Cyclamen europaeum nasal spray, a novel phytotherapeutic product for the management of acute rhinosinusitis: a randomized double-blind, placebo-controlled trial

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Rhinology 50: 37-44, 2012

Key messages from this study

✦ CE nasal spray is effective and safe for the treatment of patients with ARS assessed subjectively and objectively

✦ The specific symptom of facial pain/pressure did improve significantly after 5-7 days of treatment with CE. This is important since facial pain/pressure is undoubtedly one of the most severe symptoms affecting the patients’ quality of life in ARS

✦ Endoscopic evaluation showed that mucus oedema/nasal obstruction improved significantly with CE.

✦ Both patients and investigators reported significantly greater treatment satisfaction with CE than placebo

✦ CE is a safe product for the treatment of ARS
Study: randomized, double-blind, placebo-controlled trial of Cyclamen europaeum (CE) nasal spray at 13 centers in Germany

Objective: evaluate the clinical efficacy and safety of CE nasal spray in patients with moderate to severe ARS who were also receiving antibacterial therapy

Patients: Adult men and women aged 18 - 65 years with moderate to severe ARS according to the criteria of the first European Position Paper on Rhinosinusitis and Nasal Polyps were eligible for enrolment. Patients had inflammation of the nasal and paranasal sinuses lasting > 10 days (amended shortly after study commencement with symptoms lasting more than 7 days) and < 12 weeks with at least two of the following symptoms: nasal obstruction, anterior or posterior nasal secretion, facial pain/ tension/ pressure, and/ or impaired or loss of the sense of smell. Patients (99) were randomly assigned to treatment with either CE nasal spray (48 patients) or matching placebo nasal spray (51 patients) for 15 days. One spray of 1.3 mg (0.13 mL) was administered into each nostril once daily in the evening. In addition, all patients received amoxicillin 500 mg three times daily for the first 8 days (or a suitable alternative at the discretion of the physician for those allergic to penicillin). Concomitant treatment with corticosteroids or decongestants was not allowed during the study.

Study methods:

The primary efficacy variable was the change from baseline in the mean total rhinosinusitis symptom score after 5 - 7 days (averaged from patient assessment of nasal obstruction, mucus secretion, facial pressure/pain, and impairment or loss of smell).

Intensity of rhinosinusitis symptoms was assessed using a visual analogue scale (0 - 10 cm). ‘Moderate-to-severe’ intensity was understood when the patient answered the question ‘How troublesome are your rhinosinusitis symptoms?’ with a vertical line on a visual analogue scale (VAS) from 0 = ‘not troublesome’ to 10 = ‘unbearably bothersome’, and this line was between 5 and 10.

Secondary efficacy variables included change from baseline in the four individual nasal symptoms at 5 - 7 days, changes in total symptom scores and in the four individual nasal symptoms at 15 days, endoscopic signs at 5 - 7 and 15 days, treatment failure/need for additional treatment, onset of medical complications of
rhinosinusitis, sleep quality, and overall patient- and investigator-assessed treatment satisfaction.

Results:

Efficacy

In the primary efficacy analysis (change in mean rhinosinusitis total symptom VAS score after 5-7 days for the ITT population) there was a trend towards greater symptomatic relief with CE compared with placebo.

An analysis of secondary efficacy outcomes also demonstrated a greater decrease in mean symptom scores (nasal congestion, mucus secretion, facial pain, and impairment or loss of smell) in the CE group.

After 5 - 7 days a reduction in facial pain significantly favoured CE compared to placebo.

Endoscopic evaluation demonstrated that mucus oedema or nasal obstruction was reduced to a significantly greater extent with CE than placebo after 5-7 days.
At the end of the study, mean patient- and investigator- rated satisfaction scores were statistically significantly better in the CE group compared to placebo.

Safety

Transient mild to moderate nasal irritation/burning occurred in both treatment groups, but was more frequent with CE. No severe adverse events were reported.