Araştırma Makalesi
Research Article

# Is A Standard Intravenous Patient-controlled Analgesia Protocol Sufficient For Patients With Bilateral Knee Arthroplasty?

## BİLATERAL DİZ PROTEZİ YAPILAN HASTALARDA POSTOPERATİF ANALJEZİ İÇİN STANDART İNTRAVENÖZ HASTA KONTROLLÜ ANALJEZİ DOZU YETERLİ OLUR MU?

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**ABSTRACT**

**Objective:** This study investigates whether patients undergoing one-stage bilateral total knee arthroplasty and those undergoing unilateral total knee arthroplasty differed in their responses to standard intravenous patient-controlled analgesia protocol.

**Methods:** Data from patients with physiological status I-III, according to American Society of Anesthesiologists, aged 18-99 years, undergoing one-stage bilateral or unilateral total knee arthroplasty under spinal anesthesia and offered a standard intravenous patient-controlled analgesia with morphine were retrospectively reviewed. Demographic data, Visual Analogue Scale scores, and postoperative complications were examined. The total dose of analgesic consumed, analgesia demands, doses delivered, and the ratio of delivered doses to demands in 0-24 hours and 24-48 hours after surgery were recorded via patient-controlled analgesia pump monitors.

**Results:** Records about 68 patients who had one-staged bilateral total knee arthroplasty and 124 patients who had unilateral total knee arthroplasty were accessed. The analgesia demands and analgesic doses delivered and utilized by the patients with one-staged bilateral total knee arthroplasty were significantly higher in 0-24 hours and 24-48 hours after surgery. Visual Analogue Scale scores 24-48 hours after surgery were higher in patients with unilateral total knee arthroplasty. The side effects of analgesia were similar in both groups.

**Conclusion:** Although the patients with one-staged total knee arthroplasty received significantly higher doses of morphine, side effects due to this opioid did not differ significantly. This showed that the standard intravenous patient-controlled analgesia protocol was reliable and effective in both patient groups.

**Key Words:** Pain; Postoperative Pain; Opioid; Patient Controlled Analgesia; Total Knee Arthroplasty; Anesthesiology

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DEU Tıp Derg 2023;37(1): 25-35
J DEU Med 2023;37(1)25-35
doi:10.18614/deutip.1142863

**Gönderim tarihi / Submitted: 27**.07.2022
**Kabul tarihi / Accepted:** 07.02.2023

**ÖZ**

**Amaç:** Total diz protezi (TDP) hem unilateral prosedür hem de aynı seferde bilateral prosedür şeklinde uygulanabilir. Operasyon sonrası etkin postoperatif analjezi, komplikasyonları azaltır ve fonksiyonel iyileşmeyi kolaylaştırır. Çalışmamızın amacı, aynı seferde bilateral TDP yapılan hastaların unilateral TDP yapılan hastalara göre kliniğimizin standart intravenöz hasta kontrollü analjezi (İV-HKA) protokolüne verdiği yanıtların farklı olup olmadığını araştırmaktır.

**Gereç ve Yöntem:** Dokuz Eylül Üniversitesi Tıp Fakültesi Hastanesinde 01.01.2014- 31.12.2017 tarihleri arasında, ASA (American Society of Anesthesiologists-Amerikan Anestezistler Cemiyeti) fiziksel durum sınıflandırmasına göre ASA I-III risk grubundan, 18-99 yaş arasında, spinal anestezi altında tek seferde bilateral ya da unilateral TDP operasyonu yapılmış ve postoperatif dönemde morfin bazlı İV-HKA kullanan hastaların verileri retrospektif olarak incelenmiştir. Bulgular: Tek seferde bilateral TDP yapılan 68, unilateral TDP yapılan 124 hastanın kayıtlarına ulaşılmıştır. Kadın cinsiyet her iki grupta da daha yüksek bulunmuştur. Operasyon öncesi ve toplam hastanede yatış süresi unilateral TDP grubunda daha yüksektir. Bilateral TDP grubunda postoperatif 0-24 ve 24-48 saatleri arasında hastaların analjezik talepleri, teslim miktarları ve kullandıkları ortalama morfin miktarı unilateral gruptan anlamlı olarak yüksek bulunmuştur. İki grup arasında morfin yan etkileri benzerdir. 24-48 saatleri arasında visuel analog skala (VAS) skorları unilateral TDP grubunda daha yüksek bulunmuştur. Sonuç: Çalışmamızın sonucunda, bilateral TDP hastalarının postoperatif dönemde daha yüksek morfin kullanımı olsa da opioide bağlı yan etkilerin anlamlı farklılık göstermediği ve kullanmakta olduğumuz standart doz İV-HKA protokolümüzün iki grup için de güvenli ve etkin sınırlarda olduğu gösterilmiştir.

