

## Sore throat: echinacea-sage spray just as effective as standard medication<sup>1</sup>

### Study objective

The first symptom of almost all acute respiratory infections (ARI) is sore throat, which is caused mainly by viral infections of the nasopharynx. Even the most widespread etiological agents of common cold – rhinoviruses – first affect the throat where they cause soreness and only then spread to the nasal region [2]. A considerable proportion of all common cold treatments are therefore formulated to combat and relieve sore throat and the associated inflammation-induced symptoms such as swallowing difficulties. The study described evaluates the effectiveness of acute treatment with a throat spray containing echinacea (*Echinacea purpurea*) and sage (*Salvia officinalis*) compared to a standard combination preparation of chlorhexidine and lidocaine in acute painful tonsillitis and/or pharyngitis [1].

### Investigators

PD Dr. med. Andreas Schapowal, Landquart Allergy Clinic/CH, D. Berger, Schüpfen/CH, Dipl.-Math. Peter Klein, Rohrbach/D and Andy Suter, Roggwil/CH and 11 general practitioners.

### Study design

The study was conducted as a multicentre (11 general practices), randomised, double-blind trial with a double-dummy design in two parallel groups. The objective was to test the non-inferiority of the echinacea/sage spray compared to the chlorhexidine/lidocaine spray.

### Study participants

After approval by the ethics committees, 154 patients with acute pharyngitis or tonsillitis

and sore throat were enrolled in the study.

Inclusion criteria:

age > 12 years, onset of symptoms < 72h before enrolment and tonsillopharyngitis symptom index  $\geq 6$ . The exclusion criteria related to the use of various medications prior to study enrolment (analgesics < 12h, antibiotics < 24h, mouth and throat therapeutic preparations < 4h, systemic corticosteroids < 1 month). Further reasons for exclusion: bacterial infections or severe systemic diseases, allergies/intolerance to ingredients of the products, as well as pregnancy and breast feeding.

### Study medications

The plant-based active preparation consisted of extracts of *Echinacea purpurea* (L.) Moench (Echinaforce<sup>®</sup> concentrate: fresh herb – 95%, roots – 5%) and *Salvia officinalis* in an extract ratio of 67.8% : 32.2% (A.Vogel Halsschmerz Spray<sup>®</sup>, A.Vogel AG). The chemically defined reference product contained 1% chlorhexidine gluconate and 2% lidocaine HCl (Collunosol<sup>®</sup>, Sanofi AG).

### Treatment

Two puffs of the study medication were to be administered into the pharyngeal cavity every two hours, not more than 10 times daily. The treatment was continued until disease remission or for a maximum of five consecutive days. In addition to the baseline and final medical examination, efficacy was recorded with a patient questionnaire covering five typical sore throat parameters (throat pain, swallowing difficulties, saliva production, throat inflammation, fever) on a 4-point scale (tonsillitis severity score, max. 20 points).

[1] Schapowal A, Berger D, Klein P, Suter A: Echinacea/Sage or Chlorhexidine/Lidocaine for treating acute sore throats: a randomized double-blind trial. Eur J Med Res. 2009; 14:406-12.

[2] Winther B, Gwaltney JM Jr, Mygind N, Turner RB, Hendley JO: Sites of rhinovirus recovery after point inoculation of the upper airway. JAMA. 1986 Oct 3;256(13):1763-7.

[3] Sharma M, Anderson SA, Schoop R, Hudson JB: Induction of multiple pro-inflammatory cytokines by respiratory viruses and reversal by standardized Echinacea, a potent antiviral herbal extract. Antiviral Res. 2009 Aug;83(2):165-70.

[4] Tan T, Little P, Stokes T; Guideline Development Group: Antibiotic prescribing for self limiting respiratory tract infections in primary care: summary of NICE guidance. BMJ. 2008 Jul 23;337:a437.

[5] Moore N, Le Parc JM, van Ganse E, Wall R, Schneid H, Cairns R: Tolerability of ibuprofen, aspirin and paracetamol for the treatment of cold and flu symptoms and sore throat pain. Int J Clin Pract. 2002 Dec;56(10):732-4.

