Original article

The influence of the Travalert® dosing aid on medical treatment compliance and the quality of life of glaucoma patients

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ABSTRACT

Purpose: To study compliance in the medical treatment of glaucoma, its possible association with other factors, and quality of life of patients with glaucoma.

Material and methods: Longitudinal prospective study of 60 patients with ocular hypertension or glaucoma who were treated with travoprost, or with a fixed combination of travoprost/timolol nightly. All subjects were given a Travalert® dosing aid and were reviewed after one and four months. Strict and relative compliance data were collected on each visit. The relationship between compliance and other variables was studied using univariate analysis. In order to analyse quality of life, patients were given self-assessment STAI anxiety questionnaires after the first and last visits.

Results: Relative compliance for the four months was significantly greater than the strict compliance (p = .001). In the group of least compliance the number of patients on treatment with combination therapy was significantly higher than those on monotherapy. In the lost cases, the number of men was significantly higher than women. No association was found in the other variables. The anxiety was similar to that in the normal population.

Conclusions: Compliance is very important in the treatment of glaucoma, and our study provides objective data through the use of Travalert dosing aid with relative compliances of 70%. Patients with combined therapies have lower compliance than those on monotherapy.

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Estudio de la influencia del dispositivo de ayuda a la dosificación Travalert® sobre el cumplimiento del tratamiento médico y calidad de vida de los pacientes con glaucoma

RESUMEN

Objetivos: Estudiar el cumplimiento en el tratamiento médico del glaucoma y su posible asociación con otros factores, así como la calidad de vida de los pacientes con glaucoma.

Material y métodos: Estudio prospectivo longitudinal en 60 pacientes con hipertensión ocular o glaucoma que recibían tratamiento con travoprost o con la combinación fija travoprost/timolol todas las noches. Se les entregó a todos los sujetos el dispositivo Travalert de ayuda a la dosificación y se les revisó al mes y al cuarto mes recogiendo el cumplimiento estricto y relativo en cada visita. Mediante un análisis univariante se estudió la relación entre el cumplimiento y otras variables.

Para analizar la calidad de vida, se entregó a los pacientes el cuestionario de autoevaluación de ansiedad STAI en la visita de entrada y en la de salida.

Resultados: El cumplimiento relativo a los cuatro meses fue significativamente mayor que el estricto (p = 0,001). En el grupo de menor cumplimiento el número de pacientes que recibían terapia combinada resultó significativamente mayor que en el de aquellos que recibían monoterapia. Al estudiar los casos perdidos, el número de hombres fue significativamente mayor que el de mujeres. No se encontró asociación estadística en el resto de variables. La ansiedad fue similar a la población normal.

Conclusiones: El cumplimiento es de vital importancia en el tratamiento del glaucoma, nuestro estudio aporta datos objetivos mediante el sistema electrónico Travalert porque muestra un cumplimiento relativo del 70%. Los pacientes con terapias combinadas presentan menor cumplimiento que aquellos en monoterapia.

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Introduction

Compliance is of vital importance in the medical treatment of glaucoma and has a significant influence in patients affected by this disease. Lack of compliance is the main cause of therapeutic failure. As pointed out by the European Glaucoma Society, adherence to a treatment has 2 components: compliance, defined as taking the medication as prescribed (dosage, frequency and administration route) and persistence, defined as the continuation in the use of the medication as prescribed (regularly replacing the prescription).

Data on adherence to treatment illustrate that a considerable proportion of patients interrupt and restart medication with the passage of time. In the case of glaucoma, data confirm that adherence to treatment with anti-glaucomatous medication is poor. It has been found that instilling over two drops per day is a significant predictive factor for poor compliance.

In order to improve compliance, electronic devices for aiding the dosage of anti-glaucomatous drugs have appeared in the market, such as Travalert®, which facilitates an objective control of compliance and reminds patients in treatment to take their medication and to carry out a precise instillation into the eye.

