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Research Article

Comparison of efficacy between combined periarticular and incisional injections versus periarticular injection alone of bupivacaine for pain control after total knee arthroplasty: A prospective randomized controlled trial

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ABSTRACT

Objective: The aim of this study was to compare the efficacy of combined periarticular and incisional injections versus periarticular injection alone of bupivacaine in reducing post-operative pain after total knee arthroplasty (TKA).

Methods: In this prospective, randomized, double-blind comparative study, 90 patients with primary osteoarthritis who underwent TKA were enrolled. The patients were then randomly divided into 3 groups (30 in each): group 1, without injection; group 2, with periarticular injection of 20 mL 0.5% bupivacaine hydrogen chloride (HCl) (100 mg) after implantation; and group 3, periarticular injection of 20 mL 0.5% bupivacaine HCl (100 mg) after implantation and incisional injection of 10 mL 0.5% bupivacaine HCl (50 mg) before wound closure. Post-operative pain levels were measured using a 100-mm visual analogue scale (VAS) (0 mm: no pain and 100 mm: worst pain) at 30 min and 1, 2, 4, and 6 h, post-operatively.

Results: The mean VAS score in group 3 (the combined group-periarticular and incisional injections) within the first 4 h was lower than that in group 1 and group 2 ($p<0.001$). The mean VAS scores at the first 30 min were 65.21±9.46 in group 1, 51.86±5.96 in group 2, and 29.33±8.55 in group 3 ($p<0.001$). The mean VAS scores at the first 1 h were 64.43±9.32 in group 1, 47.26±4.77 in group 2, and 31.66±7.37 in group 3 ($p<0.001$). The mean scores at the 2 h were 61.46±8.62 in group 1, 48.33±4.66 in group 2, and 30.83±6.76 in group 3 ($p<0.001$). The mean scores at the 4 h were 64.72±8.91 in group 1, 47.53±4.35 in group 2, and 34.36±6.64 in group 3 ($p<0.001$). The differences were not significant at 6 h between group 2 (44.91±4.12) and group 3 (41.83±6.71) ($p>0.001$). However, the values were significantly lower than those of the control group (63.56±9.73) ($p<0.001$). In addition, VAS scores at all follow-up times were significantly higher in the control group compared with the other groups ($p<0.001$).

Conclusion: Evidence from this study revealed that the combined injection of bupivacaine is more effective than its periarticular injection alone and provides effective post-operative pain management after TKA.

Level of Evidence: Level I, Therapeutic study

Total knee arthroplasty (TKA) is considered an effective treatment for end-stage knee osteoarthritis (1). TKA is an important treatment for severe joint disease that can relieve joint pain and improve joint function. Approximately 90% of patients with pain and dysfunction show improvement after TKA, which also improves their quality of life. Most patients (85%) are very satisfied with the curative effect of surgery and post-operative quality of life (2, 3). However, post-operative pain has a harmful effect on important organs and directly affects post-operative rehabilitation exercises (4, 5). TKA may cause intense early post-operative pain affecting the patient's overall satisfaction with the surgery (6). The incidence of moderate-to-severe pain after TKA is reported to be about 50% (7). The clinical application of many analgesic methods is limited (8, 9). Therefore, the identification of effective and safe analgesic treatments is an important challenge. Despite the use of new drugs and new techniques, in-

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adequate post-operative pain management in TKA can contribute to immobility-related complications, longer hospital stays, decreased functional outcome, increased drug use, and increased costs. We hypothesized that administering combined periarticular and incisional injections of bupivacaine was more effective than periarticular injection alone on post-operative pain after TKA.

Although many types of analgesics are widely used after TKA, each has local and systemic side effects. Periarticular injections have the advantage of delivering analgesic drugs directly to the source of pain (10). A number of studies have demonstrated the safety and effectiveness of this technique as compared with a placebo (11). In addition, local infiltration analgesia is based on systematic infiltration of drugs, such as local anesthetics and anti-inflammatories, around all structures subject to surgical trauma. Incisional injection is an example of this method (12). Bupivacaine is a long-acting local anesthetic that stabilizes the cell membrane and reversibly decreases the rate of depolarization, causing reversible local analgesia. Combined periarticular and incisional injections of bupivacaine may effectively prevent pain and lead to a lower systemic side effect profile.

To our knowledge, no prior study has compared combined periarticular and incisional injections of bupivacaine with periarticular injection alone for post-operative pain after TKA. Our aim was to determine which method of administration would be more effective in post-operative pain after TKA.

Materials and Methods

This prospective, randomized, double-blind comparative study included 90 primary osteoarthritis patients undergoing total knee replacement at our hospital. Inclusion criteria were as follows: patients aged from 45 to 65 years, classified as American Society of Anesthesiologists (ASA) physical status I or II, with a body mass index (BMI) of 25–35, and who fully understood the study aims and agreed to participate. Exclusion criteria were as follows: patients with an allergy to the medication used in this study, use of analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) within 24 h before surgery, severe systemic diseases, bilateral surgeries, and refusal by the patient.

