LONG-TERM TENSIONAL RESULTS AFTER TRABECULECTOMY. A COMPARATIVE STUDY AMONG TYPES OF GLAUCOMA AND PREVIOUS MEDICAL TREATMENT

RESULTADOS TENSIONALES TRAS TRABECULECTOMÍA A LARGO PLAZO. ESTUDIO COMPARATIVO ENTRE TIPOS DE GLAUCOMA Y TRATAMIENTO MÉDICO PREVIO

FERNÁNDEZ S1, PARDIÑAS N1, LALIENA JL1, PABLO L1, DÍAZ S2, PÉREZ S1, HONRUBIA FM1

ABSTRACT

Objectives: To evaluate long-term intraocular pressure results after trabeculectomy in low risk patients. Therefore differences among glaucoma type and previous medical treatment will be evaluated.

Methods: A retrospective follow-up study, ranging between 3 and 20 years, was carried out on 965 trabeculectomy surgeries without any surgical-failure factor. Follow-up was carried-out one day, one week, one month, three months, six months and annually after surgery until the last visit. Primary open angle (POAG) (671 eyes), pseudoexfoliative (PSXG) (156 eyes) and chronic closure angle glaucomas (CCAG) (138 eyes) were included. IOP under 21 Hg mm without medical treatment was considered absolute success, relative success included those eyes with pressures under 21 and one or two daily antiglaucomatous drops.

Results: Mean IOP ranged between 15 and 17 Hg mm. Mean IOP decreased from 30.7 to 37.4%. Relative success ten years after surgery was better in POAG; whereas absolute success resulted to be
similar in POAG and PSXG. The group of patients less treated before surgery showed greater rate of absolute and relative success. **Conclusions:** Trabeculectomy alone is an efficient technique in long-term tensional control for uncomplicated eyes. The group of patients less treated before surgery and POAG showed greater rate success (*Arch Soc Esp Oftalmol* 2009; 84: 345-352).

**Key words:** Intraocular pressure, primary open angle glaucoma, pseudoexfoliative glaucoma, chronic closure angle glaucoma, trabeculectomy.

**INTRODUCTION**

Glaucoma constitutes one of the main causes of irreversible legal blindness throughout the world. In addition, it is the second cause of visual loss in patients over 40 in the Western world (1).

The only alternative to avoid the progression of glaucomatous disease is an early diagnostic and an adequate follow up and treatment, with surgery playing a fundamental role.

The trabeculectomy technique, broadly utilized in recent years as surgical treatment for several types of glaucoma, is considered to be an easy technique which yields good results and exhibits a small number of ocular complications. The majority of studies made on the results of this technique comprise a follow up period of ≤5 years and a number of cases under 450. Accordingly, there is a need for a study like the present one, devised for assessing the mid- and long-term results of the most broadly utilized antiglaucomatous surgical technique in an important number of patients.

**SUBJECTS, MATERIAL AND METHODS**

A descriptive, retrospective and longitudinal study of patients submitted to simple trabeculectomy without anti-mitotics. This intervention was the first surgery for the disease within the period comprised between 1975 and 2000. The data were reviewed up to early 2003 (1).

30.70% y un 37.40%. El éxito relativo a los 10 años fue mejor para el GPAA y el éxito absoluto fue similar para el GPAA y GPSX en el mismo tiempo. El grupo de pacientes que menor número de colírios se administraba antes de la cirugía fue el que presentó un mayor éxito relativo y absoluto. **Conclusión:** La trabeculectomía simple es una técnica quirúrgica eficaz en el control tensional a largo plazo, mostrando una mejor resultado en pacientes con GPAA y con menor tratamiento médico previo.

**Palabras clave:** Presión intraocular, glaucoma primario de ángulo abierto, glaucoma pseudoexfoliativo, glaucoma crónico de ángulo cerrado, trabeculectomía.

All the interventions were carried out in our centre by doctors attached to the glaucoma unit and resident doctors in training.

The inclusion criteria for the study were: Open angle primary glaucoma (OAPG), pseudoexfoliative glaucoma (PXPG), closed angle chronic glaucoma (CACG), age > 18, primary and consecutive glaucoma operations.

The patients exhibiting some type of glaucoma or risk factor involving the use of anti-mitotics (neovascular or traumatic glaucoma, African race, etc.) were excluded from the study, as well as patients with defects in the optic nerve and/or visual field due to a non-glaucomatous ocular disease or another systemic disease, as well as patients with previous ocular surgery history.

The post-op follow up data were obtained at day one after the intervention, one week, 1 month, 3 months, 6 months, and each year after the trabeculectomy up to the last exploration.

