



A comparison of the effect of intravenous paracetamol and tenoxicam on postoperative pain following septoplasty

Septoplasti sonrası ameliyat sonrası ağrı üzerine intravenöz parasetamol ve tenoksikamın etkinliğinin karşılaştırılması

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Objectives: This study aims to compare the efficacy of intravenous paracetamol and tenoxicam in the management of postoperative pain following septoplasty.

Patients and Methods: Between May 2008 and January 2009, 40 male adults (mean age 21.7 years; range 19 to 24 years) who underwent septoplasty in our clinic were included in this randomized controlled study. Patients were randomly divided into two groups, including 20 in each group. Analgesia was achieved through intravenous paracetamol 1 g every six hours in the first group (paracetamol group) and intravenous tenoxicam 20 mg at a single dose within the first 24 hours in the second group (tenoxicam group). Visual analog scale (VAS) was used to assess the pain severity preoperatively and at 30 minutes, 1, 2, 6, 12 and 24 hours postoperatively. Postoperative complications for both groups were also recorded.

Results: There was no significant difference in intraoperative pain scores between the groups ($p=0.47$). The VAS scores at 30 minutes ($p=0.018$), 1, 2 and 6 hours were significantly lower in paracetamol group, compared to tenoxicam group ($p=0.0001$; $p=0.001$; $p=0.04$, respectively).

Conclusion: Early postoperative moderate pain is accompanied following septoplasty. This can be prevented by using analgesics.

Key Words: Local; paracetamol; postoperative pain; septoplasty; tenoxicam.

Amaç: Bu çalışmada septoplasti sonrası ağrı yönetiminde intravenöz parasetamol ve tenoksikamın etkinliği karşılaştırıldı.

Hastalar ve Yöntemler: Bu randomize kontrollü çalışmaya Mayıs 2008 - Ocak 2009 tarihleri arasında kliniğimizde septoplasti yapılan 40 erişkin erkek hasta (ort. yaş 21.7 yıl; dağılım 19-24 yıl) dahil edildi. Hastalar her bir grupta 20 kişi olacak şekilde rastgele iki gruba ayrıldı. Ameliyat sonrası analjezi, birinci grupta (parasetamol grubu) her altı saatte bir intravenöz 1 gr parasetamol ile; ikinci grupta (tenoksikam grubu) ise, ilk 24 saatte intravenöz tek doz 20 mg tenoksikam ile sağlandı. Görsel analog ölçeği (GAÖ), ameliyat sırasında ve ameliyat sonrası 30. dakikada, 1, 2, 6, 12. ve 24. saatlerde ağrı düzeyini değerlendirmek için kullanıldı. Ameliyat sonrası komplikasyonlar her iki grupta da kaydedildi.

Bulgular: Gruplar arasında ameliyat sırası ağrı skorları açısından anlamlı fark yoktu ($p=0.47$). Görsel analog ölçeği skoru parasetamol grubunda 30. dakika ($p=0.018$), 1, 2. ve 6. saatlerde tenoksikam grubundan anlamlı olarak daha düşüktü (sırasıyla $p=0.0001$; $p=0.001$; $p=0.04$).

Sonuç: Septoplasti ameliyatı sonrası erken dönemde, orta düzey ağrı mevcuttur. Bu durum ise analjeziklerle önlenilmektedir.

Anahtar Sözcükler: Lokal; parasetamol; ameliyat sonrası ağrı; septoplasti; tenoksikam.

Septoplasty is one of the most common surgical procedures performed by Ear Nose Throat (ENT) surgeons. Septoplasty can be performed under local anesthesia which is occasionally preferred by surgeons and even by patients, because of avoiding general anesthesia complications

and also association of short hospitalization.^[1] Pain is the most common complaint after septoplasty. Effective postoperative pain control is essential for optimal care of patients. Postoperative pain causes a decrease at quality of life, late mobilization and an increase in treatment

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costs.^[2] Nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol are commonly used in the management of moderate to severe pain alone or in combination with opioids.^[3] The clinical use of opioids is restricted or used in low doses because of their side effects.

