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Incorporating Mortality Risk into Estimates of Five-year Glaucoma Risk

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Introduction

Although the results from the Ocular Hypertension Treatment Study (OHTS) which randomized 1636 ocular hypertensives to a topical glaucoma medication versus observation showed that treatment reduces the risk of developing glaucoma, there is still uncertainty as to whether ocular hypertensive patients (a subgroup of glaucoma suspects with elevated intraocular pressure (IOP)), who by definition are asymptomatic, should be treated.¹ At 5-years, the treatment arm in the OHTS developed glaucoma at less than half the rate of the observation arm (9.9% risk for persons randomized to observation vs. 4.4% risk for persons randomized to treatment, p -value<0.0001). However, over 90% of subjects in either arm did not develop glaucoma in the 5-year period.^{2, 3}

To assist clinicians to decide whether to initiate treatment of an ocular hypertensive patient, risk calculators have been developed to predict an individual's risk of developing glaucoma. The most well-known calculator is based on combined data from the observation arm of the OHTS trial and the placebo arm of the European Glaucoma Prevention Study (EGPS), a smaller randomized controlled trial of ocular hypertensives.⁴ In addition to the estimated risk from these calculators, clinicians are recommended to consider other factors when deciding whether to initiate treatment. The 2005 American Academy of Ophthalmology guidelines state that the decision to begin treatment in an ocular hypertensive patient is "complex and depends on ocular, systemic, medical, and psychosocial factors."⁵ The validation study for a glaucoma risk calculator acknowledged that other factors—such as a patient's life expectancy, health, and preferences—should be considered when deciding to initiate treatment.⁴

While the glaucoma risk calculators show that older ocular hypertensive patients are at an increased risk for developing glaucoma, they do not account for the fact that these patients are also at an increased risk of dying due to their older age. If a clinician knew the patient was going to die before developing glaucoma, treatment to prevent the development of glaucoma would clearly be considered unnecessary. Although it is impossible to perfectly predict when a patient will die, tools do exist to estimate the a patient's mortality risk. In this study, we explore a method of incorporating tools for predicting mortality risk into tools for predicting glaucoma risk to produce a more realistic calculation of risk that can better guide clinicians on whether to treat patients at risk for developing glaucoma.

Methods

Incorporating mortality risk into an ocular hypertensive patient's five-year risk of developing glaucoma requires two tools: an estimator of the distribution of time until a given patient develops glaucoma and an estimator of the distribution of time until that patient's death. For the first estimator, we utilized the calculator from the Vision Research Coordinating Center at the University of Washington which we refer to as the OHTS/EPGS calculator since it was derived using data from those studies.¹⁻⁶ For the second estimator, we initially examined three explicit measures of life expectancy: the Charlson index (based on comorbidity and age),⁷ the Vulnerable-Elders score (based on functional status, self-reported health status, and age),⁸⁻⁹ and life tables from National Center for Health Statistics (based on age and sex).¹⁰ We only report the results from the Charlson index here since the VES-13 has yet to be examined in conjunction with longer term survival and the aggregated life tables based on sex and age do not adequately capture a patient's mortality risk. Results from our analysis using the VES-13 and the life tables are available in Appendix D of the supplementary material at AJO.com.

Estimator of glaucoma risk

The OHTS/EPGS calculator, described above, was designed to estimate the predicted five-year risk of glaucoma. In this calculator, older age and higher values of IOP, pattern standard deviation (PSD), and vertical cup/disc (C/D) ratio are associated with greater risk of developing glaucoma while higher values of central corneal thickness (CCT) are associated with a lower risk of developing glaucoma.⁶ The OHTS/EPGS calculator uses the results from a Cox proportional hazard regression model of time until development of glaucoma to compute the predicted five-year risk of glaucoma as a function of age, IOP, PSD, vertical C/D ratio, and CCT.¹¹ This formula was estimated using data for the OHTS and EPGS trials and the formula for the calculator is provided in Appendix A of the supplementary material at AJO.com.