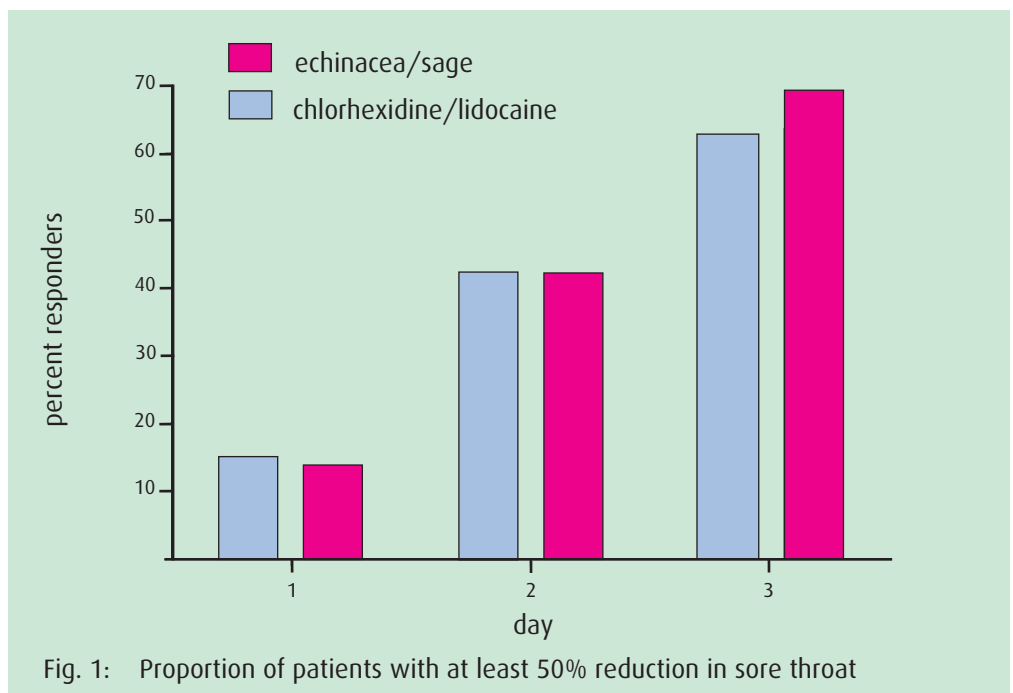
Note: the Echinacea/sage-combination studied corresponds in terms of raw materials used, manufacture and composition to the product A. Vogel (Echinaforce<sup>®</sup>) Sore Throat Spray, Bioforce AG, Roggwil, Switzerland).

## Results

Of the 154 patients enrolled, data of 143 persons were available for the per-protocol analysis (echinacea/sage – 69, chlorhexidine/lidocaine – 74). In 11 cases incorrect use of the study medication, study protocol violation, missing patient diary or

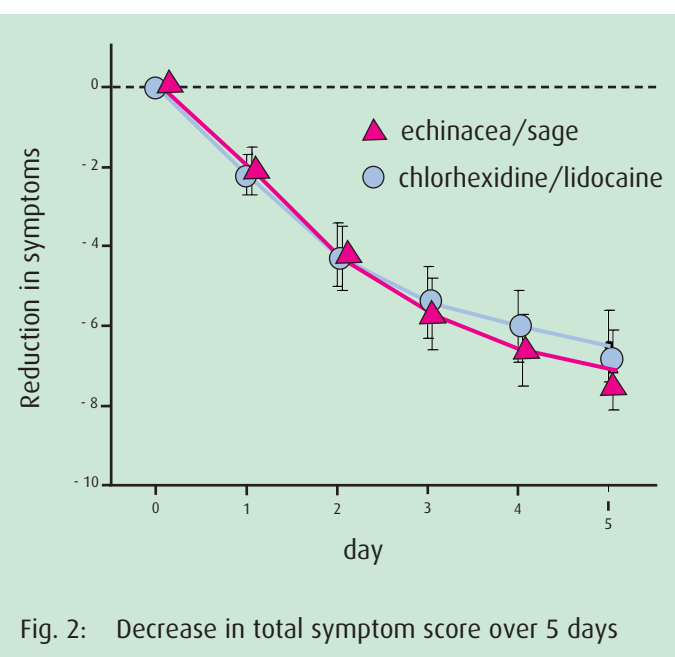
other reasons resulted in exclusion from the statistical analysis. Except for mean age, the socio-demographic and medical parameters of the two groups largely corresponded (echinacea/sage: 41.6 years, chlorhexidine/lidocaine: 33.8 years).

➔ Primary target parameter: There was no statistically significant difference in the response rate to one of the two therapies during the first 3 days.



➔ The treatments were also found to be practically equieffective in regard to all further, secondary efficacy measures. In the echinacea/sage group it took 4 days until 50% of the patients were symptom-free, in the reference group 5 days. The reduction in symptoms is shown in Fig. 2. As regards undesirable effects and tolerability, altogether 5x reversible side effects were recorded, especially product-related local pro-

blems (reddening of oral mucosa, bitter taste, dry mouth, burning feeling in the mouth). The investigators rated the tolerability as "good" or "very good" in just under 95% of cases and the efficacy as "good" and "very good" in almost 90% of cases. The tolerability and efficacy assessments by the study participants were almost identical.



## Conclusion

A throat spray based on *Echinacea purpurea* and *Salvia officinalis* is just as rapidly effective and well tolerated as a spray based on chlorhexidine and lidocaine. In addition to the high acceptance of herbal medicines, the therapeutic rationale is a particularly convincing argument in favour of the echinacea/sage combination. Example: whereas the antiseptic chlorhexidine has only antibacterial action – and therefore has no specific activity in predominantly viral respiratory tract infections – the special Echinacea extract used in the study product exerts topical antiviral, antibacterial and immunomodulating actions [3]. Echinacea/sage spray is also a natural and effective alternative to the use of antibiotics [4] or analgesics for acute sore throat [5] which is not only liable to problems but also far too frequent.