

## Ocular Hypertension Treatment

The Ocular Hypertension Treatment Study (OHTS), of which the University of Louisville is a study site, is embarking on Phase III of its goal to establish guidelines for treatment of patients with ocular hypertension. The OHTS is a multicenter, prospective, randomized, controlled clinical trial initially studying more than 1800 research subjects, evaluating the safety and efficacy of medical treatment in preventing or delaying the onset of visual-field loss and/or optic nerve damage in patients with ocular hypertension who are at moderate risk for developing primary open-angle glaucoma (POAG).

During Phase I of the OHTS half of the patients were randomized to medical therapy. Results showed that progression to glaucoma increases with higher IOPs, lower central corneal thickness (CCT), enlarged baseline vertical cup-to-disc ratio, and increased age. Over a 5-year-period, patients with ocular hypertension and IOP levels of 24 mm Hg or more have a 10% overall risk of developing glaucoma. This risk can be cut in half by medical treatment. A calculator was developed to estimate the 5-year risk that an individual with ocular hypertension will develop primary open angle glaucoma (POAG): <http://ohts.wustl.edu/risk>

Phase II of the OHTS, during which all patients received treatment, demonstrated that delayed treatment of patients with ocular hypertension quickly reduced their risk to development of POAG to the level

of the early treatment group. The true goal of managing patients with ocular hypertension is not just to prevent the onset of POAG, but to prevent functional limitations associated with the disease. Given the large number of patients with ocular hypertension, reaching this goal requires risk stratification to use medical resources in a cost-effective manner.

OHTS Phase III will re-examine study participants 20 plus years after enrollment to document clinical status and the incidence and severity of self-reported functional limitations. The 279 participants who developed POAG in OHTS Phase 1 or 2 will have more than 10 years of post-POAG follow-up by Phase 3. The timing of re-examination at 20 years is meaningful because 20 years approaches the median life expectancy of OHT patients in their 60's and 70's and half the median life expectancy of patients in their 40's and 50's. For the first time, patients with ocular hypertension and clinicians will have high quality data about the long-term risk of developing POAG and functional limitations associated with the disease. These data will facilitate patient-centered care so that patients and clinicians can decide on the appropriate frequency of tests and examinations and the potential benefit of preventative treatment

Three key goals must be accomplished to develop evidence-based, 20-year guidelines for the management of patients with ocular hypertension:

- 1) Determine the 20-year incidence and severity of POAG in the OHTS cohort.
- 2) Develop a 20-year prediction model for stratifying OHT patients by their risk for developing POAG and, among those who developed POAG, a prediction model for the rate of visual field loss.
- 3) Determine the frequency and severity of self-reported functional limitations associated with POAG.

The frequency and severity of self-reported functional limitations (SF-36, NEI VFQ, Nelson glaucoma survey, self-reported falls and vehicle accidents, Owsley Driving Habits Survey) in participants who did/did not develop POAG will be compared to differentiate functional limitations associated with POAG from normal aging and other co-morbidities. Self-reported functional limitations will be correlated with socio-demographic factors and clinical measures (ETDRS visual acuity, Pelli Robson contrast sensitivity, mean deviation) of the eye with the better mean deviation. We will examine the association of the rate and duration of visual field loss on self-reported functional limitations.

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