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## Acute and chronic sinusitis: treatment with a homeopathic sinus spray

Results of a clinical study on the efficacy and tolerability  
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# Acute and chronic sinusitis: treatment with a homeopathic sinus spray

## Results of a clinical study on the efficacy and tolerability of the homeopathic "Sinuforce Spray"

**S**inusitis is a widespread disease that affects about 30% of all people at some time in their life [1]. Thus about 15% of the population in Germany suffers from acute or chronic sinusitis, whereby the prevalence of these infections shows a tendency to increase [2]. Chronic sinusitis alone affects about 5% of the Central European population with a clearly increasing frequency in recent years [4]. Acute sinusitis is one of the most frequent infections in the USA [3] with costs in 1992 of about US\$ 200 million for prescribed medications and more than US\$ 2 billion for OTC medicaments.

Acute sinusitis is caused, like all other infections of the upper respiratory tract, by a viral infection in over 90% of the cases [5]. In the course of viral rhinitis there is retention of secretions and increased production of interleukin-1b, interleukin-6 and interleukin-8, which can lead to inflammation of the nasal sinuses. Bacterial infection may develop on the basis of this inflammation [2]. According to current estimates for the USA, the prevalence of acute bacterial sinusitis in adults with symptoms of sinusitis in General Practices is up to 38%, whereas the frequency of these bacterial infections in ENT practices is even 50 to 80%. In children with infections of the upper respiratory tract who are treated in US General Practices, the prevalence of acute bacterial sinusitis is thought to be 16 to 18% [3].

Treatment with the homeopathic "Sinuforce Spray" significantly reduced both the score for individual sinusitis symptoms and the total score for symptoms in patients with acute or chronic sinusitis. The higher initial score of patients with acute sinusitis was reduced to a greater extent than the score in patients with chronic sinusitis. Side-effects consisted of one case each of dry nose and epistaxis. The vast majority of the physicians and the patients considered the "Sinuforce Spray" in acute or chronic sinusitis to have very good or good efficacy and judged the tolerability to be very good or good.

**Key words:** Acute and chronic sinusitis, homeopathic nasal spray, tolerability, relief of symptoms, "Sinuforce Spray"

### Akute und chronische Sinusitis: Therapie mit einem homöopathischen Stirnhöhlenspray

#### Resultate einer klinischen Studie zur Wirksamkeit und Verträglichkeit des homöopathischen 'Sinuforce Spray'

Eine Therapie mit dem homöopathischen 'Sinuforce Spray' verringerte sowohl den Score der einzelnen Sinusitis-Symptome als auch den Gesamtscore der Symptome bei Patienten mit einer akuten oder chronischen Sinusitis signifikant. Bei höherem anfänglichem Gesamtscore verzeichneten die Patienten mit einer akuten Sinusitis unter Behandlung mit 'Sinuforce Spray' eine wesentlich stärkere Reduktion des Symptomscores als die Patienten mit einer chronischen Sinusitis. Als Nebenwirkungen traten nur je ein Fall von stark ausgetrockneter Nase und Epistaxis auf. Die überwiegende Mehrheit der behandelnden Ärzte sowie der Patienten schrieb der Therapie mit 'Sinuforce Spray' bei akuter und chronischer Sinusitis eine sehr gute oder gute Wirksamkeit zu und bewertete die Verträglichkeit als sehr gut oder gut.

**Schlüsselwörter:** Akute und chronische Sinusitis, homöopathischer Stirnhöhlenspray, Verträglichkeit, Symptomlinderung, 'Sinuforce Spray'

Acute bacterial sinusitis is nowadays generally treated for 10 to 15 days with antibiotics, although clinical studies so far on the efficacy of antibiotic treatment have given partially contradictory results. The newer and considerably more expensive antibiotics have proved to be comparably

efficacious to amoxicillin and folate inhibitors in the treatment of acute bacterial sinusitis, which is why they are not indicated for the treatment of uncomplicated, non-nosocomial acute bacterial sinusitis [3].

