Topical Levobupivacaine Efficacy in Pain Control after Functional Endoscopic Sinus Surgery

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Abstract

Objective. The aim of this study was to find out the efficacy of a polyvinyl alcohol (PVA) sponge (Merocel Kennedy; Medtronic Xomed, Jacksonville, Florida) sinus pack soaked with levobupivacaine hydrochloride to control postoperative pain and analgesic need following functional endoscopic sinus surgery (FESS).

Study Design. The study was designed as a prospective, double-blind, randomized, controlled study. Forty-one patients who underwent FESS were included in the analysis.

Setting. A tertiary referral hospital in Turkey.

Materials and Methods. Patients who underwent FESS were divided into 2 groups. The PVA sponge sinus packs were soaked with 5 mL of levobupivacaine hydrochloride (chirracaine 25 mg/10 mL; Abbott, Nycomed Pharma AS, Elverum, Norway) in group I and with 5 mL of saline in group II.

Main Outcome Measures. Postoperative pain levels were recorded using a visual analog scale (VAS score, 0-100) at 30 minutes and 1, 2, 8, 12, and 24 hours.

Results. There were no statistically significant differences between groups regarding age, sex, and American Society of Anesthesiologists status. Postoperative VAS values at 30 minutes and 1, 2, 8, 12, and 24 hours were significantly lower in group I than in group II (P < .05). Supplemental analgesia amount was significantly lower in group I than in group II (P = .003).

Conclusion. Using levobupivacaine-soaked PVA sponge sinus packs after FESS is an effective, easy, and quick method to control postoperative pain, and it improves patient comfort and tolerability.

Keywords
endoscopic sinus surgery, levobupivacaine, pain management, topical anesthetic application

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Anesthesiologists (ASA) criteria. The study was designed as a prospective, double-blind, randomized, controlled study. Patients having a history of severe cardiovascular, hepatic, hematologic, respiratory, or renal disease; diabetes; or peripheral neuropathy and those who were receiving chronic analgesic therapy, had an allergy to any study drug, had a history of drug or alcohol abuse, or needed septoplasty were excluded from this study.

The same surgeon (SY) performed endoscopic dissections from the anterior to posterior direction, and 41 patients undergoing elective FESS were randomly divided into 2 groups. We applied local infiltration of 4 mL lidocaine 2%, 1.25:100,000 epinephrine (Jetocaine amp; Adeka, İstanbul, Turkey) to the middle turbinate, uncinate, and spheno-palatine foramen region before starting surgery on all patients. Our surgery included uncinectomy, anterior and posterior ethmoidectomy, and opening the maxillary sinus ostium. We did not need to do any sphenoidectomy. The patients who needed septoplasty were excluded from this study. At the end of the operation, PVA sponge (Merocel Kennedy; Medtronic Xomed) sinus packs were placed into each middle meatus. Then the surgeon was given the solution by the anesthetist to soak the sinus pack without telling the surgeon the content of the solution.

Patients were divided into 2 groups. Sinus packs were soaked with 5 mL of levobupivacaine hydrochloride (chirocaine 25 mg/10 mL; Abbott, Nycomed Pharma AS, Elverum, Norway) in group I and with 5 mL of saline in group II. Postoperative pain levels were recorded using a visual analog scale (VAS score, 0-100) at 30 minutes and 1, 2, 8, 12, and 24 hours. Patients with a pain score higher than 40 were given 100 mg intravenous tramadol hydrochloride. All patients’ nasal packs were removed after recording the 24-hour VAS score.

**Statistics**

A power calculation ensured that 17 patients were needed to provide 80% power for a difference in VAS from 10 to 20 mm at the 5% significance level. All statistical procedures were performed with SPSS 11 for Windows (SPSS, Inc, an IBM Company, Chicago, Illinois). The number of the patients in each group was less than 30, and groups were not normally distributed. The continuous variables are stated as mean and standard deviation (95% confidence interval). Categorical variables are stated as numbers. Comparisons of numeric variables between the groups were performed with the Mann-Whitney U test. Comparison of categorical variables between groups was performed with the Fisher exact test. A *P* value <.05 was considered statistically significant.

