

Original Article**Comparison the efficacy of intravenous and topical tramadol on postoperative pain control after septoplasty***Septoplasti sonrası postoperatif ağrı kontrolünde intravenöz ve topikal tramadol etkinliğinin karşılaştırılması***Ahmet Kaya^{1*}**, **Burhanettin Usta²**¹University of Health Science, Mehmet Akif İnan Training and Search Hospital, Department of Anesthesiology and Reanimation Şanlıurfa, Türkiye²Department of Anesthesiology and Reanimation, Nile University, Nizamiye Teaching Hospital, Nigeria***Corresponding author:**

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Adress :University of Health Science, Mehmet Akif İnan Training and Search Hospital, Department of Anesthesiology and Reanimation Şanlıurfa, Türkiye**E-mail:**ahmetkayamd@yahoo.com**Received:**17/04/2023**Accepted:**19/06/2023**Cite as:** KAYA.A and USTA. B. Comparison the efficacy of intravenous and topical tramadol on postoperative pain control after septoplasty. IJCMBBS 2023;3(2):105-10 doi.org/ 10.5281/zenodo.8072162**Highlights**

- Nasal packings used in septoplasty surgeries cause increased pain associated with the surgery.

- Tramadol infiltrating nasal tampons reduces the need for additional analgesics in the postoperative period, similar to the effectiveness of intravenous tramadol.

Abstract**Background:**Tramadol hydrochloride is an analgesic drug used in the treatment of moderate or severe postoperative pain. The local anaesthetic effects of tramadol were demonstrated in previous studies. The aim of this study was to compare the postoperative analgesic efficacy of intravenous tramadol with the local application of tramadol by injection into merocel in patients undergoing septoplasty.**Materials and Methods**

A prospective, randomized, controlled study included ASA I-II, 18-65 aged, 60 patients who underwent elective septoplasty. The patients were divided into two groups. Group 1 (i.v) received 1mg.kg⁻¹ tramadol i.v. and Group 2 (Merocel®) 100 mg tramadol injected to the Merocel® nasal packs. Postoperative pain scores, nausea, vomiting and rescue analgesic drug were recorded at the first, second, fourth, sixth, twelfth and twenty fourth postoperative hours.

Results

No significant differences were found between two groups for demographic data. There were no statistically significant differences between two groups on VAS scores, nausea-vomiting and needing rescue drug.

Conclusion

With its local effects, topical tramadol application to nasal packs seems to be a comfortable approach for pain control in patients undergoing septoplasty.

Key words: Pain, Septoplasty, Topical, Tramadol**ÖZET****Amaç:**Tramadol Hidroklorid orta ve ciddi postoperatif ağrı tedavisinde kullanılan bir analjezik ilaçtır. Tramadolün lokal anestezi etkileri önceki çalışmalarda gösterilmişti. Bu çalışmadaki amacımız, septoplasti olan hastalarda, intravenöz tramadol ile Merocel® içine enjekte edilen tramadolün lokal kullanımını arasında postoperatif analjezik etkinliğini araştırmaktır.**Gereç ve Yöntem:**

Prospektif, randomize kontrollü çalışma, septoplasti olacak ASA I-II, 18-65 yaş 60 hasta içerdi. Hastalar iki gruba ayrıldı. Grup 1 (iv) e 1mg.kg⁻¹ tramadol i.v. yapılırken Grup 2 (Merocel®) 100 mg tramadol Merocel® nazal tampon içine enjekte edildi. Postoperatif ağrı skorları, bulantı, kusma ve ek analjezik ilaç ihtiyacı 1., 2., 4., 6., 12. ve 24. saatlerde kaydedildi.

Bulgular:İki grubun demografik bulguları arasında anlamlı fark bulunamadı. İki grubun VAS skorları, bulantı-kusma ve ek analjezik ilaç ihtiyaçları arasında istatistiksel olarak anlamlı fark bulunamadı (p>0.05).

Sonuç:Tramadolün lokal etkilerinin varlığıyla septoplasti olan hastalarda nazal tampon uygulanması, konforlu bir ağrı kontrolü sağladı.

Anahtar kelimeler: Ağrı, Septoplasti, Topikal, Tramadol

Introduction

Postoperative pain is an acute form of pain that begins with surgical trauma and ends with tissue healing. Stress response to surgery plays an important role in postoperative pain. As a result of untreated postoperative pain, an increase in the amount of catabolic hormones such as cortisol, adrenocorticotrophic hormone (ACTH), glucagon, aldosterone and catecholamines; The amount of anabolic hormones such as insulin and testosterone decreases, resulting in negative effects on the respiratory, circulatory, gastrointestinal, renal and autonomic nervous systems. Postoperative pain control is becoming increasingly important because of the undesirable and healing-delaying effects of pain (1,2).

