

## The anti-inflammatory effect of isotonic glycerol in Sjögren's syndrome-related dry eye

*Huba J. Kiss, Agnes Fust, Zoltan Z. Nagy, Janos Nemeth*

**Purpose:** In patients suffering from Sjögren's syndrome, eye surface staining is more prominent, tear secretion is decreased, and subjective symptoms are significant. First-line therapy of this disease is tear supplementation. In case of corneal complications or serious subjective symptoms, topical or systemic anti-inflammatory therapy may be advantageous. The chronic use of both topical and systemic anti-inflammatory drugs may cause various side effects.

**Methods:** 21 patients (18 female, 3 male) were enrolled into our prospective, unmasked, self-controlled study (ISRCTN17717813). The mean age of patients was  $60.4 \pm 11.4$  years. All patients fulfilled our inclusion criteria: lid parallel conjunctival folds (LIPCOF) > grade 1, lissamine green staining in Oxford scheme grade > grade 2, decreased tear secretion, clinically significant subjective symptoms [ocular surface disease index (OSDI)], diagnosis of Sjögren's syndrome. All subjects used different artificial tears before the study. During the study period, the subjects used a preservative-free, unit-dose artificial tear, Conheal<sup>®</sup>, containing isotonic glycerol and 0.015% sodium hyaluronate four times a day for three months. The patients had three visits during this period. Ordinal data and non-normally distributed data were analyzed by non-parametric Wilcoxon Signed Rank Test, meanwhile, normally distributed data were compared by Paired T Test using SPSS Statistics 22. The number of participants was verified by power analysis.

**Results:** The three-month long continuous use of Conheal<sup>®</sup> resulted in a decrease of the LIPCOF degree from an initial value of  $2.48 \pm 0.75$  on the right eyes and  $2.57 \pm 0.75$  on the left eyes to  $1.33 \pm 0.73$  and  $1.38 \pm 0.67$ , respectively ( $P_{\text{right}} < 0.001$ ,  $P_{\text{left}} < 0.001$ ). The initial lissamine green staining of the eye surface also decreased significantly ( $P_{\text{right}} = 0.001$ ,  $P_{\text{left}} < 0.001$ ) from  $1.76 \pm 0.89$  and  $1.95 \pm 0.86$  to  $0.29 \pm 0.56$  and  $0.29 \pm 0.56$ , respectively. There was a significant decrease ( $P < 0.001$ ) in the OSDI values from  $55.81 \pm 15.19$  to  $32.54 \pm 19.51$ . Tear secretion did not change significantly ( $P_{\text{right}} = 0.38$ ,  $P_{\text{left}} = 0.45$ ).

**Conclusions:** Our results show that using the investigated artificial tear resulted in a significant improvement of the subjective and objective symptoms of the Sjögren's syndrome-related dry eye disease, without the need of anti-inflammatory agents. We suspect, based on in vitro experiments, that isotonic glycerol-induced decrease of HLA-DR expression may be responsible for this favorable effect.