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Repeated early debridement does not provide significant symptomatic benefit after ESS*

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SUMMARY

Objective: *Postoperative debridement is considered essential after endoscopic sinus surgery (ESS), however, its effect on postoperative symptoms is largely unexplored.*

Methods: *In the present study 90 patients undergoing ESS were randomized to debridement of the nasal cavities either three times during the first postoperative week (intervention group), or once on the 7th postoperative day (control group). Postoperative saline douching was used in both groups. The primary outcome measure was the postoperative Lund-MacKay Symptom Score.*

Results: *The patients in the intervention group reported less severe symptoms on all domains of the Lund-MacKay Score compared with the patients in the control group both at one and four weeks. The difference between the groups was statistically significant in discharge at one week (4.1 ± 2.3 in the intervention group and 5.4 ± 2.6 in the control group, $p = 0.0025$). At four weeks, significantly fewer nasal cavities presented with nasal secretions in the intervention group compared with the control group (14/84 vs. 38/93).*

Conclusions: *Repeated debridement during the first postoperative week produced minor symptomatic benefit in patients recovering from ESS. Therefore, in terms of subjective recovery and health care costs repeated debridement is not justified during the first postoperative week after ESS.*

Key words: sinusitis, sinus surgery, endoscopic, postoperative care, debridement

INTRODUCTION

Postoperative debridement, i.e. removal of crusts, clots and secretions, is considered essential after endoscopic sinus surgery (ESS), and it has been shown to decrease postoperative crusting and the development of adhesions [(1)]. On the other hand, patients may experience debridement as unpleasant, and debridement has been associated with increased postoperative pain during the early recovery [(1-3)]. These potential adverse effects of debridement may interfere with the effective execution of postoperative care, which in turn may compromise outcome.

Optimal management of nasal secretions and congestion after ESS has not been established. Various treatments have been proposed, among which are saline douches, sympathomimetic medications, intranasal corticoids, nasal packing and postoperative debridement of the nasal cavities [(2,4)].

In the present prospective, randomized, controlled clinical trial with two parallel groups we have evaluated the effect of repeated postoperative debridement during the first week after ESS on the patients' postoperative symptoms during the early recovery period. We hypothesized, that repeated postoperative debridement during the first postoperative week after ESS may alleviate the symptoms of nasal discharge and congestion.

PATIENTS AND METHODS

Patients

This study is a part of our larger trial concerning the postoperative treatment after ESS, and the results concerning the treatment of postoperative pain have already been published [(5,6)].

A total of 90 patients (age 18-70 years), who underwent primary ESS in Kuopio University Hospital, Kuopio, Finland were included in this study. The patients suffered from either recurrent or chronic maxillary sinusitis and had American Society of Anesthesiologists physical status 1 or 2 [(7)]. The exclusion criteria were hemorrhagic diathesis, liver or kidney dysfunction, chronic malnutrition, alcoholism, pregnancy, anticoagulant therapy or inflammatory bowel disease.

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Surgery

The operation was performed by using the standard endoscopic sinus surgery technique with 4 mm rigid endoscopes (Karl-Storz, Tuttlingen, Germany) with deflection angles of 0 and 30 degrees. Maxillary ostium was identified using ostium seeker. After that, the uncinate process overlying the ostium was dissected using the ostium forceps and a 4 mm microdebrider (Xomed®, Medtronic Xomed Surgical Products, Jacksonville, USA). When needed, the maxillary ostium was cleared of swollen or inflamed mucosa with microdebrider or other non-powered instruments. Haemostasis was usually achieved with nasal packing (Merocel®, Medtronic Xomed Surgical Products, Jacksonville, USA) under the middle turbinate.

Study design

The study design was a randomized, prospective, controlled clinical trial with two parallel groups. The study flowchart is displayed in Figure 1. Randomization was computer-generated. At discharge, the patients were randomly allocated to one of the two study groups. In the first group (intervention group), the patients were scheduled for three visits during the first postoperative week i.e. on the 1st, 3-5th (follow-up visits were scheduled only on weekdays) and 7th postoperative days. On these postoperative visits the middle meatus was debrided, i.e. cleaned from blood, clots, crusts, and secretions in anterior rhinoscopy with suction cleaning. Maxillary antrum lavage was performed two times, on the 3rd-5th and 7th postoperative days.

