

ORIGINAL ARTICLE

Post-operative Analgesia After Hand Surgery: A Controlled Comparison of Dexketoprofen Trometamol and Paracetamol

El Cerrahisi Sonrası Post-operatif Analjezi: Deksketoprofen Trometamol ve Parasetamolün Kontrollü Karşılaştırılması

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Abstract

Aim: This prospective, randomized, double-blind study compared the efficacy and safety of dexketoprofen trometamol (DT) and paracetamol in managing post-operative pain for patients undergoing intravenous regional anesthesia (IVRA) during hand surgery.**Methods:** Sixty-six ASA I-II patients aged 18-70 were enrolled after exclusion criteria, including drug allergies, psychiatric disorders, Raynaud's disease, and anticoagulant therapy. Patients were randomized into two groups: Group 1 received 25 mg DT, and Group 2 received 500 mg paracetamol for post-operative pain relief. At home post-operatively, pain intensity was assessed using the visual analog scale (VAS), and rescue analgesia was provided if needed. Patients recorded pain relief efficacy, satisfaction levels, side effects, and tablet consumption over 30 hours.**Results:** Although both drugs provided adequate post-operative pain control, significant differences were found. Analgesic efficacy was significantly higher in Group 1 ($p = 0.001$), and patient satisfaction was significantly higher than in Group 2 ($p = 0.003$). While 75.8% of patients in Group 1 reported complete pain relief, this rate was recorded as 42.4% in Group 2. Additionally, the post-operative morphine requirement was significantly lower in Group 1 ($p = 0.04$), highlighting the potential of DT to reduce opioid use. The frequency of adverse events such as nausea, vomiting, headache, and insomnia was similar between the groups. It did not show statistically significant differences ($p > 0.05$), supporting the safety of both drugs.**Conclusions:** DT offers superior post-operative pain control, reduced opioid reliance, and higher patient satisfaction compared to paracetamol following IVRA in ambulatory hand surgery. These findings support DT as a promising alternative to paracetamol in multimodal analgesic strategies. Additional studies are needed to confirm these findings and examine the mechanisms behind the differences in observed outcomes. The choice of analgesic should remain patient-specific, considering individual clinical conditions, contraindications, and preferences.**Keywords:** Dexketoprofen trometamol, hand surgery, post-operative pain,

