

Nasal douching as a valuable adjunct in the management of chronic rhinosinusitis*

Michelle Taccariello, Abhi Parikh, Yvonne Darby, Glenis Scadding

Rhinology Department, Royal National Throat, Nose & Ear Hospital, London, UK

SUMMARY

The effect of nasal douching in 40 patients with chronic rhinosinusitis was tested, and two different preparations compared: 19 receiving traditional alkaline nasal douche and 21 receiving a sterile sea water spray, in addition to their regular treatment. Douching per se improved endoscopic appearances (p=.009), and quality of life scores (p=.008). These measures did not change in a control group (n=22) who received standard treatment for chronic rhinosinusitis, but no douche. There were significant differences between the two douching preparations in that the alkaline nasal douche improved endoscopic appearances but not quality of life, whereas the opposite was true for the spray.

Key words: alkaline nasal douche, sea water spray, chronic rhinosinusitis.

INTRODUCTION

Otolaryngologists prescribe douching for various nasal diseases, where viscid discharge, crusting due to dried secretions, and atrophic changes secondary to inflammation or surgery are clinical findings. Despite its widespread use there is a paucity of medical literature on its effectiveness, and underlying mechanism of action.

At the turn of the century Wyatt Wingrave gave a clinical lecture at the Central London Throat, Nose and Ear Hospital (now Royal National Throat, Nose and Ear Hospital) entitled “The nature of discharges and douches”, and later published in the Lancet (Wingrave, 1902). Nasal douching thus held a very central place in the treatment of nasal diseases. He outlines the principles of nasal douching, and the criteria for an ideal douche. Emphasis was laid on the nature of discharge, as it determined the solvents and precipitants used in making an appropriate douche. Sea water was in use even then, and got a very favourable mention, particularly for treatment of atrophic and fetid rhinitis.

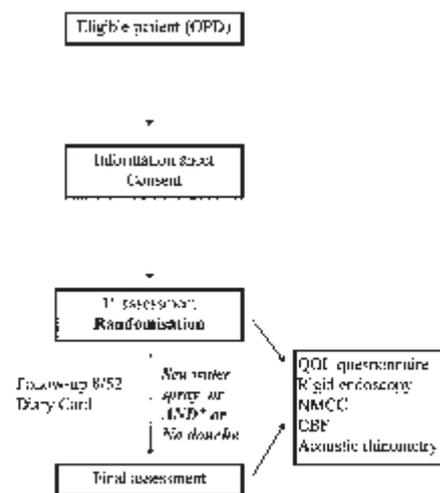
Isotonic sterile sea water solutions have been in use for over 20 years in improving nasal hygiene. They are popular on the Continent, and are available in pressurized metal containers. Application of gentle pressure on the nozzle leads to a fine spray of the solution.

The aim of this study was to evaluate the effectiveness of regular nasal douching in patients with chronic rhinosinusitis (CRS). Patients with CRS (n=40) were randomized to receive either a sea water spray or alkaline nasal douche powder to make into a solution for sniffing. This treatment group was compared to controls (n=22) who received only topical corticosteroids,

and/or antibiotics as required. The study was single-blind (observer blinded) with follow-up of 8 weeks.

MATERIALS AND METHODS

This section follows recommendations on reporting randomised trials (CONSORT group, 1994). Ethics committee approval was obtained. Follow-up patients attending the Rhinology clinics were targeted, the study design is shown in Figure 1. Criteria for chronic rhinosinusitis are outlined in Box 1. An information sheet outlining the project, patient involvement, procedures to be performed, and the degree of discomfort



*AND alkaline nasal douche

Figure 1. Design of trial.

<ul style="list-style-type: none"> ■ Discoloured nasal discharge: >2 weeks at a time >1 month plus (at least 2 of the following) <ul style="list-style-type: none"> - nasal obstruction - headache - facial pain - fever plus ◆ Endoscopic and/or CT evidence of sinusitis* (at some stage according to scoring system mentioned in references)
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*Lund et al. 1995; **Lund et al. 1991

Box 1. Diagnostic criteria for chronic rhinosinusitis, and entry into trial.

caused by them was provided. Patients were enrolled after a formal consent. Parameters assessed are shown in Figure 1.