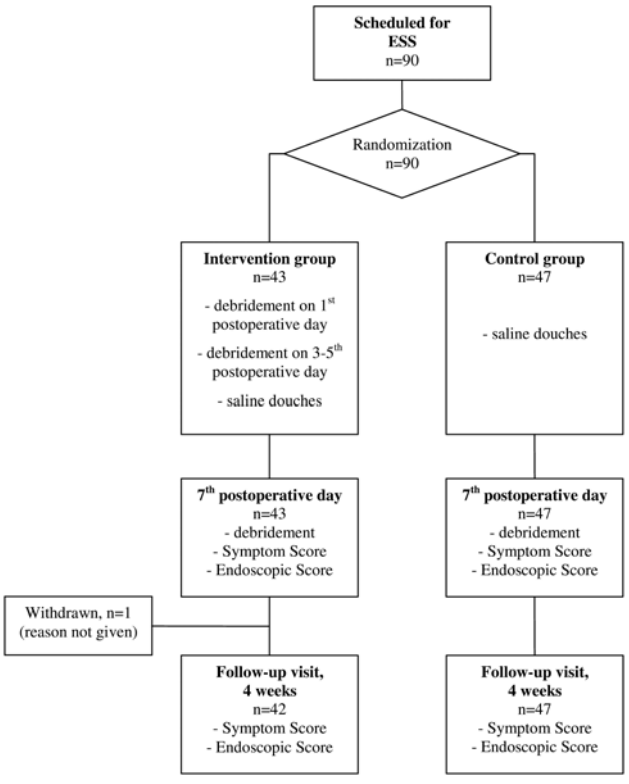

Figure 1. Study flowchart.

In the second group (control group), the patients were scheduled for a single postoperative visit on the 7th postoperative day, when the middle meatus was cleaned and maxillary sinus lavage was performed. Debridement and maxillary lavage were performed under local anesthesia with 20 μg/ml epinephrine in 40 mg/ml lidocaine.

All patients were given instructions to use nasal physiological saline douches (Humidose®, Orion, Espoo, Finland) eight times a day during the two first postoperative weeks. In addition to acetaminophen, which was prescribed for postoperative pain, no other standard medication was used.

During the follow-up visits at one and four weeks, the patients were asked to rate their symptoms (facial pain or pressure, headache, nasal blockage or congestion, nasal discharge, olfactory disturbances, overall discomfort) on an 11-point numeric scale (0 = symptom not present, 10 = greatest severity of symptoms) according to Lund-MacKay Symptom Score [8]. At the four weeks visit, rigid nasoendoscopy under local anesthesia with 20 μg/ml epinephrine in 40 mg/ml lidocaine was performed to assess the presence of polyps, edema, discharge, scarring and crusting in the middle meatus. Endoscopic staging was performed according to Lund-MacKay Endoscopic Appearance Score (Table 1) [8]. The surgeon performing the endoscopy was not blinded.

The study protocol was approved by the Research Ethics Committee of the Hospital District of Northern Savo, Kuopio, Finland, and it was conducted in accordance with the Declaration of Helsinki. The patients were given oral and written information of the study protocol, and they provided a written consent

The primary outcome measures were the postoperative ratings in the Lund-MacKay Symptom Score and the secondary outcome measures were ratings in the Lund-MacKay Endoscopic Appearance Score [8].

Statistical methods

We assumed that the incidence of nasal congestion at seven days after ESS would be 50% in the control-group and 25% in the intervention group. Based on 80% power to detect a statistically significant difference ($p = 0.05$, two-sided), it was calculated that 58 nostrils would be required for both study groups.

Table 1. Lund-MacKay Endoscopic Appearance Score. Both sides are evaluated separately.

	0 points	1 point	2 points
Polyps	Absent	Only in the middle meatus	Beyond the middle meatus
Oedema	Absent	Mild	Severe
Discharge	Absent	Clear, thin discharge	Thick, purulent discharge
Scarring	Absent	Mild	Severe
Crusting	Absent	Mild	Severe

Most patients were assumed to undergo bilateral surgery, and to compensate for some drop-outs, we planned to enroll 40-45 patients per group.

Patient characteristics and variables were analyzed with the Statistical Package for Social Sciences (SPSS software version 14.0 for Windows, SPSS Inc., Chicago, USA). Differences according to treatment assignment for categorical variables were assessed with the Pearson Chi-Square test and for the continuous and nominal variables with the Mann-Whitney *U*-test, as appropriate. Differences were regarded as statistically significant if the two-sided p-value was less than 0.05. Data are expressed as a number of cases or mean with the standard deviation (SD). For the main outcome measures, 95% confidence intervals (95% CI) were calculated.

RESULTS

A total of 90 patients were included in the study. The baseline characteristics and the surgical data are presented in Table II. One patient in the intervention group withdrew her consent after 7th postoperative day visit (reason not given). There were no other drop-outs or protocol deviations likely to have affected the study results. All except two patients in the intervention group and one patient in the control group underwent bilateral surgery. Thus, 84 nasal cavities were evaluated in the intervention group and 93 nasal cavities in the control group. No perioperative or immediate postoperative complications were noted during the study, nor were there any floppy turbinates detected at the end of the surgery.

Table 2. The baseline characteristics and the surgical data of the study patients. Data are mean (SD) or number of cases.

