Objective: To evaluate whether there was any difference in efficacy when nasal mucosa dryness was treated with pure sesame oil (Nozoil) compared with isotonic sodium chloride solution (ISCS).

Design: In a randomized, crossover study, 79 subjects with nasal mucosa dryness were enrolled. Half the subjects received pure sesame oil for 14 days followed by ISCS for 14 days, and the other half received ISCS for 14 days followed by pure sesame oil for 14 days. During the test period from March 13 to May 30, 2000, the outdoor absolute humidity was low. Nasal mucosa dryness, stuffiness, and crusts were scored every evening with a visual analog scale.

Setting: The County Hospital, Skellefteå, Sweden.

Results: Nasal mucosa dryness improved significantly when pure sesame oil was used compared with ISCS ($P<.001$). The improvement in nasal stuffiness was also better with pure sesame oil ($P<.001$) as was improvement in nasal crusts ($P<.001$). Eight of 10 subjects reported that their nasal symptoms had improved with pure sesame oil compared with 3 of 10 for ISCS ($P<.001$). Adverse events were few and temporary.

Conclusion: When nasal mucosa dryness due to a dry winter climate was treated, pure sesame oil was shown statistically to be significantly more effective than ISCS.


Many people have nasal mucosa dryness without being aware of it. They feel an irritation in the nose, such as itching and burning or smarting pain, and they often have to remove dehydrated mucus and crusts. These complaints increase when the humidity is low, as it is in air-conditioned rooms and during long journeys by airplane. During the winter months in the northern part of the world, it is cold and the absolute humidity is low. Proetz was the first to report that “with approaching winter, there was a wave of dry-nose patients appearing in the office.” He observed that this occurred when the absolute humidity fell below 5 g H2O of water per cubic meter of air (g/m3).

In the city of Skellefteå in the north of Sweden (latitude 69°), daily registrations of the humidity between 1952 and 1957 were made by the local ear, nose, and throat specialist Folke Lindwall. He found that the absolute humidity was below 5 g/m3 from December to May and noted that many of the inhabitants had problems with dry noses and throats during this period.

The usual way to treat dry nasal mucosa has been to administer isotonic sodium chloride solution (ISCS) in different ways, such as a nasal spray, nose drops, a rinsing cane, or a humidifier. In the treatment of dry nasal mucosa, pure sesame oil has also been used.

The aim of this study was to compare ISCS with pure sesame oil in subjects with dry nasal mucosa living in the city of Skellefteå during the dry-air winter period.

For subjects treated with pure sesame oil, the mean pretreatment VAS value for nasal mucosa dryness was 51 and it decreased to 24 after 14 days of treatment, while the corresponding values for subjects treated with ISCS were 46 decreasing to 42. The difference between these scores for pure sesame oil and ISCS was highly significant ($P<.001$). After 10 days of treatment, the difference started to reach statistical significance, as the confidence intervals then did not overlap (Figure 2).

When nasal stuffiness was scored, the mean VAS value for subjects treated with
SUBJECTS AND METHODS

SUBJECTS

An advertisement in the daily Skellefteå newspaper asked inhabitants who had problems with dry nasal mucosa to contact the ear, nose, and throat department at the County Hospital. Almost 300 persons answered, and 79 subjects were enrolled in the study (25 men and 54 women, aged 26-79 years [median age, 60 years]). Excluded were subjects with ongoing upper respiratory tract infections (common cold and acute sinusitis), present symptoms of allergic rhinitis, unilateral symptoms, and marked deviation of the nasal septum, and those undergoing treatment with nasal steroids, nasal decongestants, or antihistamine medication.

All subjects had a low-grade chronic inflammation due to dry nasal mucosa. On average, the subjects had had problems with dry nasal mucosa for 13 years (range, 2-41 years). All 79 subjects completed the trial. No financial incentive was given to the subjects, who wanted to participate in the study because, for years, they had had problems with nasal dryness during the winter.

TEST PERIOD

During the study period (March 13 to May 30, 2000), the outdoor absolute humidity varied between 1.9 and 7.6 g/m³; on 55 (70%) of 79 days, the value was less than 5 g/m³ (Figure 1).

TEST PRODUCTS

The products used in the study included a nasal spray containing pure sesame oil in accordance with the European Pharmacopeia in a 10 mL medical glass bottle sealed with a snap closure and with a dosage pump (Nozoil; Pharmacare AB, V Frolunda, Sweden). No preservatives were added.

The other product was a nasal spray with ISCS containing 0.9% sodium chloride in a 30 mL medical glass bottle sealed with a snap closure and with a dosage pump. The ISCS was buffered with disodium phosphate dihydrate and potassium dihydrogen phosphate to a pH of 7.4. It was preserved with 0.08% metergin (Renassans; Mirwana AB, Gällivare, Sweden).