In the treatment of postoperative pain, analgesic agents can be administered systemically or regionally, and the most commonly preferred method is parenteral administration. One of the analgesic agents used in the treatment of postoperative pain is opioids. Opioids are the leading analgesic drugs used in the treatment of moderate and severe postoperative pain in patients with cancer pain and many acute pain syndromes (3,4). One of the most preferred opioids -tramadol hydrochloride- it is a centrally effective synthetic analgesic (5). Tramadol, which is in the weak opioid group in the analgesic classification, has both opioid and nonopioid action mechanisms. In addition to its weak μ -opioid receptor agonist effect, it inhibits the presynaptic reuptake of noradrenaline (NA) and serotonin (5-HT). In addition to these effects, tramadol also stimulates the release of 5-HT (6). Thus, the additive effect obtained by potentiating the endogenous analgesia system with both the opioid agonist mechanism and its monoaminergic effect has a significant effect on antinociception, and less side effects have been the reason for the widespread use of tramadol in the treatment of moderate-severe cancer and non-cancer acute and chronic pain (7).

In our study, we aimed to show the efficacy of tramadol and saline mixture absorbed into merocel buffer for postoperative pain control after septoplasty operation, by comparing it with intravenously used tramadol.

Materials and Methods

Patient Group

Sixty patients with American Society of Anaesthesiology (ASA) evaluations core I-II between the ages of 18-65 who were planned for septoplasty operation were included in the study, whose approval was obtained by the Ethics Evaluation Commission of Fatih University at the meeting numbered 6 on 23/09/2010. The study was planned prospectively. Written informed consent was obtained from all patients who participated in the study, after giving detailed explanations about the study.

Patient Exclusion Criteria

Patients with known allergic reactions to study drugs, morbidly obese (BMI>35), patients with sleep-apnea syndrome, patients with renal, hepatic, cardiovascular or neuromuscular disease, atrioventricular conduction disorder, bleeding disorders, and patients with opioid or analgesic abuse was excluded.

The patients were randomly divided into two groups:

Group 1: intravenous tramadol group; 30 minutes before the end of the surgery, 1 mg.kg⁻¹ tramadol hydrochloride iv was administered to the patients. (8-10)

Group 2: Merocel infiltration topical tramadol group; After the post-surgical packing was placed, 50 mg tramadol hydrochloride 4 cc saline mixture (5 cc fluid in total) was injected into merocel® for both noses.

Procedure

All patients were taken to the operating room and electrocardiogram (ECG), noninvasive blood pressure, oxygen saturation (SpO₂) monitoring; Vascular access was established with a pink branule in the left hand, and fluid infusion was started, taking into account body weights and fluid deficit. Induction of anesthesia with 2.5 mg.kg⁻¹ propofol, 0.6 mg.kg⁻¹ rocuronium and 1 μ g.kg⁻¹ fentanyl

was applied to all patients with a tube size 8.0-8.5 for men and 7.0-7.5 for women. After intubation, 6% desflurane anesthesia was administered. Mean arterial pressure (MAP), heart rate (HR), SpO₂ and end-tidal carbon dioxide (ETCO₂) values were recorded before induction of anesthesia, after intubation, every 10 minutes during the operation, before and after extubation.

If tachycardia developed 20% above preoperative values during anesthesia, it was considered as insufficient anesthesia and iv bolus 1 µg.kg⁻¹ fentanyl was administered. If hypotension below 60 mmHg and heart rate values below 20% of preoperative values occurred, iv 5 mg ephedrine for hypotension and iv 0.5 mg atropine for bradycardia were administered.

Desflurane maintenance was discontinued when the surgery was over. 30 minutes before the end of surgery, 1mg.kg⁻¹ tramadol hydrochloride was administered to Group 1 (intravenous) patients. Group 2 (merocel® infiltration) patients were injected with 50 mg tramadol hydrochloride 4 cc saline mixture (5 cc fluid in total) into merocel® for both noses after post-surgical packing was placed. When necessary, neuromuscular blockade was reversed with neostigmine and atropine, and the patients were extubated. The time to 9-10 Aldrete Scale Score was recorded, and after reaching this score, the patient was removed from the operating room. The pain of the patients was evaluated with the Visual Analogue Scale (VAS)(11).