Estimator of mortality risk

The primary explicit measure of mortality risk that we examined was the Charlson Comorbidity Index, developed over 20 years ago.^{7, 12} A systematic review showed that it is the single most commonly used measure to predict mortality.¹³ To use this tool, one first calculates the comorbidity score, a weighted sum of 19 conditions in which more points are assigned for more serious diseases (see Table 1). For example, an individual with diabetes (1 point) and congestive heart failure (1 point) would have a total comorbidity score of 2 while an individual with diabetes with end stage organ (2 points) and myocardial infarct (1 point) would have a total comorbidity score of 3. Then, the comorbidity score and age in decades are entered into a formula based on a Cox proportional hazard regression model to compute a predicted probability of dying before time t (see Appendix B of the supplementary material at AJO.com for more details).¹⁴

Estimating mortality adjusted five-year risk of glaucoma

Appendix C in the supplementary material at AJO.com contains the formula we used for computing the mortality adjusted five-year risk of glaucoma. Specifically, we computed the probability that an individual develops glaucoma in the next five-years or before they die, whichever comes first. We choose a five-year time frame to be consistent with the timeframe used in the OHTS/EPGS calculator. Figure 1 illustrates the key ideas behind these calculations using traditional multistate models. The top panel shows unadjusted two-state model for development of glaucoma where patients move from a disease free state (e.g., no glaucoma) to the disease state (e.g., glaucoma) at a particular rate depending on their characteristics. The bottom panel shows the competing risk multistate model for development of glaucoma in the presence of death. Here, patients move from the disease free state (e.g., no glaucoma) to either the disease state (e.g., glaucoma) or the death state. To illustrate the impact mortality can have on a patient's risk of glaucoma in this figure, assume we have a population of 100 patients and a fixed (unadjusted) annual risk of glaucoma equal to 14% and 14 patients would come down with glaucoma. In the competing risk framework, if we also assume a 14% risk for death, we would have 14% of our 14 glaucoma developers (i.e., 2) dying before the end of the year. Assuming 50% of those cases die before they develop glaucoma, this would give us an adjusted one year risk of glaucoma equal to 13% instead of 14%. Compounding these risks over five years, we have an unadjusted glaucoma risk of 53% and a mortality-adjusted risk of 39%.

Our hypothetical sample

Below, we illustrate the type of impact that mortality can have on estimated risks of developing glaucoma using a set of 16 hypothetical ocular hypertensive patients. We created our hypothetical ocular hypertensives such that we had patients who represented a range of unadjusted risks for glaucoma (e.g. from low to high). Specifically, we considered the following four combinations of IOP, CCT, PSD, and vertical C/D ratio: (26 mmHg, 550 μ m, 1.9 db, .6), (30 mmHg, 550 μ m, 1.9 db, .8), (30 mmHg, 500 μ m, 1.9 db, 0.8), and (27.9 mmHg, 532 μ m, 1.98 db, 0.48) and, for each combination of clinical values, we considered the ages of 55, 65, 75, and 85. We note that the later combination of clinical factors was selected based on mean values of patients from the OHTS study sample¹ who were at high risk of developing glaucoma. For each patient, we computed their unadjusted five-year risk of developing glaucoma using the OHTS/EPGS calculator above and their mortality adjusted five-year risk of mortality using the technique described above. The statistical software package, R version 2.5.1, was used to implement all analyses.

Results

Summary of life expectancy measures

Table 2 shows the estimated five-year mortality risk using the Charlson Comorbidity Index. As shown, an individual's predicted five-year mortality risk increases as age and/or comorbidity score increases. An increase of 10 years in age is equivalent in mortality risk to an increase of 1 point on the comorbidity score. Thus, an individual who is 75 with a comorbidity score of 0 has the same five-year predicted risk of dying as an individual who is 65 with a comorbidity score of 1.

Accounting for mortality risk as predicted by Charlson index

To examine the unadjusted and adjusted five-year predicted risk of glaucoma using the Charlson index, we selected three sets of hypothetical values for IOP, CCT, PSD, and vertical C/D ratio and examined how the patient's unadjusted and adjusted risk for these values varied at different ages and comorbidity scores (see Table 3). As a patient's Charlson comorbidity score increases, their adjusted risk for developing glaucoma in the next five-years or before