In view of the low therapeutic benefit of antibiotics in the treatment of

acute sinusitis as well as the rarity of serious complications, there is a rational and cost-beneficial treatment strategy of treating the sinusitis symptoms for the first 7 to 10 days symptomatically and only subsequently deciding on the basis of clinical criteria whether the symptomatic treatment will be continued or antibiotic treatment is necessary [3]. Salt water sprays, irrigation, inhalation of steam and mucolytics are used for the symptomatic treatment of sinusitis. They produce a certain degree of relief of the symptoms. While a considerable regression of the symptoms may be achieved with decongestant drugs, potentiation of the nasal obstruction may occur if the duration of treatment is more than 3 to 5 days. Treatment with steroids, which are predominantly indicated in the presence of nasal polyps or allergically-induced swelling, can also relieve the symptoms [6].

In view of the considerable side-effects of conventional preparations, there is a need for homeopathic drugs which are characterised by good tolerability for the treatment of acute and chronic sinusitides. On the basis of the results of a clinical surveillance study, the symptomatic treatment of acute and chronic sinusitis with an orally administered homeopathic compound drug consisting of *Hydrastis canadensis* D6, *Lemna minor* D4, *Luffa operculata* D6, *Cinnabaris* D8 and *Kalium bichromicum* D6 led to a marked regression of the sinusitis symptoms, with very good tolerability of the treatment [4]. Against this background, the present study was carried out to determine the efficacy and tolerability of local treatment with a nasal spray which contains the same homeopathic drugs as the oral preparation.

## Patients and methods

In this open, multicentre clinical trial, 81 patients with acute or chronic sinusitis were treated in 12 General Practices in Switzerland between July and November 2001 in order to investigate the efficacy and tolerability of treatment with the homeopathic "Sinuforce Spray". Men and women

aged 18 to 80 years in whom uncomplicated acute or chronic sinusitis had been diagnosed were enrolled in the study. Patients who had undergone antibiotic treatment in the two weeks prior to the study and patients who had carried out local treatment in the three days prior to the study were excluded. In accordance with the legal requirements for the performance of clinical studies with homeopathic medicines, the present study was notified to the Swiss Health Authority Swissmedic. The patients were informed by means of an information sheet and verbally about the study and gave their informed consent for participation verbally.

To determine the efficacy of the treatment, nine symptoms of sinusitis (headaches, purulent rhinorrhoea, seromucous rhinorrhoea, pressure pain at the nerve endings, nasal congestion, loss of sense of taste and smell, raised temperature, general malaise and other symptoms) were classified on an intensity scale from 0 to 3 points, which were equivalent to 'not perceptible', 'slightly perceptible', 'perceptible' and 'severe', at the start of the study and after a period of treatment of 10 days by the physician and the patient. In addition, the treatment success was quantified as 'poor', 'satisfactory', 'good' and 'very good' by the physician and by the patient. To assess the tolerability, the frequency of side-effects was determined after a treatment period of 10 days and in addition was assessed by the doctor and by the patients as 'poor', 'satisfactory', 'good' or 'very good'. In addition, the patient's compliance and his/her acceptance of the treatment was assessed by the attending physician.

The patients applied one or two puffs of the homeopathic "Sinuforce Spray" three to five times daily into each nostril. The "Sinuforce Spray" is a compound medicine consisting of the herbal components *Hydrastis canadensis* D6, *Lemna minor* D4, *Luffa operculata* D6, plus *Cinnabaris/Hydrargyrum sulfuratum rubrum* D8 and *Kalium bichromicum* D6. The use of other nasal sprays and other local rhinological drugs was not permitted throughout the entire duration of the

study. Other medicaments or treatments that could have influenced the symptoms of the sinusitis were only permitted in urgent cases and had to be documented.

