ONLINE EXCLUSIVE

Marc Labetoulle

Following the hugely successful 10th Tear Film & Ocular Surface Society (TFOS) 2024 Conference which took place in Venice, Italy between 30 October – 2 November, we managed to have a quick Q&A with presenting attendee, Marc Labetoulle.

Delivering his talk on 'Nutrition' as part of the 'Ocular surface disease: What we do to ourselves' session, Dr Labetoulle is the General Secretary of the French Society of Ophthalmology (SFO) and the Head and Chair of the Ophthalmology Department at Bicêtre Hôpital, Paris-Saclay University.

Dr Labetoulle also featured an ePoster highlighting the multicentre trial findings of a comparison of two preservative-free artificial tears with sodium hyaluronate for the relief of dry eye, showing that lipid containing sodium hyaluronate with carbomer and triglycerides was noninferior to the aqueous-based tear substitute in the studied population and may offer additional advantage in ameliorating symptoms of dry eye. We were lucky to speak to him about his findings.

What was the primary goal in comparing these two preservative-free artificial tear formulations for dry eye relief, and how was the study structured across multiple centres?

The aim of the study was comparing the performance and safety in patients with moderate to severe dry eye disease of a preservative-free tear substitute composed of 0.24% sodium hyaluronate (SH) with carbomer and triglycerides (SH-CB-TG) with another preservative-free 0.18% SH tear substitute.

Could you describe the key differences between the multicomponent 0.24% SH-CB-TG eye drop, and the aqueous-based comparator (C-SH) with 0.18% SH?

The study product is a solution of 0.24% SH, carbomers, medium chain triglycerides, glycerol and sodium hydroxide, thus expected to provide both mucomimetic properties (high concentration of SH and presence of carbomers) and enhanced stability of the tear film (thanks to the presence of triglycerides). The comparator product is a usual tear substitute containing the common concentration (0.18%) of SH. Both of them were non-preserved products.

Your study concluded that SH-CB-TG was noninferior to the aqueous-based substitute. What were some of the specific measures or outcomes that led to this finding?

The primary endpoint was from a change in baseline in the ocular surface fluorescein staining (OSFS) score (0–15 per the extended Oxford scheme) on day 28. According to the non-inferiority nature of the study, the analysis was made using the per-protocol population. The primary endpoint was met with groups within the non-inferiority margin of 2 grades (after 28 days, the OSFS score decreased by a mean (±SD) of 2.1 (± 1.7) from a baseline of 5.7 (± 1.2) in the SH-CB-TG group and by 1.5 (± 1.6) from a baseline of 5.8 (± 1.3) in the control group.

In terms of patient-reported outcomes, did the multicomponent SH-CB-TG show any unique advantages or additional benefits over the aqueous-based formulation?

A significant difference was observed between the two groups concerning a quality-of-life questionnaire (named OSD-QoL questionnaire) that had been previously validated in several studies to explore the burden of ocular surface diseases.

What are the potential implications of your findings for clinicians in selecting between lipid-containing and aqueous-based tear substitutes, especially for patients with chronic dry eye?

The favourable results in the SH-CB-TG group concerning the questionnaire on quality-of-life suggest that the presence of high concentration of SH together with lipids and carbomers participate in the relief of symptoms.

As preservative-free artificial tears become more widely used, do you think this study will influence how eyecare providers approach dry eye management in patients with sensitivity to preservatives?

The use of preservative-free tear substitutes has already become part of care in several countries, based on the numerous studies that showed the deleterious consequence of a chronic instillations of preservatives, especially when benzalkonium chloride is used.

Looking ahead, are there additional aspects of artificial tear formulations you believe warrant further investigation to improve outcomes for dry eye patients?

Together with the sensation of stinging / burning / presence of foreign body in the eyes, which is explored by the questionnaires, one of the more annoying consequences of DED for patients is the unstable quality of vision due to the very unstable tear film on the ocular surface. This is however still difficult to assess, even in the context of clinical trials, but would deserve to be more accurately explored in the future.

INTERVIEWEE

Marc Labetoulle,

Professor of Ophthalmology, Hospital Bicêtre and Quinze-Vingts Hospital, Paris-Saclay University, France.

Declaration of competing interests: Marc Labetoulle has been expert consultant / expert during the last five years for: Alcon, Allergan-Abbvie, Amgen, Baush + Lomb, Biotest, DMG, Horus, Marinomed, Merck, MSD, Novartis, Quantel, Santen, Shire, Topivert, Théa.