

Drug Use Pattern In POAG & Assessment Of QOL Using Glaucoma Specific Questionnaires

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Abstract: Introduction: POAG is a chronic disease which affects the quality of life. There is a direct need to analyze the drug utilization pattern of glaucoma in a developing country like India. The main goal of treatment in patients of glaucoma is to improve clinical outcomes thereby improving the patient's QOL. Objective: To study the drug use pattern in Primary Open Angle Glaucoma and to evaluate quality of life using Glaucoma Quality of Life 15 (GQL-15) Questionnaire and the National Eye Institute Visual Function Questionnaire (NEIVFQ-25). Methods: Prospective cross sectional study was carried out for 8 weeks. Written Informed Consent, IEC permission was taken before hand. Patients of either gender with POAG on medical therapy for at least a month were included in the study. The data was recorded in a case record form containing patient's demographic details, diagnosis and the complete prescription. Quality of life assessment was done using the interviewer-administered format of the NEIVFQ-25 and the GQL-15 questionnaires. Result: A total of 300 patients were enrolled, male: female ratio was 1.52:1. POAG was found to be more prevalent in age group of 61-70(30.6%). Total number of drugs prescribed were 494(mean=1.6). Most common drug used was Timolol (60%), followed by Travoprost (12.75%). Brimonidine and Timolol was the most common drug combination used. In our study mean score of QOL was 30.08. In GQL-15, 37% of respondents showed impaired QOL in reading newspaper. In the NEIVFQ-25 more than two third of the population were worried about their eyesight and around half of the population reported impaired vision even with the use of glasses or contact lenses. Conclusion: Timolol was the most frequently used drug for POAG. [A Dodiya Natl J Integr Res Med, 2018; 9(1):31-35]

Key Words: Drug use pattern, Questionnaire, QOL, POAG

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Introduction: Glaucoma, a chronic, progressive, and most often asymptomatic disease, is the second leading cause of blindness worldwide. Primary open angle glaucoma (POAG) is defined as a chronic optic neuropathy with characteristic changes in the optic disc and visual field.^{1,2} Drug therapy has revolutionized the treatment of glaucoma both in terms of reduction in intraocular pressure (IOP) as well as damage to the optic nerve. The classical non-selective beta blockers like Timolol, alpha agonists like Apraclonidine, miotics like Physostigmine and Pilocarpine as well as oral Carbonic anhydrase inhibitors CAI like Acetazolamide have long since been used in the management of glaucoma.

Over the past few decades, there have been drugs which have increased efficacy and lesser side-effects. These include prostaglandin analogues like Latanoprost and Travoprost, newer beta-blockers like Betaxolol and Carteolol, topical CAI like Dorzolamide and alpha agonist like Brimonidine to name a few.³ Hence, there is a need to analyze the drug utilization pattern of glaucoma in a developing country like India. POAG being a chronic disease itself affects the quality of life and superimposed on it are various drugs,

which the patient uses and can also have a negative impact on quality of life because of numerous adverse effects. Hence, the main goal of treatment in patients of glaucoma is to improve clinical outcomes thereby improving the patient's QOL.² The NEIVFQ25 (a non-glaucoma-specific questionnaire) and the GQL-15 (a glaucoma-specific questionnaire) are compared in this study. The NEIVFQ25 has five non-visual domains: general health, mental health, dependency, social function, role limitations; and seven visual domains: general vision, distance vision, peripheral vision, driving, near vision, color vision, and ocular pains.

The GQL-15 is a 15-item questionnaire designed to take into account the effect of binocular visual field loss on visual function. It consists of four domains: outdoor mobility, peripheral vision, near vision, glare and dark adaptation. This questionnaire is shorter than the NEIVFQ25, and therefore, easier to use and faster to administer. It has shown to be reliable and has good internal consistency⁴. GQL-15, however, focuses mainly on vision-related difficulty and does not address other issues, such as mental health, role difficulty, dependency, or general health, as does the NEIVFQ25.⁴ Thus, both these questionnaires are

compared with a view to assessing their correlation in this group of participants and to determine which of the instruments is better suited to assess QOL issues in Indian glaucoma patients, given the paucity of data on QOL for this population. The main objectives of the study were to study the drug use pattern in Primary Open Angle Glaucoma and to evaluate quality of life using Glaucoma Quality of Life 15 (GQL-15) questionnaire and the National Eye Institute Visual Function Questionnaire (NEIVFQ25) in Glaucoma patients.