they die decreases. For example, a 75-year old with IOP of 30 mmHg, CCT of 550 μ m, PSD of 1.9 db, and vertical CD ratio of 0.8 has an unadjusted five-year risk of glaucoma based on the OHTS/EPGS calculator equal to 51.0%. This same patient has a mortality adjusted glaucoma risk of 46.9% when he/she has a comorbidity score of 0, a mortality adjusted risk of 41.8% with a comorbidity score of 1, and a mortality adjusted risk of 20.2% with a comorbidity score of 3. Thus, in this case, mortality adjustment can dramatically decrease the patient's five-year risk of developing glaucoma when the patient has moderate to significant comorbidities. Conversely, the average high risk patient from the OHTS study¹ at 65 years of age with IOP of 27.9 mmHg, CCT of 532 μ m, PSD of 1.98 db, and vertical CD ratio of 0.48 has an unadjusted five-year risk of glaucoma based on the OHTS/EPGS calculator equal to 38.4%. This same patient has a mortality adjusted glaucoma risk of 37% when he/she has a comorbidity score of 0, and a mortality adjusted risk of 24% with a comorbidity score of 3. Thus, in this case the mortality adjustment from a clinical perspective is much less dramatic since the patient had a very low unadjusted risk.

Figure 2 shows how the five-year risk of glaucoma varies with age and comorbidity score for patients with IOP of 30 mmHg, CCT of 550 μ m, PSD of 1.9 db, and vertical CD ratio of 0.8. The unadjusted five-year risk of developing glaucoma increases with age (shown by the black line) because older age is associated with a greater risk of developing glaucoma. However, since the risk of death also increases with age, the age group at highest risk of developing glaucoma for the adjusted risk curves is not necessarily the oldest. For example, for an individual with a Charlson index of 3 (line marked by diamonds), the 5-year risk of developing glaucoma is highest at age 55.

Table 3 also quantifies the impact that mortality adjustment might have on treatment decisions made by clinicians for our hypothetical patients assuming the clinician treats patients with a risk of 20% of developing glaucoma in the next 5 years (treatment threshold of 20). Areas in grey in the table indicate times when treatment would not be recommended under the 20% treatment threshold. The impact of mortality risk adjustment on treatment decisions depends on how close the patient's unadjusted risk is to the treatment threshold and the value of the patient's comorbidity score. In general, for patients 1 through 4, treatment decisions do change once a patient has a certain comorbidity score. For example, prior to using mortality adjustments, the patient who is 75 years old, has an IOP of 30 mmHg, CCT of 550 μ m, PSD of 1.9 db, and vertical CD ratio of 0.8, treatment would clearly be recommended because the patient has an unadjusted five-year risk of glaucoma equal to 51.0%. However, once the risk calculations take into account mortality risk, this patient would only be recommended for treatment if his/her comorbidity score was less than or equal to 3. Conversely, treatment decisions under the 20% treatment threshold do not change for patients whose unadjusted risk is already below the treatment threshold of 20% such as when patient 3 is 55 years-old.

Discussion

Our results show that incorporating mortality risk always reduces five-year risk of glaucoma. However, the impact of that reduction varies depending on the patient's unadjusted risk for glaucoma and the severity of the patient's health. After accounting for reduced life expectancy, ocular hypertensive patients who have high unadjusted risk of glaucoma, who are elderly, and who have comorbidities have a dramatically lower risk of developing glaucoma than estimated from unadjusted glaucoma risk calculators which do not account for life expectancy. Among these patients, the impact on treatment decisions will also be greatest since a patient may quickly move to a low level of risk after mortality risk is taken into account. Our results suggest that clinicians may want to consider the mortality risk of such persons when deciding whether to initiate glaucoma treatment.

Distributions of Charlson Index scores are hard to find for the general population. However, there are two large studies which do report the distribution of Charlson index scores.^{15, 16} In the first study, Charlson scores for over 400,000 low-income Medicare enrollees in two states are presented with the first state having a mean score of 1.3 (standard deviation = 1.8; median = 0; 75th percentile = 2) and the second having a mean of 1.8 (standard deviation = 2.0; median = 1; 75th percentile = 3).¹⁵ In the second study, Charlson scores for over 140,000 post-menopausal women enrolled in the Women's Health Initiative Study were presented, broken down by two age groups.¹⁶ Among women ages 50 to 64, 68% had a score of 0, 19% a score of 1, 9% a score of 2, and only 4% a score greater than or equal to 3. Among women ages 65 to 79, 59% had a score of 0, 22% a score of 1, 13% a score of 2, and 6% a score greater than or equal to 3. Given these numbers, it appears that the percent of the general population with comorbidity scores greater than or equal to 3 could range anywhere from 4 to 25%. However, the populations from these two studies are not easily generalizable to elderly ocular hypertensive patients. We conjecture that the majority of ocular hypertensives would have Charlson scores of 0 and 1 (1 since a handful of ocular hypertensives have diabetes).

