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Original

Predictors of Progression of Primary Open Angle Glaucoma: Multivariate Survival Analysis

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Purpose: To identify significant risk factors for progression of primary open angle glaucoma (POAG). **Design:** Retrospective cohort study. **Participants:** One hundred forty-nine POAG patients. **Methods:** Multivariate survival analysis of risk factors predicting disease progression using the Cox proportional hazards model. **Main Outcome Measures:** Disease progression was defined as an irreversible increase of the stage of visual field defect, or irreversible increase of more than two consecutive probability symbols less than 0.1% of pattern deviation in Humphrey STATPAC II, in either the upper or lower hemifield of each patient. The visual field stage was determined separately in upper and lower hemifields according to Aulhorn's classification modified by Greve. **Results:** Minimum intraocular pressure (IOP) and the initial visual field stage (sum of upper and lower hemifields) were the most significant predictors. The risk of POAG progression doubles for every 4 mmHg increase in IOP. The most rapid visual field progression occurs as the initial visual field stage transitions from normal (sum −2) to abnormal (sum −1 to 1). The initial cup-to-disc ratio is a less significant risk factor. **Conclusion:** To reduce the rate of progression of POAG, intraocular pressure should be kept as low as possible, with a target IOP of no higher than 17 mmHg, and preferably 13 mmHg or less in many POAG patients.

Key Words: POAG, visual field progression, multivariate survival analysis, IOP

Introduction

Intraocular pressure (IOP) is generally considered to be the most important risk factor determining the progression of primary open angle glaucoma (POAG)[1)~25)]. Various factors besides IOP, such as age, race, sex, family history, and initial visual field have also been reported to affect the progression of POAG[1)~4)8)~10)13)16)22)26)~29)]; however, there is much discrepancy in these reports. Since POAG is a slowly progressive chronic disease, it is necessary to examine a large number of patients over a long period of follow-up to determine risk factors for progression. In this study, we evaluated various risk factors on the progression of POAG during the period when the treatment condition was considered to be "stable" (i.e. no surgical intervention), using a multivariate survival analysis on a large number of patients who had long-term follow-up.

Subjects and Methods

1. Subjects

We retrospectively reviewed the charts of all POAG patients at the Glaucoma Center of San Francisco from December 1982 to January 1997. One hundred forty-nine POAG patients meet the following inclusion criteria and were included in the study. The patient must have been followed for at least two years after 1983, when the Humphrey Field Analyzer (Humphrey Instruments, Inc., San Leandro, California) became available in our clinic. Patients must have had an opthalmological examination which included IOP measurement by Goldmann applanation tonometry, slit lamp examination, and cup-to-disc evaluation performed at least every three months. Patients must have had reliable vis-

Table 1 Patient characteristics

Age (years)	24-83 years (mean 62.7 ± 11.9)
Sex	
Male	71
Female	78
Refractive error (diopters)	−16 to +10.5 (mean −1.9 ± 3.9)
Initial stage of visual field	
No defect	21
Stage 0-1	17
Stage 1	15
Stage 2	23
Stage 3	26
Stage 4	17
Stage 5	30
Surgical history	
No surgery	82
Cataract	2
Trabeculectomy	48
Both	17

Table 2 Visual field stage of upper and lower hemifields

		Upper visual field stage (eyes)							
		no	0-1	1	2	3	4	5	6
Lower visual field stage (eyes)	No	21	2	2	3	2	1	1	0
	0-1	4	11	5	2	1	3	0	0
	1	2	4	2	1	1	2	3	0
	2	3	4	3	7	3	2	2	0
	3	6	3	2	4	4	2	5	1
	4	1	0	2	1	2	2	6	2
	5	1	0	0	0	1	1	3	2
	6	0	0	0	0	1	0	1	0

ual field test results at least every 6 months during the follow-up period with reliability indices of fixation loss, false positive, and false negative all less than 33%, using the Humphrey 30-2 or 24-2 full threshold program.

Only one eye of each patient was used for the analysis. When both eyes of a patient met the inclusion criteria, the right eye was chosen. The characteristics of the 149 study subjects are summarized in Table 1.

