



Original Articles

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Common cold and infections of the paranasal sinuses: Treatment with Rhinitisan and Sinuforce

Clinical observational study to confirm the efficacy and tolerability of a homeopathic remedy used to treat sinusitis

Infections of the upper airways are, with an average of 5 episodes per year, the most common illnesses in both children and adults. Most visits to the doctor are prompted by these conditions.

Homeopathic treatment of rhinitis and sinusitis

Viral rhinitis is characterised by an unspecific symptomatology and is a ubiquitous condition. It is the initial stage of a variety of afflictions of the upper aerodigestive tract. Owing to the numerous serological types of rhinovirus, adenovirus and other viruses, susceptibility to this condition is lifelong. Typical symptoms include headache, nasal congestion with obstruction, watery rhinorrhoea and a «scratchy» throat, coupled with a general feeling of malaise. Early treatment with Rhinitisan is able to effectively ameliorate these symptoms by stimulating regeneration of the mucosa, and by its positive action on the general symptoms. All the components of Rhinitisan have a proven effect on inflamma-

Rhinitisan is a complex homeopathic remedy formulated from 7 herbal components (*Aralia racemosa*, *Hedera helix*, *Hydrastis canadensis*, *Luffa operculata*, *Pulsatilla pratensis*, *Sambucus nigra* and *Teucrium scorodonia*). The medicinal plants used in the formulation of Rhinitisan have been thoroughly tried and tested and have been approved by the Commission of the former German Federal Health Office responsible for homeopathic treatments, for use in the treatment of infections of the airways and the common cold.

Sinuforce is a complex homeopathic remedy formulated from *Hydrastis canadensis*, *Lemna minor* and *Luffa operculata*, three select medicinal plants and two mineral components (*Hydrargyrum sulfuratum rubrum* = *Cinnabaris* and *Kalium bichromicum*). Each component has a recognized effect against infections of the paranasal sinuses. In an open multi-centre observational study, a total of 83 patients were treated with a daily maximum of 12 tablets of Sinuforce for acute sinusitis, and 3 × 2 tablets to treat chronic sinusitis. Assessment of efficacy was based on a 4-step symptoms score covering the symptoms pain or tenderness frontal, parietal, peri-orbital and/or at the root of the nose, purulent or seromucous rhinorrhoea, nasal congestion, anosmia/hyposmia, raised temperature and a general feeling of malaise. Already after 2 days of treatment, a statistically significant improvement in the symptoms was observed. After 10 days of treatment, Sinuforce was found to have had an excellent effect in 22% of the patients with acute or chronic sinusitis, and a good effect in 44% of the cases of acute sinusitis and 41% of those with chronic sinusitis. Complete regression of the symptoms was, however, in this short time – at least in the case of chronic sinusitis – not achievable. 94% of the patients in both groups reported good to excellent tolerability. A total of 10 patients whose symptoms worsened abandoned treatment prematurely. Direct medication intolerance was not seen in any of the cases.

tion of the airways, and develop a synergistic action against the symptoms of colds. Repeated or long-term use of this homeopathic rhi-

nological agent leads neither to mucosal damage nor to dependence. Known complications of rhinitis are transient hydrotympa-

num and secondary bacterial superinfection. The latter manifests as a change in the colour of the rhinorrhoea from watery and clear to a yellowish-green. A mucopurulent discharge indicates bacterial infection, which, in turn, can lead to sinusitis, otitis media, bacterial pneumonia and tonsillitis.

Viral or allergic rhinitis is thus the most common cause of acute sinusitis. Owing to the unfavourable drainage, the maxillary sinus is most commonly involved. The symptoms are similar to those of rhinitis but more severe. Typically, they include headache and infra-orbital spontaneous pain or pain on percussion, with occasional referral to the teeth due to involvement of the maxillary division of the trigeminal nerve. Acute frontal infection is accompanied by orbital pain and frequently throbbing pain in the forehead. In the case of the fairly rare sphenoidal sinusitis, pain is referred to the occipital area and the neck. Possible complications are cavernous sinus thrombosis and retrobulbar neuritis. An acute inflammation of the ethmoidal cells usually occurs only in babies and young children, and may initiate a sinobronchial syndrome.

Sinusitis may be either acute or chronic. Chronic sinusitis often produces uncharacteristic symptoms and, apart from mild post-nasal discharge (post-nasal drip), nasal obstruction, bad breath or a cough, may be asymptomatic. In chronic sinusitis, pansinusitis is more common than the purulent infection of an isolated paranasal sinus. Inflammation of the paranasal sinuses are generally very common. Roughly 5% of the Central European population is affected by chronic sinusitis. The medicinal plants and minerals contained in Sinuforce have proven efficacy, and are approved by the Commission of the former German Federal Health Office responsible for homeopathic treatments, for use in the treatment of paranasal catarrh and purulent sinusitis.