Patients were followed up for 24 hours in terms of postoperative side effects such as nausea, vomiting and tremor (none/available), pain and additional analgesia need. Patients with pain (VAS 3 and above) were given 0.5 mg.kg⁻¹ tramadol hydrochloride iv, and patients with nausea and vomiting were given ondansetron 4 mg iv.

Statistical analysis

13 of SPSS (Statistical Package for Social Sciences) for Windows package program was used in the analysis of statistical data. Student-t test in the analysis of continuous variables with normal distribution by testing the suitability of the data for normal distribution; Mann Whitney U test was used in the analysis of continuous variables that did not show normal distribution. Chi-square test was used in the analysis of discrete variables. Results were expressed as mean±standard deviation (mean±SD), median (min-max), n (number of patients), and percent (%). According to the results of the analysis, cases where the p value was <0.05 were considered statistically significant.

Results

Demographic Data

Our study was performed on a total of 60 cases, 20 female and 40 male, ranging in age from 18 to 65. No statistical difference was observed between the age, weight, height, and gender (p:0.584) and ASA scores (p:0.519) of the 1 and 2 groups (**Table 1**).

Table 1: Demographic Data of Patients

Variabales	Group 1 (n:30)	Group 2 (n:30)	p value
Age (years)	29±5	29±6	0.668
Weight (kg)	79±14	81±14	0.551
Height (cm)	174±9	175±8	0.629
Gender Male (n,%)	19 (63)	21 (70)	0.584
ASA			
I (n,%)	23 (77)	25 (83)	0.519
II (n,%)	7 (23)	5 (17)	
Anesthesia Duration (min)	58 (49-65)	63 (54-71)	0.473
Surgery Time (min)	50 (44-60)	55 (45-61)	0.687
Time to Aldrate 9-10 (min)	9 (5-10)	8 (6-10)	0.858
Total Desflurane Consumption (ml)	35 (30-40)	35 (30-40)	0.886
Total Tramadol Consumption (mg)	78 (69-93)	100 (100-100)	0

Abberivations: ASA: American Society of Anaesthesiology

Pre-induction, post-intubation, 5th minute, 10th minute, 20th minute, 30th minute, 40th minute, 50th minute, 60th minute, 70th minute, 80th minute, 90th minute, pre-extubation and after extubation,

there was no statistically significant difference between mean arterial pressure and heart rate values measured ($p>0.05$).

Postoperative VAS Scores

There was no statistically significant difference between the postoperative, postoperative 1st hour, postoperative 2nd hour, postoperative 4th hour, postoperative 6th hour VAS scores of the groups ($p>0.05$) (**Table 2**). No pain was observed in any of the patients at the postoperative 12th hour and postoperative 24th hour, and the VAS scores were evaluated as 0.

Table 2: Postoperative VAS Scores

	Group 1 (n:30)	Group 2 (n:30)	p value
Basal VAS	1 (1-2)	1 (1-2)	0.289
1st hour VAS	2 (1-2)	2 (1-2)	0.543
2nd hour VAS	1 (1-2)	1 (1-2)	0.559
4th hour VAS	1 (0-1)	1 (0-1)	0.657
6th hour VAS	1 (0-1)	0 (0-1)	0.608

Postoperative, postoperative 1st hour, postoperative 2nd hour, postoperative 4th hour, postoperative 6th hour nausea and vomiting complaints of the groups were questioned and no statistically significant difference was found between them ($p>0.05$). Nausea and vomiting were not observed in any of the patients at the postoperative 12th hour and the postoperative 24th hour.

Postoperative Shivering Evaluation

There was an equal number of tremors in the postoperative and postoperative 1st hour in the groups, and there was no statistically significant difference between them ($p:1,00$) (**Table 3**). No shivering was observed in any of the patients at the postoperative 2nd hour, postoperative 4th hour, postoperative 6th hour, postoperative 12th hour and postoperative 24th hour.

Table 3: Postoperative Shivering Evaluation

		Group1 (n:30)	Group2 (n:30)	Total (n:60)	
1st hour Tremor (n,%)	None	24 (80)	24 (80)	48 (80)	p:1.00
	Available	6 (20)	6 (80)	12 (80)	

Evaluation of Postoperative Additional Analgesic Need

Comparing the need for additional analgesia in the first 24 hours postoperatively in the groups, it is seen that 2 patients in Group 1 and 7 patients in Group 2 received additional medication in a total of 9 patients (**Table 4**). No statistical difference was observed between the 1 and 2 groups in terms of additional analgesia need ($p:0.071$) (**Table 4**).