Öz

Amaç: Bu prospektif, randomize, çift kör çalışma, intravenöz rejyonel anestezi (İVRA) uygulanan hastalarda postoperatif ağrının kontrol altına alınmasında dexketoprofen trometamol (DT) ve parasetamolün etkinlik ve güvenilirliğini karşılaştırmayı amaçlamaktadır.**Gereç ve Yöntemler:** Çalışmaya Amerikan Anesteziyoloji Derneği (ASA) I-II olan, 18-70 yaş aralığında 66 hasta alınmıştır. Çalışmaya dahil edilme kriterleri arasında ilaç alerjileri, psikiyatrik hastalıklar, Raynaud hastalığı ve antikoagülan tedavi kullanımı bulunan hastalar dışlanmıştır. Hastalar rastgele iki gruba ayrılmıştır: Grup 1'e 25 mg DT, Grup 2'ye ise 500 mg parasetamol postoperatif analjezi amacıyla uygulanmıştır. Hastalar taburculuk sonrası ağrı düzeylerini görsel analog skala (VAS) ile değerlendirmiş, ek analjezik ihtiyacı olduğunda kurfarıcı analjezi kullanılmıştır. Hastalar 30 saat boyunca ağrı kesici etkinliği, memnuniyet düzeyleri, yan etkiler ve tüketilen tablet miktarlarını kaydetmiştir.**Bulgular:** Her iki ilaç da yeterli postoperatif ağrı kontrolü sağlamasına rağmen, önemli farklılıklar saptanmıştır. Grup 1'de analjezik etkinlik anlamlı derecede daha yüksek bulunmuş ($p = 0.001$) ve hasta memnuniyeti Grup 2'ye kıyasla belirgin şekilde daha fazla olmuştur ($p = 0.003$). Grup 1'de hastaların %75,8'i tam ağrı kesilmesi bildirirken, bu oran Grup 2'de %42,4 olarak kaydedilmiştir. Ayrıca, Grup 1'de postoperatif morfin ihtiyacı anlamlı olarak daha düşük bulunmuştur ($p = 0,04$), bu da DT'nin opioid kullanımını azaltma potansiyelini vurgulamaktadır. Mide bulantısı, kusma, baş ağrısı ve uykusuzluk gibi advers olayların sıklığı gruplar arasında benzer bulunmuş ve istatistiksel olarak anlamlı farklılık göstermemiştir ($p > 0,05$), bu da her iki ilacın güvenilirliğini desteklemektedir.**Sonuçlar:** DT, İVRA sonrası el cerrahisi geçiren hastalarda parasetamole kıyasla daha üstün postoperatif ağrı kontrolü sağlamakta, opioid gereksinimini azaltmakta ve hasta memnuniyetini artırmaktadır. Bu bulgular, multimodal analjezi stratejileri içinde DT'nin parasetamole alternatif olarak değerlendirilmesi gerektiğini göstermektedir. Bulguların doğrulanması ve elde edilen sonuçların mekanizmalarının ayrıntılı olarak araştırılması için ek çalışmalara ihtiyaç duyulmaktadır. Analjezik seçimi, hastanın klinik durumu, kontrendikasyonları ve bireysel tercihleri göz önünde bulundurularak yapılmalıdır.**Anahtar Kelimeler:** Deksketoprofen trometamol, el cerrahisi, post-operatif ağrı

Introduction

Local or regional anesthesia (RA) techniques have been proven safe and effective, especially for patients undergoing ambulatory hand surgery (1, 2). Rebound pain after RA has been reported by at least 40% of outpatients (3). The combination of non-opioid multimodal analgesia and anesthesia (such as RA) techniques increases the likelihood that patients

will be pain-free at and after discharge and provides a strong foundation for an excellent quality recovery trajectory (3).

Various RA blocks have emerged over the last century, many utilized in ambulatory anesthesia. Bier block, or intravenous regional anesthesia (IVRA), was introduced by Dr. August Bier in 1908 (4). This technique entails IV

injection of a local anesthetic after inflating a proximal tourniquet. In common upper extremity IVRA, a double cuff tourniquet is placed on the upper arm, with 40 to 50 mL (200-250 mg) of 0.5% lidocaine injected.

The Bier block has several advantages over local anesthetic (LA) infiltration. Widening surgical incisions is easy by anesthetizing a larger forearm area distal to the tourniquet, enabling multiple procedures with one injection, common in hand surgery (5). Preserved tissue planes enhance the identification of anatomical structures, and the absence of edema from local anesthetic infiltration improves surgical visibility, making this an advantageous RA method for detailed observation. Bier's block has no motor blockage, allowing active movement during surgery. This effective anesthesia technique ensures rapid onset and quick recovery. However, IVRA has risks and disadvantages. Along with tourniquet pain and limited post-operative analgesia, systemic local anesthetic toxicity — although extremely rare — makes Bier block less common in ambulatory hand surgery compared to extravascular injections, with or without IV sedation (6, 7).

An effective strategy for post-operative pain control is essential for patient satisfaction in surgical procedures, including hand surgery. Insufficient pain control can result in stiffness and slow the healing process of hand function (8). For ambulatory patients, oral medications prescribed for post-operative pain typically include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), opioid-containing analgesics like codeine-acetaminophen, or combinations of these medications. The approach uses multimodal analgesia to manage pain effectively while reducing opioid use. This strategy is supported by guidelines recommending NSAIDs and paracetamol as first-line treatments, reserving opioids for more severe pain cases (9). Numerous studies demonstrate equivalent efficacy when directly comparing opioids with alternative analgesics, such as paracetamol (acetaminophen) and ibuprofen (10). Paracetamol is one of the most widely used analgesics and is generally recognized as a safe and effective drug with a favorable adverse effect profile (11). Dexketoprofen trometamol (DT) is an NSAID known for its strong analgesic effects and low side effects. Studies show that DT effectively addresses acute pain, often outperforming other NSAIDs in safety and efficacy for post-operative and dental pain situations (12). However, many patients still do not achieve effective postoperative pain relief at

home.