Sinuforce in acute sinusitis and chronic sinusitis

With the aim of confirming the effectiveness and tolerability of Sinuforce in the treatment of acute and chronic infections of the paranasal sinuses, a multi-centre observational study was carried out between February and September 1995. Twenty-one general practitioners took part in this study, four of whom were predominantly homeopathy-oriented, four naturopathy-oriented, and 13 conventional medicine-oriented. After giving their informed consent, all those patients consulting the doctor with uncomplicated infections of the paranasal sinuses were admitted to the study. Of these 83 patients, whose average age was 40 years, 59 (71%) were women, and 24 (29%) men. Thirty-two patients (39%) presented with acute, and 51 (61%) with chronic sinusitis of up to 49 years standing. Sixty-one patients (73%) had already experienced at least one prior episode of sinusitis. 85% were using concomitant medication such as contraceptives or antihistaminics, and 37% had intercurrent illnesses, including 5 patients with an allergy and 3 with asthma.

During the consultations prior to the start and after 10 days of treatment, the following parameters were recorded with the aid of a four-step score:

1. pain or a sensation of fullness located frontally, parietally, periorbitally or at the root of the nose,
2. purulent or seromucous rhinorrhoea,
3. nasal congestion,
4. anosmia/hyposmia,
5. elevated temperature, and
6. general feeling of malaise

The patients were asked to record the severity of their symptoms in a diary throughout the course of treatment. Exclusion criteria were treatment with antibiotics or decongestive agents within

two weeks prior to the first consultation. The data of patients who, during treatment with Sinuforce, also used antibiotics or decongestive agents, or who had taken less than 90% of the scheduled dose of Sinuforce were not evaluated. Simultaneous medical treatment of complaints other than those affecting the sinuses or upper airways, was permitted, but had to be recorded. A quantification of the results of treatment was carried out by scoring efficacy as follows: 0 = none, 1 = moderate, 2 = good, 3 = excellent effectiveness.

For the patients with chronic sinusitis, a daily dose of 3×2 tablets of Sinuforce was scheduled for the 10-day treatment period. Patients with acute sinusitis were free to choose dosage and duration of treatment, but a daily total of 12 tablets was not to be exceeded.

The statistical evaluation of the data was carried out using ANOVA and correlation analyses, as well as the Wilcoxon, Mann-Whitney-U, chi squared and T test.

Results

Of the 45 patients with chronic sinusitis, 9 (20%) showed a compliance of <90%. These figures are in accord with those reported in the literature, which indicate that an unsatisfactory compliance of up to 30% must be expected in any single group. While older age groups showed better compliance, patients with more severe symptoms did not. The use of concomitant medication led to no significant differences in terms of the course of the symptoms, as compared with monotherapy with Sinuforce.

Acute sinusitis

At the follow-up examination after 10 days of treatment, patients with acute sinusitis showed a statistically significant improvement in headache, mucopurulent nasal discharge, nasal obstruction and anosmia/hyposmia. The seromucous discharge and the elevated

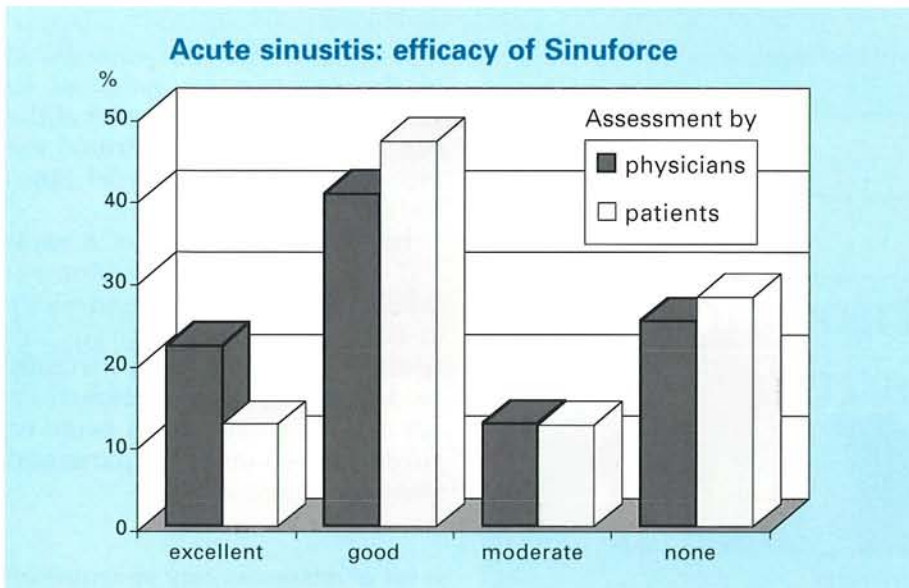


Figure 1: Clinical observational study in patients with acute sinusitis (n=32): Efficacy of Sinuforce after 10 days of treatment as assessed by physicians and patients.

