

Balanced physiological saline in the treatment of chronic rhinitis

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SUMMARY

The effects of a special balanced physiological saline on nasal symptoms of 93 patients with chronic rhinitis were studied. The main diagnoses of the patients were allergic rhinitis, atrophic rhinitis and ozaena, rhinitis sicca, chronic sinusitis, nasal polyposis and postoperative condition after nasal surgery. The tested solution was administered by a simple metered dose pump. 85 (91%) of the patients reported beneficial effects of the tested solution on nasal symptoms. In addition, 22 (71%) of those patients who used continuous anti-allergic medication, mainly intranasal steroids, reported that the tested solution improved the efficacy of their ordinary drug. So the tested solution proved to be beneficial in humidifying atrophic or otherwise dry mucosa, douching crusty nose and as adjuvant therapy in the treatment of allergic rhinitis.

INTRODUCTION

The main function of the ciliated nasal mucosa and its mucous blanket is to condition and filter the inspired air and to protect the organism against noxious elements in the atmosphere. Mucociliary clearance is affected by several factors. If nasal secretion decreases, e.g. as a result of atrophy of mucus-producing elements or disturbances in regulatory neural mechanisms, drying of the mucosa may cause marked impairment of mucociliary function. In pathological conditions, such as chronic allergic or non-allergic rhinitis, mucociliary clearance is usually impaired and nasal breathing is hampered by accumulating secretion or crusts. Mucosal cilia may be destroyed and the composition or viscoelastic properties of the mucus may be altered. Many of the drugs used for treatment of nasal symptoms may also interfere with nasal physiology.

Nasal irrigation with saline (Smiegelöf's irrigation) has been used since the beginning of this century to remove crusts and improve nasal breathing in severe chronic rhinitis and ozaena. It is still the main treatment for ozaena and for acute rhinitis in infants, as excessive use of vasoconstrictor nose drops is contraindicated in early childhood.

In a recent study by Spector et al. (1982) physiological saline was shown to have a beneficial wetting effect in 12 patients with perennial rhinitis. Nasal irrigation with large amounts of saline is, however, an inconvenient procedure, and patients are often reluctant to use it. We have studied the effect of a special humidifying agent delivered with a simple metered dose pump on 93 patients with chronic allergic or non-allergic rhinitis.

PATIENTS AND METHODS

Ninety-three patients, 64 females and 29 males, entered the study. The mean age of the patients was 48.6 years (range 8–83). The patients had had nasal symptoms for at least two years. The otorhinolaryngological examination of the patients included anterior and posterior rhinoscopy, sinus X-ray and clinical examination and, if allergy was suspected, nasal cytological examination, skin testing, and nasal or conjunctival provocation tests were carried out. The diagnoses of the patients are listed in Table 1. Nineteen patients used intranasal steroids regularly (12 flunisolide and 7 beclomethasone dipropionate). Eight patients used vitamin A nose drops, three used antihistamines and one patient sodium chromoglycate.

Table 1. Diagnoses of the patients.

diagnosis	number of patients
allergic rhinitis	20
allergic rhinitis with nasal polyposis	9
rhinitis atrophicans	6
ozaena	8
vasomotor rhinitis	4
chronic (operated) sinusitis	5
chronic rhinitis of unknown etiology	25
other (postoperative condition, septal deviation etc.)	16
total	93

The composition of the test solution was as follows:

Sodium chloride	7.72 mg
Potassium chloride	0.42 mg
Calcium chloride	0.12 mg
Benzalkonium chloride	0.1 mg
Aq. purif. ad	1 ml

The solution is commercially available (Humidose) in a 20 ml bottle equipped with a metered dose pump giving 0.09 ml of solution at each dose. The patients were instructed to use the solution ad libitum for one week, and recorded the number and frequency of applications on a diary card.

At the end of the trial the patients completed a questionnaire about the effect of

the test solution on nasal blockage and on the efficacy of their ordinary nasal medication. They were asked to rate the effect as good, moderate or none. They were also requested to report possible side-effects.

RESULTS

Thirty-eight patients (41%) used the solution 1–2 times, 52 patients (56%) 3–5 times, and three patients (3%) 6–10 times daily. The mean number of applications was 3.3 (± 0.4) times daily. Seventy-seven (83%) patients administered 1–2 metered doses, 7 (7%) used 3–5 “puffs” and 9 (10%) 6–10 “puffs” at each application.

Eighty-five (91%) stated that the test solution had relieved nasal blockage and 22 (71%) patients that the efficacy of their ordinary medication for nasal symptoms had improved (Table 2). Seventy-six (81%) of the patients reported no side-effects. Of the 17 patients (19%) who reported side-effects, 16 complained of itching of the nose or sneezing, and one reported bloody secretion from the nose. The side-effects were transient, lasting only for a few seconds after application. The patient who reported bloody secretion used a nasal steroid on a regular basis.