	Intervention group n=43	Control group n=47
Age (years)	43 (12)	37 (13)
Gender: male/ female	17/26	11/36
Height (cm)	169 (9)	169 (8)
Weight (kg)	72 (13)	73 (19)
Local / General anesthesia	40/3	44/3
Packing	34	35
Operative diagnosis:		
- recurrent /chronic sinusitis	30/13	28/19
Concomitant disease:		
- Nasal polyposis	9	5
- Asthma	4	13
- Aspirin sensitivity	0	0
Preoperative Medication:		
- intranasal corticosteroids	18	19
- p.o. corticosteroids	2	3
- p.o. antihistamine	7	14
Operation type :		
- uncinectomy	36	40
- middle meatal antrostomy	7	7
- polypectomy	5	2
- anterior ethmoidectomy	1	2

Symptom scores

At baseline, there were no statistically significant differences between the two study groups in the ratings according to the Lund-MacKay symptom score.

At seven days, the complaints of nasal discharge on an 11-point Lund-MacKay Symptom Score were significantly less severe in the intervention group (4.1 ± 2.3) compared with the control group (5.4 ± 2.6, mean diff 1.5, 95% CI of the diff 0.3 to 2.7, p = 0.025, the Mann-Whitney U-test). Furthermore, there was a consistent pattern in favor of frequent postoperative debridement in nasal blockage, headache and facial pain, but the differences between groups did not reach statistical difference (Figure 2). The proportion of patients with significant nasal blockage (Lund-MacKay Symptom Score ≥ 5) was similar in both groups, 49% in the active group and 55% in the control group.

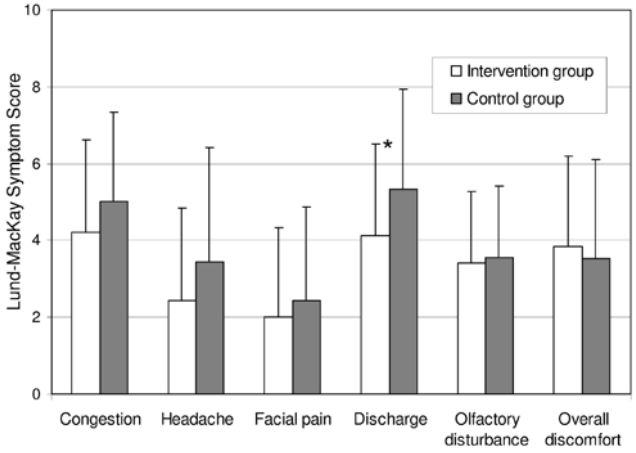

Figure 2. 11-point Lund-MacKay Symptom Score at 7 days in the intervention group (white bar) and in the control group (grey bar). (0=symptom not present, 10=greatest severity of symptom). *p = 0.025.

At four weeks, the ratings in nasal blockage, discharge and olfactory disturbance were significantly reduced in both groups compared with the ratings at seven days. The total symptom scores at four weeks were 13 ± 9 in the intervention group and 14 ± 10 in the control group, which were lower compared with ratings at seven days (20 ± 10 and 23 ± 12, respectively, p < 0.001 for both groups). There were no statistically significant differences between the two groups in the symptom scores at four weeks. However, there was a consistent pattern in favor of the intervention group in all domains of Lund-MacKay Symptom Scores also at four weeks, as illustrated in Figure 3.

In post-hoc analysis, it appeared that females reported more headaches at seven days (3.4 ± 2.8) when compared with male patients (1.9 ± 2.3) in both study groups (p = 0.013). Accordingly, females experienced significantly more overall discomfort (4.1 ± 2.7) compared to their male counterparts (2.8 ± 2.0, p = 0.03).

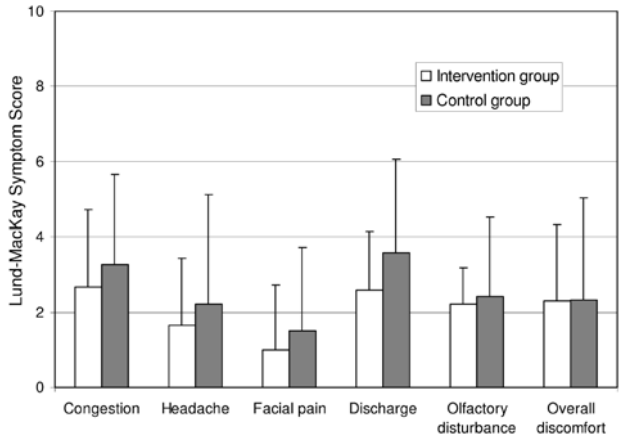

Figure 3. 11-point Lund-MacKay Symptom Score at four weeks (0=symptom not present, 10=greatest severity of symptom).