In this prospective, randomized, double-blind study, we aimed to compare the effectiveness of DT and paracetamol in treating post-operative pain in ambulatory hand surgery performed with IVRA.

Materials And Methods

After receiving approval from the Hacettepe University, Faculty of Medicine local ethics committee (HET 08/207-47,30 Jan 2009) and obtaining informed consent, we included ASA I and II patients aged 18-70, undergoing hand surgery with IVRA in our study. Patients with drug allergy, alcoholism, history of psychiatric disease, Raynaud's disease, pregnant or lactating patients, those with bleeding disorders or those receiving anticoagulant therapy, and those with liver and kidney dysfunction were excluded from the study.

All patients were taken to the operating room without premedication and were standardly monitored with noninvasive blood pressure (NIBP), peripheral oxygen saturation (SpO₂), and electrocardiography (ECG). All patients received 2.5 mg IV midazolam after establishing an intravenous line with a 22G IV cannula on the dorsum of the nonoperative hand, and Ringer's lactate solution was started. For IVRA, patients received 3 mg/kg of IV prilocaine (Citanest, AstraZeneca, Turkey) via the IV cannula in the arm with the tourniquet applied before surgery.

After the surgery, the patients were taken to the recovery room, and if the pain score was > 3 on the visual analog scale (VAS; 10-value pain scale), one of the study drugs was given (Group 1: 25 mg DT, Group 2: 500 mg paracetamol) by the study physician after randomization in a sealed envelope by the recovery room nurse who was blind to the study. If the pain was not relieved, IV 2-3 mg morphine (Morphine HCl, Galen, Türkiye) was titrated until VAS ≤ 3 in the recovery room. The anesthesiologist knew what medication was being given to the patient. Patients meeting the ambulatory discharge criteria, including an Aldrete score of ≥9 and remaining complication-free during the initial 2-hour post-operative observation period, were safely discharged from the hospital. The patient was informed verbally and in writing about post-discharge analgesia management before discharge. In addition, the study physician gave the patient 2 days of study drugs and a rescue analgesic drug to be used according to the following plan. Group 1 patients were informed in writing to use 25 mg oral DT (Arveles®, UFSA, Türkiye)

every 8 hours. Group 2 patients were informed in writing to use 500 mg oral paracetamol (Parol®, Atabay, Türkiye) every 6 hours. If VAS ≤ 3 was still not achieved with the study drug, taking a second dose one hour after the first dosage was recommended. In cases where analgesia could not be achieved after the 2nd dose, the study physician prescribed a single dose of diclofenac sodium (Voltaren®, Novartis, Türkiye) 100mg as a rescue analgesic.

The patients were given a diary and a study protocol to evaluate the effectiveness of the analgesic they used at home according to the VAS every 6 hours (Figure 1). An anesthesiologist contacted them via phone to provide additional information based on their diary entries. Patients wrote down the total number of tablets they used, the pain relief activity of the analgesic between 0 and 5 (0: not practical and 5: wholly relieved my pain), their sleep patterns, their satisfaction levels between 0 and 4 (0: not satisfied and 4: satisfied), and any side effects experienced, including urticaria, itching, dry mouth, nausea, vomiting, heartburn, constipation, diarrhea, and headache, along with their frequencies in the provided diary. The effectiveness of the analgesic and patient satisfaction were evaluated using the

Patient Diary

1. Describe the severity of your pain at the specified hours with a number between 0 and 10.
 0: I have no pain 10: I have unbearable pain
 6 hours after surgery;
 12 hours after surgery;
 18 hours after surgery;
 24 hours after surgery;
 30 hours after surgery;
 36 hours after surgery;