**Anahtar Kelimeler:** Total diz protezi, ağrı yönetimi, anesteziyoloji

### Main points of the study

1) Insufficient postoperative analgesia disrupts the rehabilitation process and increases complications such as myocardial ischemia, pulmonary dysfunction, paralytic ileus, urinary retention and thromboembolism, and hospital stay.

2) While providing adequate postoperative analgesia, side effects likely to be experienced by the patients should be considered.

3) The patients with one staged bilateral TKA had higher analgesic consumption than unilateral TKA after surgery. However, when there is a significant difference in side effects due to morphine consumption, the analgesic agent used in the PCA protocol can be considered safe and effective analgesia in both groups.

Chronic refractory knee pain can be treated with one-stage bilateral or unilateral total knee arthroplasty (TKA) (1-2). Postsurgical complications and pain considerably affect postoperative knee rehabilitation and total knee arthroplasty outcomes (3). Adequate analgesia can improve postoperative rehabilitation outcomes and decrease complications (4).

Factors that affect postoperative pain should be examined to cope with it. Among these factors are long duration of surgery and the severity of surgical trauma (5). One-stage bilateral TKA can increase postoperative pain severity due to the more extensive surgical trauma field. Therefore, whether patients with bilateral TKA have more pain than those with unilateral TKA is frequently debated in the literature (6-7).

Several studies have revealed that the total doses and side effects of intravenous opioids in patients with unilateral TKA and those with bilateral TKA are similar (3-6). However, one study by Wang et al. showed that patients with bilateral TKA had more sedation and side effects, such as nausea and vomiting, 24-48 hours after surgery (7). Conflicting evidence about postoperative pain severity in patients with unilateral TKA and those with bilateral TKA hampers reaching an agreement about this issue.