The American Geriatrics Society recommends that clinicians take into account a patient's life expectancy when making medical decisions.¹⁷ However, studies show that clinicians may not be able to accurately estimate life expectancy using their implicit judgment. In a study that compared 18 physicians' implicit judgment of life expectancy in 70 patient scenarios against a common measure of life expectancy based on comorbidities, the physicians' estimates ranged from an underestimation of 33% to an overestimation of 4%.¹⁸ Some of these physicians gave different estimates of life expectancy for scenarios of patients with the same characteristics, suggesting that their implicit estimates of life expectancy have poor intra-rater reliability. In another study, some providers were able to make accurate predictions of death, while a substantial minority gave inaccurate estimates.¹⁹ Explicit measures of life expectancy as utilized in this study are likely to be more accurate and reliable than implicit measures.

Some previous approaches to considering life-expectancy in treatment decisions use a sequential approach. For example, guidelines for prostate cancer recommend different treatment depending on whether a patient is expected to live at least 10 years.²⁰ However, these rules may have undesirable threshold effects. For example, it is possible that treatment is recommended for a lower risk case with an 11-year life expectancy, but not for a higher risk case with a 9-year life expectancy. In order to avoid these threshold effects, we describe a methodology that more fully integrates mortality risk in the form of an adjusted risk of glaucoma. We note here that we are not recommending a particular risk threshold to use; instead we are illustrating a new technique to explicitly estimate a patient's five-year risk of glaucoma adjusting for the risk of mortality within the same time span.

There are several limitations to the study. First, we assumed that time to glaucoma development and time to death are independent. The evidence supporting this assumption is mixed. One large study reported that glaucoma patients have an increased mortality rate after adjusting for a number of basic demographic and health status variables,²¹ while other studies found no significant association between the two.^{22–24} Unfortunately, we could not assess the association in our study since the actual data used to create our glaucoma and mortality risk estimators is unavailable to us. If our assumptions are not true, then our results will underestimate the impact of life expectancy. Second, the current risk calculators address the risk of developing glaucoma whereas the more clinically important risk is the risk of developing visual disability from glaucoma. Unfortunately, no tools are currently available to compute the risk for developing visual disability from glaucoma. Third, the threshold to initiate treatment based on the predicted risk of developing glaucoma – either adjusting for mortality risk or not – is still not well-established, thus we cannot make explicit treatment recommendations based on our findings. Because glaucoma treatment may have relatively few adverse effects, and

some patients will live longer than what the life expectancy measures predict, it may not be unreasonable for clinicians to initiate treatment in very high-risk ocular hypertensive patient even when the predicted life expectancy is quite short. Also, while the explicit measures of life expectancy explored in this study, the Charlson index, is the most commonly used and well-validated,¹³ some variables – such as race/ethnicity and socioeconomic status are not used in this measure, even though they have a strong association with life expectancy.^{25, 26}

We note that it is not possible to provide 95% confidence intervals for our results shown in Table 2 and Table 3 since our calculations depend on using prediction models for which standard errors are not available. Publications on the OHTS/EPGS risk calculator and Charlson Index do not provide readers with such measures and it is not possible to incorporate such error into our model. We are also unable to validate the mortality adjusted risk estimates on actual population data since such data is not available. It would be beneficial to do such validation studies in the future.

In summary, incorporating mortality risk into estimates of five-year glaucoma risk for ocular hypertensive patients can substantially lower the risk of a patient's developing glaucoma before death. Given its importance, we believe that explicit measures of life expectancy such as the Charlson Index provide important information to clinicians when deciding whether to treat ocular hypertensive patients. We advocate wider use of explicit measures of life expectancy in risk calculations and further research to determine how clinicians can best use life expectancy information in their medical decision-making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Computing mortality adjusted five-year risk of developing glaucoma. Top Panel describes the simple unadjusted multistate model for development of glaucoma. The bottom panel described the competing risk multistate model for development of glaucoma in the presence of death.

Figure 2.

