100,0
NEI DA	95,8	87,5	100,0	95,8	87,5	100,0	95,4	79,1	100,0
NEI VSSF	100,0	100,0	100,0	100,0	100,0	100,0	100,0	91,6	100,0
NEI VSMH	95,0	85,0	95,0	90,0	70,0	95,0	87,5	60,0	95,0
NEI VSRD	93,7	75,0	100,0	100,0	87,5	100,0	84,4	62,5	100,0
NEI VSD	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0
NEI D	62,5	29,2	79,1	87,5	75,0	91,6	66,6	0,0	100,0
NEI CV	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0
NEI PV	100,0	100,0	100,0	100,0	100,0	100,0	100,0	75,0	100,0

Table 4: Sub-scales median values and IQR for three groups.

Other sub-scales were near the statistically significance such as PF ($p=0.088$) with a difference only between group B and C ($p=0.055$) and VSSF ($p=0.052$).

When comparing the 3 groups' median values of all the SF-36 sub-scales, it was noted that general health (GH), vitality (V) and social functioning (SF) gradually improved from group A to group C and that the worst values were those of group A for all the SF-36 subscales apart from BP. About NEI-VFQ sub-scales, the only sub-scale that worsened from A to C was VSMH. While general vision was similar for all the groups, ocular pain statistically improved from group A to group C (Table 4).

The recorded total mean values of NEI-VFQ questionnaire were similar for the three groups (A= 83.6, B=89.7 and C=86.8, respectively).

Conclusions

The prevailing hypothesis in the glaucoma community has been that the simpler the therapeutic regimen the more likely the patient's compliance and better QL.

Few previous papers have specifically studied the correlation between QL and number of glaucoma medications [8-10]. In 2001 Montemayor and colleagues found that while the number of orally



administered medications is a determinant of QL, the number of glaucoma medications is not predictive of QL as measured by the NEI-VFQ 25 [10]. Parrish and associates reported that the number of glaucoma medications was not correlated with visual function or QL [8]. Wilson and co-workers found no relation between number of applications of eye drops or number of orally administered glaucoma medication and QL [9].

Authors had hypothesised a priori that QL would be associated with the number of glaucoma medications and believed that the major number of topical medications might significantly impair QL of glaucoma patients. Based on European Glaucoma Society guidelines [14] ophthalmologists usually first prescribe only one drop given once a day in order to obtain patients' compliance and better QL. But we have to remember the results of a paper of Tsai and co-workers [15] that referred that "over half of the patients examined said taking only one drop once a day would not make it any easier to adhere to their regimen" and therefore, we conclude, to improve their QL. These observations comply with recorded data.

The present study pointed out a weak correlation between number of glaucoma medications and QL that interests only few QL domains.

Two sub-scales weakly related to three groups: PF of SF-36 and VSSF of NEI-VFQ (Table 3).

Only the social functioning sub-scale was statistically related to group. The recorded correlation was opposite to the hypothesized one: QL was statistically better in more treated patients.

How the higher number of medications may have a positive effect on POAG patients' quality of life?

Patients without any therapy but followed for the risk to develop glaucoma have a statistically significant worst quality of life than those treated: an explanation to this may be they are more worried about their eye condition that requires frequent examinations but that is not completely defined. It has been previously reported that the world "glaucoma" itself may alter patients QL and the diagnostic doubt is a worrying condition too [3,4].

On the other hand, in the considered POAG groups, patients treated with more drugs may think to be more controlled, maybe they feel doctors to take more care of them and therefore refer lower therapy's influence on their QL perception.

Authors believe that the patient-doctor communication may play a fundamental role in perceived QL according to Stein that, evaluating the disparities between ophthalmologists and their patients in estimating QL, reported "the differences in QL estimates may be related to poor physician-patient communication" [16]. In fact most of selected POAG was followed from the same glaucoma specialist from more than 10 years and had developed a trust-relationship with this doctor probably improving their QL evaluation.

In conclusion, glaucoma affects QL perception but independently from number of glaucoma medications. Authors suggest the physician-patient relationship may play a fundamental role in patients' QL. Time should be spent to explain to glaucoma suspect their presumed

risk to develop glaucoma and the aims of following them without treating. Authors believe doctors should ensure glaucoma suspects about the safety of non treatment, in this way they may improve their QL perception.

Further controlled clinical studies enrolling more patients to verify the communication's role on QL are recommended. At last it must be remembered that the patients' point of view is often different from our ("glaucomatous specialists"). Only patients themselves know their values and needs regarding treatments and outcomes: physicians should routinely allow patients to participate in decision making about treatment to obtain the better QL for such chronic patients.

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