Short-term use of paracetamol at adequate dosages has a well-established safety profile and has been well known as a safe and effective analgesic and antipyretic.^[4,5] Intravenous (i.v.) administration is the route of choice when oral administration is not possible or when rapid analgesia is needed after surgery.^[5] An i.v. formulation of paracetamol has recently become available, and it achieves target plasma concentration more rapidly with reduced variability compared with the rectal and oral formulations.^[6,7] Intravenous paracetamol is used perioperatively in many surgeries such as caesarean, endoscopic sinus surgery, adenotonsillectomy, lumbar discectomy, dental surgery, abdominal and breast surgery.^[5,7-9]

Tenoxicam is a NSAID that can be used parenterally and has high potential for analgesic and anti-inflammatory effect, with an advantage of single use per day because of its long half life and high reliability.^[10,11] Most of the traditional NSAIDs such as tenoxicam have effects on both cyclo-oxygenase-1 (COX-1) and cyclo-oxygenase-2 (COX-2) enzyme isoforms. Many of the side-effects of NSAIDs such as gastrointestinal effects are attributed to inhibition of COX-1.^[10]

We searched the literature and found few reports that compared analgesics for evaluating postoperative pain during the first 24 hours after septoplasty with local analgesia. However, there was no study comparing the effectiveness of i.v. paracetamol and i.v. tenoxicam on pain control after septoplasty. This is the first study comparing both drugs.

PATIENTS AND METHODS

This study included 40 male patients (mean age 21.7 years; range 19 to 24 years) that had undergone septoplasty in our clinic between May 2008 and January 2009. The local ethics committee approved the study protocol. Exclusion criteria were as follows: a known history of allergy to paracetamol and tenoxicam, chronic diseases, immunodeficiency or any sign of infection at the time of surgery, nasal trauma in last three months, previous history of nasal and inferior turbinate surgery, and nasal polyps or chronic sinusitis. Patient selection for surgery was based on clinical history, otorhinolaryngological examination, and nasal endoscopy findings. In order to standardize operations, we used the nasal septum

deviation classification of Guyuron et al.^[12] for selection of patients who underwent surgery. We operated on type 1 patients (in which the septal tilt was described as a septum that had no curve, yet was tilted to one side of the nose anteriorly and to the opposite side posteriorly in relation to the sagittal plane) as the maxillary crest remained straight. Preoperative laboratory evaluation included complete blood count, thrombin time, prothrombin time, and thromboplastin time.

All operations were performed under local anesthesia and vital signs were monitored during the operation. All patients were informed on research protocol, surgical risks, and possible complications related to the operation itself before they signed the informed consent. Oral amoxicillin-clavulanate antibiotic therapy was administered to all patients for seven days after the surgery.

Surgery and postoperative pain treatment

Patients were randomly allocated into two groups. Atropine sulfate 0.25 mg and midazolam 2 mg were used for premedication. Local anesthesia was achieved with lidocaine 2%, adrenalin 1:100,000 (Jetokain 2% ampule; Adeka, Istanbul, Turkey). The local anesthetic agent was infiltrated on both sides of the nasal septum in the submucoperichondrial-subperiosteal plane at multiple points. Five minutes after infiltration, the surgical procedure started. At the end of surgery polyvinyl alcohol packings (Merocel TM, Medtronic Xomed, Jacksonville, FL) were coated with antibiotic ointment and inserted into both nasal cavities. Packings were removed after 48 hours. No other preoperative analgesic medication was used. Two surgeons did all the surgeries.

Postoperative analgesia was achieved with paracetamol (Perfalgan flakon, Bristol-Myers Squibb, 1 g/100 ml) 1 g every six hours intravenously in the paracetamol group (n=20) and with tenoxicam (Tilcotil flakon, Roche, 20 mg) 20 mg single dose intravenously in the tenoxicam group (n=20) in the first 24 hours. The first dose of both drugs was administered at the end of the surgery. The patients and surgeons were blinded to the type of the analgesic agent used. Patients were hospitalized during the postoperative 24-hour period.