Half the subjects were randomized to receive pure sesame oil for 14 days followed by ISCS for 14 days, and the other half received ISCS for 14 days followed by pure sesame oil for 14 days. Both treatments were administered with 1 to 3 sprays in each nostril 3 times daily and presented to the subjects as active therapies.

CRITERIA FOR EVALUATION

Every evening, each subject evaluated the efficacy of the treatment that day by using visual analogue scale (VAS) scores. The following 3 symptoms were graded: (1) Nasal mucosa dryness (itching, irritation, and smarting pain); 0, no nasal dryness; and 100, worst imaginable nasal dryness. (2) Nasal stuffiness; 0, no nasal stuffiness; and 100, the nose completely blocked. (3) Nasal crusts (dehydrated mucus); 0, no crusts; and 100, the nose filled with crusts.

After each 14-day treatment period, the subjects answered questions about overall assessments of symptoms and adverse events.

STUDY DESIGN

The planning and monitoring procedures were performed in compliance with good clinical practice, including essential documents being archived by Clinical Data Care AB, Lund, Sweden, and the study was approved by the Umeå Independent Ethics Committee. The subjects were given oral and written information about the study, and all consented to participate.

STATISTICAL METHODS

The VAS measurements were analyzed using the analysis of variance technique for repeated measures. The model allowed for variations due to subjects within sequence, treatment, day, and period. The results are expressed as least-square means and are presented with 95% confidence intervals to estimate the magnitude of any treatment effect. No imputations were performed. All tests were 2-tailed, and P values less than .05 were considered statistically significant. Differences in the proportion of adverse events between treatments were tested using McNemar test. The statistical analyses were performed using SAS statistical software, version 6.12 (SAS Institute Inc, Cary, NC).

pure sesame oil decreased from 46 to 24, compared with 43 to 37 for those treated with ISCS (P<.001). A statistically significant difference was seen on day 14, when the confidence intervals did not overlap (Figure 3).

The mean VAS value for nasal crusts for subjects treated with pure sesame oil decreased from 45 to 19, and from 40 to 37 for subjects treated with ISCS (P<.001). After 9 days of treatment, the confidence intervals did not overlap, showing that pure sesame oil is a significantly better treatment than ISCS (Figure 4).

In the overall assessments of symptoms after each 14-day treatment period, it was shown that pure sesame oil produced a statistically significantly more efficacious treatment effect compared with ISCS (P<.001). Most subjects (58 [73%]) reported that their symptoms improved after the pure sesame oil treatment, 6 (8%) reported that their symptoms had disappeared, 8 (10%) reported that their symptoms were unchanged, and 2 (3%) reported that their symptoms had worsened. The question was not answered by 5 subjects.

During the study, 6 subjects (8%) in the pure sesame oil group and 4 (5%) in the ISCS group reported adverse events (no difference between groups [P=.30]). In the pure sesame oil group, 4 subjects (5%) contracted an upper respiratory tract infection compared with 2 (3%) subjects in the ISCS group; 2 (3%) subjects in the pure...
sesame oil group contracted rhinitis compared with 1 (1%) subject who developed sinusitis and 1 (1%) who had nosebleeds in the ISCS group. Two of 4 subjects who contracted an upper respiratory tract infection when using pure sesame oil were cured while continuing this treatment.

COMMENT

In many parts of the world, the outdoor climate during the winter is characterized by low humidity. When the absolute humidity falls below 5 g/m³, the inhabitants have problems with dry nasal mucosa.1,2 In this study, we compared the effect of pure sesame oil with that for ISCS for people with nasal problems due to dry outdoor air. We found that the efficacy of pure sesame oil was statistically significantly better than that for ISCS. It is clear that nasal problems due to dry outdoor air are a common complaint in the northern part of Sweden during the winter, as almost 300 of 30,000 inhabitants wanted to participate in our study.

During the study period, the outdoor humidity was measured every day and the mean value was below 5 g/m³ of air on 70% of the days. During the last 2 weeks in May, the humidity increased somewhat.

When the subjects rated their nasal complaints, it was found that nasal mucosa dryness produced the highest score, followed by nasal stuffiness and nasal crusts. During the treatment period, we noted that there was a significant decrease in complaints about nasal crusts after 9 days of treatment with pure sesame oil, about nasal dryness after 10 days, and about nasal stuffiness after 14 days. When pure sesame oil was used, a confirmed improvement was seen from day to day. This was not observed for ISCS.

After 14 days of treatment with pure sesame oil, more than 8 of 10 subjects reported that their symptoms had disappeared or improved. When ISCS was used, this was seen in only about 3 of 10 subjects. In the ISCS group, one third of the subjects reported that their problems were unchanged and about the same number reported that their problems had worsened. When pure sesame oil was used, only 2 subjects reported that their symptoms had worsened; both had contracted an upper respiratory tract infection.