Unadjusted and mortality adjusted five-year risks of developing glaucoma by age and Charlson comorbidity score for patients with a cup/disc ratio of 0.8, IOP of 30 mm Hg, CCT of 550 μ m, and PSD of 1.9 dB.

Table 1

Weighted Index of Comorbidities for Charlson Index.

Charlson index	
Conditions	Assigned Weights for Diseases
Myocardial infarct; Congestive heart failure; Peripheral vascular disease; Cerebrovascular disease; Dementia; Chronic pulmonary disease; Connective tissue disease; Ulcer disease; Mild liver disease; Diabetes	1
Hemiplegia; Moderate or severe renal disease; Diabetes with end organ damage; Any tumor; Leukemia; Lymphoma	2
Moderate or severe liver disease	3
Metastatic solid tumor; AIDS	6

Table 2

Five-year mortality risk based on Charlson Comorbidity Score.

	Age 55	Age 65	Age 75	Age 85
Charlson Comorbidity Score				
0	2.2%	5.3%	12.6%	28.1%
1	5.3%	12.6%	28.1%	55.6%
2	12.6%	28.1%	55.6%	86.5%
3	28.1%	55.6%	86.5%	99.3%
4	55.6%	86.5%	99.3%	100.0%
5	86.5%	99.3%	100.0%	100.0%
6	99.3%	100.0%	100.0%	100.0%

Table 3

Unadjusted and mortality adjusted predicted 5-year risk of developing glaucoma for 55-, 65-, 75- and 85-year-old patients with different values of IOP, CCT, PSD, and vertical CD ratio by Charlson Comorbidity Score. Grayed areas indicate that there would not be a recommendation to treat if one uses a 20% fixed treatment threshold above which treatment would be always be recommended.

	Age 55	Age 65	Age 75	Age 85
Patient 1: (30 mmHg, 500 μm, 1.9 db, 0.8)				
<i>Unadjusted Risk</i>	66.5%	74.9%	82.5%	88.9%
<i>Mortality Adjusted Risk by Charlson Comorbidity Score</i>				
0	65.6%	72.5%	76.7%	75.5%
1	64.4%	69.3%	69.4%	61.8%
2	61.4%	62.4%	55.9%	43.3%
3	55.1%	49.6%	38.0%	26.9%
4	43.3%	32.8%	22.6%	18.4%
5	28.0%	18.8%	14.9%	17.4%
6	15.5%	12.1%	14.1%	17.4%
Patient 2: (30 mmHg, 550 μm, 1.9 db, 0.8)				
<i>Unadjusted Risk</i>	36.1%	43.2%	51.0%	59.3%
<i>Mortality Adjusted Risk by Charlson Comorbidity Score</i>				
0	35.6%	41.7%	46.9%	48.9%
1	34.8%	39.6%	41.8%	38.2%
2	33.1%	35.2%	32.4%	24.2%
3	29.4%	27.2%	20.2%	13.1%
4	22.5%	16.7%	10.7%	8.1%
5	13.7%	8.6%	6.5%	7.5%
6	7.0%	5.2%	6.0%	7.5%
Patient 3: (26 mmHg, 550 μm, 1.9 db, 0.6)				
<i>Unadjusted Risk</i>	19.7%	24.2%	29.4%	35.6%
<i>Mortality Adjusted Risk by Charlson Comorbidity Score</i>				
0	19.4%	23.3%	27.0%	29.0%
1	19.0%	22.1%	23.9%	22.2%
2	18.0%	19.6%	18.3%	13.5%
3	15.9%	14.9%	11.0%	6.9%
4	12.1%	8.9%	5.5%	4.1%
5	7.2%	4.4%	3.2%	3.8%

	Age 55	Age 65	Age 75	Age 85
6	3.5%	2.6%	3.0%	3.8%
Patient 4: (25 mmHg, 573 μm, 1.9 db, 0.39)				
<i>Unadjusted Risk</i>	8.7%	10.9%	13.6%	16.8%
<i>Mortality Adjusted Risk by Charlson Comorbidity Score</i>				
0	8.6%	10.5%	12.4%	13.6%
1	8.4%	10.0%	11.0%	10.3%
2	8.0%	8.8%	8.3%	6.1%
3	7.1%	6.7%	4.9%	3.0%
4	5.3%	3.9%	2.4%	1.7%
5	3.1%	1.9%	1.4%	1.6%
6	1.5%	1.1%	1.3%	1.6%