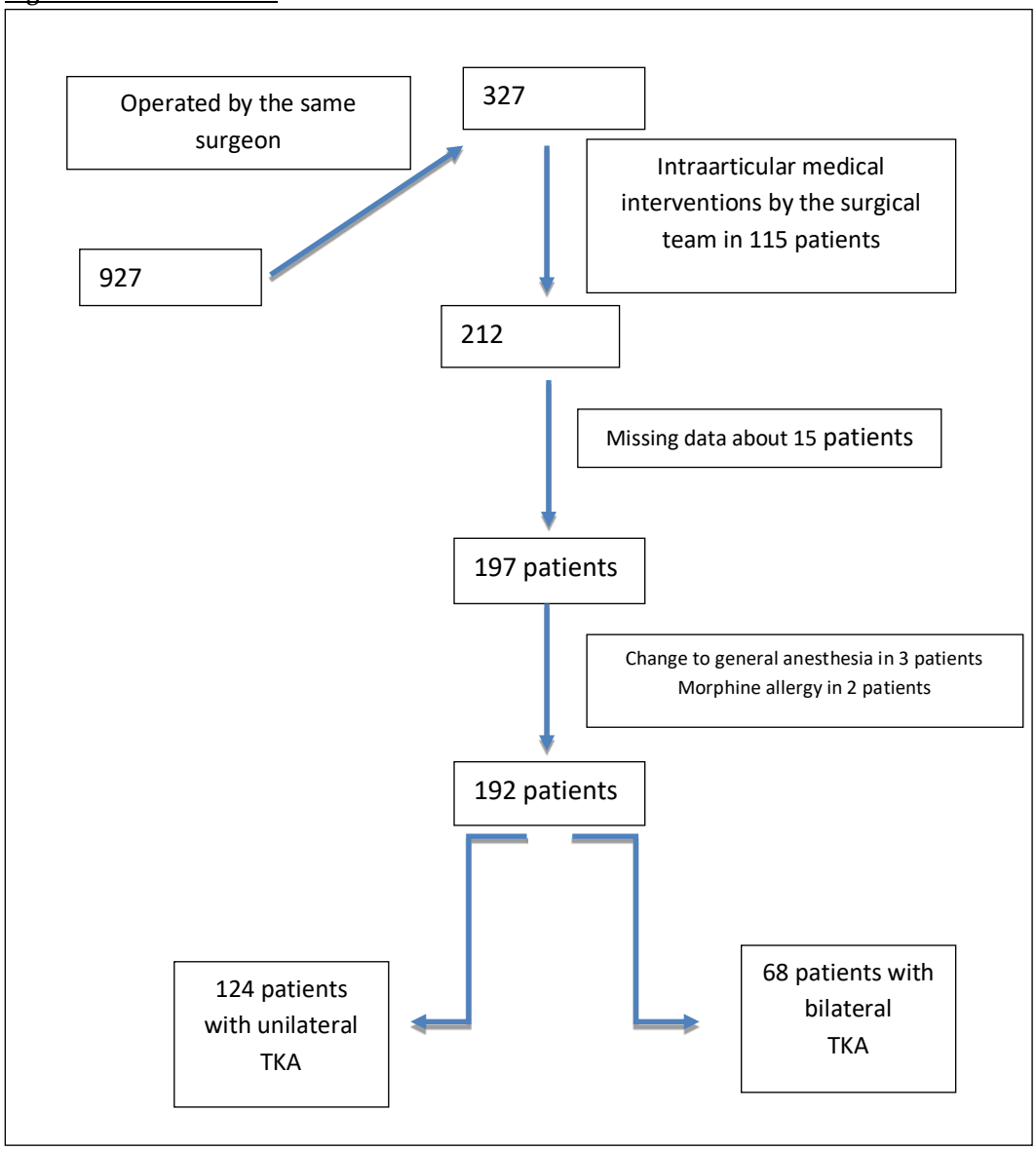
No definite recommendation has been made about the optimum dose, volume, and type of analgesics in knee arthroplasty cases. There have been studies with diverse conclusions, and the primary aims are to decrease postoperative pain and thus reduce postoperative complications, hospital stay, and the total healthcare cost and to enhance functional recovery in the patients. While achieving these aims, side effects likely to be experienced by the patients should be taken into account, and methods of analgesia and doses of analgesics that can provide the best analgesia and create the fewest side effects should be determined. To these aims, factors affecting postoperative pain should be known well. One of these factors is surgical trauma. The severity of the surgical trauma has an impact on postoperative pain. Based on this view, the present study hypothesized that the patients with bilateral TKA would have higher postoperative pain scores and need higher doses of analgesics than patients with unilateral TKA.

This study aimed to evaluate postoperative pain and analgesia uses of the patients with one-stage bilateral TKA and those with unilateral TKA. In addition, it was examined whether these patients differed in their responses to the standard intravenous patient-controlled analgesia (PCA) protocol utilized in the hospital where this study was conducted. The study results can reveal whether postoperative pain is similar in patients with bilateral TKA and those with unilateral TKA and whether the standard intravenous PCA offered to patients with TKA in the hospital is sufficient. The results will also provide evidence about whether the analgesic doses should be increased or reduced.

## MATERIALS AND METHOD

After ethical approval was obtained, data from our hospital records about patients who had one-stage bilateral TKA or unilateral TKA between 1 January 2014 and 31 December 2017 and received intravenous morphine-based PCA in the postoperative period were retrospectively evaluated. Nine hundred twenty-seven patient records were examined regarding exclusion criteria, and data about 192 patients fulfilling the inclusion criteria were analyzed (Fig 1).

**Fig 1**. Flowchart of Patient




Inclusion criteria were age 18-99 years, having the physiological status I-III of American Society of Anesthesiologists (ASA I-III), receiving postoperative PCA with morphine, and being operated on by the same surgeon. Exclusion criteria were administration of general anesthesia and changing the anesthesia method during surgery (n=3), not using the PCA device in the postoperative 48 hours and morphine allergy (n=2), using a different analgesic/opioid other than morphine (n=115), morphine-related contraindications and missing information in patient records (n=15). Data about demographics (age, gender, weight, height, body mass index, and ASA score), having primary surgery or reoperation, comorbidities, preoperative hospital stay, total hospital stay, duration of surgery, maximum VAS scores in the recovery room, duration of recovery from anesthesia, postoperative complications and postoperative VAS scores at rest were obtained from patient files. Data about the total doses of analgesics consumed in 0-24 hours and 24-48 hours after surgery, doses of analgesics demanded and delivered.