Pain measurement

To determine the level of postoperative pain, a continuous 10 cm visual analog scale (VAS) was used, with 0 points indicating no pain and 10 points indicating the most severe pain. An independent blinded observer marked the severity of their pain on the scale at predefined time points (at intraoperative time, 30th minute, 1st, 2nd, 6th, 12th and 24th postoperative

hours), and the scores were measured and recorded in millimeters.

Patients were given 500 mg of paracetamol peroral (p.o.) in paracetamol group and 20 mg of tenoxicam p.o. in tenoxicam group when the pain VAS score was >4 mm, and the total amount of analgesic use was recorded. Postoperative complications were also recorded in both groups by a surgeon who was blinded to the patient groups.

Statistical analysis

Statistical analysis was performed using SPSS for Windows version 15.0 (SPSS Inc., Chicago, Illinois, USA). Kolmogorov-Smirnov goodness-of-fit test was used to test the normality of data. Homogeneity of the variances was tested using Levene's test. For normally distributed continuous data, groups were compared using independent samples t-test, and Mann-Whitney U test was used for the variables without normal distribution. General linear model for repeated measurements was used for intragroup comparisons. The Chi square-test was used for the comparison of categorical variables. A value of $p < 0.05$ indicated statistical significance.

RESULTS

The data of all patients were included in the statistical study. Groups were similar with regard to mean age: 23.4 years and 22.35 years in the paracetamol and tenoxicam groups. No nasal complication was established. No cardiovascular, neurological or other complication was observed in both groups either. Groups did not differ with regard to age and frequency of postoperative complications ($p > 0.05$). All patients were symptom-free at the follow-up visit on the 30th postoperative day.

There were no significant differences in intraoperative pain scores between the tenoxicam and paracetamol groups ($p = 0.47$). This result proved the reliability

of evaluation of the postoperative pain levels and comparing two groups.

The VAS scores were significantly lower in the paracetamol group at the 30th minute, 1st, 2nd and 6th postoperative hours than those of the tenoxicam group ($p < 0.05$) (Table 1). The VAS scores at the 12th and 24th hours were similar in both groups but the difference did not reach statistical significance ($p = 0.062$, $p = 0.076$, respectively). Evident reduction in the severity of pain was recorded at the 30th minute postoperatively in the paracetamol group ($p < 0.05$) but was not significant in the tenoxicam group (Table 1).

DISCUSSION

Postoperative pain after the septoplasty performed under local anesthesia remains an important problem for many surgeons. Pain is a subjective, unpleasant sensory and emotional sensation. The extent of postoperative pain depends on the kind of premedication given, the operation type and the patient's individual sensitivity. Postoperative pain can also result in nausea and vomiting. Postoperative pain management is directly associated with the patients comfort and success of surgery. Only a few studies were available in the English literature about the effectiveness of paracetamol on pain control after ENT surgeries such as septoplasty.^[3,9,13] There was no study found comparing paracetamol and tenoxicam on pain control after septoplasty under local anesthesia. Results of this randomized controlled study showed that the administration of 1 g every six hours i.v. paracetamol is more effective for postoperative pain than 20 mg tenoxicam intravenously once.

The most important cause of the pain is inflammation. By inhibiting cyclooxygenase enzyme NSAIDs inhibit synthesis of prostaglandin which is one of the most important hyperalgesic and inflammatory mediators.^[6,7,14] Tenoxicam is one of the NSAIDs which it has minimal lacks of tinnitus, dizziness and