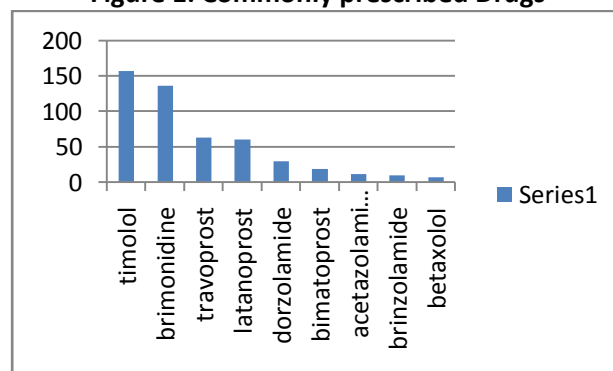
Methods: A prospective, cross sectional study was carried out in outpatient department of a tertiary care ophthalmology hospital in Ahmadabad, Gujarat, India during a period of 8 weeks after receiving the Institutional Ethics Committee approval for initiating the study. Written Informed Consent was taken from the patients. The data was collected from patients who fulfilled the inclusion and exclusion criteria. Patients with POAG who are 18 years and above belonging to either gender and on medical therapy for at least a month were included. Newly diagnosed glaucoma patients, patients having Acute Closed Angle glaucoma and patients who have been surgically treated for POAG were excluded. The data was recorded in a case record form containing patient's demographic details, provisional/final diagnosis and the complete prescription, which included names of prescribed anti-glaucoma drugs, their dose, frequency, duration and route of administration. For drugs prescribed by their brand names, the generic names of drugs and generic contents of each formulation were obtained from commercial publications like Indian Drug Review. Quality of life assessment was done using the interviewer-administered format of the NEIVFQ25⁵ and the GQL-15⁶ questionnaires.

For respondents who were not literate in English, the NEIVFQ25 and the GQL-15 questionnaires were translated into Hindi and Gujarati which are the two most prominent languages in Gujarat. Care was taken to reduce any bias that could occur because of translation. The complete data was entered into MS Excel 2013 and then analysis was done using SPSS software version 22.0. The analysis was carried out using appropriate software. Cronbach's alpha was used to check the reliability and internal consistency of the questionnaires. Spearman ranks coefficient was used to calculate the correlation between the two

QOL questionnaires. P value less than 0.05 was considered as statistically significant.

Result: A total of 300 patients were enrolled in the study. Most common age group was 61 to 70 years with 92 patients (30.6%). A total of 181 Males (60.3%) and 119 female (39.66%) were enrolled for the study. Ratio of Male: Female = 1.5:1. A total of 11 (3.66%) patients had a positive family history of POAG. Majority of the patients presented with chief complaint of diminished vision with a prevalence of 99.66%, followed by pain with 39.66% and halos with 24%. IOP was noted at the time of initial visit and also at the time of assessment. Mean difference in IOP was 3.72 mm of Hg. Most common drug group used was beta-blockers (n=164) followed by prostaglandin analogues (n=142), alpha agonists (n=136) and carbonic anhydrase inhibitors (n=52). Amongst beta blockers, Timolol was most frequently prescribed. At least 60% of the patients were given single drug therapy which was observed to be Timolol. (Fig. 1)

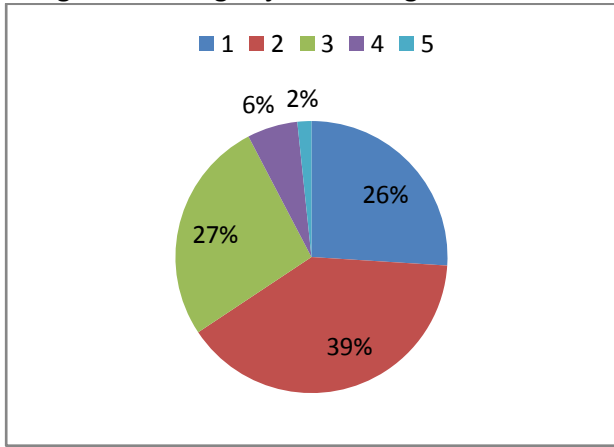
Figure 1: Commonly prescribed Drugs



About 58% of the patients received monotherapy in the form of one topical agent. Around 26.3% received combination therapy with two topical agents. The combination of Timolol and Brimonidine was prescribed most frequently which was 77% followed by Travoprost and Timolol 7.8%. All the patients were managed with drugs given topically and only 4 patients received Acetazolamide orally. In GQL-15 (1- no difficulty, 2 a little bit of difficulty, 3 some difficulty, 4 quite a lot of difficulty, 5 severe difficulty) around 37% of the respondents reported impaired (some to severe difficulty) QOL in relation to reading newspapers. Around 20% of the respondents had quite a bit of difficulty (some to severe difficulty) in walking at night, walking on uneven ground and adjustment to lights. About 17% of the respondents had difficulty (some to severe) on tripping over

objects. About 35% of respondents felt difficulty in seeing objects coming from the side. (Fig. 2)

