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Management of post-ethmoidectomy crust formation: Randomized single-blind clinical trial comparing pressurized seawater versus antiseptic/mucolytic saline*

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SUMMARY

This study compared the efficacy of mechanical nasal lavages with pressurized seawater versus nasal irrigations with saline plus benzododecinium (antiseptic) plus oleosorbate (mucolytic). Twenty patients agreed to participate in a randomized, single-blind clinical trial. All patients underwent endoscopic endonasal ethmoidectomy for nasal polyps. The packing was removed after 48 h and patients were asked to start the same day nasal lavages three times a day. Clinical evaluations were performed: (1) by weighing residual nasal crusts and secretions after 21±2 days; and (2) by using visual analogue scales to daily record symptom scores. Data are presented as mean±SEM. T-test statistics for two independent groups were applied. The mean residual crust and secretion weights were 1,756±688 mg and 1,033±422 mg in the pressurized seawater group, 932±414 mg and 1,222±435 mg in the antiseptic-mucolytic saline group. No statistical differences were found. Sample size calculations showed that 100 subjects in each group would be necessary to confirm a 700-mg reduction in residual crusts in the antiseptic/mucolytic saline group (power=0.80; two-sided type-I error=0.05). Daily symptom score curves were similar in both groups and allowed us to give a description of post-operative complaints. The role of antiseptic, mucolytic and mechanical lavages in preventing post-ethmoidectomy crust formation is discussed.

Key words: nasal polyps, endoscopic sinus surgery, post-operative care

INTRODUCTION

Despite a general agreement on the need for post-operative care after endonasal surgery, no consensus exist on the way to do it. Many authors propose to clean the ethmoid cavities under endoscopic control, once or twice a week, for one or more months (Stammberger, 1986; Goubert et al., 1987; Levine, 1990; Danielsen, 1992; Kennedy, 1992; Fombeur et al., 1993). Since 1987, the use in our group is to schedule the first post-operative visit for endoscopic cleaning of the ethmoid cavities one month after surgery. Patients are discharged on the second day with a prescription of twice-a-day nasal lavages followed by local steroid sprays.

Because nasal lavage seems very important for helping patients to clean their nose, it appears necessary to improve knowledge on its usefulness.

The aim of the present study was to compare in a controlled clinical trial the efficacy of two different nasal lavages:

1. nasal irrigation with saline and antiseptic (benzododecinium) plus mucolytic (oleosorbate), or so-called "chemical lavage";
2. nasal lavage with pressurized seawater, or so-called "mechanical lavage."

PATIENTS AND METHODS

Patients

Twenty patients (14 males and 6 females; age range: 28-69 years; mean: 46 years) undergoing bilateral endoscopic endonasal sphenoethmoidectomy for nasal polyposis agreed to participate in the study. All patients were operated on by the same surgeon using the same technique.

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Post-operative care

All patients received antibiotics (1,000 mg josamycine, twice a day, for 5 days after surgery) and a single intramuscular injection of delayed corticosteroids (80 mg triamcinolone). On the second day, the nasal packing (Merocel®; Collin ORL, Paris, France) was removed and the patient was discharged, being asked to start nasal lavages three times a day on a regular basis for at least one month. Each lavage was recommended to be followed by local steroid sprays (beclomethasone, 600 µg per day).

Nasal lavage protocol

"Chemical" and "mechanical" lavages were compared in a randomized, single-blind clinical trial. Patients were randomly assigned into both groups by the use of a random number table. The physician was blind to the treatment. All patients gave informed consent before entry into the study. For chemical lavages, a saline solution containing 0.05 mg/ml of benzododecinium (antiseptic agent) and 2 mg/ml of oleosorbate (mucolytic agent) was used. Standing in front of a basin with his head backwards, the patient had to take a deep breath and to keep his respiration while he filled one nostril with 10 ml of the solution. After a while, he could blow his nose into the basin. The same procedure was repeated on the other side.