The success criteria (control) for IOP were: Relative success, IOP ≤21 mm Hg without additional pressure-reducing medical treatments or with one or two eye drops; absolute success: IOP ≤21 mm Hg without additional pressure-reducing medical treatment (2,3).

All the data were collected in a database created in the FileMaker version 6.0 application (FileMaker Inc. USA, 2002) and statistically processed with the statistical program SPSS version 11.0 (SPSS Inc. USA, 2001). The longitudinal study for assessing the evolution of the groups according to the previously established failure and success criteria was made applying Kaplan-Meier survival curves,
which were compared with the Log Range analysis. For all the analyses confidence intervals of 95% were utilized, which means that a level of p<0.05 was considered to be statistically significant.

RESULTS

The sample of the study comprised 965 eyes belonging to 638 patients. The mean follow-up time was 7.5 years, with a range between three and 20 years (mean=7). The gender distribution exhibited a higher number of female patients (52%). The mean age at the beginning of the study (glaucoma surgery date) was of 66.80 SD 10.5 years. The range was between 22 and 92 years. In what concerns the distribution in groups based on previous treatment, the most numerous groups were the group of 2 eye drops (427 eyes) and 3 eye drops (426 eyes). The group without previous treatment comprised 70 eyes. The most frequent type of glaucoma was OAPG, which comprised 69.5% (671 eyes). The least frequent glaucoma was CACG with 14.3% (138 eyes), while the eyes with PXPG amounted to 16.2% (156 eyes).

The mean IOP values throughout the study were maintained between 15 and 17 mm Hg, excepting at the end of the follow-up (year 20), where the mean increased up to 18.50 SD 2,51 mm Hg (fig. 1).

The percentage of pressure reduction varied between 30.70% to 37.40%, with the higher percentage as well as the mean reduction being found in years 9 and 10 after the surgery (fig. 2).

By means of the aggregate Kaplan-Meier survival analysis, an IOP control of 21 mm Hg without treatment or with one or two eye drops was observed (relative success) at year one after surgery in 99.3%, at year 5 90.6%, at year 10 76.7%, at year 15 70.1%, with 45.9% maintaining survival at year 20 (fig. 3).

Figure 4 compara the IOP control with relative success of the 3 types of glaucoma under study. The survival curves exhibit significant differences in relation to the type of glaucoma (p < 0.05).

At year 5 of evolution, the control was similar in the three types of glaucoma, at year 10 the control was slightly higher in OAPG and after 15 years of evolution up to the end of the study the IOP control was slightly higher in PXPG.

The comparison between groups was statistically significant between OAPG and PXPG and also between OAPG and CACG (p < 0.05). No statistically significant differences were found between PXPG and CACG.

The differences in the IOP control with relative success throughout the study between the various treatment groups before surgery (fig. 5) are highly significant (p < 0.001), exhibiting better IOP control in the treatment group with 0 or one eye drops up to 15 years of evolution (97.8%).

The group exhibiting the worst IOP control was that receiving the maximum treatment for pressure control, with a survival rate at 10 and 15 years

Fig. 1: Mean intra-ocular pressure (IOP) (mmHg) throughout the study.

Fig. 2: Percentage (%) of IOP reduction throughout the study.
under 50%. The latter group always exhibited a survival curve with a worse evolution than the other groups in the various groups of treatment.

The comparison between treatment groups exhibited statistically significant differences without exception.

The IOP control with absolute success (IOP ≤21 without treatment) throughout the study exhibited a probability of 98.7% after one year of follow-up, 82.4% at year 5, 53.9% at year 10, 40.3% at year 15 and 16.1% at year 20 (fig. 6).

Figure 7 illustrates the comparison of IOP control with absolute success for the three types of glaucoma of the study.
At year 5, the three types of glaucoma exhibited a survival above 80%. At year 10, PXPG and OAPG exhibited a similar survival. The best IOP control at year 20 was for PXPG, with 59.5%. OAPG exhibited at year 20 a survival of 14.7%.

The ratio between the IOP control with absolute success and the glaucoma type was highly significant, p< 0.001. CACG was the type of glaucoma with the worst IOP control with absolute success, with a survival at 15 years of 16.6%. The comparison between groups exhibited statistically significant (p < 0.05) and highly significant differences (p < 0.001) between PXPG and CACG.

The IOP control in the various treatment groups exhibited a very high statistical significance (p< 0.001), with a greater control of IOP in the group receiving zero or one eye drop up to year 15 of evolution. At year 20, the best survival was for the two eye drops group against the three or more eye drops group. After year 15 there are no data for the group receiving 0 or 1 eye drop (fig. 8).

The differences were not significant for the comparison between the topical and oral treatment groups with the 2-eyedrop and the 3 or more eye drops group. For the rest of groups the differences were statistically significant.