Table 2. The effect of the humidifying solution on nasal symptoms.

	effect on nasal obstruction		effect on ordinary medication	
	N	%	N	%
good	27	29	7	22
moderate	58	62	15	49
none	7	8	7	23
no answer	1	1	2	6
all	93	100	31	100

DISCUSSION

This study of a physiological humidifying agent was conducted as an open trial, because a suitable placebo is difficult to find. Our solution contains less physiological saline than is usually used in irrigation of the nasal passages. A metered dose pump is also easy for the patient to use and improves compliance. The beneficial effect of the solution on nasal blockage is apparently mostly due to the rinsing effect of the solution rather than to any pharmacological action. As yet, very little is known about the effect of different electrolytic solutions on mucosal physiology. Large amounts of irrigation fluids dilute or wash away the mucus blanket and can cause impairment of mucociliary function (Negus, 1958). McLean et al. (1976) found that phosphate-buffered saline aerosolized into the nostrils of atopic and non-atopic subjects increased nasal airway resistance by on average 22.5%. During repeated challenges with saline, nasal resistance in-

creased more than 50% from the baseline value in some patients. Intranasal atropine effectively blocked the increase in nasal resistance, suggesting parasympathetic stimulation as a mechanism. This effect of saline is not important in clinical use but must be taken into account when nasal challenge tests are evaluated. The pH value of the intercellular fluid is one of the most important factors influencing ciliary movement. Optimal pH is 7 ± 0.5 . Respiratory cilia tolerate an alkaline environment better than an acidic environment. Cilia are still working at pH 8.5, whereas their action is markedly impaired below pH 6.4 (Negus, 1958; van de Donk et al., 1980a). Hypertonic or hypotonic solutions are harmful for ciliary function, and osmolality should be normal (van Donk et al., 1980a; Tore-malm et al., 1983). These factors are regulated by the hydrostatic pressure, diffusion and osmosis between the cell membranes and the tissue compartments. Calcium is an essential constituent for intercellular fluid. Calcium ions are thought to play an important role in the physiology of the respiratory mucosa and to interfere with mucociliary function. Calcium is one of the constituents in Ringer's and Locke-Ringer's solutions, and it has been shown that ciliary beat frequency remains normal longer in these solutions than in 0.9% NaCl solution (van de Donk et al., 1980a). The solution used in this study was a balanced physiological Ringer-based, iso-osmolal neutral solution, but conclusions as to its effect on nasal mucociliary function cannot be drawn on the basis of this study.

Commercial preparations of nose and eye drops contain some preservative to inhibit bacterial growth. In experimental circumstances all commonly used preservatives inhibit ciliary beat frequency to some extent, lipophilic and mercuric compounds being the most ciliotoxic. Benzalkonium chloride was found to be the least ciliotoxic of the preservatives tested by van de Donk et al. (1980b). Our solution contained benzalkonium chloride at minimum bacteriostatic concentration. This seemed to be the best choice, because data on the long-term effects of less cilia-inhibitory agents are still lacking. Moreover, the effect exerted by the preservative in the living nose may not be identical with the effect observed in experimental conditions where e.g. the diluting effect of the mucus is absent. In a study of a benzalkonium chloride containing steroid solution, benzalkonium chloride was found to inhibit ciliary beat frequency *in vitro*, but no impairment of mucociliary function was observed *in vivo* (Stanley et al., 1985). Preservatives have been the subject of much discussion in the past few years, and the main issue is perhaps not to find less harmful preservatives but to develop such preparations and applicators that no preservatives are needed.

The patients of the present study considered the humidifying solution a good addition to their ordinary nasal medication. They were instructed to use the solution in the morning and before administration of other medication, e.g. an intranasal steroid. This may have contributed to better distribution of the drug. The patients who had undergone septal reconstruction, polypectomy or sinus surgery

also found that the solution had a beneficial effect in douching of the nose. We agree with Spector et al. (1982) that, at least in mild cases of perennial rhinitis, wetting agents such as physiological saline are worth trying before the institution of or in conjunction with other therapeutical agents.

ZUSAMMENFASSUNG

Die Wirkungen einer speziell balancierten physiologischen Kochsalzlösung auf Nasensymptome wurden an 93 Patienten mit chronischer Rhinitis untersucht. Die Hauptdiagnosen der Patienten waren: allergische Rhinitis, atrophische Rhinitis mit Ozäna, Rhinitis sicca, chronische Sinusitis, nasale Polyposis und post-operativer Zustand nach Nasenchirurgie. Die Testlösung wurde mittels einer einfachen Dosierpumpe verabreicht. 85 Patienten (91%) gaben eine günstige Wirkung der Testlösung auf ihre Nasensymptome an. Ausserdem berichteten 22 (71%) von den 31 Patienten unter einer kontinuierlichen antiallergischen Medikation – hauptsächlich unter intranasaler Steroide – von einer verbesserten Wirksamkeit dieser Medikation. Mit der Testlösung wurden also bei der Anfeuchtung einer atrophischen oder sonst trockenen Mukosa, Spülung bei Borkenbildung und als Adjuvans in der Behandlung der allergischen Rhinitis günstige Resultate erzielt.

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