The PCA device monitoring forms obtained the ratio of delivery doses to demands.

Patients planning to have TKA in the hospital where this study was conducted firstly recommended regional anesthesia, and those without contraindications undergo TKA under spinal anesthesia. Following the standard monitoring, the patients are administered spinal anesthesia through vertebral spaces L2-3 or L3-4 when seated. To achieve spinal anesthesia, bupivacaine heavy 2,5 - 3ml (12,5-15mg) and morphine (0.1 - 0.2mg) are administered intrathecally. Surgery is initiated when the Bromage motor blockade score of the patients is 2 or 3. Intravenous PCA is utilized after surgery; While informing the PCA after the operation, the patients are told to press the device button whenever they feel pain. Our goal was to achieve VAS score below 3. The patients using PCA are followed, and data from the PCA pump are routinely recorded. PCA is achieved by an intravenous 1mg bolus of morphine with a lockout interval of 20 min.

Due to the retrospective nature of the study, informed consent of the patients was not required because the study analyzed anonymous clinical data of the patients.

### Statistical Analysis

Obtained data were analyzed with Statistical Package Program for Social Sciences 22.0 (SPSS Inc, Chicago, IL, USA). Parametric data were expressed in mean values, and standard deviation and categorical data were expressed in percentages. Independent t-test, Mann-Whitney U test, and Chi-square test were utilized to compare patient characteristics, and PCA uses between the patients with bilateral TKA (bilateral TKA group) and those with unilateral TKA (unilateral TKA group). Data about continuous variables were expressed in mean ± standard deviation. Data about frequencies were expressed in numbers and percentages. Statistical significance was set at $p<0.05$.

## RESULTS

Patient records from about 927 cases were examined, and data about 192 patients fulfilling the inclusion criteria were retrospectively analyzed. Out of 192 patients, 124 had unilateral TKA, and 68 had one-stage bilateral TKA. Analyses of their demographic characteristics showed that the gender female was predominant in both groups ($p=0.045$). Demographics of the patients are presented in Table 1.

| **Table 1.** Demographic Features of the Patients | **Bilateral TKA n (%) or mean (±SD)** | **Unilateral TKA n (%) or mean (±SD)** | **p** |
|---|---|---|---|
| **Age (years)** | 64.51 (±8.04) | 67.34 (±10.63) | 0.055 |
| **Gender** | | | |
| **Female** | 58 (%85.3) | 90 (%72.6) | **0.045*** |
| **Male** | 10 (%14.7) | 34 (27.4) | |
| **Weight (kg)** | 80.85 (±11.00) | 81.09 (±13.76) | 0.203 |
| **Height (cm)** | 163 (±6.8) | 162 (±7.77) | 0.143 |
| **Body Mass Index (cm²/kg)** | 30.43 (±3.97) | 31.81 (±4.68) | 0.054 |
| **ASA scores** | | | |
| **ASA I** | 6 (%8.8) | 7 (%5.6) | 0.079 |
| **ASA II** | 51 (%75.0) | 79 (%63.7) | |
| **ASA III** | 11 (%16.2) | 38 (%30.6)) | |
| **Smoking status (Yes/No)** | 17/51 (%25.0/%75.0) | 20/104 (%16.1/%83.9) | 0.136 |
| **Comorbidities** | | | |
| **Cardiovascular** | 43 (%63.3) | 84 (%67.7) | 0.528 |
| **Respiratory System** | 7 (%10.3) | 23 (%18.5) | 0.132 |
| **Endocrine System** | 23 (33.8) | 42 (%33.9) | 0.995 |
| **Neurological System** | 1 (%1.5) | 7 (%5.6) | 0.264 |
| **Chronic Renal Failure** | 1 (%1.5) | 3 (%) | 1.000 |
| **Obesity** | 37 (%54.4) | 84 (%67.7) | 0.067 |
| **Obstructive Sleep Apnea Syndrome** | 0 | 4 (%3.2) | 0.299 |
| ***p<0.05: significant difference**<br>**SD: standard deviation** | | | |

The mean preoperative hospital stay was 2.55 (±1.88) days in the bilateral TKA group and 4.08 (±3.50) days in the unilateral TKA group, with a significant difference (p=0.003). The mean total hospital stay was 9.17 (±2.98) days in the bilateral TKA group and 12.95 (±6.91) days in the unilateral TKA group, with a significant difference (p<0.001). The mean preoperative and total hospital stays were longer in the unilateral TKA group than in the bilateral TKA group (Table 2).

