

A Daily Nasal Spray with Saline Prevents Symptoms of Rhinitis

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Objective—To ascertain whether a daily nasal spray with physiological saline could prevent symptoms of common cold in a population of otherwise healthy adults.

Material and Methods—This was a study involving 10 weeks of daily use of a nasal saline spray and 10 weeks of only recording symptoms. Young adults eligible for military service at an army barrack in Boden, Sweden were invited to participate in the study and 108 healthy conscripts aged ≈ 20 years agreed to do so. Data were recorded by the participants in a diary at home. In the diary the participants noted symptoms such as rhinitis, blocked nose, cough, fever and sore throat (pharyngeal pain). They also recorded inability to perform their duties due to the symptoms, and any medication or antibiotics necessitated by upper respiratory tract infection.

Results—A total of 69 subjects completed the 20-week diary period. For 60 of them, compliance during the spray period exceeded 60% and their data were used in the statistical calculations. During the spray period the number of days with nasal secretion and/or blocked nose (mean 6.4 days) was significantly ($p = 0.027$) lower than that during the observation period (mean 11 days). Furthermore, the participants had a mean of 0.7 episodes of upper respiratory tract infection during the spray period, compared with 1.0 episodes during the observation period ($p = 0.05$).

Conclusion—A daily nasal spray with saline can prevent nasal symptoms of common cold in a population of otherwise healthy adults. *Key words:* common cold, nasal spray, rhinitis, saline, upper respiratory tract symptoms.

INTRODUCTION

Upper respiratory tract infections (URTIs) are one of the commonest forms of disease. Although seldom serious, they affect society to a great extent, for example in terms of loss of working days. In a population of young adults eligible for military service, one might expect an even higher incidence of URTI, due to the more crowded living conditions and therefore increased risk of the spread of viruses and bacteria.

Previous studies on nasally administered physiological saline as a remedy have shown amelioration of the severity of subjective symptoms and an improved mucosal appearance at endoscopic examination in patients with chronic sinusitis (1). A Finnish study (2) indicated a positive effect of nasal saline irrigation on nasal symptoms in patients with chronic rhinitis. Spector et al. (3) reported that a nasal spray with saline reduced stuffiness and sneezing and improved the mucosa microscopically in patients with perennial rhinitis. The use of nasal saline drops (4 times a day for 10 days) in children with acute sinusitis gave a better outcome than antibiotic treatment (4). The above examples demonstrate the beneficial effect of nasally administered saline in persons with a variety of conditions. Furthermore, the results of a cross-sectional study of otherwise healthy people working in an industrial environment affected by air pollution showed a reduction in nasal symptoms and improved mucociliary clearance following nasal rinsing with saline (5). Studies are lacking, however, on the possible preventive effects of a daily nasal spray with physio-

logical saline in healthy persons living in a non-polluted environment. The aim of this study was to establish whether such treatment could prevent or reduce symptoms of URTI in otherwise healthy adults.

MATERIAL AND METHODS

As the most commonly accepted placebo solution is physiological saline, it was not possible to conduct a placebo-controlled study. The study was designed as a clinical investigation among young adult military conscripts. In this way, all study participants served as their own controls. One of the battalions stationed in Boden, Sweden was invited to participate in the study. A total of 108 men enrolled and were randomly divided into 1 of 2 groups: 1 started with the nasal spray, while the other started by only registering symptoms of URTI (see Table I). We defined an URTI episode as follows: (i) at least 1 of the symptoms must be rhinitis; (ii) a blocked nose alone was not sufficient as a symptom; (iii) the symptom episode must last for at least 3 days; and (iv) there must be an interval of at least 7 healthy days before the next episode. The study started in October 2002 and ended in February 2003.

On enrolment, all participants filled in a form with anamnestic data and gave their written informed consent to participate. Every participant undertook a 10-week period of nasal spraying with physiological saline (Renässans[®]; Miwana AB, Gällivare, Sweden) twice daily (3 puffs in each nostril), and a 10-week period of only registering symptoms. The two periods were separated by a wash-out period of 2 weeks; the

Table I. Example of the diary filled in at home by the participants. Under "Symptoms" the participants also recorded any side-effects of the spray

Date of birth:			Name:		Number in the study:					
Date	Spray		Symptoms ^a		Duties affected ^b		Visit to doctor		Medicines ^c	
Week 1	AM	PM	No	Yes (specify)	No	Yes (specify)	No	Yes (specify)	No	Yes (specify)

^aHigh temperature, sore throat, nasal blockage, nasal secretion, sinusitis, ear ache, cough.