One of the most important objectives in glaucoma treatment is to maintain adequate quality of life. This is closely related to the visual function. In general, patients with slight or moderate glaucoma exhibit good visual function and a moderate reduction of their quality of life, but when the disease progresses it involves a considerable quality of life reduction.

The STAI status-trait anxiety questionnaire indirectly assesses the quality of life of patients in order to improve their compliance.

The objective of this paper is to study compliance of patients in medical treatment for glaucoma and its possible association with other factors as well as the quality of life of glaucoma patients.

Material and methods

A longitudinal prospective study carried out in the glaucoma Dept. of the San Carlos Clinic Hospital (HCSC). The study was carried out in accordance with the clinically good practices standard and was approved by the Ethical Committee of the San Carlos Clinic Hospital. Each patient signed an informed consent prior to being included in the study. Overall, the study recruited 60 patients in treatment with travoprost or a fixed combination of travoprost/timolol every night.

All patients had submitted to an exploration upon being included in the study, and were assessed after 1 and 4 months (AQ; for edit). The initial assessment collected the demographic data, the complete ophthalmological history (topical medication, stage of glaucoma, etc.) and each patient was given the Travalert® device, which was programmed to remind the patient every day about the application of eyedrops at a predetermined time (20:00 ± 1h). The use of the device was explained, insisting on the importance of compliance. The patients were requested to bring the device to the 2nd and 3rd assessment.
Quality of life was assessed with the STAI self-assessment anxiety/condition and anxiety/trait questionnaire at the first and last assessment in 18 randomly selected patients.

Compliance was taken as the main variable to be analyzed and, for each patient and assessment, compliance was determined with 2 parameters: strict compliance (defined as the number of drops applied in the interval of one hour around the predetermined time/total number of prescribed drops) and relative compliance (defined as the number of drops actually applied/total number of prescribed drops, without taking into account the application time).

The results were analyzed with the SPSS statistical program version 15.0 (SPSS Inc., Chicago, IL, USA). A value of $p < 0.05$ was taken as significant.

**Results**

In the sample, 58.3% of patients in the study were female. The mean age of patients was of 73 years (RIC 64–76). The most frequent type of glaucoma was simple chronic glaucoma and 51.7% of patients exhibited an incipient stage of the disease. Of all patients, 53.3% received monotherapy (Travatan) against 46.7% received combined therapy (Duotray). The mean intraocular pressure (IOP) before the study was of 20 mm Hg (RIC 18–23).

In the analysis of the strict and relative compliance at month 4, differences were found between both groups, with a mean value for strict compliance of 47 (2–74.2) and for relative compliance of 70 (25–86.2); $p = 0.001$. Relative compliance was significantly better than strict compliance (Fig. 1).

A univariant analysis was carried out subsequently, seeking statistical association between 2 main variables: good compliance, defined as over 60%, and poor compliance, defined as under 30%, relating both with the remaining variables.

The first variable of the study was sex. No statistically significant differences were found in compliance based on sex, with good compliance for females being of 62.9% and males of 61.5% with $p = 1$; and for poor compliance in women, the value was of 22.2% and it was 30.7% in males, with $p = 0.7$.

In what concerns the stage of glaucoma, a significant association was not found either, with the value for the good compliance group being of $p = 0.54$; and for the poor compliance group of $p = 0.59$.

Analyzing compliance in the groups receiving monotherapy and combined therapy, a significant association was not found either in the good compliance group, which had a value of $p = 0.1$; however, a statistically significant association was identified for the poor compliance group receiving combined treatment, with $p = 0.028$.

The next variable to be studied was the number of eye-drops. Significant differences were not found, with $p = 1.0$ in the good compliance group and $p = 0.62$ in the poor compliance group.

Regarding the systemic treatment variable, no significant association was found, with $p = 1.0$ in both groups.

The analysis of age as a continuous quantitative variable did not yield a significant correlation between said variable and compliance. Spearman’s correlation coefficient was of 0.076, with $p = 0.63$ in the good compliance group, and the correlation coefficient was of $-0.08$ with $p = 0.96$ for the poor compliance group.