**DISCUSSION**

For a more reliable comparison between the reviewed articles we decided to divide the discussion of the IOP control in three sections, based on the follow up time after surgery. The majority of published papers describe a follow-up time of around five years (4-9). Other papers have a follow-up time of 10 years (10-13) and three authors published follow-up periods exceeding 10 years (2,14,15).

As regards the IOP control after five years of follow up, Zaidi et al (4) achieved a pressure control of 80% of cases and 69.4% of IOP control without treatment. The percentage of control obtained is lower than ours, but it must be pointed out that this author included in the study neovascular glaucomas with worse post-op IOP control, as demonstrated and confirmed by other publications (5).

Of note is the research published by Mills et al (5) which carried out one of the studies with the highest number of data analyzed, totaling 444 eyes. The follow up of these patients ranged between one and seven years, exhibited a pressure control of 80% and of 71.9% without additional treatment.
This percentage only includes OAPG, CACG and closed angle glaucoma. On the other hand, D’Ermo et al (8) achieved a pressure control of 80% with or without treatment and 71.1% without additional treatment. These results, together with those of Mills (5) are slightly lower than ours, possibly due to the inclusion of glaucoma types with worse prognosis such as secondary glaucoma, which were not considered in our study.

One of the recently published papers (2002) is by Ehrnrooth et al (6), who made a follow-up of 138 eyes with OAPG and PXPG. Pressure control figures are considerably different to ours because of relative success was defined at 42% and absolute success at 40%. We believe these results are explained by the high percentage of PXPG included in the study, amounting to 57% of all examined eyes.

As regards IOP control after 10 years of follow up, Nouri et al (10) found an aggregate IOP control probability with or without treatment at nine years of 75%. In 1985 García Sánchez (11) included IOP control within a more complex criterion to define the control of glaucomatous diseases. The control percentage achieved at seven years follow-up was of 80.2% and 65% without added treatment for pressure control.

An additional author who introduced the concept of glaucomatous disease control was Törnqvist et al (13) who in 1991 carried out a study on 277 eyes including several types of glaucoma, among them PXPG. The result of this control after 10 years was of 77% of cases, 42% of which went without treatment. The IOP control percentages with or without additional treatment, both for García Sánchez (11) and Törnqvist (13), are slightly below those obtained in our study (87.2%), probably due to the strict criteria utilized by said authors not only for IOP control in the case of Törnqvist (13), but also due to the inclusion of control parameters such as progression of the visual field and the optic nerve.

In what concerns IOP control in studies with over 10 years of follow up, the 1999 paper by Molteno et al (2) is one of the best publications to compare its results with our study because they share a number of characteristics: The cases included in this study belonged to three types of glaucoma: 69.5% OAPG, 17.3% PXPG and 13.2% CACG, the follow-up time was from 1 to 19 years, the statistical analysis was also made with Kaplan-Meier survival curves, the criteria for IOP control, the mean age of the population, the most frequent age range as well as the gender of the population in the study. The differentiating parameter was the number of cases followed up: the Molteno study (2) comprised 289 eyes while the instant study totals 965 eyes.

The IOP control probability with and without treatment was of 85% after 15 years of evolution. In our study, this figure was 70.1% at 15 years and 45.9% after 20 years of follow up. This difference could be explained by the tighter criterion for defining IOP control with treatment in the survival analysis. In our study, we only included patients receiving one or two eye drops, while the rest of patients with treatment did not form part of the success percentage.

On the other hand, Parc et al (14) included in his study other types of glaucoma in addition to OAPG and PXPG, such as neovascular, pigmentary and juvenile glaucoma. IOP control after 20 years of evolution was rated in this study at 62%.

Popovic et al (15) achieved an IOP control percentage of 90% with or without treatment and 61% without treatment. These numbers were the results of a study and made over 75 eyes with several types of glaucoma, with a high percentage of congenital glaucoma (41%) and of PXPG (41%).

In what concerns pressure controlled between various types of glaucoma, there is a controversy in the literature because some studies achieved better control of IOP in PXPG after 5 years and without additional medical treatment (13), while others obtained a similar IOP control number with or without treatment in OAPG and PXPG (6). Mills (5) presented a better IOP control with and without treatment in OAPG. The last study published in 2005 (16) discussed the lack of influence of the type of glaucoma in the final pressure success percentage.

The majority of published studies illustrate a poorer pressure control in patients with maximum anti-glaucomatous treatment before surgery (16,17).

Trabeculectomy is an efficient surgical technique for pressure control of long-term glaucoma patients, exhibiting better results in patients with less medical treatment prior to surgery.

As regards the type of glaucoma, OAPG obtained the best IOP control up to 15 years of follow up, while PXPG did best in the period comprised between 15 and 20 years.
REFERENCES