^bRest inside at the ward or rest at the garrison hospital.

^cDecongestants, paracetamol, mucolytic preparations, antibiotics.

diaries were collected from the participants during the wash-out period and at the end of the study. Throughout the 20-week period, each participant recorded the following details in a diary at home: (i) all upper airway symptoms; (ii) whether they were unfit to carry out their duties; and (iii) whether they were taking any medication (Table I).

The study was approved by the ethics committee of Umeå University (approval No. 03-322).

Statistical analysis

The SPSS computer program was used and the paired *t*-test was applied for the statistical calculations. When analysing the number of URTI episodes, the Wilcoxon rank sum test was used. $p < 0.05$ was considered significant.

RESULTS

Of the 108 participants, 69 completed the 20-week study period. Thirty-four participants stopped taking the medication for reasons such as inconvenience or forgetfulness. Three conscripts discontinued the study because they were drafted and two because of a sensation of dryness in the nose during the saline

spray period.

Regarding the possible days of nasal spraying, a compliance level of at least 60% was deemed appropriate in order to evaluate a potential protective effect of the spray. No more than 10 unrecorded days were permitted during the 20-week period of symptom recording. Sixty persons fulfilled the above criteria and were analysed statistically.

The mean number of days with any kind of airway symptoms (Table I) was 9.4 during the spray period and 13.4 during the observation period and this difference was not significant ($p = 0.069$) (Table II). There was, however, a significant reduction in nasal secretion and blocked nose events during the spray period. During this period the subjects recorded a mean of 6.4 days with nasal blockage or secretion, while during the period without spraying they recorded nasal symptoms on 11 days ($p = 0.027$), giving a symptom reduction of 40% with spraying (Fig. 1). The mean number of URTI episodes was 0.7 during the spray period and 1.0 during the observation period, and this difference was significant ($p = 0.05$).

There were no significant differences in antibiotic consumption, use of other medicines or duration of episodes of URTI symptoms between the two periods.

Table II. The results calculated for the participants who had no more than 10 spray days missed in the journal and had a compliance of $> 60\%$ ($n = 60$). All values shown are means

Parameter	Spray	Observation	<i>p</i>
Symptoms of URTI (days) ^a	9.4	13.4	0.069
Nasal symptoms (days) ^b	6.4	11	0.027
No. of episodes of URTI	0.7	1.0	0.05 ^f
Duration of episodes (days) ^a	7.3	10.6	0.173
Affected duties (% of symptom days) ^c	22.3	18.3	0.599
Total medicine consumption (days) ^d	2.8	2.5	0.082
Antibiotic consumption (days) ^e	0.3	0.7	0.298

^aAll symptoms listed in Table I.

^bNasal obstruction or nasal secretion.

^cAll symptoms listed in Table I.

^dAll medications used, including decongestants, pain relief and antibiotics (Table I).

^eAntibiotics used against URTI.

^fWilcoxon signed ranks test; all other comparisons were made using the *t*-test.

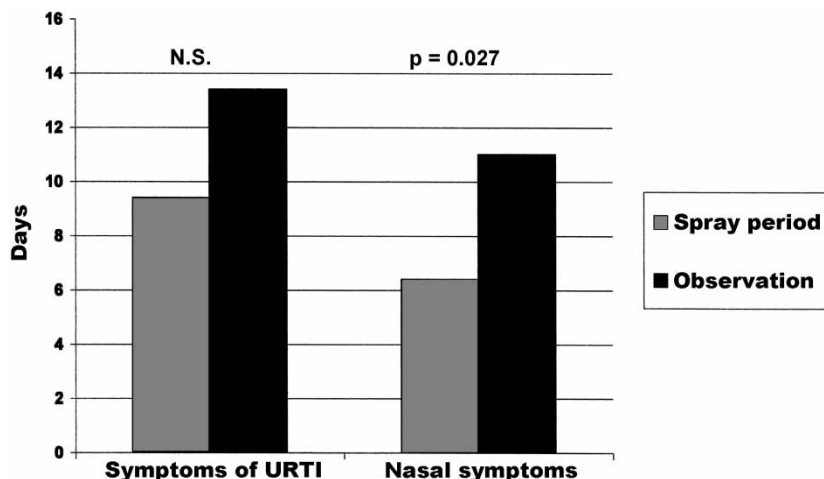


Fig. 1. Graph constructed from the results shown in Table II. "Symptoms of URTI" = "a" in Table II; "Nasal symptoms" = "b" in Table II.