Table 4: Evaluation of Postoperative Additional Analgesic Need

		Group 1 (n:30)	Group 2 (n:30)	Total (n:60)	
Postoperative Additional Analgesic Need (n,%)	None	28 (93)	23 (77)	51 (85)	p:0.071
	Available	2 (7)	7 (23)	9 (15)	

Discussion

Septoplasty is one of the most common surgical procedures in the practice of otolaryngology. Two important problems encountered after septoplasty are pain and bleeding (12). After Septoplasty operations, dry merocel®, which is among the tampons used to prevent bleeding and possible hematoma, is inflated with saline after it is placed into the nose. Most of the studies on merocel and pain in the past aimed to prevent the pain that will occur when the tampon is removed (13, 14).

The ideal agent should be short-acting, safe, inexpensive, and easy to administer to deal with pain or discomfort during nasal packing removal. Many previous reports were about injection methods into

nasal packings. Local anesthetics such as lignocaine, prilocaine, prilocaine plus meperidine, levobupivacaine were used in nasal packing (15-18). In these studies, it was stated that the local anesthetics mentioned in the early period, alone or in combination, reduced the level of pain and anxiety compared to the control group.

In recent studies; Tramadol hydrochloride, which is a frequently used opioid providing effective analgesia and mild sedation, stands out in this regard. In the retrospective study of Tulaci et al. (18); Prilocaine, tramadol 1 mg/kg combined with prilocaine, and tramadol 2 mg/kg combined with prilocaine in merocel nasal packings were compared in terms of pain, sedation, and anxiety related to this removal procedure before removal of the nasal packing using normal saline solution, which is the control group. The combined infiltration of prilocaine and tramadol 1 mg/kg into the nasal packing was found to be effective in reducing the pain and anxiety of the patients during the removal of the nasal packing.

Şimsek et al. (19) conducted the most recent study on this subject, and in their retrospective study, patients were divided into three groups according to the application of lidocaine, tramadol and 0.9% NaCl on merocel nasal packings. In the postoperative period, VAS scores, side effects, and additional analgesic requirements were recorded for 24 hours, starting from the PACU (post-anesthesia care unit). They stated that tramadol infiltrated into nasal packings reduces the need for additional analgesics in the postoperative period, increases patient satisfaction, decreases the length of hospital stay, and as a result, reduces the secondary infection rate. In our study, tramadol was compared with iv as infiltration and although no significant differences could be detected between the two groups, the iv of the infiltrated tramadol group was compared. It was found that the effect was equivalent to the group that was administered.

In many previous postoperative studies, it was reported that tramadol caused less respiratory depression and less sedation compared to strong opioids (20). In our study, the frequently used Aldrate recovery score was used to evaluate the recovery process of patients in the postoperative period, and the time it took for patients to reach 9-10 points in this assessment was measured. While we expected the recovery time to be longer in the group that received intravenous tramadol because of its involvement in the systemic circulation and its possible sedative feature, the average time to reach Aldrate recovery score of 9-10 in Group 1 was 9 minutes, while in Group 2 this time was determined to be 8 minutes on average. No statistical difference was found between them.

Another parameter examined in the study was tremor in the postoperative period. Only tremors were detected in the groups after the operation and at the postoperative 1st hour, and there was no statistically significant difference between the groups. It was attributed to the coldness of the operating room and the infused fluid.

Limitation

Analgesia was provided with tramadol administered to the patients. While the average amount of tramadol in Group 1 was 79 mg, this amount was 100 mg in Group 2. There was no statistically significant difference between the groups. As a result of insufficient data on the absorption of tramadol in merocel®, the difficulty in determining the drug dose used in this group was the limitation of our study, with the routine use of 100 mg tramadol for each patient in Group 2 in this parameter.

Conclusion

In conclusion, it was shown in our study that peripheral nerves were blocked by the nasal route and that nociception was prevented, providing a comfortable postoperative analgesia, as well as its effectiveness and side-effect profile being indistinguishable from intravenous administration. Thus, we think that tramadol can be used topically in the septoplasty operation, avoiding possible side effects, since there is no need for systemic administration and additional analgesia.

Acknowledgements: None

Ethical Approval: Permission was obtained from Ankara Fatih University, Faculty of Medicine, Clinical Research Ethics Committee (Date 23/09/2010 Meeting Number: 6)

Author Contributions: Concept: AK, BU Literature Review: AK, BU Design: AK, BU Data acquisition: AK, BU Analysis and interpretation: AK, BU Writing manuscript: AK, BU Critical revision of manuscript: AK, BU

Conflict of Interest: The author(s) do not have any potential conflict of interest regarding the research, authorship and/or publication of this article.

Financial Disclosure: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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