For mechanical lavages, seawater contained in a pressurized bottle was used. No antiseptic nor mucolytic agent was added. Preparation of the seawater included sterilization by ultrafiltration and reduction of the NaCl content by electrolysis. Sitting in front of a basin with his head downwards, the patient irrigated each nostril for a few seconds. Patients were asked to wash their nose three times a day on a regular basis until the first post-operative visit, that was planned 21±2 days later. During these three weeks post-operatively, patients were asked to fill in a diary to record on 10-point visual analogue scales the following subjective complaints: rhinorrhoea, nasal obstruction, facial pain, cacosmia, sneezing, facial oedema, and pruritus. At the first post-operative visit on day 21±2, residual nasal crusts in each nostril were removed under endoscopic control using forceps, and weighed. Residual secretions were collected by aspiration, using preweighed glass canules, and weighed.

Statistics

Data are presented as mean±SEM (standard error of the mean). T-test statistics for two independent groups were applied to compare residual crusts and secretions. Analysis of variance for repeated measures were applied to compare daily subjective complaint curves.

RESULTS

Crust and secretion weights

The mean residual crust weight (Figure 1) was about twice as high in the pressurized seawater group (1,756±688 mg) than in the antiseptic/mucolytic saline group (932±414 mg). This difference, however, was not statistically significant. The mean residual secretion weight was about the same in both groups

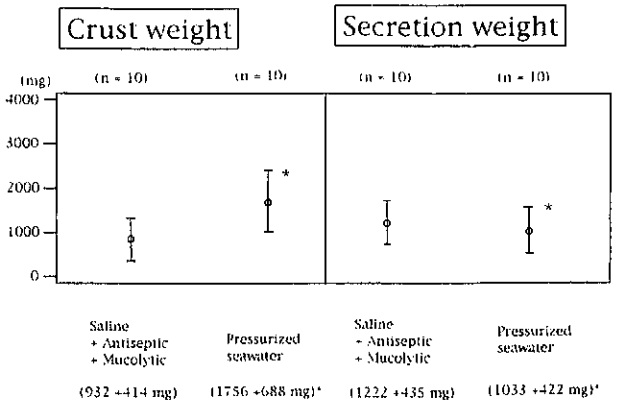

Figure 1. Residual crust and secretion weights (mean±SEM) at 21±2 days after total ethmoidectomy for bilateral diffuse polyposis (*: not significant).

(1,033±422 mg in the pressurized seawater group, and 1,222±435 mg in the antiseptic/mucolytic saline group).

Subjective symptom scores

Daily symptom score curves were similar in both groups. Nasal obstruction, the main pre-operative complaint, quickly resolved after the first week post-operatively (Figure 2). Rhinorrhoea, actually the need for blowing the nose, was the main post-operative complaint, occasioning a discomfort around five points on a 10-point scale during the first week, and slowly decreasing over the following two weeks (Figure 3). Cacosmia became a minor complaint only a few days after surgery, but usually resolved quickly after the crusts had been removed on day 21±2

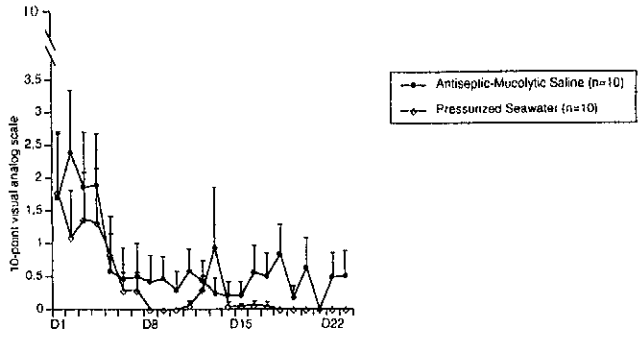

Figure 2. Daily subjective assessment of nasal obstruction on a 10-point visual analogue scale (mean±SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