Of 49 patients enrolled for the trial, 41 formed the treatment group, and 8 were controls. The remaining controls (n=17) were patients from a simultaneous study evaluating the effect of nasal steroids on chronic rhinosinusitis. The control group were not using a douche as adjunctive treatment. The treatment group comprised 22 females and 19 males with a mean age of 41 years (range: 14-76).

The majority had (77%) undergone surgery for sinus disease in the past. 16 patients had been operated once, 8 twice, 1 three times, 1 four times, and 1 had undergone eight operations. Procedures included endoscopic sinus surgery, intranasal polypectomy/ethmoidectomy, and septal/turbinate surgery. Current medical therapy included intranasal steroids-INS-(n=31), long-term once daily antibiotics (n=1), a combination of the two (n=3), intranasal antihistamine and intranasal steroids (n=2), and intravenous immunoglobulin therapy for deficiency (n=3). The eight control group patients had the same baseline and end of study assessments as the other two groups, and also kept a diary.

This control group comprised 5 males and 3 females with a mean age of 44 years (range: 27-59). Sixty-three percent had undergone surgery, the range of surgery being similar to the main group. All patients in this group were on regular intranasal steroids.

Nasal mucociliary clearance time (NMCC)

This was measured using the saccharin test. A quarter granule of saccharin was placed about 1 cm behind the anterior end of the inferior turbinate. Patients were asked to sit in the waiting area, without sniffing or blowing their nose. The time taken to sense a sweet taste was noted. The patients were 'blind' to the nature of the test substance.

Ciliary beat frequency (CBF)

Ciliary brushings were taken from the inferior turbinate using a rhinoprobe, and stored in Eagle's solution until analysis, which was done within 2 hours. Examination of this specimen is done on a microscope slide placed on a pre-warmed stage (37°C) as previously described (Scadding et al., 1995). CBF is measured using the photometric method (Greenstone et al., 1984).

Rigid endoscopy

This procedure was performed using a 2.7 mm (0°/30°) telescope without a local anaesthetic so that the above measurements were not compromised. If needed, local anaesthetic application was made after NMCC and CBF. A scoring system was used as suggested by the Staging and Therapy group (Lund et al., 1995). The signs evaluated included discharge, oedema, crusting, polyps, and scars or adhesions. Each sign was rated on a 0-2 scale.

Acoustic Rhinometry

This procedure was performed using the gm instruments acoustic rhinometer. Parameters studied included changes in minimum cross sectional area and volume. A standardised protocol was used to minimise within-run, and test-retest variability. Prior to the procedure patients were seated in the Rhinology laboratory for 10 minutes to acclimatise. Variability was reduced by seating the patient at the same height, using the same size nose piece, and avoiding distortion of nasal contours. A protractor fixed to the rhinometer box ensured that the same angle of the tube was used for repeated measurements. Click sounds separated by 2 milliseconds were used to acquire 5 readings. Inter-reading variability was kept below 10%. The parameters measured were the minimal cross-sectional area (Amin), and Volume (Vol.) between 2-4 centimetres.

Quality of life questionnaire

We used a modified version of the Juniper questionnaire (Juniper and Guyatt, 1991). To make it more disease-specific unvalidated questions were added or substituted based on several years experience of history taking and symptom scoring in CRS patients. Patients were asked to complete the questionnaire at the initial and final visits.

Diary Card

Nasal discharge (anterior/posterior), blockage, headache, and facial pain were marked on a 0-3 scale (0 = no symptoms; 3 = severe) daily for the 8 weeks of the trial.

Randomisation

This was generated within the pharmacy. No observer was involved in the generation of randomisation numbers. The code was broken after the final patient had been assessed. A control group of patients were maintained on their usual therapy without additional douching, and were evaluated as for the trial subjects at the start of the trial and again 8 weeks later.

Therapy

Patients were given either the sterile sea water spray (Sterimar™) or alkaline nasal douche. The spray is available in a pressurised container with 250 actuations. The douche powder is a 1:1 mixture of sodium chloride (BP), and sodium bicarbonate (BP) prepared by the hospital pharmacy. Subjects were given typewritten instructions for preparing the douche. Half level spoonful of the powder was to be added to 60 mls of warm water. This solution was poured into the cupped hand and sniff-

fed. Fresh solution was prepared for every use. Either treatment was used twice daily. This treatment was used along with their current intranasal medication. No other alteration in treatment was made immediately prior to entry into trial or during its 8 weeks.