**Table 2.** Preoperative Hospital Stay and Total Hospital Stay

| | **Bilateral TKA n (%) or Mean (±SD)** | **Unilateral TKA n (%) or Mean (±SD)** | **p** |
|---|---|---|---|
| **Preoperative hospital Stay (days)** | 2.55 (±1.88) | 4.08 (±3.50) | **0.003*** |
| **Total Hospital Stay (days)** | 9.17 (±2.98) | 12.95 (±6.91) | **<0.001*** |
| ***p<0.05: statistically significant difference**<br>**SD: Standard Deviation** | | | |

A significantly higher rate of the unilateral TKA group had reoperations (p<0.001). The mean duration of surgery was 155.85 (±36.13) minutes in the bilateral TKA group and 134.38 (±39.26) minutes in the unilateral TKA group, with a significant difference (p=0.001). However, there was no significant difference between the groups' duration of recovery from anesthesia. Postoperative complications did not significantly differ between the groups, either.

Concerning the comparison of PCA recordings, the mean number of doses delivered in the first 24 hours was 10.16 (±7.02) in the bilateral TKA group and 7.53 (±5.52) in the unilateral TKA group, with a significant difference (p<0.001). The mean number of demands in the first 24 hours after surgery was 27.22 (±60.58) in the bilateral TKA group and 13.00 (±15.88) in the unilateral TKA group. Although the number of demands significantly differed between the groups (p<0.001), the ratio of delivered doses to the number of demands was not significantly different. The mean total morphine consumption of the bilateral TKA group in the first 24 hours after surgery (8.92 (±7.04) was significantly higher than that of the unilateral TKA group (6.01 (±5.15) (p=0.001).

Both bilateral TKA and unilateral TKA groups significantly differed in their delivery, demand, and total morphine consumption in 24-48 hours after surgery (p=0.01, 0.007, and 0.004, respectively), but they were not significantly different in the ratio of delivery to demand (p=0.137) (Table 3).

**Table 3.** Information about PCA Uses

| | **Bilateral TKA Mean (±SD)** | **Unilateral TKA Mean (±SD)** | **p** |
|---|---|---|---|
| **24 hours** | | | |
| **Delivery** | 10.16 (±7.02) | 7.53 (±5.52) | **<0.001*** |
| **Demand** | 27.22 (±60.58) | 13.00 (±15.88) | **<0.001*** |
| **Ratio of Delivery to Demand** | 0.61 (±0.64) | 0.68 (±0.25) | 0.059 |
| **Total Morphine Consumption (mg)** | .04) | 6.01 (±5.15) | **0.001** |
| **24-48 hours** | | | |
| **Delivery** | 8.17 (±5.16) | 6.13 (±4.43) | **0.010*** |
| **Demand** | 14.05 (±12.18) | 9.13 (±6.77) | **0.007*** |
| **Ratio of Delivery to Demand** | 0.67 (±0.23) | 0.73 (±0.23) | 0.099 |
| **Total Morphine Consumption (mg** | 7.07 (±5.44) | 4.79 (±3.83) | **0.004*** |
| **Total** | | | |
| **Delivery** | 18.20 (±8.61) | 13.63 (±8.28) | **<0.001*** |
| **Demand** | 39.95 (±60.70) | 22.10 (±19.49) | **<0.001*** |
| **Ratio of Delivery to Demand** | 0.65 (±0.29) | 0.60 (±0.21) | 0.137 |
| **Total Morphine Consumption (mg** | 15.75 (±8.79) | 10.80 (±7.59) | **<0.001*** |
| ***p<0.05: statistically significant difference**<br>**SD: standard deviation** | | | |

VAS scores during recovery from anesthesia did not significantly differ between the bilateral TKA and unilateral TKA groups. The maximum mean VAS score in the first 24 hours was 4.05 (±2.06) in the bilateral TKA group and 4.00 (±1.81) in the unilateral TKA group (p=0.849) without a significant difference.