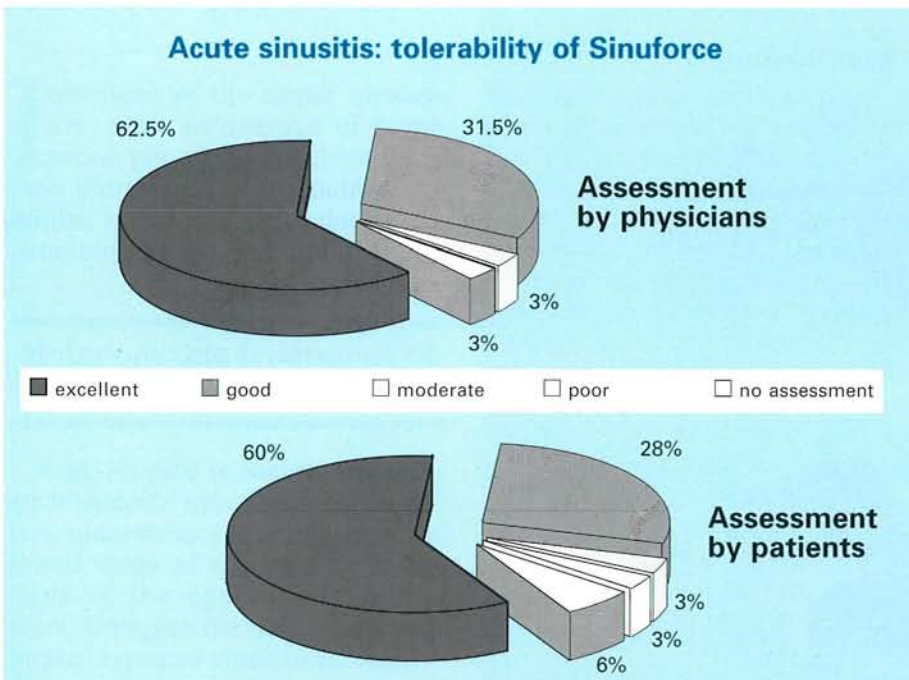


Figure 2: Clinical observational study in patients with acute sinusitis (n=32): Tolerability of Sinuforce after 10 days of treatment as assessed by physicians and patients.

temperature, however, remained largely unaffected. The care-providing physicians noted no effect of Sinuforce in 25% of the cases, a moderate effect in 12.5%, a good effect in 40.5%, and an excellent effect in 22% (Figure 1). 28% of the patients considered Sinuforce

to be ineffective, 12.5% considered it moderately effective, 47% thought it had a good effect, and 12.5% an excellent effect.

With respect to the physicians' assessment of tolerability (Figure 2), 3% made no assessment, 3% considered it moderate, 31.5% good,

and 62.5% excellent. In the assessment of the patients, 6% made no judgement, 3% indicated poor, 3% moderate, 28% good and 60% excellent tolerability.

Chronic sinusitis

At the end of 10 days of treatment of patients with chronic sinusitis, a statistically significant and clinically relevant improvement in headache, purulent nasal discharge, seromucous discharge, nasal obstruction, anosmia/hyposmia and general malaise was recorded. The increased temperature showed no significant change. The effect ascribed by the physicians to Sinuforce was none in 23%, moderate in 13.5%, good in 41%, and excellent in 22.5% of the patients (Figure 3). The corresponding figures for the patients were no effect 28%, moderate 12.5%, good 47%, and excellent 12.5%.

The assessment of tolerability by the physicians was poor 3%, moderate 3%, good 31.5%, and excellent 62.5% (Figure 4). Of chronic sinusitis patients, 3% considered the tolerability of Sinuforce to be poor, 3% moderate, 28% good and 66% excellent.

A total of 14 patients dropped out of the study. The reasons given were holidays (1) forgetting to take the tablets (1), nausea (2) and worsening of symptoms in the remaining 10 cases.

