Efficacy of Siccoral Solution in Xerostomia and Pharyngitis sicca

Offprint
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Siccoral Solution was tested in a clinical study with 5 E.N.T. specialists in Switzerland in a total of 62 patients with xerostomia or pharyngitis sicca. The patients’ complaints were of various origins. After 7 days of application, 78.3% of the patients treated with Siccoral witnessed a therapeutic success with regard to dryness of the mucosa in the mouth and throat and 80% with regard to irritation of the mucosa. The improvement in both symptoms was statistically highly significant. Efficacy of the treatment was rated as “very good” and “good” by the physicians in 70% of the cases, as well as by 73.3% of the patients. Local tolerability was judged to be “good” in 90.3% of the patients.

The aim of this study was to investigate the efficacy and tolerability of Siccoral Solution in patients with xerostomia or pharyngitis sicca under conditions of specialist practice.

Methods

Patients and dosage regime

Male and female patients presenting with a dried out or atrophic mucosa, who had consulted an Ear-Nose-Throat (ENT) specialist for these complaints, participated in the study. The administration of topical antiseptics and of systemic antibiotics were exclusion criteria. Siccoral treatment was applied on 7 subsequent days according to the following schedule: the patients were told to gargle and rinse their mouth with a tablespoonful (15 ml) of undiluted Siccoral solution every 4 hours. Efficacy and local tolerability were evaluated on Day 7 of the application of Siccoral.

Study design

The design of the study was open and non-comparative. The primary efficacy parameter was the clinical improvement in the symptoms Dryness and Irritation of the mucosa in mouth and throat (none, slight, marked, severe). Further efficacy parameters were the evaluation of the symptomatology by the patients and by the physicians according to a 4-point evaluation scale (very good, good, satisfying, insufficient). Local tolerability was rated using a 3-point scale (good, moderate, poor). The study was conducted according to the principles of GCP (Good Clinical Practice). There

Xerostomia (dryness of mouth) and pharyngitis sicca (chronic irritation of the bucco-pharyngeal cavity) may often cause severe complaints. In most cases the symptoms originate in external influences such as smoking, alcohol consumption or prolonged sojourns in air-conditioned rooms with low humidity. Dryness and irritation in the buccopharyngeal realm may also arise when respiration is mostly through the nose, e.g. snoring or nasal obstruction. Furthermore, pharyngitis sicca and xerostomia may be caused by endocrine disorders such as hypothyroidism or diabetes mellitus or by hormonal changes occurring after the menopause. Especially in the elderly, prolonged administration of certain medications (antidepressants, antihypertensives, antihistamines, anticholinergics, etc.) may inhibit the production of saliva. Irradiation of tumors in the head and neck region or Sjögren’s syndrome are rare causes [1].

Siccoral is a new product containing sea salt (10 mg NaCl in 1 ml of solution) and glycerol. Sea salt has osmotic activity, i.e. it humidifies and cleanses the mucous membranes of the throat and mouth and therefore exerts a positive effect on the healing process in damaged epithelium of the mucosa. Glycerol has hygroscopic properties [2]. It binds water, thereby preventing dehydration of the buccopharyngeal mucosa. This prevents lesions of the mucosal epithelium through dehydration [3–6]. The combination of sea salt and glycerol regenerates the protective barrier function of the mucosal epithelium and therefore reduces the susceptibility to infections in the buccopharyngeal region.
were 2 visits, Visit 1 (Day 0) before the beginning of the treatment with Siccoral; and Visit 2 (Day 7) after 7 days of application of Siccoral.

Statistical analysis
The Cochran-Armitage trend test (chi square test) was used to compare the symptoms Dryness and Irritation of the buccopharyngeal mucosa before and after treatment.

Results
The study was conducted in Switzerland with 5 Ear-Nose-Throat specialists with their own practice. A total of 62 out-patients aged 19–86 (median age 60) participated in the study. The data of 60 patients were evaluated for efficacy and the data of 62 patients for tolerability. Two patients were excluded from the efficacy evaluation because of the use of antibiotics and unclear indications, respectively. For one patient, the time elapsed between the first and second visit was 6 weeks, but the indications given by the patient of the 7-day treatment with Siccoral were clear. All patients participating in the study complained of dryness and mucosal irritations in the mouth and throat. The complaints were partly of unclear origin and partly caused by hormonal changes, smoking, medications, postoperative conditions or radiotherapy. There was also one case with Sjögren’s syndrome.