Statistical analysis

Baseline clinical characteristics were compared for patients randomised to spray, alkaline nasal douche, or control groups using the Kruskal-Wallis test. To evaluate the effect of nasal douching irrespective of the delivery method we compared the following parameters at the start and end of the 8 week period, for the treatment group as a whole, using the Wilcoxon signed ranks test: acoustic rhinometry (Amin, Vol.), endoscopic appearances, diary card score (week 1 vs. week 8), and quality of life score. The NMCC time and CBF were compared using the paired *t*-test.

RESULTS

Of the 41 patients enrolled for the treatment group 21 were randomised to spray and 19 to alkaline nasal douche (Figure 2). One patient refused randomisation as he had used alkaline nasal douche in the past, had found it unhelpful, and insisted on being ‘randomised’ to the spray. Three patients were withdrawn from the trial. One patient when contacted by telephone said that he had an acute attack of sinusitis, and stopped using his trial medication, after the first week. The other two could not be contacted. Data on 5 patients from the control group was available for analysis as the other 3 did not follow-up and complete the study. We thus included 17 patients from a parallel study that was ongoing in our department. There were no differences in baseline clinical characteristics amongst the groups.

Table 1. Changes in outcome measures for the douching group, and controls over the trial period (8 weeks); Wilcoxon signed ranks test.

	Better	Worse	Same	Missing	p.value*
Douching group: (n=37)					
Endoscopic appearances	23	8	5	1	.009
Quality of life score	24	12	0	1	.008
Diary card score	20	16	1	0	.593
Amin	15	22	0	0	.331
Volume	18	18	1	0	.615
Non-douching group: (n=22)					
Endoscopic appearances	9	8	5	0	1.000
Quality of life score	15	7	0	0	.163
Diary card score	10	6	1	5	.391
Amin	11	8	0	3	.778
Volume	7	10	2	3	.309

*Wilcoxon signed ranks test

The treatment group showed significant improvements in endoscopic appearances and quality of life scores (Table 1). Sub-group analysis of the individual treatment methods shows alkaline nasal douche had a significant effect upon endoscopic appearances ($p=0.038$), whereas the spray did not ($p=0.1$); conversely sea water spray improved quality of life ($p=0.021$), whereas alkaline nasal douche did not ($p=0.199$). Acoustic rhinometry measurements, diary card scores, NMCC, and CBF did not alter significantly in any of the groups.

DISCUSSION

Our study shows that regular nasal douching in the short term, improves the clinical appearances as seen by rigid endoscopy and improves quality of life. These measurements did not alter significantly in the control (non-douching) group. We did not find any significant changes in the mucociliary clearance rate (NMCC) or ciliary beat frequency (CBF) in any of the three groups. The internal geometry of the nose did not change, as monitored by acoustic rhinometry (AR). We found a large variability in the NMCC rate in our patients (34.5 ± 35.4 minutes). A douche is a liquid used to rinse or mechanically clean a part of the body. In addition, recent studies have demonstrated a possible link with alterations in the mucociliary function. Majima et al. (1983) showed that the rate of transport of mucus from patients with chronic rhinosinusitis (CRS) was significantly less as compared to that from normals, when placed on a dissected bullfrog palate. However, on exposure to nebulised saline, the transport of mucus from patients with CRS increased significantly. They speculated a change in the rheological properties of mucus as the basis for the abnormal clearance mechanism rather than abnormal cilia. In another study, on patients with cystic fibrosis without evidence of sinus disease (Middleton et al., 1993), nebulised saline improved NMCC rate significantly from 1554 seconds (± 222) to 959 (± 157). As in our study NMCC rate was prolonged with large individual variations. They hypothesised a change in mucus viscoelasticity as a result of rehydration which improved ciliary beating in the sol layer, and led to