Figure 2: Seeing objects coming from the side

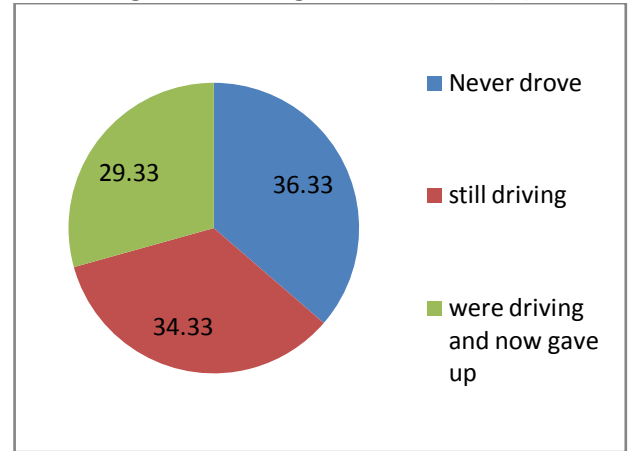


QOL was not impaired in relation to questions like walking on steps, bumping into objects or finding dropped objects were concerned. A little bit of difficulty (53%) occurred in glaucoma patients while judging distance. In relation to recognizing faces (33%) the respondents showed poor QOL. In NEIVFQ-25, the first part of the questionnaire deals with general health and vision, majority of the patients reported good health 74%. (Excellent to good). When questioned about their eyesight, around half of the respondents responded that vision was impaired even with the use of glasses or contact lenses. (Poor /very poor).

A majority of the patients, almost 67 % (All the time) were worried about their eyesight. Around three quarter (very severe) of the respondents had severe symptoms of glaucoma in the form of pain or discomfort in the eyes. As far as difficulties with daily activity was concerned, 37% (moderate to extreme) reported difficulty in reading newspaper. Around 75 % (no difficulty/a little difficulty) reported little impairment in QOL dealing with activities involving closed work/picking things from the crowded shelf /reading street signs /going down steps, stairs or curbs. A little bit of difficulty occurred in glaucoma patients while performing work. About 37% (moderate to extreme) of respondents felt difficulty with respect to Temporal Vision. About 43% had a little difficulty in seeing reactions of other people. A little bit of difficulty was encountered by the respondents (44%) in picking out and matching own clothes. A little bit of difficulty occurred in glaucoma patients (46%) while attending parties. A little bit of

difficulty occurred in glaucoma patients (47%) while watching Sports and Movies. 30 % of the respondents quit driving because of eyesight loss due the disease. Out of 34 % who were still driving, around 11 % had difficulty in driving at night/difficult situations. (Fig. 3)

Figure 3: Driving skills affected (%)



About 17% felt difficulty (all the time /most of the time) in accomplishing target work less than they would like to. Nearly 16% were able to perform limited activities (all of the time/most of the time) in a day. A severe difficulty occurred when pain limited the work in glaucoma patients. Out of the total respondents, 33% had impaired QOL (All of the time-most of the time) due to pain, ache in the eyes because of the disease.

Around 29% of the respondents felt that the disease kept them confined to home, made them feel frustrated and they felt much less control over the work (definitely true/mostly true) because of eyesight. Near about 18% of the respondents (definitely true/mostly true) had to rely on what other people tell. 17% of the respondents felt that they were dependent on others for their functioning and social needs (Definitely true/mostly true). Only 14% of the respondents felt embarrassed (definitely true/mostly true) because of their eyesight. Cronbach's alpha value for reliability and consistency analysis was calculated for GQL-15 and was found to be 0.977. Cronbach's alpha value for reliability analysis for NEIVFQ-15 was found to be 0.676. Correlation of age and number of drugs was 0.137. Correlation of age and GQL-15 was 0.134. Correlation of age and NEIVFQ-25 was 0.139. Mean score of GQL-15 was 30.08±11.18. Mean score of NEIVFQ-25 was 73.94±8.86. The correlation between

two QOL questionnaires in Spearman correlation was $r=0.414, p<0.0001$. (A moderate or weak correlation is defined as $r < 0.31$, values ranging from 0.32-0.55 were defined as moderate correlation and 'r' values greater than 0.55 show strong correlation.) In our study the value depicted moderate correlation ($r=0.414, p<0.0001$).

