Tear film osmolarity excels in characterising the severity of dry eye disease

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A NEW proprietary device for measuring tear film osmolarity (TearLab™ Osmolarity System, TearLab Corporation) appears to be a useful advance in diagnosing dry eye disease (DED) and assessing its severity, reported investigators at the XXVII Congress of the ESCR.

Jesus Fraile-May MD, Department of Ophthalmology, Hospital Clínico San Carlos, Madrid, Spain, reported a study comparing the osmolarity test and several other assessments conventionally used in the evaluation of DED. A continuous variable analysis of data collected in 277 subjects showed the osmolarity test was superior to the Ocular Surface Disease Index (OSDI), tear film break-up time (TBUT), meibomian gland dysfunction scoring, Schirmer test, and ocular surface staining scores. In particular, tear osmolarity was the only test that performed linearly in discriminating patients with mild to moderate DED whereas the other tests showed good utility primarily for identifying severely affected patients.

“Dry eye disease is a chronic and progressive condition estimated to affect approximately 100 million people worldwide, but persons with mild to moderate disease represent more than 90 per cent of this patient population. Our study reinforces that traditional dry eye tests exhibit no correlation to disease severity in the mild to moderate range whereas osmolarity effectively characterises these patients,” said Dr Fraile-May.

Measurement of tear osmolarity with the new system is done using a handheld instrument to obtain a 50-nl sample from the inferior tear lake near the lateral canthus. Collection of the specimen is completed in just a fraction of a second without disturbing the tear film onto a disposable lab-on-a-chip that also performs the analysis. A read-out is quickly generated by a separate desktop machine.

The study reported by Dr Fraile-May included patients enrolled at 13 clinical sites across Europe, the US, and in Japan. DED severity for each patient was graded using a modified version of the Dry Eye WorkShop (DEWS) severity scale. Tear osmolarity and the five other parameters were equally weighted and then normalised on a scale of zero to one where zero represents normal, and mild to moderate disease was defined as a score of 0.2 to 0.4.

Results of the continuous variable analysis showed roughly a linear relationship between tear film osmolarity and disease severity with much less data spread and a higher correlation value compared with any of the other dry eye assessments.

Schirmer test data showed that while most patients with a severity score > 0.4 were likely to have a low score (<10mm wetting), such a result was also obtained in a high proportion of patients in the mild to moderate cohort, and the correlation between disease severity and the Schirmer result was poor. Similarly, for TBUT, all patients with a severity score > 0.4 showed a very unstable tear film with a TBUT of about six seconds or less. However, about half of the subjects categorised in the normal to moderate cohort also had a TBUT < 6 seconds.

Correlations were better between disease severity and both corneal staining and the OSDI, but again these tests had less than ideal discriminative value. Staining scores showed significant variability within the mild to moderate cohort and even among patients with more severe disease, although the latter individuals tended to exhibit large amounts of staining that contributed to a better correlation between this parameter and DED severity. The OSDI data showed that patients with mild to moderate disease were about as likely as those with worse severity to be experiencing more symptoms, reported Dr Fraile-May.

Michael A Lemp MD, Washington, DC, is a co-author of the study and DEWS organiser. He told EuroTimes, “Of the approximately 15 tests that are traditionally used to diagnose DED, none are very good at identifying and differentiating patients with mild to moderate severity. For example, within this sub-population, a very low percentage of patients exhibit ocular surface staining, and Schirmer test results are often variable. Furthermore, Schirmer test only captures persons with DED due to aequous deficiency, not those with evaporative disease.

“Symptom severity shows poor correlation with disease severity given the tremendous psychological overlay influencing this subjective parameter, and while TBUT should be a good discriminator because tear film instability correlates well with osmolarity, obtaining valid data depends on a high degree of detail in performance.”

Dr Lemp noted that the analysis reported by Dr Fraile-May has practical significance for guiding management decisions considering that the DEWS panel developed recommendations for a stepwise therapeutic approach to DED based on its severity level.

He also told EuroTimes that ophthalmologists could look forward to more information from additional analyses of tear film osmolarity data collected as part of this very large study, including a forthcoming diagnostic algorithm.

“Based on our findings, we don’t think patients should be evaluated with osmolarity alone. However, it seems to be the single best test for identifying persons with early DED and the best tool for assessing severity of the disease. We believe the diagnosis should not be made without knowing osmolarity.”

The findings from the osmolarity studies are also causing DED experts to change their perspective about the disease process, said Dr Lemp.

“Previously, dry eye was considered a binary disease – either you have it or you don’t. Now we understand that, like glaucoma, DED is more of a continuum and that there is a grey zone where people begin to develop an increased probability of having DED and can be identified by changes in tear film osmolarity, reflecting their inability to maintain osmolarity homeostasis in response to environmental stresses via intrinsic compensatory mechanisms.”

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