Efficacy
Statistical analysis of the data using the Cochran-Armitage trend test revealed a highly significant improvement in the symptoms Dryness (p <0.001) by a displacement from “marked” or “severe dryness” before treatment with Siccoral Solution to “none” or “slight dryness” after 7 days of treatment (see Fig. 1).

For the symptom Irritation, statistical analysis with the Cochran-Armitage trend test also showed a highly significant improvement (p <0.001) through displacement from “marked” or “severe irritation” before the treatment with Siccoral Solution to “none” or “slight irritation” after 7 days of treatment (see Fig. 2).

The judgements of the physician and the patient revealed clear statements of “very good” and “good” concerning the therapeutic success: in 70% of the cases (69.99%) the investigators rated the result of the treatment as “very good” and “good”, while more than 73% of the patients (73.33%) rated the result as “very good” and “good” (see Table 1).

Local tolerability
Local tolerability was judged to be good in 56 patients (90.32%) and moderate in 4 patients (6.45%). Two further patients found that Siccoral Solution foamed too much and in an unpleasant way; a third patient found Siccoral too sweet. However, local tolerability was rated as “poor” only in two of these three patients (3.22%).

Adverse events
One patient presented with an intercurrent infection which was treated by a general practitioner with an antibiotic, another patient complained about nausea. One patient presented with a dry cough and complained about intertubal pain and pressure in the ears; since mouth dryness also persisted, this patient discontinued the treatment. No other adverse events were observed.

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**Figure 1: Symptom Dryness**

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Dryness (1 = none 2 = slight 3 = marked 4 = severe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial examination (Day 0)</td>
</tr>
<tr>
<td>1</td>
<td>Final examination (Day 7)</td>
</tr>
</tbody>
</table>

**Figure 2: Symptom Irritation**

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Dryness (1 = none 2 = slight 3 = marked 4 = severe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial examination (Day 0)</td>
</tr>
<tr>
<td>1</td>
<td>Final examination (Day 7)</td>
</tr>
</tbody>
</table>
Summary

Patients with xerostomia and pharyngitis sicca applied Siccoral Solution for 7 days. Before the beginning of the treatment, 80% of the patients complained about marked or severe dryness in the mouth and throat. After 7 days, 78.3% no longer presented with any, or only a slight dryness in the buccopharyngeal region. Irritations of the buccopharyngeal mucosa were even slightly more prevalent at the beginning; in 80% of the patients, this symptom disappeared or improved markedly. Seventy percent of the physicians and 73.3% of the patients were very satisfied with the result of the treatment. Almost all patients considered Siccoral Solution as well tolerated. Adverse events were recorded in isolated cases, and only one case (dry cough) was possibly related to the treatment with Siccoral Solution.

In conclusion, Siccoral Solution can be said to be a very effective treatment for xerostomia and pharyngitis sicca, with few adverse events.

TABLE 1: EVALUATION OF THERAPEUTIC SUCCESS BY PHYSICIAN AND PATIENT.

<table>
<thead>
<tr>
<th>Therapeutic success</th>
<th>Physician's rating after 7 days</th>
<th>Patient's rating after 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of patients (N=60)</td>
<td>Number of patients (N=60)</td>
</tr>
<tr>
<td>Very good</td>
<td>16 (26.66%)</td>
<td>20 (33.33%)</td>
</tr>
<tr>
<td>Good</td>
<td>26 (43.33%)</td>
<td>24 (40.00%)</td>
</tr>
<tr>
<td>Satisfying</td>
<td>13 (21.66%)</td>
<td>10 (16.66%)</td>
</tr>
<tr>
<td>Insufficient</td>
<td>5 (8.33%)</td>
<td>6 (10.00%)</td>
</tr>
<tr>
<td>Total</td>
<td>60 (100%)</td>
<td>60 (100%)</td>
</tr>
</tbody>
</table>

References