2. Methods

All of data was anonymoised before analysis and we chose the time period when the treatment condition was considered to be "stable" (i.e., no surgical intervention). If a patient underwent intraocular surgery, such as trabeculectomy and/or cataract surgery during the follow-up period, the longer period before or after (or in between) the surgery(s) was selected for the analysis. The analyzed time period (from the first day to the last visit for patients with no visual field progression, and from the first day to the endpoint for patients with visual field progression or to the day when the patient underwent the surgery) ranged from 7 months to 11.7 years (mean 6 ± 2.5 years). Each visual field result was divided into upper and lower hemifields (Table 2). The visual field stage in each hemifield was determined using Aulhorn's classification modified by Greve[30]. Visual field stage was determined in a masked fashion, with the interpreter being unaware of patient clinical information. Visual field progression was defined as an irreversible increase of the stage of visual field defect, or irreversible increase of more than two consecutive probability symbols less than 0.1% of pattern deviation in Humphrey STATPAC II, in the upper or lower hemifield on two consecutive tests. The first day of the two consecutive tests was defined as the day of visual field progression (endpoint).

Multivariate survival analysis was used to identify significant risk factors for progression of POAG. The Cox proportional hazards model was used to compare the ability of prognostic variables including demographic risk factors (age, sex), refractive error, IOP, initial visual field, initial cup-to-disc ratio, and surgical history to predict visual field progression. Age and refractive error were analyzed as continuous variables, while sex was coded as male or female. The IOP measures evaluated were the maximum, minimum, average, range, and standard deviation (SD) during the time period analyzed. The mean IOP and SD were calculated based on IOP measurements which were obtained every three months, from the beginning of the time period analyzed to the last visit for patients with no visual field progression, or from the beginning to the endpoint for patients with visual field progression. The initial visual field measures evaluated were the upper hemifield, lower hemifield, and maximum, minimum and sum of both hemifields. Visual field measures were evaluated based on an ordinal scale of

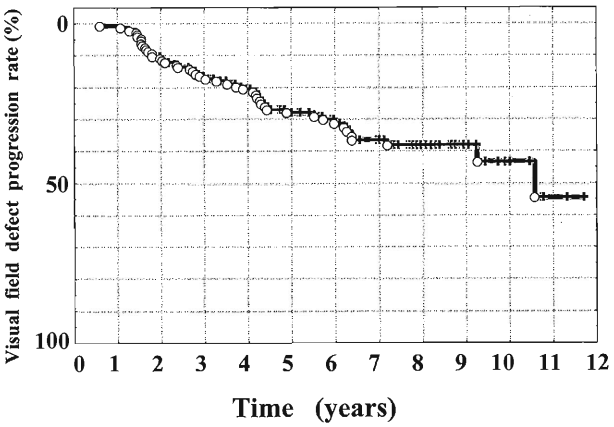

Fig. 1 The result of the life table analysis of visual field deterioration in all cases

−1 to 6 for each hemifield (−1: normal; 0: Aulhorn classification 0−1; and from 1 to 6: Aulhorn classification 1 to 6). The initial cup-to-disc ratio measures evaluated were horizontal, vertical, and their sum. The cup-to-disc ratio was evaluated based on an ordinal scale of 1 to 10, dividing the 0 to 1 range of cup-to-disc ratio into 10 equal categories (i.e. $0 < \text{ratio} \leqq 0.1$; $0.1 < \text{ratio} \leqq 0.2$; etc.).

In order to ensure that linear ordering existed between consecutive categories of each predictor variable, the survival characteristics of each individual category were evaluated and compared to that of all other categories. Where necessary, the data for a given predictor variable will be transformed by recoding them into ordered, parsimonious subgroups; therefore, for each variable, individual categories that have similar survival characteristics which do not differ significantly from one other will be combined into a single subgroup for purposes of analysis. The actual number of subgroups that are formed, therefore, will vary depending on the observed survival characteristics of the individual categories for any given predictor variable.

The risk ratio and associated probability level was calculated for each predictor variable using both univariate and multivariate analysis. All of the predictor variables evaluated in the univariate analysis were included in the multivariate analysis. The stepwise procedure was used to build the final multivariate model.

Table 3 Results of univariate analysis

Risk factor	p-value
Intraocular pressure	
Minimum	0.000001
Average	0.0002
Range	0.0003
Maximum	0.05
SD	0.13
Visual field	
Sum (upper + lower)	0.000002
Maximum	0.0001
Upper hemifield	0.007
Lower hemifield	0.01
Minimum	0.08
C/D ratio	
Vertical + horizontal	0.005
Vertical	0.009
Horizontal	0.13
Others	
Type of surgery	0.003
Refractive power	0.35
Age	0.26
Sex	0.12

Results

Of 149 eyes studied, 47 (32%) demonstrated visual field progression. The number of eyes that progressed for each initial visual field stage was: 4 of 21 eyes with no visual field defect; 11 of 17 eyes with stage 0-1; 8 of 15 eyes with stage 1; 7 of 23 with stage 2; 5 of 26 with stage 3; 5 of 17 with stage 4; and 7 of 30 eyes with stage 5. Kaplan-Meier product-limit analysis showed progression of 43% of eyes at 10 years and 50% or more after 10 years (Fig. 1). Based on a detailed evaluation of the survival characteristics of individual categories for each predictor variable, the initial visual field measures and the initial cup-to-disc measures were recoded into several subgroups in the manner described in the Methods section. Age, sex, refractive error, type of surgery, and the various measures of IOP were not recoded for statistical analysis.