However, the maximum mean VAS score at rest in 24-48 hours was significantly lower in the bilateral TKA group. It was 2.52 (±2.32) in the bilateral TKA group and 3.29 (±2.17) in the unilateral TKA group (p=0.030) (Table 4).

**Table 4.** VAS Scores of the Patients

| | **Bilateral TKA Mean (±SD)** | **Unilateral TKA Mean (±SD)** | **p** |
|---|---|---|---|
| **Maximum VAS score in the recovery room** | 0.85 (±1.24) | 1.02 (±1.26) | 0.311 |
| **VAS score at rest in 0-24 hours** | 4.05 (±2.06) | 4.00 (±1.81) | 0.849 |
| **VAS score at rest in 24-48 hours** | 2.52 (±2.32) | 3.29 (±2.17) | **0.030*** |
| ***p<0.05: statistically significant difference<br>SD: standard deviation** | | | |

Regarding the side effects of the opioid (sedation, vomiting, itching, and constipation), no significant difference was found between the groups (p>0.05)

## DISCUSSION

Pain resulting from TKA affects rehabilitation and surgical outcomes of the patients (3). Insufficient postoperative analgesia disrupts the rehabilitation process and increases complications such as myocardial ischemia, pulmonary dysfunction, paralytic ileus, urinary retention and thromboembolism, and hospital stay. Therefore, both patient satisfaction decreases and healthcare costs increase (7).

Various methods exist to provide postoperative analgesia. PCA has been utilized in the hospital where this study was performed for a long time in that it improves patient satisfaction and is helpful, simple, and easy to monitor (8-10). The patient-machine interaction in PCA gives hints at many issues. Examination of demands and delivered doses recorded by the machine can help to evaluate patient adherence to the analgesia offered. The total number of press in buttons refers to the number of demands and shows the need for analgesics and the severity of anxiety (11). At intervals when the machine is not locked, the successful administration of analgesia demanded by the patient refers to the number of delivered analgesics and shows the severity of pain (12). The ratio of delivery to demand indicates the compatibility between the patients and the PCA machine. Increased ratios show that the programmed dose and lockout interval have been well-adjusted to the patient's needs. In contrast, decreased ratios show that the patient needed to press the pump button more frequently during lockout intervals. This can be attributed to patient anxiety, failure to offer adequate information to the patient about the machine, insufficient doses of analgesics, and long lockout intervals (7).

While data about postoperative pain and analgesia uses were examined in the present study, the effects of the differences in the anesthesia method used, surgical trauma, and postoperative care were minimized. To achieve this, only the patients undergoing spinal anesthesia were included in the study. In addition, data about the patients operated on by the same surgeon were analyzed to eliminate the effects of differences in surgical technique, experience, and ability on pain scores. When these criteria were considered, data about 192 patients were included in the analysis.

Regarding demographic features, the gender female was predominant in both bilateral and unilateral TKA groups. Studies show the relationship between gender and postoperative pain and provide conflicting results (13-15). In the present study, the female patients in both groups were found to have significantly higher morphine consumption. The predominance of the female gender and the significantly higher morphine consumption only affect the total morphine consumption in the first 24 hours. Morphine consumption became equal between the genders, and the significant difference in morphine consumption disappeared later. In addition, the gender female had higher VAS scores in the first 24 hours after surgery, though it was insignificant. This insignificant difference can be ascribed to the small sample size. In light of the primary conclusions drawn from this study, it does not seem that gender affects analgesics consumption and VAS scores due to the predominance of the female gender in both patients with bilateral TKA and those with unilateral TKA.

In the current study, preoperative hospital stay and total hospital stay were found to be longer in the unilateral TKA group. It may be that most of the patients having unilateral TKA were cases of reoperations. In these cases, preoperative preparations and postoperative hospitals stay last longer. However, several studies have revealed varying results regarding hospital stays. These conflicting results can be attributed to differences in the study settings and the social structure of the societies.

In the present study, the mean number of demands and morphine consumption in the first 24 hours was higher in the patients with bilateral TKA. Wang et al. showed higher morphine consumption in patients with one-stage bilateral TKA in postoperative 6-12, 12-18, and 18-24 hours (7). In addition, they revealed higher morphine demands in these patients in 12-18 and 18-24 hours and higher morphine deliveries in 12-18, 18-24, and 30-36 hours. Although follow-up intervals are different, their results are similar to the ones in the present study.