2. How many painkillers did you use in the 48 hours after surgery?

3. Did you have to use rescue medication?

4. Rate the painkiller's effectiveness between 0 and 5.
 0: It had no effect. 5: My pain is completely gone.

5. Did you have insomnia due to the pain?

6. Check any of the following undesirable effects that you experienced.

- Rash on body
- Itching
- Dry mouth
- Nausea, vomiting
- Heartburn
- Constipation
- Diarrhea
- Headache

7. Rate your satisfaction with a number between 0 and 4.
 0: Not satisfied. 4: Satisfied

Figure 1. Patient Diary

system used by Rawal et al. (13). The anesthesiologist receiving information by phone kept the records without knowing which analgesic the patient used.

Statistical Analysis

The statistical analyses for the study were performed using SPSS Statistics 25 software. Demographic data were presented as frequencies, percentages, and means ± standard deviations. The normality of the distribution of numerical data was assessed using the Shapiro-Wilk test. Accordingly, the Student's t-test or the Mann-Whitney test was used where appropriate. Pearson's hi-square test evaluated differences in categorical variables. A p-value of <0.05 was considered statistically significant.

Results

The study planned to include 94 patients whose hand surgery would undergo ambulatory surgery. A total of 28 patients were excluded from the study, categorized as follows: 8 had drug allergies, 1 had alcoholism, 6 had a psychiatric history, four suffered from Raynaud's disease, three were pregnant or breastfeeding, and 6 had bleeding disorders or were on anticoagulant therapy study. After applying the exclusion criteria, 66 patients, 33 in Group 1 and 33 in Group 2 were enrolled in the study (Figure 2). IVRA provided adequate

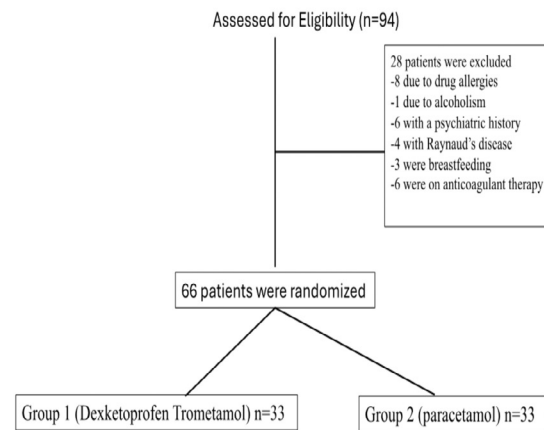


Figure 2. Consort Diagram

anesthesia in all patients; no patients needed general anesthesia.

Table 1 presents demographic data, including age, sex, height, weight, and body mass index, as well as operational data, including the duration of the surgical operation and the duration of the tourniquet. There was no statistical difference between groups regarding these parameters.

Table 1. Sex (n), Age (years), operation duration (min), and anesthesia duration (min) of the groups

	Sex (F/M) (n)	Age (year) mean± SD	Operation Duration (min) mean± SD	Anesthesia Duration (min) mean± SD	VAS
GROUP I n:33	21/12	44±14	32±11	51±11	1 (0-7)
GROUP II n:33	22/11	46±15	27±8.6	49±9.7	1 (0-8)

**Group 1: Patients given dexketoprofen trometamol;
Group 2: patients receiving paracetamol

There was no statistically significant difference regarding post-operative VAS values between groups in the recovery room ($p > 0.05$). The use of post-operative drugs between the two groups, the need for morphine, and the use of savior drugs (used: yes/not used: no) were compared (Table 2). While there was no significant difference between the groups in the use of post-operative drugs and the use of rescue drugs ($p > 0.05$), $p = 0.04$ was found in the need for post-operative morphine, and the difference was considered significant (Table 2).