The results of univariate analysis are summarized in Table 3. The most significant individual risk factors (all with $p < 0.0001$) are minimum and initial visual field stage (sum of upper and lower hemifields). The other IOP measures (average, range, maximum) were significant ($p < 0.05$), except for the standard deviation, which was non-significant ($p =$

Table 4 Results of Cox regression multivariate analysis

Risk factor	Parameter estimate	Risk ratio	p-value
Minimum IOP (in mmHg)	0.1738	1.190	0.0002
Initial VF stage (4 subgroups)	0.4964	1.643	0.0005
Cup-to-disc ratio (3 subgroups)	0.4782	1.613	0.01

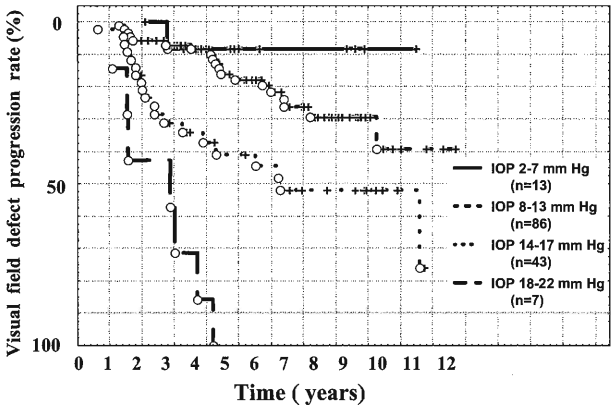

Fig. 2 The result of the life table analysis of visual field deterioration in each minimum IOP group

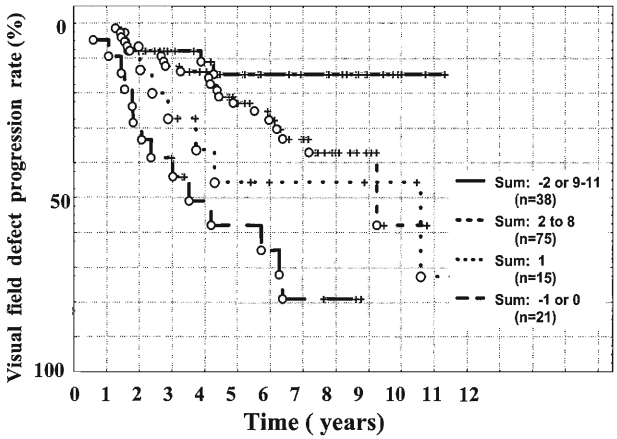

Fig. 3 The result of the life table analysis of visual field deterioration in each initial visual field stage group

0.13). The other measures of initial visual field stage (maximum, upper hemifield, lower hemifield) were significant ($p < 0.05$), except for the minimum hemifield, which was non-significant ($p = 0.08$). Most of the significance of the visual field sum, therefore, can be attributed to the maximum and not the minimum hemifield. In regards to the cup-to-disc ratio, the most significant individual measure was the sum of vertical and horizontal components ($p = 0.005$), with most of the significance of the sum attributable to the vertical ($p = 0.009$) rather than the horizontal component ($p = 0.13$). As to the other remaining risk factors, the surgical history is significant ($p = 0.003$), primarily depending on whether the patient underwent trabeculectomy or not. Refractive error ($p = 0.35$), age ($p = 0.26$), and sex ($p = 0.12$) were all non-significant risk factors.

The results of Cox regression multivariate analysis are summarized in Table 4. Only three risk factors were identified as being significant on multivariate analysis—minimum IOP, initial visual field stage (sum of upper and lower hemifields), and initial cup-to-disc ratio (sum of vertical and horizontal components). Of the three significant risk factors, minimum IOP ($p = 0.0002$) was the most important followed closely by the sum of the initial visual field stage of the upper and lower hemifields ($p = 0.0005$). The sum of the initial horizontal and vertical cup-to-disc ratios was significant but comparatively much less important ($p = 0.01$) than IOP or initial visual field stage. In order to identify the inherent prognostic subgroups that exist for each of the three risk factors identified as being significant on multivariate analysis, a detailed evaluation of the survival characteristics of individual categories of each of these risk factors was performed, and the results of recoding the data into discrete prognostic subgroups are illustrated in Fig. 2～4.