**Results**

Our series consisted of 41 patients (16 women and 25 men) aged 24 to 62 years (mean [SD], 38.3 [12.5] in group I and 33.1 [7.5] in group II). The flow diagram of the trial is presented in Figure 1. There were no statistically significant differences between groups regarding age, sex, and ASA status (Table 1). Postoperative VAS values at 30 minutes and 1, 2, 8, 12, and 24 hours were significantly lower in group I than in
Supplemental analgesia amount was significantly lower in group I than in group II \( (P = .004) \) (Table 2). No complications or side effects regarding the topical use of levobupivacaine were observed.

### Discussion

Appropriate management of postoperative pain is known to reduce postoperative morbidity, complications, hospital stay, and costs. There is a worldwide undersupply of adequate pain management after surgery.\(^5\) In particular, there is a lack of knowledge about pain and specific pain management after FESS.\(^6\) Nonsteroidal anti-inflammatory drugs have been demonstrated to reduce the severity of postoperative pain in the first 24 hours after FESS,\(^7\) but these agents are associated with gastrointestinal, neurological, and hematological adverse effects and especially may cause postoperative mucosal bleeding.

Numerous studies have investigated the pain-relieving effect of topical local anesthetics after septoplasty. Yilmaz and colleagues\(^4\) presented the results of using a levobupivacaine-soaked PVA sponge (Merocel Kennedy; Medtronic Xomed) as a nasal pack after septoplasty and found statistically significant lower postoperative VAS values at 30 minutes and 1, 2, 8, and 12 hours, as well as less need for supplemental analgesia. Kuo et al\(^8\) found that topical 5% lignocaine ointment significantly decreased postoperative nasal packing pain in the first 3 hours. Also, some methods have been described to decrease pain during removal of the nasal packs. Apuhan et al\(^9\) found that patients could benefit from PVA sponge-packing rehydration with levobupivacaine or prilocaine 15 minutes before removal of the packs. Karaaslan et al\(^10\) found similar results with injection of prilocaine plus meperidine into the nasal pack before pack removal. However, we did not find any study investigating the pain-relieving effect of a local anesthetic—soaked sinus pack after FESS.

Furthermore, by using a sinus pack, all sinus surgeons aim to achieve excellent hemostasis, postoperative healing that avoids adhesion formation, and lateralization of the middle turbinate. But there is still disagreement with regard to postoperative care. The use of nasal packing is especially controversial. Some authors have stated that nasal packing should be withheld in most patients.\(^11,12\) Mo et al\(^13\) stated that nasal packing can be safely used less frequently to help the patients experience less discomfort after FESS, but in their study, 1 patient from the no-packing group needed nasal packing postoperatively because of persistent nasal bleeding. Bugten et al\(^14\) advocated the use of nasal packing and concluded that nonabsorbable packing in the middle meatus (MM) for 5 days significantly reduced the extent of adhesions in MM compared with saline irrigation alone. Toffel\(^15\) stated that use of nasal packing had a positive effect on wound healing. Thomas et al\(^16\) concluded that postoperative nasal packing for only 2 hours rather than 24 hours significantly reduces pain without a concomitant risk of hemorrhage. Postoperative bleeding and nasal packing a day after surgery are very unpleasant conditions for the patients, but we support packing after sinus surgeries. As a result, it is not acceptable to omit nasal packing after FESS just because of the pain and discomfort it causes.