Table 1
Statistical results between groups, tenoxicam and paracetamol

	VAS intraoperative	VAS 30 minutes after surgery	VAS 1 hour after surgery	VAS 2 hours after surgery	VAS 6 hours after surgery	VAS 12 hours after surgery	VAS 24 hours after surgery
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Tenoxicam	5.7±1.4	5.8±1.6	4.9±1.7	3.9±2.0	2.8±1.9	1.9±1.6	0.94±0.725
Paracetamol	5.7±2.5	3.9±2.9	2.3±2.3	1.7±1.9	1.9±2.6	1.8±2.3	0.90±0.912
Total	5.7±2.0	4.8±2.6	3.5±2.4	2.7±2.2	2.3±2.3	1.8±2.0	0.92±0.818

SD: Standard deviation.

gastrointestinal side effects.^[11] In one study it was suggested that rofecoxib gave significantly better pain control than tenoxicam after surgical extractions of third molar teeth.^[10]

Paracetamol is a non-opioid analgesic that is devoid of risks of NSAID side effects. Its analgesic action is assumed to be mediated by a serotonergic mechanism, and the antipyretic action is via inhibition of COX-3 in the hypothalamus.^[15] Paracetamol also has little antiplatelet activity and does not affect bleeding time, unlike NSAIDs.^[15] Short-term use of paracetamol at adequate dosages has a well-established safety profile.^[4]

In pain assessment, the most frequently used research tool in the early postoperative period is the VAS. Uysal et al.^[8] showed that the i.v. formulation of paracetamol was associated with similar analgesic properties and early recovery to i.v. tramadol after adenotonsillectomy in children. They observed pain scores at 30 minutes, 2, 3, 4, 5, 6, 8, 12, and 24 hours postoperatively. We used a similar study protocol for pain scoring times and also scored intraoperatively. There were no significant differences between the intraoperative period pain scores of both groups ($p=0.47$). This result proved the reliability of evaluation of the postoperative pain levels when comparing two groups.

A review emphasized that the faster onset of i.v. paracetamol compared with oral or rectal administration should be helpful when treating acute surgical pain.^[5] Paracetamol is an effective analgesic in a variety of surgical procedures such as cesarean, hysterectomy, dental surgery, breast surgery, endoscopic sinus surgery and knee surgery.^[5] Brodner et al.^[9] showed that i.v. paracetamol has equivalent efficacy to non-opioids dipyrone and parecoxib that improves postoperative pain therapy when used as part of a multimodal concept after minor-to-intermediate surgery. Nonsteroidal anti-inflammatory drugs other than those tested in their trial that might be equally effective after different kinds of surgery include ketorolac and diclofenac.^[16,17] In these studies i.v. paracetamol was as effective as some NSAIDs. Compatible with these studies, we found that i.v. paracetamol is effective for treatment of postoperative pain after septoplasty in comparison with tenoxicam ($p<0.05$). We showed that i.v. paracetamol is sufficient with its safe and effective analgesic properties during the postoperative 24 hours starting from 30 minutes postoperatively compared with tenoxicam. We did not determine any differences in postoperative complications in both groups.

Septoplasty is performed as a day case surgery, so the first 24 hours are important for pain relief. Therefore we established VAS scores for the first 24 hours and

found that the scores of the paracetamol group were significantly lower than those of the tenoxicam group at the 30th minute, 1st, 2nd and 6th postoperative hours ($p<0.05$).

There are few studies comparing the drugs for acute postoperative pain relief after septoplasty. Şener et al.^[18] compared the efficacy of injectable lornoxicam with diclofenac, ketoprofen and dipyrone for acute postoperative pain and found that lornoxicam was not superior to the other analgesics. Sağıt et al.^[19] stated that preoperative pregabalin is effective for postoperative pain control. Some researchers used different local anesthetic-soaked nasal packs for postoperative pain control, and concluded that bupivacaine is an effective easy method.^[20,21] Szychta et al.^[3] mentioned in their study that NSAIDs could be used for postoperative nasal surgery. There was no study comparing paracetamol with any drug for septoplasty and our study is the first.

In conclusion, septoplasty is associated with moderate pain in the early period after surgery that can be prevented with adequate analgesics. Intravenous paracetamol is a sufficient analgesic for postoperative pain control with few side effects.

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