Modern Retina

New telemonitoring device makes impact in detecting CNV

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Take-home: Home monitoring of patients with age-related macular degeneration results in earlier detection of choroidal neovascularization with the ForeseeHome device resulted and increased preservation of vision.

Reviewed by Michael J. Elman, MD

Dr. Elman **Baltimore–**Telemonitoring technology has expanded over the years to include more and different patient populations. Data accumulated from recent studies, like the Comparison of AMD Treatments Trials (CATT) study, provide clear evidence to the importance of early detection and the initial treatment for neovascular AMD (nvAMD).

In the Age-Related Eye Disease 2-HOME Study, the investigators used telemonitoring via a home-monitoring device to evaluate the effectiveness of the early detection of nvAMD–with the goal of determining if such a step could improve the detection of choroidal neovascularization (CNV) compared with the standard care of patients in retina clinics.

Michael J. Elman, MD, who is in private practice in Baltimore, addressed three topics:

1) Why early nvAMD detection is important;

2) Current status of nvAMD detection;

3) Findings from the HOME study that evaluated a solution to improve that detection.

Early detection important

When considering the importance of early detection, "the earlier the better" was the resounding finding. Dr. Elman first looked at the data from the CATT study. Basically, he found that the time point at which the detection process starts influences the visual end point for patients.

"Patients with CNV want to end up at 20/20," Dr. Elman emphasized. "However, usually this is not realistic. The better the vision at the start of treatment, the better the 1- and 2-year outcomes will be, according to the CATT."

In addition to the CATT study results, this was also true in the UK Neovascular AMD EMR data at 2 years. The 5-year visual acuity data from an Australian observational study showed the same pattern.

"The theme is the same," Dr. Elman said. "The better the vision at baseline, the better the 5-year outcome will be with treatment."

The driving force behind these consistent findings seems to be visual acuity and lesion size at baseline. In the CATT study, the better the vision and the smaller the lesion size at diagnosis, the better the visual acuity was after 1 year of treatment.

Current status of nvAMD detection

Current status of nvAMD detection

Periodic monitoring of AMD patients during pre-scheduled office visits is the standard of care. In between scheduled visits, physicians rely on at-risk patients to present for examinations once patients realize that symptoms are present.

Dr. Elman noted that physicians depend on these elderly patients to use rudimentary tools, such as the Amsler grid, to monitor visual changes in between office visits. This raised the question regarding the effectiveness of this form of monitoring to identify CNV.

Results from studies published between 2000 and 2013 showed that only a limited number of eyes (about 40%) were diagnosed with CNV with a visual acuity of 20/40 or better, Dr. Elman demonstrated. Monitoring based on patient realization of symptoms plus periodic routine eye exams seemed inadequate.

Road to improved early nvAMD detection

The randomized HOME Study, conducted by the National Eye Institute in 44 U.S. centers, tested the efficacy of CNV monitoring using the ForeseeHome device (Notal Vision) plus standard care compared to control for standard care alone.

The study population included patients who had one or more large drusen (125 μm or larger) with visual acuity that was at least 20/60 and no nvAMD in testing eye(s).

“The AREDS criteria considered patients at high risk if they had only 1 drusen that was 125 μm,” Dr. Elman pointed out. “Physicians are likely overlooking many of these high-risk patients using standard monitoring practices.”

The HOME study included 1,520 patients, 763 of whom were randomized to the device arm and later analyzed by 3 groups based on frequency of their testing; and 757 to the standard care arm. The mean visual acuity at study entry was 20/25 and patients were followed for a mean of 1.4 years.

“We found that in the device arm, 51 CNV events were detected compared with only 31 CNV events in the standard care arm, with significantly less visual acuity loss from their baseline vision” Dr. Elman said,

The difference occurred, he explained, because in the device arm CNV events accumulated and were detected earlier. As a result, the Data and Safety Monitoring Committee (DSMC) recommended that the study be terminated early because of ethical considerations–that is, it was no longer considered ethical to continue the study randomization.

Importantly, the patient compliance with the use of the device was good and described as “constant” throughout the study at mean of 4 to 5 times each week during the follow-up period.

The study data showed that the DSMC terminated the study because of the visual deterioration in the standard care group. “Thirty patients lost a median of 9 letters from baseline compared to the intention to treat group (n = 51 patients) that lost a median of 4 letters,” Dr. Elman said.

Reaching significance

The difference between the two reached significance ($p = 0.021$). When compared with the patients who used the device as recommended at least 2 times per week (Per Protocol Treatment group 1 and 2), there was a difference of 6 letters between the device arms and the standard care arm ($p = 0.007$).

In maintaining the level of visual acuity with frequent monitoring, more patients in the device arm had visual acuity of 20/40 or better at the time the CNV was detected, increasing from 87% to 94% with more use of the device compared with 62% in the standard care group.

“The result was an increase of from 43% to 51% in the likelihood of maintaining good functional vision at 20/40 or better,” Dr. Elman said.

He explained that compared with other studies, the results in the HOME Study were superior to the studies published between 2000 to 2013. “This is so because the lesions are being identified when they are still small–0.23-disc area in the device arm compared with 0.7-disc area in the standard care group ($p < 0.05$),” he added. “With much smaller lesions, there is less fibrosis and less scarring, better vision and better potential.”

The study found that in contrast to the current home-monitoring strategies, patients do benefit from home monitoring with the device to detect CNV earlier. The benefits include better visual preservation with CNV detection with 87% to 94% of patients have 20/40 or better visual acuity and smaller lesions and a better chance of maximizing the visual acuity results after intravitreal injections of anti-vascular endothelial growth factor drugs.

“We definitely can do a better job,” Dr. Elman concluded. “While we fight over which treatment is better for preserving a few letters of vision, we must remember the big picture.

“We should stop fighting over letters when optimizing treatments, when we should be doing a better job in upstream management, focusing on early detection, at which point we can save lines of vision,” Dr. Elman concluded. “Saving lines means more patient independence. They can drive and have less depression. Saving lines of vision may actually save lives.”

Michael J. Elman, MD

Dr. Elman is a consultant to Notal Vision Inc., which sponsored the HOME study. This article is based on his presentation at the 2015 American Academy of Ophthalmology meeting.

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