

Assessment of Two Capsaicin Containing Solutions for Symptoms Relief in Subjects with Persistent Allergic Rhinitis

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ABSTRACT

RATIONALE. Sinol™ nasal spray, registered as a homeopathic product in the US, is intended to relieve symptoms of allergic rhinitis (AR) but has not been evaluated in controlled clinical studies. We aimed to document efficacy and tolerability of both Sinol and a 2nd generation capsaicin solution (Sinol-M™), formulated with mucoadhesive technology.

METHODS. Twenty four patients with symptomatic AR completed this double-blind cross-over study. After a 1 week run-in period, they were randomly assigned to Sinol or Sinol-M and were instructed to use one spray in each nostril as needed up to 12 times/day for 1wk. The number of sprays and adverse events were recorded in diaries along with symptoms scored from 0 (none) to 4 (severe). After a 1wk wash-out, they crossed to the other formulation.

RESULTS. Both treatments significantly decreased the total nasal symptom score (TNSS) compared with the run-in/washout periods. The overall usage of Sinol-M was reduced, especially morning usage; 36% of subjects reported less burning sensation with Sinol-M using a Visual Analog Scale.

CONCLUSION. Both Sinol and Sinol-M decreased nasal symptoms of allergic rhinitis. By adding a “coat” of hypromellose, the mucoadhesive formulation Sinol-M reduces the frequency of use and diminishes the discomfort related to application.

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BACKGROUND

- Sinol™ is a homeopathic nasal spray based on capsaicin. It is used for the relief of allergy, sinus symptoms and headache, but has not previously been studied in controlled clinical trials. Unlike many other intranasal therapies, Sinol can be used liberally and is not associated with rebound congestion or other serious side effects.
- Sinol-M is a second generation product that incorporates a mucoadhesive molecule - MucoAd™ (hypromellose). Theoretically, this formulation should prolong contact of the active ingredient to the nasal mucosa, thereby increasing bioavailability, reducing the frequency of application and diminishing the “hot pepper” sting associated with capsaicin.

PATIENTS

Table 1. Patient Demographics (N=24)

Characteristic	N (%)
GENDER	
Male	7 (29.1)
Female	17 (70.9)
RACE / ETHNICITY	
African American	11 (45.8)
Caucasian	11 (45.8)
Asian	1 (4.2)
Indian	1 (4.2)
AGE	
13-19	4 (16.6)
20-29	2 (8.3)
30-39	1 (4.2)
40-49	6 (25)
50-59	9 (37.5)
60-69	0
70-79	1 (4.2)
>80	1 (4.2)

Patient Characteristics

- All patients had a history of allergic rhinitis for at least 2 years, with a positive, relevant skin prick test, and provided written informed consent.
- Excluded were drugs and medications that could interfere with the study results:*

 - Intranasal corticosteroids
 - Systemic antibiotics
 - Ipratropium bromide
 - Nedocromil or cromolyn sodium
 - Ocular anti-allergy medications NSAID's
 - Cough, cold & sleep remedies
 - Leukotriene pathway modifiers
 - Antifungal agents
 - Atropine
 - Antihistamines (oral, nasal)
 - Decongestants (oral, nasal)
 - Ocular or nasal saline

*Patients taking these medications at the initial visit underwent a washout period of 1-3 weeks, depending on the drug.

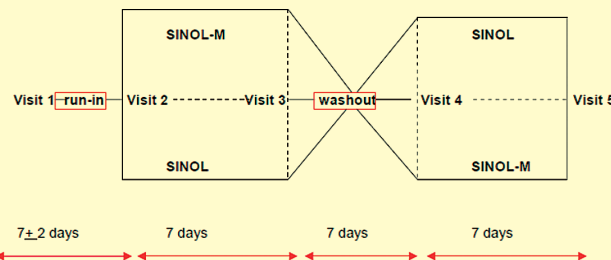
PURPOSE

To compare Sinol and Sinol-M with regard to:

- Frequency of use
- Efficacy (non-inferiority)
- Adverse events
- “Burning” sensation

METHODS

Study Design: a double-blind, randomized, cross-over comparison of Sinol and Sinol-M



- Patients recorded the following in diaries, AM and PM:
 - The frequency of study medication use since previous entry
 - Reflective nasal symptom scores (congestion, runny nose, itchy nose, sneezing; scale: 0=none, 4= severe)
- Total Nasal Symptom Score (TNSS) = sum of the subjects daily AM and PM individual nasal symptom
- Safety parameters were evaluated in all patients who received at least one dose of study medication.
 - Extent of exposure
 - Adverse events

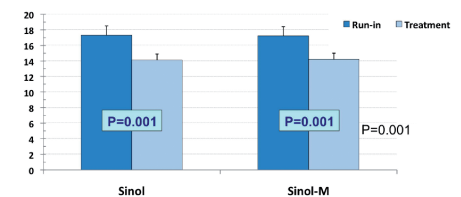
CONCLUSIONS

- Sinol is a well-tolerated homeopathic therapy used for fast relief of nasal symptoms associated with allergic rhinitis, sinus congestion and headache
- Sinol-M adds a soothing mucoadhesive component that prolongs the duration of treatment in the nose
- Comparable improvement in nasal symptoms was evident with Sinol-M, but at less frequent dosing than Sinol
- Both products were well tolerated

RESULTS

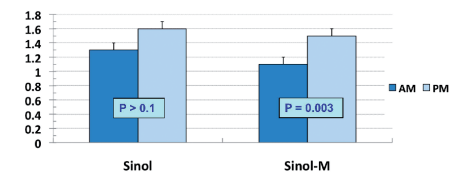
- Both treatments significantly decreased TNSS from run-in/washout periods (Figure 1)
- Use of both formulations, especially Sinol-M, was less during the night (Figure 2)
- No treatment related adverse events were reported with either Sinol or Sinol-M

Figure 1. Mean daily TNSS diminished in both active treatment arms.



Similar efficacy was evident despite less daily use of Sinol-M compared to Sinol (average, 2.6 vs 3.0 puffs/day, respectively).

Figure 2. Mean daily number of Sprays of Sinol vs Sinol-M



While on Sinol-M patients recorded less overnight usage, in their morning diary, suggesting an improved night's sleep.