In the final multivariate model, the risk ratio for minimum IOP was 1.190. This means that the risk of POAG progression doubles for every 4 mmHg increase in IOP. As shown in Fig. 3, four discrete prognostic subgroups were identified, and eyes with minimum IOP from 18 to 22 have a substantially greater risk of disease progression than eyes with minimum IOP of 2 to 7.

For the initial visual field sum, four discrete prognostic subgroups were identified (Fig. 4). Examina-

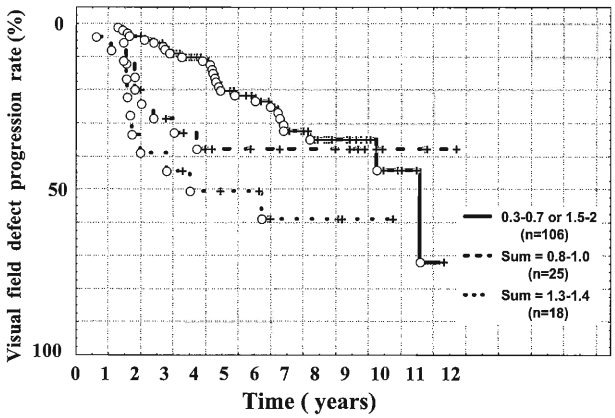

Fig. 4 The result of the life table analysis of cup-to-disc ratio in each subgroup

tion of these subgroups indicates the importance of early changes in the initial visual field sum, because when the initial visual field first transitions from completely normal (sum of −2) to early stages of abnormality (sum −1 to 1), there is a substantial increase in risk of disease progression. Intermediate stage disease (sum 2 to 8) demonstrated little prognostic value, with survival characteristics which are similar to that of the overall population. Late stage disease (sum 9 to 11) demonstrated relatively slow disease progression.

Cup-to-disc ratio was a significant risk factor on multivariate analysis but is much less useful than IOP and initial visual field stage; therefore, clinical management should be focused primarily on IOP reduction and prevention of early visual field progression rather than specific values of cup-to-disc ratio. Three discrete prognostic subgroups were identified in our analysis (Fig. 4); however, the primary usefulness of cup-to-disc ratio probably lies in the fact that "intermediate" values of cup-to-disc ratio (sum of 0.8 to 1.4, or in more familiar clinical terminology, vertical cup-to-disc ratio of 0.4 to 0.7) is associated with slightly increased risk of disease progression than other values of cup-to-disc ratio.

Discussion

In the present study, the minimum IOP proved to be the most important predictor of visual field progression in POAG. The initial visual field stage was also very important, with the initial cup-to-disc ratio less important. The age, sex, surgical history and refractive power of the eye did not affect POAG progression significantly. We used multivariate analysis to detect the factors which affect deterioration of visual field defects in POAG in order minimize effects of reciprocity of factors. Although this study is a retrospective one, the long follow up period and multivariate analysis design at least partly assured validity of the study. The risk ratios obtained by Cox proportional hazard model indicate that an increase of 4 mmHg in the minimum IOP would double the risk of deterioration of visual field defects. It was also shown that eyes with the sum of initial upper and lower visual field stage of −1 or 0, i.e. very early stage, had the greatest risk of progression as compared with other stages.

Our results are similar to those reported from Japan in which 215 Japanese POAG patients were analyzed using the Cox proportional hazard model[18]. Suzuki and Shirato et al reported that mean IOP during the follow up period and initial visual field stage significantly affected POAG progression[18]. In the present study, the minimum IOP during the follow up period was derived as the most important factor affecting POAG progression. The average IOP during the follow up period was also significant, but to a lesser extent. Suzuki and Shirato et al found that an increase in average IOP of 4 mmHg doubled the risk of deterioration of visual field defects[18]. We found that a 4 mmHG increase in minimum IOP doubled the risk of deterioration of visual field defects.

This difference between our results and their report[18] may be due to differences in treatment conditions during the follow up periods analyzed. Suzuki et al analyzed the whole follow-up period including surgery[18]. We selected the term when the treatment condition was considered stable during the follow up period to avoid the effects of large IOP changes caused by surgery. Both studies illustrate the importance of maintaining low IOP in the prevention of visual field deterioration.

