The PERSPECTIVE study: use of cyclosporine A 0.1% eye drop cationic emulsion in patients with dry eye disease and severe keratitis in the real-world setting – patient demographics and baseline characteristics

Gerd Geerling[1], Samer Hamada[2], Stefan Trocmé[3], Sten Ræder[4], Claudia Fassari[5], Ines Lanzl[6]

[1]Department of Ophthalmology, University Hospital Duesseldorf, Duesseldorf, Germany
[2]Queen Victoria Hospital, East Grinstead, United Kingdom
[3]Aleris Specialistvård Sabbatsberg, Europakliniken Department of Ophthalmology Sabbatsbergs Hospital Stockholm, Sweden
[4]The Norwegian Dry Eye Clinic, Oslo, Norway
[5]Santen SA, Geneva, Switzerland
[6]Chiemsee Augentagesklinik, Prien, Germany

Purpose

The PERSPECTIVE study was a 12-month European, multicentre, non-interventional, prospective clinical study to evaluate (in routine clinical practice) the effectiveness, tolerability and safety of cyclosporine (CsA) 0.1% eye drop emulsion in controlling severe keratitis, in adult dry eye patients who have not improved despite treatment with tear substitutes. Data presented here provide a summary of the final study population demographics and clinical characteristics at baseline.

Methods

Baseline data were prospectively collected between 11 April 2017 and 14 November 2019 at 44 ophthalmology clinics based in Finland, Germany, Norway, Sweden and the UK. The primary study endpoint was change in the grade of corneal fluorescein staining (CFS), from baseline to 12 months, following initiation of CsA 0.1% eye drop emulsion treatment.

Inclusion criteria

- Adults (aged ≥18 years)
- Diagnosis of DED and severe keratitis according to DEWS II criteria
- Currently treated with artificial tears (ATs)

Exclusion criteria

- CsA eye drop emulsion treatment
- Immunosuppressant treatment (within 6 months)
- Eye surgery
- Pregnancy or nursing

Baseline measures

- Patient demographics and characteristics:
  - Sex
  - Age
  - Associated systemic disease
  - Previous steroid use
  - Frequency of AT use
- Reported clinical signs:
  - CFS (Oxford grade scale)
  - Schirmer's test
  - Tear film breakup time (TBUT)
- Subjective symptoms
- Reasons for changing to CsA 0.1% eye drop emulsion therapy

Results

Patient demographics and associated systemic disease

The study included 471 subjects

Most frequent reasons for initiating CsA 0.1% eye drop emulsion:

- Insufficient keratitis/DED control with prior medication 79.8%
- Keratitis/DED progression 22.7%

Table 2. Associated systemic disease

Systemic disease, n (%)	Measure
Diabetes	33 (7.0)
Rheumatologic diseases	65 (13.8)
Primary Sjogren syndrome	41 (8.7)
Other:	229 (48.6)
Hypertension	67 (29.3)
Thyroid disorders	55 (24.0)
Hypercholesterolemia	29 (12.7)
Allergy	16 (7.0)
Asthma	15 (6.6)

Table 1 Patient demographics

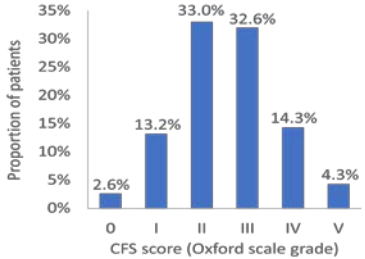
Demographics	Patients, n (%)
Male	114 (24.2)
Female	357 (75.8)
Age (mean ± SD)	61.9 ± 15.41 years

Table 3. Concomitant DED medications

Medications	Patients, n (%)
Baseline steroids	36 (7.6)
Daily artificial tear use:	
Once	203 (23.4)
Twice	63 (7.3)
3 times	107 (12.3)
4 times	108 (12.4)
5 times	83 (9.6)
6 times	60 (6.9)
As needed	122 (14.0)

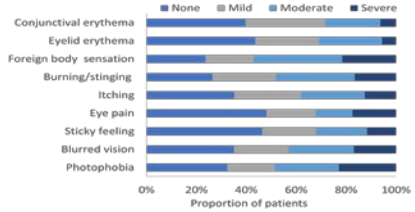
Objective and subjective measures at baseline

Figure 1. CFS score at baseline



- Schirmer's test (mean ± SD) (n=171) 9.95 ± 9.69 mm
- VA decimal score (mean ± SD) (n=453) 0.65 ± 0.36
- TBUT (mean ± SD) (n=350) 4.25 ± 2.97 seconds

Figure 2. Severity of objective and subjective measures



Discussion

Participants included in the PERSPECTIVE study population represent the spectrum of DED and severe keratitis patients that may seek treatment from ophthalmology clinics in the real-world setting. The reported population was typically female and average age was 45–75 years. Mean CFS score (Oxford scale grade) was 2.56 and most (81.4%) reported scores below IV. Approximately 15% of patients recruited demonstrated a CFS score ≤I, reflecting the real-world nature of the study. Severe clinical signs and subjective symptoms were found in relatively few patients. T use was frequent and insufficient disease control was the main reason for initiating CsA 0.1% eye drop emulsion treatment

Conclusions

The data presented provide an indication of the population likely to attend ophthalmology clinics for relief from symptoms of DED and severe keratitis, despite treatment with AT or steroids. Once published, the full study results will provide important real-world insights regarding the effectiveness, tolerability and safety of CsA 0.1% eye drop emulsion in controlling the signs and symptoms DED and severe keratitis.

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