Analyzing the lost cases on the basis of the sex variable, a statistically significant association was found, with $p = 0.042$ in the group of males (Fig. 2).

As for the analysis of the STAI questionnaire, no significant differences were found between anxiety/state (A/E) pre-intervention and anxiety/state (A/E) post-intervention, with $p = 0.609$.

Finally, the distribution of anxiety/trait in our something followed a similar pattern to that of the global population, although it was tightly grouped due to the small sample size (Fig. 3).

**Fig. 1** – Treatment compliance in month 4, expressed in percentages (%). Relative compliance was significantly better than strict compliance ($p = 0.001$).

**Fig. 2** – Compliance and lost cases studied on the basis of sex, expressed in percentages. Statistically significant association with $p = 0.042$ in the group of males.

**Fig. 3** – Distribution of anxiety/trait in the normal population and in the study sample, showing a similar pattern to that of the normal population.
Discussion

This study analyzed compliance with medical treatment for glaucoma in a specialized practice. As glaucoma is a chronic disease which does not express before reaching advanced stages, compliance is more difficult.

The majority of studies agree in that the patients overestimate treatment compliance when asked directly about it, ranging between 23% and 59%. For this reason, it is necessary to develop a reporting system to analyze compliance objectively. A number of these types of systems have been developed, such as C-cap and Timecap among others, but without a doubt, electronic monitoring is the most precise method to assess compliance. The studies utilizing this method report compliance figures between 76% and 86%. Recent electronic monitoring studies analyzing compliance with glaucoma treatments include the one carried out by Okeke et al. who found a compliance rate of 71% after 3 months of prostaglandin treatment in 196 patients. Friedman reported that 44.4% of these patients utilized the device less than 75% of monitored days. When studying the variables associated to good or poor compliance, he found that Caucasian patients with ages between 50 and 79 in good health, with good knowledge of the disease and good subjective compliance exhibited the best adherence to the treatment.

The above results are superior to those obtained in our study in what concerns strict compliance, which reached 47%. However, it is considerably closer as regards relative compliance, which rose to 70% at month 4. This means that there is a large amount of patients that instill the prescribed eyedrops not within the time range recommended by the specialist.

In what concerns the rest of variables we did not find statistically significant differences as regards age, sex, stages of glaucoma, systemic treatment and regime. However, we did find statistically significant differences when analyzing lost cases, where the number of men who give up treatment is significantly higher than the number of women. Accordingly, it can be deduced that women adhere more to treatment than men. We also found a statistically significant association between the poor compliance group and those patients receiving combined therapy. This could be because these patients are in the higher age brackets and receive more systemic treatments which leads to diminished compliance or who are in anti-glaucomatous treatment longer.

As for quality of life and glaucoma patients, some studies did not find a relationship between quality of life and the number of anti-glaucomatous drugs, whereas other studies suggest a relationship between the number of drugs and reduced compliance and quality of life. Goldberg et al. carried out a study in 121 patients with glaucoma and 13 controls who were given a quality of life questionnaire (Glaucoma Quality of life). CGL-15 Questionnaire) with the results that patients with glaucoma had a quality of life that was significantly lower than controls and that it diminished in accordance with the progression of the disease.

Holló et al. studied the relationship between personality types, anxiety and depression and adherence to treatment with a device. To analyze compliance, the STA1 self-evaluation questionnaire applied in our study was utilized, with the conclusion that compliance was of 77% and was not influenced by personal factors or the degrees of patient anxiety. All patients exhibited a stage of anxiety similar to that of the normal population, as was the case in our study. We did not find either a statistically significant association between anxiety levels and compliance.

The present study emphasizes the importance of compliance in the medical treatment of glaucoma, showing a mean relative compliance of 70%. It is important for the ophthalmologist to be able to utilize an objective source to analyze said compliance as well as to educate patients about the evolution of the disease and the importance of good adherence to treatment in order to maintain a good quality of life.

Conflict of interest

ALCON Laboratories provided the Travalert electronic device.

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