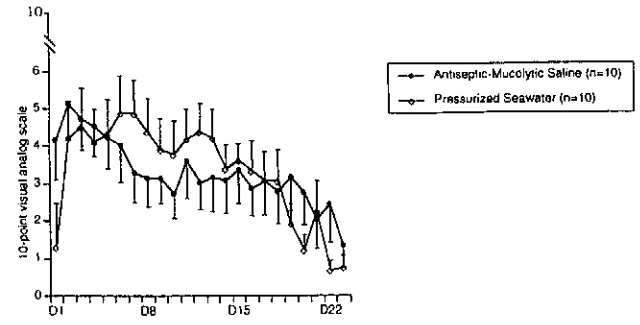

Figure 3. Daily subjective assessment of rhinorrhoea (the need to blow the nose) on a 10-point visual analogue scale (mean±SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

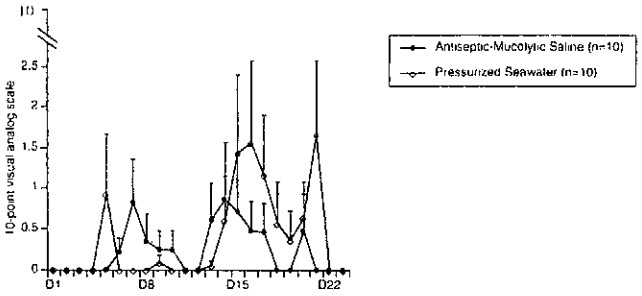

Figure 4. Daily subjective assessment of cacosmia on a 10-point visual analogue scale (mean±SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

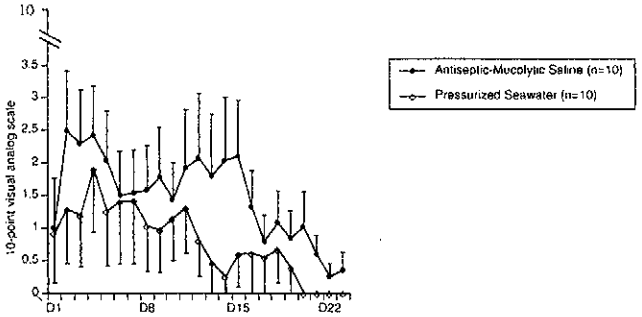

Figure 5. Daily subjective assessment of facial pain on a 10-point visual analogue scale (mean±SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

(Figure 4). A slight sensation of facial pain lasted at least 3 weeks after surgery (Figure 5). Pruritus, sneezing, and sensation of facial oedema were reported at a very low level by only a few patients.

DISCUSSION

Our hypothesis was that mechanical nasal lavages, using the power of a pressurized water beam, could be more effective for post-ethmoidectomy self-removal of crusts and secretions than chemical lavages, based on moistening the ethmoid cavities with saline added with antiseptic (benzododecinium) and mucolytic (oleosorbate). We did not find any differences between the two treatment groups. However, the mean crust weight surprisingly appeared to be lower in the chemical lavage group. Power calculation showed that 100 subjects in each group were necessary to confirm that this difference in favour of chemical lavages is real (power=0.80; two-sided type-1 error=0.05). No difference at all was found in secretion weight, nor in subjective assessment. These results question the usefulness of antiseptics and mucolytics in preventing post-ethmoidectomy crust formation. No additional or similar data could be found in the literature. Crust formation could be related to bacterial proliferation. Local antiseptics, by reducing bacterial proliferation, may be important in preventing crust formation. Mucolytics could act as an interesting co-factor. Local antiseptics might, moreover, be more interesting than systemic antibiotics, because antiseptics are delivered directly and mixed into the secretions while antibiotic, distribution is probably poorer, especially when the ethmoid mucosa has been totally or subtotally removed.