Table 2. Postoperative use of study drug, morphine, and rescue drug between groups

Variables	Group 1		Group 2		p
Study Drug (n)	Yes	12	Yes	16	0.22
	No	21	No	17	
Morphine (n)	Yes	5	Yes	12	0.04*
	No	28	No	21	
Rescue Drug (n)	Yes	3	Yes	8	0.09
	No	30	No	25	

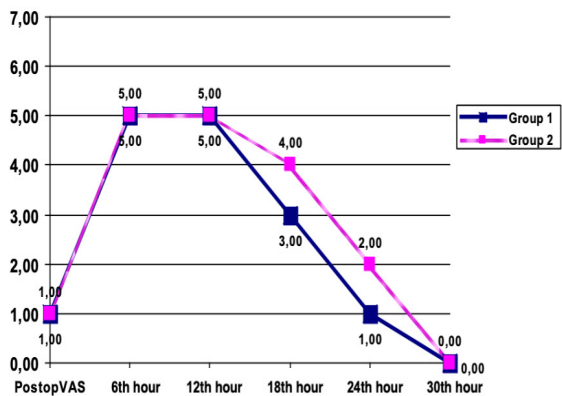


Figure 3. Medians of the groups' postoperative VAS values

The VAS was recorded at the 6th, 12th, 18th, 24th, 24th, and 30th hours, and the medians were compared between the groups. No statistically significant difference was observed ($p > 0.05$) (Graph 1) (Table 3), and since VAS was determined as '0' at the 30th hour, the values at the 36th hour were not considered.

The highest VAS value in Group I was at the 6th hour, while the highest VAS value in Group II was at the 12th hour. The minimum and maximum (min and max) VAS values of the 18th, 24th, and 30th hours were similar (Table 3).

Table 3. Postoperative VAS scores of groups in different timings

Timing (hour)	Group	Median (Min-Max)	p value
6th	I	5 (0-8)	0.123
	II	5 (2-7)	
12th	I	5 (0-7)	0.547
	II	5 (0-8)	
18th	I	3 (0-7)	0.318
	II	4 (0-7)	
24th	I	1 (0-6)	0.289
	II	2 (0-6)	
30th	I	0 (0-6)	0.410
	II	0 (0-6)	

The difference was considered significant when the drug efficacy was evaluated between the groups ($p = 0.001$) (Table 4). Also, an important difference was found between the two groups in terms of patient satisfaction ($p = 0.003$) (Table 4). In Group I, 25 patients (75.8%) reported that their pain was "wholly relieved" with a score of 5. Similarly, 25 patients (75.8%) indicated a high level of drug satisfaction, rating it as "4 = I was satisfied." In Group II, 14 patients (42.4%) stated that their pain was "wholly relieved" with a score of 5, while 17 patients (51.5%) rated their drug satisfaction as "4 = I was satisfied." The groups had no significant difference in the total number of tablets used at home ($p = 0.12$).

Table 4. The median (min/max) and p-values for patient satisfaction, drug efficacy, and the total number of tablets ($p < 0.05$ *)

Variables	Group	Median (Min-Max)	p Value
Patient Satisfaction	Grup I	4(2-4)	0.003*
	Grup II	4(0-4)	
Drug Efficacy	Grup I	5(3-5)	0.001*
	Grup II	4(1-5)	
Total Number of Tablets	Grup I	4(0-8)	0.121
	Grup II	4(1-7)	

When comparing side effects, including itching, nausea, vomiting, headache, and insomnia, no

significant differences were found between the groups ($P > 0.05$). Insomnia was observed in five patients (15.2%) in Group I and seven patients (21.2%) in Group II. In Group II, one patient reported nausea, and one patient reported itching.

Discussion

Pain may be significant after outpatient hand surgery and is managed effectively with oral analgesics in most patients. This prospective, randomized, double-blind trial compared the effectiveness of DT and paracetamol in treating post-operative pain following outpatient hand surgery performed with IVRA. The study findings indicate that while both analgesics offered adequate post-operative pain relief, notable differences were observed in specific outcomes between the two groups.