Statistical analysis of the data was by means of descriptive statistics in which the assessments of the individual symptoms and the sum totals of all symptoms at the start and at the end of the study were submitted to a t-test. In addition, the assessments of the individual symptoms were submitted to a Wilcoxon paired comparison in which the number of patients was determined for each symptom in whom the pertinent symptom was increased, reduced or unchanged. The data analysis was carried out as an 'intention-to-treat analysis' in all patients who had used the nasal spray at least once, and as a 'per-protocol analysis' in all patients who kept to the study protocol. Other parameters determined in the context of the study were presented as means and standard deviations or by means of frequencies or as tabular lists.

## Results

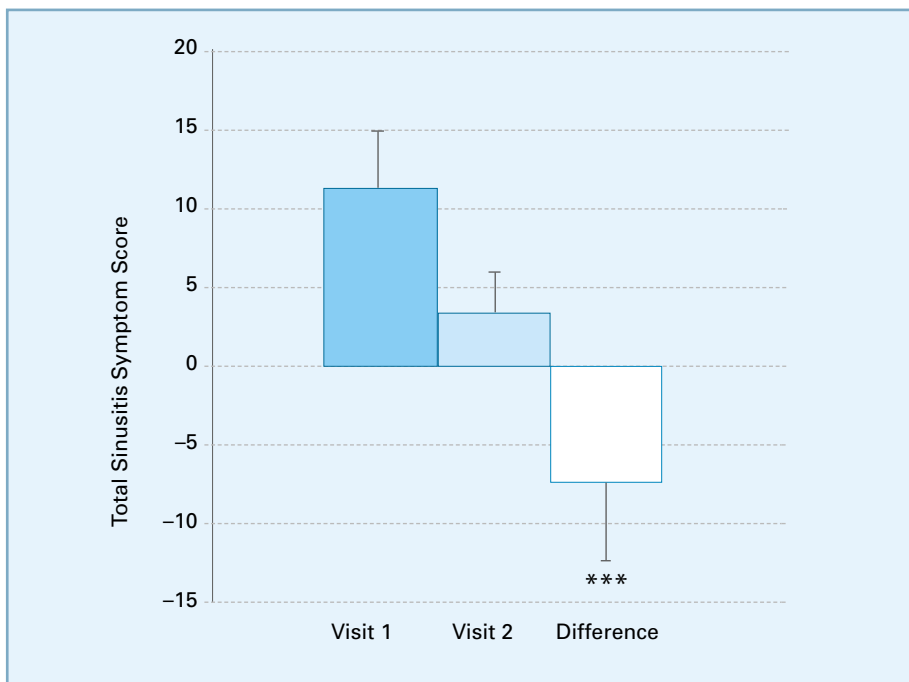
### Demographic data

Out of the total of 81 patients with a mean age of 40.3 years who participated in the study, 55 were female, 24 were male and 2 patients did not give any gender (Table 1). Fifty-three of the patients had acute sinusitis and 27 patients chronic sinusitis, with a mean duration of the illness of 2.56 years.

None of the patients stopped the study prematurely. Thirty patients violated the study protocol at least once and were dropped from the per-protocol group. The doctors classified compliance to be 98.8% and all the study participants used the medication without interruption. Altogether, 50 patients used at least one further medicament, whereby 21 patients used a non-permissible medicament according to the study protocol. As no significant differences were found for the efficacy data between the intention-to-treat and the per-protocol groups, only the intention-to-treat group results will be given in the present publication.

**Table 1:** Characteristics of the study participants

	Intention-to-treat-population		Per-protocol-population	
	Number	Percentage	Number	Percentage
Number of patients	81	100%	51	63.0%
Mean age ( $\pm$ SD) years	40.32 $\pm$ 16.78	–	40.56 $\pm$ 16.86	–
Men	24	29.6%	18	35.3%
Women	55	67.9%	33	64.7%
No clinical history data	2	2.5%	0	0%
Acute sinusitis	53	65.4%	34	66.7%
Chronic sinusitis	27	33.3%	16	31.4%
Mean duration of chronic sinusitis (years)	2.56	–	2.56	–