The subjects were informed before they started the study that pure sesame oil and ISCS were both active therapies. Isotonic sodium chloride solution has long been the most commonly used therapy for nasal dryness. It has been shown that ISCS results in little interference with the nasal mucosa or mucociliary clearance.3

1. Isotonic sodium chloride solution has long been the most commonly used therapy for nasal dryness.
2. ISCS indicates isotonic-sodium chloride solution.

Figure 1. The absolute humidity (grams of water per cubic meter of air) in the outdoor air during the test period from March 13, 2000, to May 30, 2000.

Figure 2. Nasal mucosa dryness improvement expressed as a visual analog scale (VAS) score, where 0 indicates no nasal dryness at all and 100, worst imaginable nasal dryness. The mean values for each day of treatment are presented, as well as the 95% confidence intervals. The difference between pure sesame oil and isotonic sodium chloride solution (ISCS) is significant (P<.001).

Figure 3. Nasal stuffiness improvement expressed as a visual analog scale (VAS) score, where 0 indicates no nasal stuffiness and 100, the nose completely blocked. For each day of treatment, the mean values and 95% confidence intervals are presented. The difference between pure sesame oil and ISCS is significant (P<.001).

Figure 4. Nasal crusts improvement expressed as a visual analog scale (VAS) score, where 0 indicates no crusts and 100, the nose filled with crusts. For each day of the two 14-day treatment periods, the mean values and 95% confidence intervals are presented. The difference between the 2 therapies is significant (P<.001). ISCS indicates isotonic-sodium chloride solution.
As ISCS is inert, with the main purpose of humidifying the mucosa, we have chosen to regard ISCS as a kind of placebo therapy against which we wanted to test the efficacy of pure sesame oil on nasal mucosa dryness.

The adverse effects from using the pure sesame oil were few in number and mild. Six of 79 subjects experienced signs of upper respiratory tract infections, which is to be expected in a community where these infections are common at this time of year. Two of the subjects were cured while continuing to use the pure sesame oil. There was no difference in the frequency of these infections between the periods with pure sesame oil and ISCS.

In a review by Spencer, the risk of lipoid pneumonia and paraffin granuloma was mentioned when mineral oils like paraffin are used as drops or sprays in the nose. Mineral oils that remain in the lung will eventually cause fibrosis. For the body, there is, however, a great difference between mineral oils and vegetable oils such as pure sesame oil. Both are substances that can be digested and not encapsulated, as paraffin is. Vegetable oils are not hydrolyzed by the lung lipases, but “they are mainly expectorated, causing little or no damage to the lung.”

When the mucociliary movements from nasal biopsy specimens from 8 healthy volunteers, it was shown that the ciliary beat frequency was the same before and after 1-hour exposure to pure sesame oil (Herbert Riechelmann, MD, PhD, written communication, March 19, 1995). Therefore, the ciliary movements are unaffected by pure sesame oil, and any small amounts of pure sesame oil that reach the bronchi can be transported away.

Sesame oil of pharmaceutical quality has been used for many years as a solvent for drugs that are given intramuscularly, such as testosterone, and no adverse effects have been observed. It has also been used when bronchographies have been performed since the sesame oil is stable, neutral, nonirritating, and inert.

A few subjects have been reported to be allergic to sesame seed. However, when they received oral 1-mL doses of pharmaceutical quality sesame oil, no allergic reactions were observed. The reason is that the pure sesame oil contains no proteins that can cause allergic reactions.

When pure sesame oil was studied in patients who had previously undergone nasal irradiation and outpatients who were experiencing problems with dryness of the nose, it was found that the nasal problems decreased significantly during treatment with pure sesame oil.

It is well-known that many vegetable oils contain vitamin E, and sesame oil is one with a high concentration. The batch of pure sesame oil used for the study comprised 35 mg/kg of α-tocopherol and 308 mg/kg of β+γ-tocopherol. One potential mechanism of action of pure sesame oil might be as a scavenger. The tocopherols might neutralize oxidants such as ozone and oxides of nitrogen in the inhaled air and prevent tissue damage and inflammation that would otherwise occur. When tocopherols are incorporated into the cell membranes, a carryover effect might be expected.

The present study underlines the fact that the best way to treat nasal mucosa dryness is to use pharmaceutical quality sesame oil and not ISCS. The test was conducted in the winter when it is known that the humidity is low. There are, however, other situations with low humidity when complaints of nasal mucosa dryness occur. These include long journeys by airplane, air-conditioned rooms, and areas with a warm, dry inland climate or deserts. The aging nose is also sensitive to drying and crust formation. As shown here, half the test subjects were older than 60 years.

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