Discussion: In this study of 300 patients, number of male patients was 181 and female respondents were 119 with preponderance of male patients. POAG was found to be more prevalent in age group of 61-70 years (30.6%). This is in contrast to another study where the most prevalent age group was 40-60 years with preponderance of female patients.⁷ Total number of drugs prescribed were 494. The average number of drugs prescribed per patient was 1.6 which is in accordance to another study where the number of drugs per prescription was 1.23⁸. In this study all the patients received drug topically with only Acetazolamide being used orally in 4 cases. This is in accordance with other study in which topical route of administration was most prescribed by the physician.⁸ Compared with oral medications, topical medications are associated with less amount of systemic side-effects.⁹

In this study, 60% patients received single drug. Most common drug group used was beta-blockers out of which Timolol (31.78%) was most frequently prescribed. This is in accordance with another study which also reported the same findings.^{7; 8} The next most commonly prescribed drug group was Prostaglandin analogues (28.74%), in which Travoprost was the most commonly prescribed drug (12.75%). This reported higher amount of Prostaglandin analogues as compared to previous studies suggesting increase in trends of Prostaglandin analogues. Compared with Timolol, Travoprost has more favorable local and systemic side-effect profile. Travoprost can be administered once a day and unlike Timolol has a more sustained effect on lowering of IOP.

The Alpha adrenergic agonist primarily Brimonidine was the third most commonly prescribed drug. Combination therapy was prescribed in 121 patients. Brimonidine and Timolol (77%) was the most common drug combination followed by Travoprost and Timolol^(7,8). This in contrast to another study, where Timolol and Acetazolamide was the most commonly

prescribed drug combination.⁷ Mean score was 30.08 in our study. This is higher in comparison with another Nigerian study which reported a mean score of 24.07 suggesting a lower QOL in our population.⁴ The correlation between two QOL is Spearman correlation $r=0.414, p<0.0001$ When selecting a QOL scale for a glaucoma patients, we hope that the instrument fulfils the following criteria:

1. Ease of use in a clinical setting.
2. Contains minimal complex mathematics.
3. Allows reproducible data to be obtained.
4. Corrects underlying principles pertaining to glaucoma.
5. Simple understandable questions with unambiguous answers.

The GQL-15 (The Glaucoma Quality of Life-15) is a 15item, 4-domain tool that is short and easy to use. The instrument is based on the principle that perceived visual disability (dark adaptation, disability glare, outdoor-mobility tasks and activities using peripheral vision) is significantly associated with binocular visual field loss. It has good internal consistency and reliability. The tool has been shown to demonstrate the difficulties in everyday life which are mirrored by poor performance in a number of psychophysical tests.

The tool does concentrate on the physical impact of the disease process and does not address the broader QOL factors. However, if these factors are addressed then the instrument becomes less user friendly in clinical practice^(4, 10). The NEIVFQ-25 (The 25-item National Eye Institute Visual Function Questionnaire) is a 25 item, 12-domain tool that appears to be an improved version of its predecessor NEIVFQ-51 in that it has a more clinical emphasis. The instrument takes roughly 5minutes to use, is reliable and fully validated. However, the lack of visual field consideration causes this tool to fall down in comparison to some of the more specific glaucoma tools.

The NEIVFQ-25 is easy to use which explains why it has been translated into many languages and forms the basis of a number of ocular studies. The NEIVFQ-25 is used as benchmark against which more specific glaucoma QOL tools are compared.⁵ The impairment in the QOL was more in some areas in comparison to others in both GQL-15 and NEIVFQ-25 questionnaires. In this study in GQL-15, 37% of respondents showed

impaired QOL in reading newspaper. In GQL-15, there was less impairment in QOL with regards to adjustment to lights, but poor QOL as far as seeing objects coming from the sides and recognizing faces was concerned. In the NEIVFQ-25, in relation to the questions on general health more than two third of the population were worried about their eyesight and around half of the population reported impaired vision even with the use of glasses or contact lenses.

A large number of population showed little impairment in QOL in dealing with activities with closed work. Around 30% of the respondents quit driving because of eyesight loss due to disease. About one third of the respondents have impaired QOL due to pain and ache in the eyes. A similar percentage of the respondents felt that the disease made them frustrated and limited their activities due to eyesight.

Hence, looking at the results of the QOL it shows that patients suffering from chronic diseases like glaucoma are affected psychologically and physically because of the disease. Never the less our study has some limitations. Firstly, we used cross-sectional survey to collect the data and we were not able to determine long term QOL associated with visual impairment. The sample size was inadequate. Visual function test was not performed in all the patients. QOL can be taken twice, before and after the drug treatment.

All the drugs which are given for co-morbid conditions were not included. We have not taken control group. To conclude, beta-blockers were the most frequently used drugs for POAG, where in Timolol was used most frequently. Timolol and Brominidine were the most frequently prescribed drug combination. For glaucoma, whatever therapy is chosen the concept to be kept in mind is that the glaucoma therapy is lifelong and needs consideration in the cost-effectiveness and convenience in the individual patient.

The NEIVFQ-25 and the GQL-15 both appeared reliable questionnaires in the assessment of QOL in this study. They showed similarities in their correlation with visual function. The NEIVFQ-25 however, is a broader instrument better evaluating psychosocial wellbeing than the GQL-15, while the GQL-15 is a shorter, simpler instrument, which could be easily administered in clinical practice.

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