

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 $\pm$ SEM. T-test statistics for two independent groups were applied. The mean residual crust and secretion weights were $1,756 \pm 688$ mg and $1,033 \pm 422$ mg in the pressurized seawater group, 932 ± 414 mg and $1,222 \pm 435$ 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; Fombour 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.

* Received for publication November 1, 1994; accepted December 9, 1994

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 $\pm$ 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 ($1,756 \pm 688$ 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

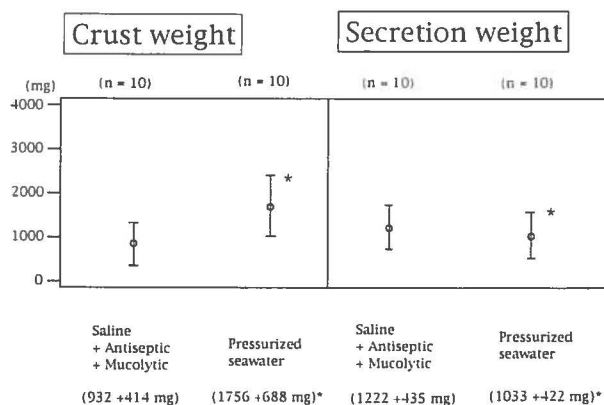


Figure 1. Residual crust and secretion weights (mean $\pm$ SEM) at 21 ± 2 days after total ethmoidectomy for bilateral diffuse polyposis (*: not significant).

($1,033 \pm 422$ mg in the pressurized seawater group, and $1,222 \pm 435$ 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

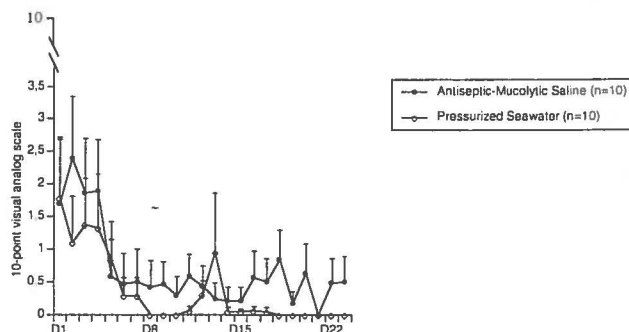


Figure 2. Daily subjective assessment of nasal obstruction on a 10-point visual analogue scale (mean $\pm$ SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

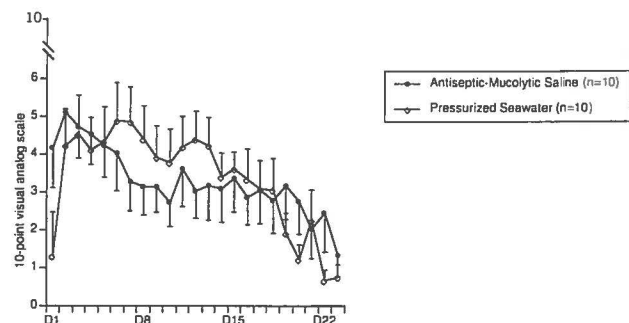


Figure 3. Daily subjective assessment of rhinorrhoea (the need to blow the nose) on a 10-point visual analogue scale (mean $\pm$ SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

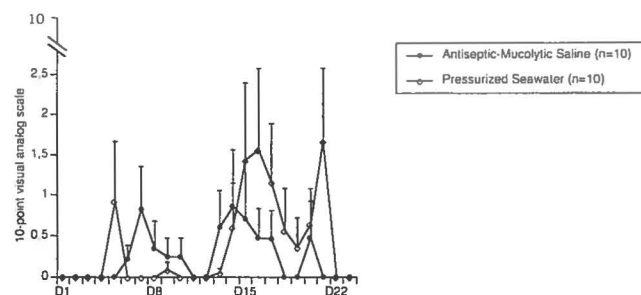


Figure 4. Daily subjective assessment of cacosmia on a 10-point visual analogue scale (mean $\pm$ SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

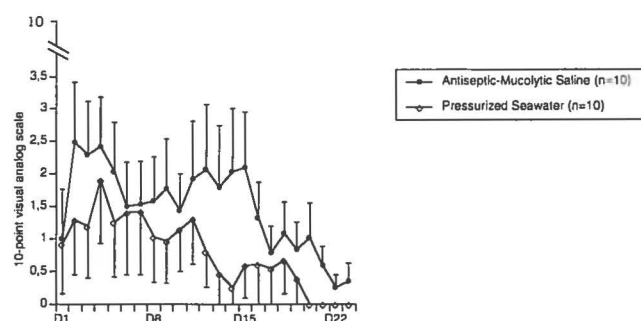


Figure 5. Daily subjective assessment of facial pain on a 10-point visual analogue scale (mean $\pm$ SEM) after total ethmoidectomy for bilateral diffuse polyposis (no significant difference between the two curves).

(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.

ACKNOWLEDGEMENTS

The authors wish to thank Dr. F. Guillemin for statistics, Mrs. M. Bedel, A. Acker, MC Vermount, E. Godscheck, M. Marchal, R. Didierjean, and S. Marchand for technical assistance, and the Laboratory Goemar (Saint-Malo, France) for financial support.

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