**Fig. 1.** Means and standard deviation of the total sinusitis symptom score at the start and at the end of the treatment and the difference (n = 81), \*\*\*p<0.001.**Efficacy**

At the beginning of the study, nasal congestion was the severest symptom with a score of  $2.3 \pm 0.8$  points, whereas all the other sinusitis symptoms were merely moderately severe with values of 0.2 to 1.5 points. The values for the individual sinusitis symptoms were clearly reduced during treatment with the spray, whereby the reduction achieved significance, apart from the value for 'other symptoms'. Furthermore, the total score for the 9 sinusitis symptoms was significantly reduced

during treatment with the "Sinuforce Spray" from an initial score of  $11.2 \pm 3.6$  points to  $3.4 \pm 2.3$  points ( $p < 0.001$ ) (Fig. 1). In accordance with the observed improvement of the symptoms, a majority of 73% of the physicians classified the efficacy of "Sinuforce Spray" at the end of treatment as very good or good and only 25% of the doctors reported only satisfactory or even insufficient efficacy. At the end of the study the majority of patients (72%) rated the treatment with "Sinuforce Spray" as very good or good and

only 28% of the patients attributed the treatment only satisfactory or even poor efficacy (Fig. 2).

**Tolerability**

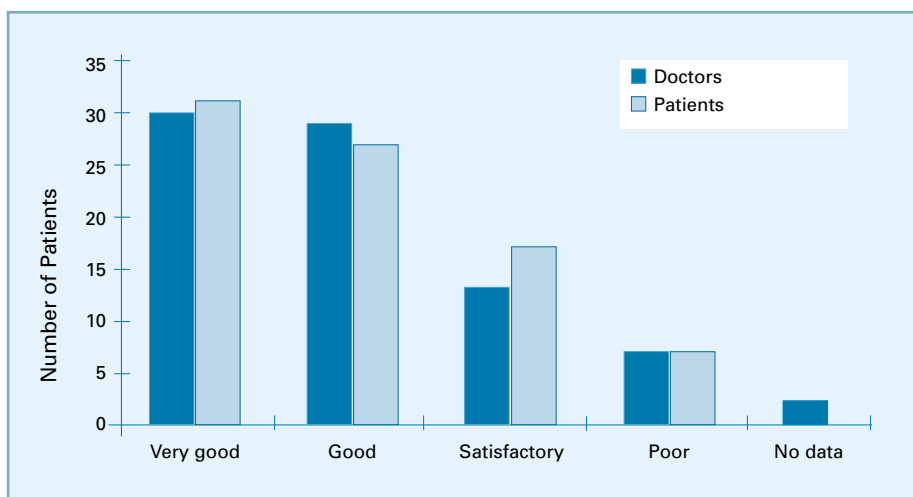
One patient each suffered from tinnitus, pain on chewing, extremely dry nose and epistaxis as side-effects; these adverse reactions were, however, only mild. Furthermore, it could be assumed that only the extremely dry nose and epistaxis were side-effects associated with the treatment. The majority of physicians assessed treatment with "Sinuforce Spray" to be tolerated very well or well and only 2% of the doctors classified the tolerability of the treatment as only satisfactory (Fig. 3). The patients also found the treatment with the "Sinuforce Spray" to be well or very well tolerated and only two patients ascribed the spray only satisfactory or even poor tolerability. The great majority, 88.9%, of the patients answered the question whether they would use the spray again positively.

