EVALUATION OF THE SAFETY AND TOLERANCE OF THE COMMERCIAL PRESENTATION OF CICLOSPORINE 0.1% COLLYRIUM

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BACKGROUND

Ciclosporine collyrium is used in the treatment of severe keratitis in adult patients with xerophthalmia who did not improve despite the treatment with eyedrops. The presentation currently commercialised has a concentration of 0.1% although there is also a 0.05% compounding.

PURPOSE

The purpose is to evaluate the safety of 0.1% ciclosporine collyrium assessing the rate of patients who do not tolerate this presentation and its causes.

MATERIAL AND METHODS

- This is a **retrospective observational** study.
- It has been realised in a model hospital in this area.
- All patients treated with **ciclosporine collyrium** between january and september of 2021 were included.
- **Demographic** (sex and age) **data** were collected from the computerised clinic history.
- A **questionnaire** was made **for the clinic interview** of the external patients who had **adverse reactions** after the treatment **with 0.1% ciclosporine collyrium thus they had to switch to the 0.05% formula**. In this questionnaire the reason of the switch, kind of adverse reaction, severity and time of appearance (immediate/late) were included.

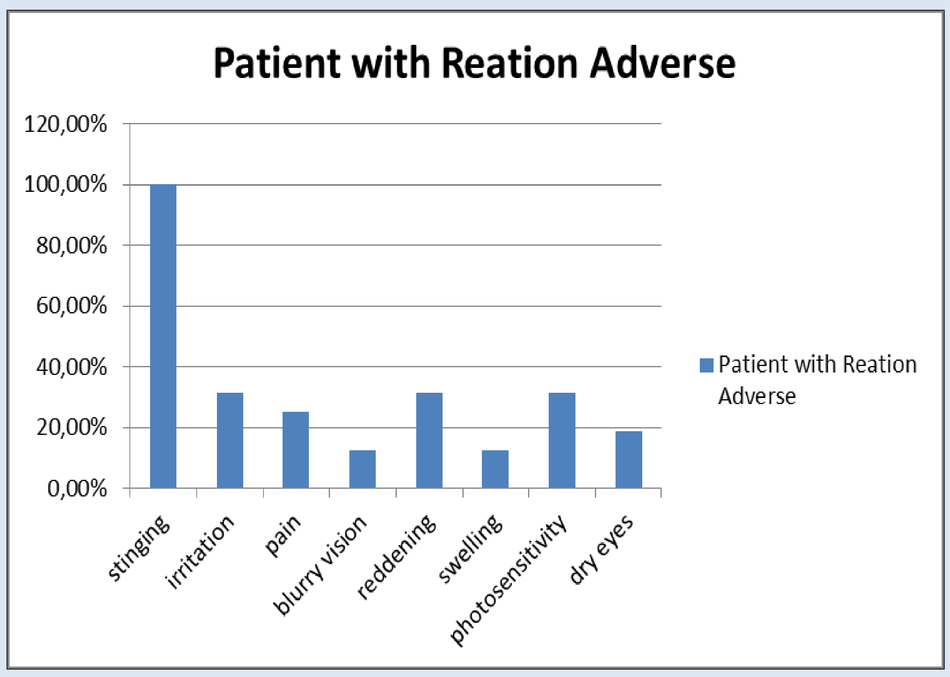
RESULTS

11.67% of the patients suffered some adverse reaction which forced to switch the 0.1% ciclosporine presentation to the 0.05% ciclosporine Pharmacy Unit made compounding.

137 patients who picked up 0.1% ciclosporine collyrium

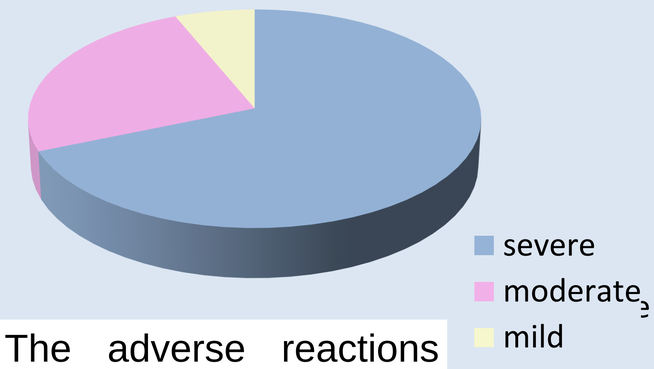
84,7% 15,3%

The mean age was 64 years old



100% of adverse reactions happened **immediately**

DEGREE OF SEVERITY



The adverse reactions were **reversible** and **autolimited.**

The switch to our compounding (0,05% **ciclosporine collyrium formula)** were well tolerated in 100% of the cases.

CONCLUSION

The 0.1% ciclosporine presentation is safe thus it was well tolerated in most of our patients, just 11.67% had some adverse reaction.
Moreover these patients did not suffer any adverse reaction with our free preservative 0.05% ciclosporine Pharmacy Unit made compounding, thus we cannot know if this reaction is due to the ciclosporine bigger concentration or some of its excipients, further research is needed.