Illness leading to an inability to carry out duties was the same in both groups, regarding the proportion of symptom-free days. However, the total number of "sick days" that affected duties was less during the spray period, as the number of days with symptoms was also less during that period.

DISCUSSION

In this study we have shown that nasal spraying with physiological saline, twice daily, significantly reduced the number of days with the commonest symptoms of rhinitis, namely nasal blockage and secretion. The study period chosen was October to February in order to cover the period when problems with URTI are most frequent.

In this study we used a crossover design, instead of having a separate control group of different individuals. We believe that the symptoms reported will be more reliable in this way, as they are "calibrated" by the same person during both study periods. One weakness of the study is that we did not perform any objective measurements of the nasal mucosa.

Most previous studies on the effects of saline nasal irrigation were performed postoperatively (6, 7). Furthermore, some of the earlier studies did not use

a control group (2). Our study had the same design as that of Holmström et al. (5), with the exception that in their study the subjects were working in a polluted environment. Many authors have used nasal irrigation or lavage (6, 7), but our study indicated that use of a nasal spray twice daily is sufficient to prevent nasal blockage and secretion.

The design of this study, using a diary which had to be filled in daily at home, was not easy to comply with, and this explains why $\approx 30\%$ of participants did not complete the study. There is, however, no reason to believe that those who discontinued the study differed from those who completed it regarding the risk of having URTI symptoms. In the statistical calculations we included only those who used the spray on $>60\%$ of the possible days. Among the 69 persons who completed the study, some had a compliance of $<50\%$ and the results would have been subsequently poorer had they been included. If we had included only persons with a compliance of $>70\%$, we would naturally have seen a better effect of the nasal spray, which would also be expected if the effects of the spray were real (Table III).

There was a tendency towards fewer days with any kind of URTI symptoms during the spray period, but this did not reach significance. In contrast, the effects

Table III. Variation in duration of nasal symptoms as a function of compliance level

Compliance level (%)	n	Mean no. of days with nasal symptoms ^a		p ^b
		Spray	Observation	
0	69	8.9	12.6	0.088
> 60	60	6.4	11.0	0.027
> 70	54	5.8	10.9	0.02

^aEquivalent to "b" in Table II.

^bt-test.

regarding nasal symptoms were significant. It is probable that a nasal spray predominantly affects the nose and has hardly any effect on symptoms of tonsillitis or pneumonia. The ability of the saline spray to prevent episodes of URTI reached significance. A study by Adam et al. (8) showed no difference in the duration of a common cold between a group of patients with common cold or sinus infection who used a nasal saline spray and another group who were observed only. In that study, however, the preventive effect of nasal saline was not investigated. Inability to work in the present study was the same in both groups when we divided the number of days absent from duties by the number of days with symptoms of URTI, thus indicating that the nasal spray did not affect the severity of illness.

Some *in vitro* studies (9) have shown that rinsing of the nasal mucosa with physiological saline makes the mucus less viscous, thereby enhancing the transport of irritants from the mucosal surface. Theoretical explanations for the positive effect of a daily nasal spray with saline include: (i) an anti-inflammatory reaction to a reduction in inflammatory mediators in nasal secretions (10); (ii) mechanical removal of potentially harmful substances (11); and (iii) improved ciliary function due to the increased amount of fluid or dampness in the nose (12).

In conclusion, we have shown a preventive effect of a daily nasal saline spray on nasal symptoms of the common cold. Taken together with the results of previous studies, one can conclude that a nasal spray of physiological saline is an inexpensive remedy, has no serious adverse effects and is easy to administer. If regular use of such a spray can significantly reduce the number of days with rhinitis, it would have considerable effects on general health, especially during the winter when URTIs are rife.

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