There are many studies which indicate the effects of IOP on POAG progression[1)~25)], but some draw an opposite conclusion[31)~38)]. Weber, et al reported that patients with a higher standard deviation of IOP during the follow up period showed the

steeper mean deviation decay[21]. Mao, et al reported that visual fields deteriorated in all POAG patients with mean IOP's higher than 21 mmHg during the follow up periods, but that no visual field deterioration was found in cases with mean IOP's less than 17 mmHg[6]. Stewart et al reported that the mean IOP's and peak IOP's were markedly lower in patients with stable glaucoma than in patients with progressive glaucoma[17]. Odberg reported the IOP level was of great significance for progression of advanced glaucoma and the prognosis was better when the IOP was kept stable below 15 mmHg[7]. On the other hand, Chauhan & Drance[31], Hitchings et al[32], Popovic & Sjöstrand[29], Watson et al[38], Schulzer et al[37], and Mickelberg & Drance[34] did not find a significant influence of pressure level on POAG progression. The discrepancies among these reports may be due to analysis methods. They analyzed the relationship between IOP and VFD progression using a univariate analysis in which the effects of reciprocity of factors can not be excluded.

Concerning the importance of the initial visual field, we found that the most rapid progression occurs as the initial visual field stage transitions from normal to abnormal. Previous studies show varying results[3)6)8)9)13)16)18)20)22)26)~29)31)38)]. Suzuki et al found that patients with early and intermediate advanced initial visual field stages had a greater risk of progression than with other stages[18]. Popovic & Sjöstrand, using Aulhorn's classification, reported that visual fields which continued to worsen were generated from preoperative stages 0-3, and no cases with preoperative stages 4-5 worsened during the follow up period[29]. Chauhan and Drance stated that a significantly larger number of patients with initially abnormal fields showed progression than did patients with initially normal fields[31]. Wilson et al divided the initial visual field into 3 groups and reported that patients with advanced visual field loss experienced further field loss at a faster rate[22]. Grant concluded that the late stage progresses much faster than early stages in his longitudinal study[3]. Mikelberg reported that the rate of visual field deterioration is slow, but more rapid linear progression of the field occurs in more advanced stages[28]. Watson et al, Mao et al, did not find an influence of the initial visual field on progression[6)38)].

Part of this discrepancy may be caused by differences in the staging method of the visual field. We used Aulhorn's classification modified by Greve because it is frequently used in clinical studies. In this classification, however, differences in visual field defects between stages is so broad that intermediate progression cannot be estimated. Therefore, we adopted the irreversible increase of more than 2 consecutive probability symbols less than 0.1% of pattern deviation in Humphrey STATPAC II in upper or lower hemifields as the definition of progression as well as an increase in the visual field stage. This enabled an earlier detection of visual field progression. Second, we used the sum of upper and lower hemifields as a variable. In the Aulhorn's classification, the worse hemifield stage determines the stage of whole field. In contrast, the sum of the upper and lower hemifields make it possible to reflect the total visual field condition.

Progression rate differs according to the stage of the initial visual field. The highest rate is seen in the change from completely normal to abnormal. This appears to be an area of significant concern from a clinical standpoint. These patients must be monitored in an especially careful manner and significant lowering of their IOP must be obtained.

In evaluating the relationship between IOP and visual field progression, the data in this study demonstrates the importance of significant IOP reduction. Regarding target IOP we found that 100% of patients in this study with minimum IOP's of 18-22 mmHg had progressive visual field damage. Significantly fewer patients with minimum IOP's of 14-17 mmHg showed progression, and those with minimum IOP's of 13 mmHg or less were significantly more stable than the 14-17 mmHg group.

The data in this study indicates that the target IOP for many POAG patients should be no higher than 17 mmHg, and preferably should be 13 mmHg or less.

In conclusion, our study results indicate that we should keep IOP level as low as possible in the management of POAG.

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原発開放隅角緑内障における視野進行因子の多変量解析

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〔目的〕原発開放隅角緑内障（POAG）における視野進行因子の解析を検討する．〔対象と方法〕POAG 149例を対象とし，COX比例ハザードモデルによる多変量解析をもちいて視野障害進行に影響する因子を解析した．視野障害は，上下各半視野を判定し，Aulhorn分類Greve変法で非可逆性の視野障害が認められた場合，もしくは，ハンフリー視野計のパターン偏差において隣接する2点以上の0.1%以下の確率表示の増加が2回連続で認められた場合を進行と定義した．〔結果〕最低眼圧と開始時視野病期（上下半視野の合計）がもっとも重要な因子であった．POAGにおける視野進行障害確率は，眼圧が4 mmHg増加するごとに2倍に増加した．もっとも急速な視野障害進行が認められたのは，開始時視野病期が正常（上下視野病期合計－2）から初期（上下合計－1～＋1）であった．開始時のC/D比は視野障害進行への関与は認められなかった．〔結論〕POAGの進行を軽減するには，眼圧は可能な限り低く保ち，17 mmHgを越えないこと，13 mmHg以下に保つことが好ましい．