**Subgroup analysis: chronic versus acute sinusitis**

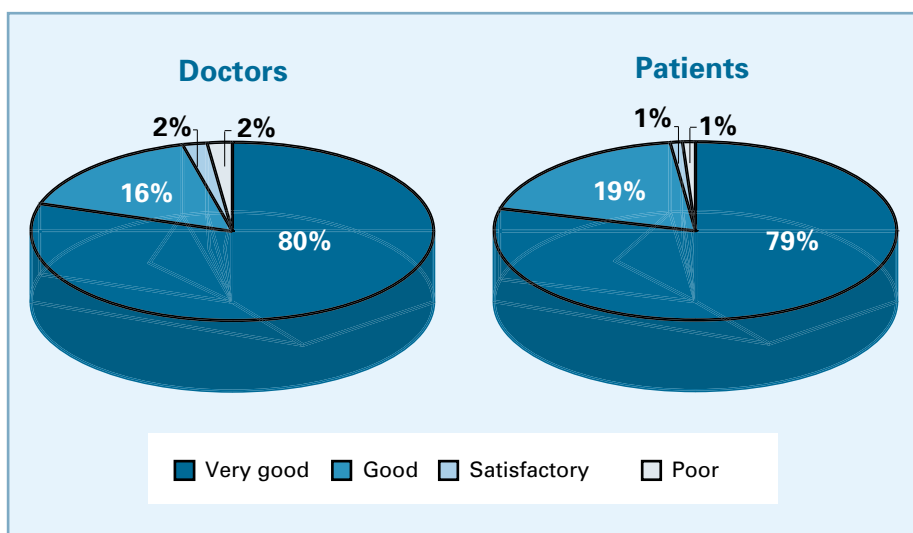
In a subgroup analysis, the initial values for the individual symptoms of sinusitis in the patients with an acute attack of sinusitis were higher than those in patients who suffered from chronic sinusitis. The severity of the individual symptoms was generally reduced to a greater extent by treatment with the "Sinuforce Spray" in the patients with acute sinusitis than in the patients with chronic sinusitis. The reductions achieved, however, were statistically significant in both subgroups, with the exception of the value for 'other symptoms' (Table 2). The initial total score for sinusitis symptoms in the patients with acute sinusitis was, with 11.9 points, higher than that in patients with chronic sinusitis (total score 9.2 points). During treatment with "Sinuforce Spray" the patients in both groups experienced a significant reduction of the total score for sinusitis symptoms which, however, with a reduction of 9.1 points in those with acute sinusitis was considerably more marked than that in those with chronic sinusitis in whom the reduction of the total score was 4.6 points.

## Discussion

This open study demonstrates the efficacy and tolerability of the homeopathic “Sinuforce Spray” in the treatment of acute and chronic sinusitis. The majority of the physicians and also of the patients confirmed very good or good efficacy and tolerability for the spray. Thus there was a marked reduction of the various symptoms of sinusitis as well as a significant reduction of the total score for the symptoms after a study period of ten days in the majority of the patients. These results are in agreement with those of a previous surveillance study of the efficacy and tolerability of an oral form with the same active ingredients (*Hydrastis canadensis* D6, *Lemna minor* D4, *Luffa operculata* D6, *Cinnabaris* D8 and *Kalium bichromicum* D6) as in the “Sinuforce Spray” [4]. In this previous open multicentre study, 83 patients with acute or chronic sinusitis participated. The patients with acute infection took up to 12 tablets of “Sinuforce Tablets” daily and those with chronic disease 2 tablets t.i.d.. After a study period of ten days, 62.5% of the physicians and 59.5% of the patients assigned the oral homeopathic preparation very good or good efficacy in the treatment of acute sinusitis, while 63.5% of the doctors and 59.5% of the patients assigned the preparation very good or good efficacy in the treatment of chronic sinusitis. In addition, the tolerability of the tablets