Conclusions

Both in acute and chronic sinusitis, most cases experienced a clinically relevant and statistically significant improvement in their symptoms already within the first two days of treatment. Although we have no data on the spontaneous course of acute sinusitis, the rapid response of the symptoms under treatment with Sinuforce in the absence of any other medication with an action on the nasal mucosa, is highly meaningful. With respect to the success of treatment, no significant differences

Chronic sinusitis: efficacy of Sinuforce

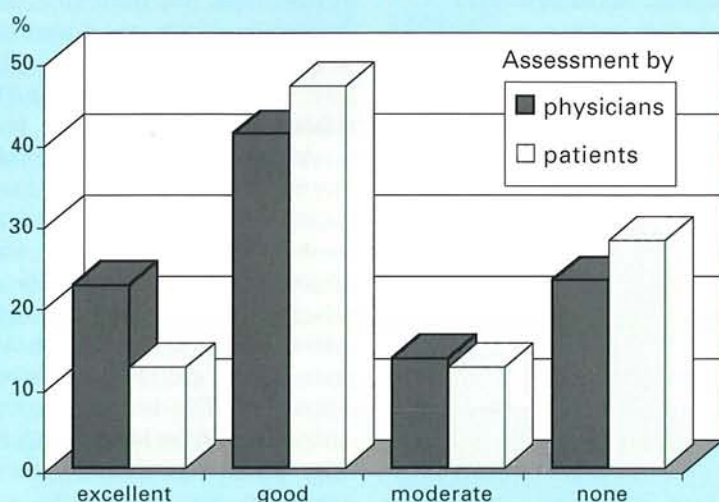


Figure 3: Clinical observational study in patients with chronic sinusitis (n=51): Efficacy of Sinuforce after 10 days of treatment as assessed by physicians and patients.

limited – amelioration of symptoms, but also towards the stimulation of the regenerative potential to achieve healing. The results of the study have also demonstrated the high level of tolerability of Sinuforce.

In summary, in view of a medical «certification» of «good-to-excellent» results in 62.5% and 63.5% in acute and chronic sinusitis, respectively, Sinuforce may certainly be classified as an appropriate remedy for the treatment of acute or chronic infections of the paranasal sinuses.

A list of references may be requested from the authors.

Chronic sinusitis: tolerability of Sinuforce

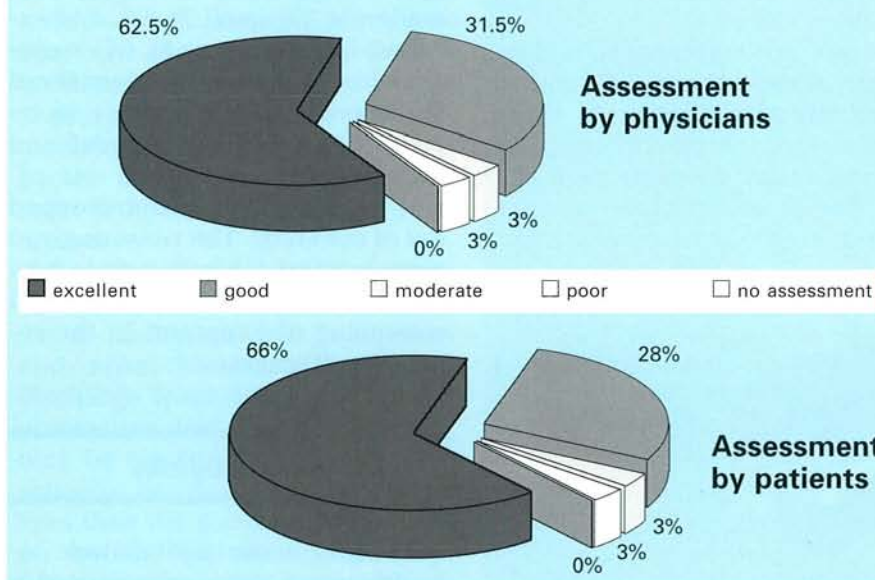


Figure 4: Clinical observational study in patients with chronic sinusitis (n=51): Tolerability of Sinuforce after 10 days of treatment as assessed by physicians and patients.

were found between acute and chronic sinusitis. However, complete healing was not achieved within the 10-day treatment period. In particular in the case of illnesses of long-standing, longer administration is needed. Among the preconditions for an optimal

medication effect, particularly in the case of homeopathic remedies, is an adequately long period of treatment and observation. This is in accord with therapeutic objectives when using homeopathic medication, which is directed not only towards the immediate – at best

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