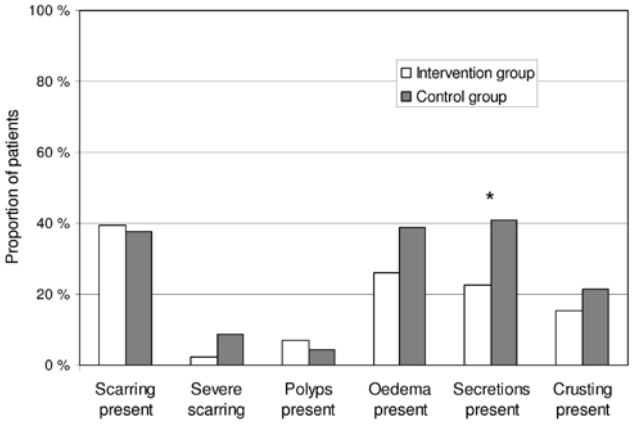

Figure 4. Endoscopic findings in the two study groups at four weeks. *p = 0.009 (2-sided Pearson Chi-square test).

Endoscopic appearance

At four weeks, nasal secretions were less often detected in the intervention group, in which 23% (19/84) of nasal cavities presented with secretions, while in the control group secretions were detected in 41% (38/93) of nasal cavities (mean diff. 17%, 95%CI of the diff. 3 to 31%, p = 0.009, Pearson Chi-square test). There were no other statistically significant differences in the Lund-MacKay Endoscopic Appearance Score (Figure 4). For instance, scarring was detected in 33 out of 84 (39%) nasal cavities in the intervention group and in 35/93 (38%) nasal cavities in the control group (p = 0.822).

DISCUSSION

In the present study, the patients undergoing repeated postoperative debridement during the first postoperative week reported less nasal secretions at one week after ESS when compared with patients with a single postoperative debridement. This is in agreement with a previous study, in which the patients undergoing postoperative debridement experienced less nasal congestion when compared with saline irrigation only [1]. There were no other statistically significant differences between the groups in other domains of the Lund-MacKay symptom score; however, the patients in the intervention group seemed to feel slightly better both at one and four weeks visits with regard to nasal congestion, facial pain, headache and overall discomfort.

Postoperative debridement, i.e. removal of crusts, clots and secretions, is frequently considered as an important means of facilitating the healing of nasal mucosa [2,3,9], and on the contrary to the findings of the present study, it has been shown to prevent the development of crusting and adhesions in the middle meatus [1]. On the other hand, patients may experience postoperative debridement unpleasant. In fact, debridement during the second postoperative week has been associated with more postoperative pain [1]. This was not the case in the present study, since no difference was found between the study groups regarding nasal pain, headache or overall discomfort at seven days postoperatively. Therefore, our results indicate that postoperative debridement can be performed without compromising patient comfort, even during the first postoperative week.

Nasal secretions were rated significantly less in the intervention group in the endoscopic examination at four weeks. However, repeated postoperative debridement during the first postoperative week after ESS did not decrease the presence of scarring at four weeks visit, whereas it has been previously reported that debridement on 6th and 12th days can result in a significant reduction in scarring when compared with saline irrigation only [1]. This discrepancy may be due to a previous finding, i.e. debridement during the first postoperative week avulsed parts of epithelium in one of four patients [10]. However, our follow-up period of four weeks has to be considered relatively short, and a longer follow-up time is required to assess the actual effect of debridement on the endoscopic outcome.

In post-hoc analysis, females reported more headache and overall discomfort at the seven day assessment. This is in accordance with a previous study, in which females experienced more symptoms after ESS despite similar endoscopic and radiological findings. Irrespective of this difference, female subjects have been shown to gain an equal benefit from ESS [11].

Saline douching was used in both groups; hence it is not likely to induce bias into our results. Postoperative saline douching is widely used after ESS, but its effect on the postoperative symptoms is controversial [12].

One of the main limitations of the present study was that the surgeon assessing the outcome at four weeks was not blinded for the patient allocation. Furthermore, the Lund-MacKay Endoscopic Appearance Score contains only five domains, and does not include all important aspects of postoperative endoscopic findings, for example blood clots in the middle meatus. One must also bear in mind that our series consists of cases of simple uncinectomy or middle meatal antrostomy, in which a

rather small amount of mucosal damage is likely to occur. More extensive surgery with larger areas of disrupted mucosa and accompanying hemorrhage may necessitate a more active postoperative treatment regimen in order to facilitate optimal mucosal healing [(2)].

According to the present study, repeated debridement during the first postoperative week provided only slight symptomatic benefit when compared with a single debridement one week postoperatively. On the other hand, two additional postoperative visits result in considerable increase in resources needed and therefore it may not be cost-effective. When weighting the health care costs, the time and resources spent in the execution of debridement against the minor favourable effects on symptoms, the debridement may not be justified during the first week after ESS.

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