Post-operative subjective assessment shows that physical discomfort after ethmoidectomy is relatively mild and well tolerated. These data question the need for early and repeated endoscopic cleanings. In our experience with chemical lavages (1987-1994), the need to see patients before the end of the first month post-operatively is justified in only 10-15% of the cases because of acute infection of the crusts. Many of these infections seem a consequence of either bad therapeutic observance or technical difficulties. Facial pain, oedema of the lower eyelids, and increased purulent rhinorrhoea is the usual triad that brings back the patient to the physician. Crusts and secretions are meticulously removed endoscopically in the out-patient clinic and a prescription of antibiotics and painkillers is given to the patient.

In a long-term follow-up study (Jankowski et al. 1991), we observed that less than 17% of the patients (n=100 ethmoid cavities) still had only minor crusts 18 months post-operatively (range: 12-34 months). However, the role of repeated endoscopic cleanings could be of importance in avoiding adhesion and recurrent ostiomeatal obstruction but has to be demonstrated.

In conclusion, nasal lavages with saline seem to be very useful in post-ethmoidectomy care. Our study suggests that added antiseptics and/or mucolytics could improve their efficacy.

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

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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.

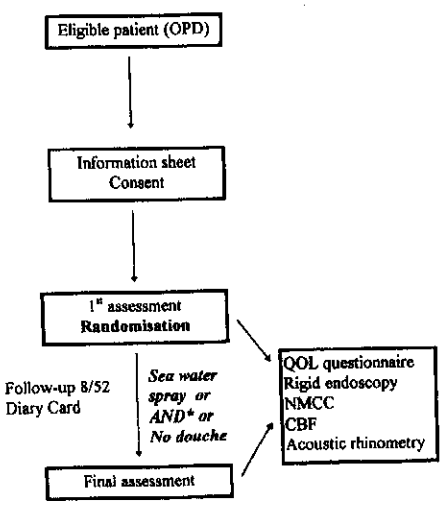
At the turn of the century Wyatt Wingrave gave a clinical lecture at the Central London Throat, Nose and Ear Hospital (now Royal National Throat, Nose and Ear Hospital) entitled "The nature of discharges and douches", and later published in the Lancet (Wingrave, 1902). Nasal douching thus held a very 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.

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- Discoloured nasal discharge: >2 weeks at a time
  >3 months

plus (atleast 2 of the following)

- nasal obstruction
- headache
- facial pain
- fever

plus

- Endoscopic* and/or CT evidence of sinusitis** (at some stage according to scoring system mentioned in references)

*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 snif-

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.

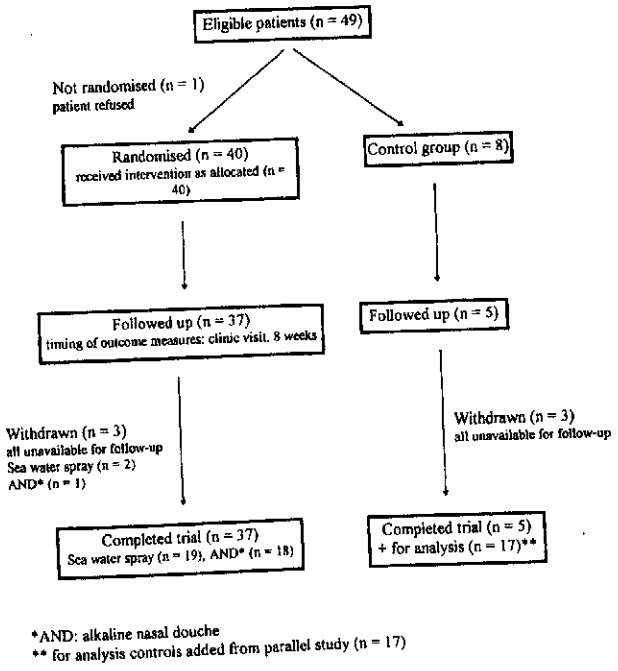

Figure 2. Flow chart of trial stages, withdrawals, timing of outcome measures.

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). Subgroup 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 (Middletone 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 cilial beating in the sol layer, and led to

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 cilial 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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