In the current study, the bilateral TKA group had high demands, deliveries, and total morphine consumption 24-48 hours after surgery, which is consistent with the literature (7,16). The patients with bilateral TKA were found to consume more morphine in postoperative two days. The ratio of delivery to demand was not significantly different between the groups in the present study. Wang et al. (7) showed that patients with bilateral TKA had a lower ratio of delivery to demand in postoperative 6-18 hours. They attributed this lower ratio to increased anxiety in this group, though they did not use a scale to determine anxiety levels. Similarly, the anxiety levels of the patients were not measured with a scale in the present study. The evaluation of anxiety using the ratio of delivery to demand showed no difference between the groups. This suggests that the type and dose of the drug and the lockout interval utilized in the postoperative PCA protocol are sufficient for both groups.

The severity of postoperative pain experienced by patients has been measured with VAS and VAS scores have been compared in several studies. Huang et al., in their randomized, controlled study with 144 patients (17), found no significant difference in pain scores between their groups. Similarly, Na et al. (22) retrospectively evaluated 513 patients with unilateral TKA and 612 patients with bilateral TKA and showed no significant difference in pain scores between them. However, they did not mention the type of anesthesia and analgesia they utilized. Unlike Na et al.'s study, Shetty et al. (6) provided the types of anesthesia and analgesia. They also showed that postoperative pain scores were similar in their groups. Although they explained the standard analgesia protocol in detail, they did not mention additional opioid doses the patients needed. Teng et al. (18) supplied the types of anesthesia and analgesia used and detected no significant difference in postoperative pain scores between their patient groups. According to the results of a study by Powell et al. (16), pain scores of patients with bilateral TKA were one point higher than in patients with unilateral TKA.

The results of the present study about pain scores were different from those reported by Teng et al. and Powell et al. Although the VAS scores in the recovery room and at rest in the first 24 hours after surgery were not different between the groups, the maximum mean VAS scores at rest in 24-48 hours were lower in the bilateral TKA group. This can be explained by the fact that the number of reoperations was higher in the unilateral TDA group. These

patients might have perceived pain as a natural result of surgery due to prior experiences. However, the bilateral TKA group had a higher morphine consumption in the first 48 hours. This result suggests that the patients with bilateral TKA might have had lower VAS scores due to their higher analgesic consumption. The mean postoperative VAS score at rest in the present study is higher than that of Wang et al. (7). This can be due to using boluses instead of basal infusions for PCA in Wang et al.'s study. In our daily practise basal infusions for PCA are not routinely used due to conflicting evidence and worries about side effects. Although there is no general agreement about which method provides better analgesia and causes fewer side effects, most studies suggest that basal infusions can create more side effects (19,20,21,22) .

In the current study, opioid-related side effects did not significantly differ between the groups. Wang et al. reported that a higher rate of patients with bilateral TKA had sedation, nausea, and vomiting 24-48 hours after surgery than those with unilateral TKA (7). The reason for this difference can be the presence of basal infusions in PCA management. Despite the significantly higher morphine consumption in the first 24 hours in the bilateral TKA group, the lack of a significant difference in side effects that the PCA protocol utilized in the present study is safe.

Studies have provided evidence that as incisions increase, so does postoperative pain. (23,24,25). The reason for the higher analgesic consumptions in the bilateral TKA group in our study can be their wide incision area and more severe surgical trauma. The most important limitation of the current study is its retrospective design. Also, sufficient data about some variables could not be collected; postoperative functional recovery and the effects of pain on their recovery could not be observed. In addition, data about whether the patients were informed about the PCA machine and their education levels and mental status could not be obtained.To conclude, the patients with bilateral TKA had higher analgesic consumption after surgery. However, their VAS scores were lower, possibly due to their higher analgesic consumption, and VAS scores were acceptable in both patient groups. When the lack of a significant difference in side effects due to morphine consumption and the ratio of delivery to demand are considered, the analgesic agent used in the PCA protocol, its dose, and lockout interval can be considered to provide safe and effective analgesia in both groups.

The authors declare no conflict of interest or financial support from an industry source in the current study.

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