We found a significant difference between the groups when patient satisfaction and analgesic efficacy were evaluated. In patients with DT, patient satisfaction and analgesic efficacy were superior to those of the paracetamol group ($p=0.001, p=0.003$). Findings from a review comparing dexketoprofen with other painkillers from 2018 to 2021 showed that dexketoprofen is a more potent painkiller than paracetamol. It has a similar effect to lidocaine and dexmedetomidine (14). Also, in a recent study, oral tramadol/dexketoprofen (Tram/DKP) provided faster and more effective pain relief than intravenous paracetamol/tramadol (P+Tram) following total hip arthroplasty. Additionally, fewer Tram/DKP group patients required rescue medication, with both treatments demonstrating good tolerability (15).

Both groups demonstrated similar demographic characteristics and had comparable anesthesia and surgical durations, supporting the internal validity of the study. The VAS scores, recorded at several post-operative intervals, showed no statistically significant differences between the groups ($p > 0.05$). This suggests that DT and paracetamol are equally effective in acute post-operative pain management. Interestingly, while the peak VAS score in the DT group occurred at the 6th hour post-operatively, the peak in the paracetamol group occurred at the 12th hour. We believe that the number of patients in the DT group requiring post-operative morphine (5/33) and rescue analgesics (3/33) was lower than that in the paracetamol group, which may have contributed to these results.

There is a significant difference in the requirement for

post-operative morphine ($p = 0.04$). The reduced need for morphine in the DT group may indicate that DT provides a more sustained analgesic effect, thereby minimizing the need for additional opioid analgesia. This is clinically relevant, given the increasing emphasis on reducing opioid use due to the risk of dependence and adverse effects. In a study, paracetamol and ibuprofen (IBU) were compared with oxycodone for pain management following hand surgery. The study found that there was no significant difference in post-operative pain levels or pill consumption between opioids and non-opioids. The differences in average daily pain scores between the IBU and paracetamol groups were also insignificant ($p>0.05$) (16). These findings suggest that non-opioid analgesics may be equally effective as opioids in managing post-operative acute pain following hand surgery.

In some patients, oral NSAIDs may have limited effectiveness due to gastrointestinal, hemostatic, and renal side effects (17). However, side effects such as itching, nausea, vomiting, headache, and insomnia were minimal and comparable in both groups, with no statistically significant differences observed in the study. This shows that both drugs are relatively safe with similar patient side effect profiles. Patients should be advised that post-operative pain may last longer than a day and that analgesic medications may have some side effects. Patients may need to be prescribed routine home rescue analgesics. A status check interview with the patient may be appropriate to determine if any issues need to be addressed.

While our study provides valuable insights into the comparative effectiveness of DT and paracetamol in managing post-operative pain following outpatient hand surgery with IVRA, certain limitations should be acknowledged. Firstly, although we found significant differences in analgesic efficacy and morphine requirements between the DT and paracetamol groups, the sample size was relatively small, which may restrict the generalizability of the findings. A larger cohort would offer more robust statistical power to confirm these results. Another limitation is that we did not assess long-term post-operative pain or functional recovery beyond the acute pain phase. While both analgesics were effective in managing acute post-operative pain, it remains unclear whether differences in pain control influence long-term recovery, patient satisfaction, or rehabilitation outcomes. Future studies with extended follow-up periods could address this gap. Despite these limitations, our findings contribute

valuable data on the role of DT in reducing opioid consumption and enhancing patient satisfaction in the post-operative setting.

Conclusion

This study provides evidence that DT may be a better alternative to paracetamol for pain management in IVRA. It offers effective pain relief with reduced opioid requirements and higher patient satisfaction. Further studies are needed to confirm these findings and explore the underlying mechanisms behind the differences observed between these two analgesic regimens. However, it is important to note that while DT may have some advantages over paracetamol, the selection of analgesics should be tailored to the patient's clinical condition, potential contraindications, and preferences.

Conflict of interest

The author reported no potential conflict of interest or financial or non-financial interest.

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