**Fig. 2.** Assessment of the efficacy of the homeopathic “Sinuforce Spray” by the doctors and patients.



**Fig. 3.** Assessment of the tolerability of the homeopathic “Sinuforce Spray” by the doctors and patients.

**Table 2:** Means of the individual sinusitis symptoms in patients with acute and chronic sinusitis

Symptoms	Acute sinusitis (n=53)			Chronic sinusitis (n=27)		
	Start	End	Significance	Start	End	Significance
Headaches	1.7	0.4	p<0.001	1.0	0.3	p<0.001
Purulent rhinorrhoea	1.3	0.2	p<0.001	1.3	0.6	p<0.01
Seromucous rhinorrhoea	1.5	0.7	p<0.001	1.4	0.9	p<0.05
Pressure pain at nerve endings	1.4	0.2	p<0.001	1.2	0.5	p<0.001
Nasal congestion	2.4	0.6	p<0.001	2.1	1.3	p<0.01
Loss of senses of taste and smell	1.2	0.2	p<0.001	1.0	0.5	p<0.01
Raised temperature	0.5	0.0	p<0.001	0.2	0.1	p<0.05
General malaise	1.5	0.3	p<0.001	0.7	0.3	p<0.001
Other symptoms	0.3	0.1	n.s.	0.2	0.2	n.s.
Total score	11.9	2.7	p<0.001	9.2	4.7	p<0.001

was classified by 94% of the doctors and 94% of the patients as very good or good in the treatment of acute sinusitis, while with respect to the treatment of chronic sinusitis the tolerability of the preparation was classified as very good or good by 63.5% of the doctors and 59.5% of the patients [4].

The therapeutic benefits of systemically administered homeopathic drugs for the treatment of sinusitis was already demonstrated in a double-blind study published in 1989. In this 152 patients with acute or chronic infections were randomised to three different homeopathic preparations or were treated with placebo [7]. According to the results of this study, complete regression of the symptoms was achieved in 81% of the patients with acute sinusitis and in 67% of the patients with chronic sinusitis. Similar efficacy was shown for the preparation consisting of the three components *Luffa operculata* D4, *Kalium bichromicum* D4 and *Cinnabaris* D3 and for the preparation consisting of the two components *Kalium bichromicum* and *Cinnabaris* D3 as well as for the preparation consisting of a single component *Luffa operculata*. In addition, an open surveillance study in 119 previously untreated patients with symptoms of acute sinusitis showed that complete freedom from symptoms could be achieved with a combination of *Lobaria pulmonaria* D2, *Luffa operculata* D4 and *Kalium bichromicum* D6 in 81.5% of the cases [8]. The efficacy of local rhinological drugs in the treatment of sinusitis has up to now only been investigated in isolated randomised studies, whereby their results sometimes indicate an improvement of the symptoms [3]. The local rhinological drugs in these studies were, however, mostly used in combination with an antibiotic, which makes the assessment of the therapeutic benefit of these preparations more difficult. Furthermore, there are only a few placebo-controlled studies available for the efficacy of antibiotic treatment of acute bacterial sinusitis. The cure rates obtained in these studies vary over a wide range [3]. However, a meta-analysis of six placebo-controlled stud-

ies showed that in patients with acute bacterial sinusitis about 83% of the cases achieved a cure with antibiotic therapy, whereas only 69% of the patients were cured in the placebo group [9].

In the present surveillance study, the homeopathic sinus spray was characterised by very good tolerability, as adverse events occurred in only four patients and were, in addition, only mild. Of these, only the extremely dry nose and a slight epistaxis were classified as being adverse reactions associated with the treatment, which is why the actual side-effect rate during treatment with the spray was only 2.5%. The incidence of side-effects determined in the present study therefore was considerably lower than that in the treatment with the topical steroid fluticasone, which caused the adverse reactions of dry nose and mild epistaxis in 6.5% of the patients with acute sinusitis [10]. Furthermore, mometasone furoate exhibited in a randomised placebo-controlled study a higher side effect rate than “Sinuforce Spray”, as treatment with the topical steroid mometasone furoate led to epistaxis, burning nose and irritation of the nose in a total of 7% of the patients [6]. Finally, the “Sinuforce Spray” showed considerably better tolerability than the decongestant rhinological drugs which, according to the results of various studies, already cause damage to the nasal mucosa after a duration of treatment of approximately one week.

In conclusion it can be said that treatment with the homeopathic “Sinuforce Spray” led to a marked regression of the symptoms in the majority of patients with acute or chronic sinusitis. As the nasal spray is, in addition, characterised by good tolerability, this homeopathic sinus spray can be regarded as being a suitable medicament for the symptomatic treatment of acute and chronic sinusitis.

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