Absorbable biomaterials also could be used for sinus packing, which do not require pack removal. Wormald et al\(^17\) stated that hyaluronic acid–based nasal packing (MeroGel, Medtronic Xomed, Jacksonville, Florida) has no significant beneficial or detrimental effect in terms of synchia, edema, or infection when placed in the middle meatus after FESS. But I

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**Table 1. Demographic data.**

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 20)</th>
<th>Group II (n = 21)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>38.3 (12.5)</td>
<td>33.1 (7.5)</td>
<td>.033</td>
</tr>
<tr>
<td>Sex, M/F</td>
<td>11/9</td>
<td>14/7</td>
<td>.751</td>
</tr>
<tr>
<td>ASA, I/II</td>
<td>12/8</td>
<td>15/6</td>
<td>.362</td>
</tr>
</tbody>
</table>

**Table 2. VAS pain scores and supplemental analgesia amount.**

<table>
<thead>
<tr>
<th>Time</th>
<th>Group I, Mean (SD) (n = 20)</th>
<th>Group II, Mean (SD) (n = 21)</th>
<th>Mean Difference (95% CI)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 min</td>
<td>41 (13.73)</td>
<td>56.90 (33.26)</td>
<td>–15.90 (–32.13 to 0.32)</td>
<td>.054</td>
</tr>
<tr>
<td>1 h</td>
<td>8 (11.05)</td>
<td>47.62 (26.82)</td>
<td>–39.62 (–52.70 to –26.54)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>2 h</td>
<td>4 (9.95)</td>
<td>42.14 (27.77)</td>
<td>–38.14 (–51.46 to –24.83)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>8 h</td>
<td>5 (12.77)</td>
<td>22.14 (16.17)</td>
<td>–17.14 (–26.38 to –7.91 )</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>12 h</td>
<td>4 (9.95)</td>
<td>22.14 (16.17)</td>
<td>–18.14 (–26.67 to –9.61 )</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>24 h</td>
<td>2 (6.16)</td>
<td>8.10 (13.27)</td>
<td>–6.10 (–12.69 to 0.50)</td>
<td>.069</td>
</tr>
<tr>
<td>Supplemental analgesia amount (( \times 100 ) mg)</td>
<td>0.95 (1.05)</td>
<td>2.33 (1.77)</td>
<td>–1.38 (–2.31 to –0.46)</td>
<td>.004</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; VAS, visual analog scale (score, 0-100). Group I received levobupivacaine. Group II was the control group.
animal study showed induced bone formation within the sino-
nasal cavity, indicating that MeroGel may have osteogenic
potential.18 Rudmik et al19 demonstrated that a cellulose-based
pack (Stammberger Sinu-Foam, Artrocare ENT, Stockholm,
Sweden) does not improve endoscopic outcomes in the early
postoperative period following FESS. In another study, they
found satisfactory results with using dissolvable nasal packs
(Sinu-knit, Artrocare ENT, Stockholm, Sweden).20 A collagen
gelatin-based sinus pack (Gelfilm, Pharmacia and Upjohn
Company, Kalamazoo, Michigan) was associated with adverse
healing with increased granulation tissue.21 Thus, different
studies have revealed the advantages and the disadvantages of
the absorbable biomaterials as a sinus pack.

With our new method, we benefit from the advantages of
sinus packing and also avoid the pain and discomfort
caued. We preferred the use of a long-acting local anes-
thetic, levobupivacaine hydrochloride, for topical applica-
tion. We found statistically significant lower pain scores in
patients whose sinus packs were soaked with levobupiva-
caine hydrochloride. Unfortunately, we must also remember
that there is a risk of systemic absorption that has not been
studied. Our results demonstrate that using levobupivacaine-
soaked PVA sponge sinus packs improves postoperative
analgesia and patient comfort and reduces the need for sup-
plemental analgesia during the first 24 hours after FESS.
Also, we believe that our new method can be applied to
absorbable biomaterials used as a sinus pack.

Conclusion
Because FESS is a commonly performed procedure, post-
operative pain, especially headache, facial pain, and nasal
pain, is an important complaint that needs to be managed.
Using levobupivacaine-soaked PVA sponge sinus packs after
FESS is an effective, easy, and quick method to con-
tral postoperative pain, and it improves patient comfort and
tolerability.

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Süleyman Yılmaz, wrote article, designed study; Şahnr
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Güjlü, revised article, collected data, analyzed data; Hüseyin
Yaman, revised article, collected data; Gülbin Yalçın Sezen,
revised article, designed study, analyzed data.

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