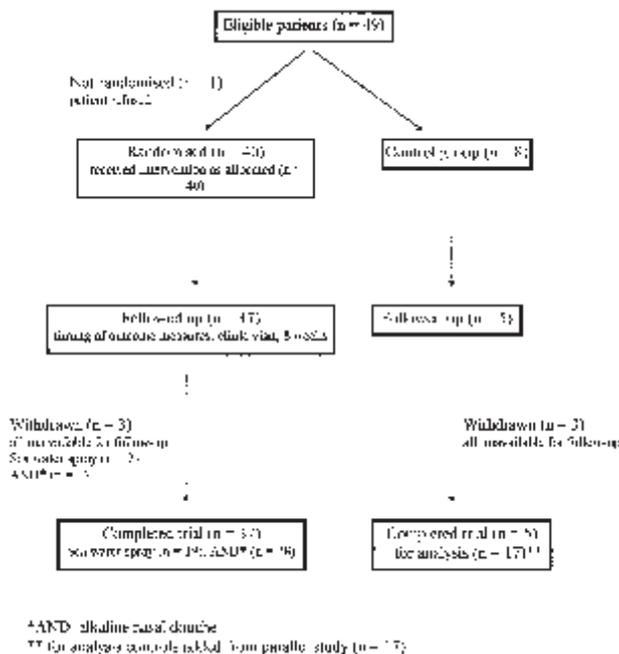


Figure 2. Flow chart of trial stages, withdrawals, timing of outcome measures.

an increase in mucociliary clearance. This is contrary to observations made in a recent study (Talbot et al., 1997). Increase in clearance time was not seen with normal saline, but it increased significantly following hypertonic saline irrigation. However, the study was in normal subjects without any evidence of nasal or sinus disease. Another cause of reduced NMCC in CRS is ciliary disruption following prolonged microbial colonisation of the nasal mucosa (Wilson and Cole, 1988). This is reflected in the low CBF, and its increase following long-term antibiotic therapy (Scadding et al., 1995).

We postulate that irrespective of the tonicity of the douche solution, regular use of this adjunctive treatment aids in reducing microbial load. In addition, the nasal douche powder, prepared in hospitals is both hypertonic and alkaline. The alkaline nature of the douche tends to make the mucus thinner, more 'sol' like (Talbot et al., 1997). A reflection of all these changes in NMCC rate would probably need long-term use on a regular basis, especially in patients with CRS who have had surgery in the past to improve drainage from the ostiomeatal complex. Another factor likely to play an important role is the ciliary apparatus, particularly in the operated middle meatal and ethmoid sinus area. Our brushings were from the inferior turbinate. Thus the subtle changes in the mucus are unlikely to change the CBF from this untouched region. No study has been done to evaluate CBF from the ostiomeatal complex region, as this may differ from routine brushings. It is likely that the ciliary mechanism from this area does beat more efficiently after nasal irrigation on a regular basis.

The preparation of a douche from powder, and administration is a cumbersome, inconvenient, time consuming process especially if it needs to be repeated 2-3 times a day. Patients who had used this method prior to being randomised to sea water spray found the ease of administration of the latter very helpful. Intranasal sprays are easy to carry and can be used whenever the need arises. This probably explains its significant effect on quality of life when compared to alkaline nasal douche. Compliance in the long-term is likely to be better. Many surgeons advocate a douche in the postoperative period to clean the nose of secretions and crusts, thus helping in epithelialisation and preventing the formation of adhesions. Contamination of the nasal lining by pathogens transferred from the palm of the hand has been shown (Johannssen et al., 1996). The use of a spray bottle, together with cleaning of its nozzle after use should prevent any contamination.

In conclusion, our study shows the benefits of using nasal irrigation as a adjunctive therapy in patients with Chronic Rhinosinusitis. Alkaline nasal douche is effective in improving endoscopic appearances and is probably best used during exacerbations. The use of sea water spray should improve compliance, and this is likely to improve nasal mucociliary function in the long-term.

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Dr. Glenis K. Scadding
 Consultant in Allergy, /
 Clinical Immunology & Rhinology
 Rhinology department
 Royal National Throat, Nose & Ear Hospital
 Gray's Inn Road
 London WC1X 8DA, UK
 Tel./fax: +44-171-9151674