HIGHLIGHTS

- Combined periarticular and incisional injections of bupivacaine provide effective postoperative analgesia after total knee arthroplasty.
- Periarticular and incisional injections were easy to perform, effective and safe.
- Descreasing pain after total knee arthroplasty improves the patients' overall satisfaction.

All patients were transported to the operating room after premedication with midazolam 0.01 mg/kg intramuscularly. After the patients were transferred to the operating room, peripheral oxygen saturation, non-invasive blood pressure, and electrocardiogram monitoring were performed. General anesthesia was induced with remifentanyl 1 mg/kg IV, propofol 2 mg/kg IV, and rocuronium 0.5 mg/kg IV, and an endotracheal tube was placed. Anesthesia was maintained with sevoflurane 1%-3% in 50% O_2. A urinary catheter was inserted. Surgery was performed with the use of a tourniquet. The patients were randomly divided using the sealed-envelope method into 3 groups of 30 patients each. All patients had the procedure performed through an anterior midline incision. Group 1 patients (n=30) did not receive bupivacaine hydrogen chloride (HCl) injections. Group 2 patients (the periarticular group, n=30) were given a periarticular injection of 20 mL 0.5% bupivacaine HCl (100 mg) after implantation. Group 3 patients (the combined group, n=30) received a periarticular injection of 20 mL 0.5% bupivacaine HCl (100 mg) after implantation and an incisional injection of 10 mL 0.5% bupivacaine HCl (50 mg) before wound closure. The periarticular injections were administered into the posterior capsule (5 mL), medial capsule/synovium/periosteum (5 mL), quadriceps tendon (5 mL), and lateral capsule/synovium/periosteum (5 mL) after implantation. The incisional injection was applied to the subcutaneous tissue around the midline incision (10 mL) before wound closure. All surgeries were performed or supervised by the senior orthopedic surgeon of our hospital (Mehmet Akif Altay). The same prosthesis was used for all patients. No patient received patient-controlled analgesia or a peripheral nerve block.

A blinded observer recorded the post-operative pain levels reported by the patient using a visual analogue scale (VAS) at 30 min and 1, 2, 4, and 6 h post-operatively. Clinical evaluation of knee pain was measured using a 100-mm VAS (0 mm: no pain and 100 mm: worst pain). Any complaint of pain indicated by a VAS score greater than 50 was treated with a single dose of pethidine HCl 1 mg/kg intramuscularly. In this study, pre-op pain medication was not used. Pethidine HCl was administered by intramuscular injection to 37 patients in the first 4 h post-operatively.

This study was approved by the local Research Ethics Committee of the Harran University (approval number: 74059997.050.01.04/197), and informed consent was obtained from all patients before the study.

Statistical analysis

All statistical analyses were conducted using the Statistical Package for Social Science (SPSS) version 20 (IBM Corp.; Armonk, NY, USA). Continuous variables were expressed as mean±SD. The normality of distributions was evaluated using the one-sample Kolmogorov–Smirnov test, revealing a uniform distribution. The chi-square test was used for cat-

egorical variables. Repeated-measures analysis of variance (ANOVA) was used to evaluate the differences between the groups with the least significant difference post hoc test. A p value of <0.05 indicated statistical significance. The power of the study was calculated by post-hoc power analysis.

Results

The demographic characteristics of patients are shown in Table 1. No significant differences were observed in age, BMI, female/male ratio, the operated knee (right/left), ASA status, and hospital length of stay among the groups.

The VAS values of all groups are shown in Table 2. The ANOVA test indicated significant differences among the groups. VAS values of group 3 (the combined group-periarticular and incisional injections) within the first 4 h were lower than those of group 1 (control-no injections) and group 2 (the periarticular injection), and the difference was statistically significant (p<0.001). VAS values of the groups in the first 30 min were 65.21±9.46, 51.86±5.96, and 29.33±8.55 in group 1, group 2, and group 3, respectively (p<0.001). VAS values of the groups in the first 1 h were 64.43±9.32, 47.26±4.77, and 31.66±7.37 in group 1, group 2, and group 3, respectively (p<0.001). VAS values of the groups in the 2 h were 61.46±8.62, 48.33±4.66, and 30.83±6.76 in group 1, group 2, and group 3, respectively (p<0.001). VAS values of the groups in the 4 h were 64.72±8.91, 47.53±4.35, and 34.36±6.64 in group 1, group 2, and group 3, respectively (p<0.001). The differences were not significant at 6 h between groups 2 and 3, 44.91±4.12 and 41.83±6.71, respectively (p>0.001); however, the values were significantly lower than those of the control group (63.56±9.73; p<0.001). In addition, VAS scores at all follow-up times were significantly higher in the control group compared with the other groups (p<0.001). The power of the study was calculated as 84.2%.

Table 1. Demographic characteristics of both groups

	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	p
Age (years), mean±SD	54.56±6.87	56.61±6.49	58.11±4.64	0>0.05
Gender, n (%)				
Female	18 (60)	21 (70)	16 (53.3)	0>0.05
Male	12 (40)	9 (30)	14 (46.6)	
BMI (kg/m^2), mean±SD	28.58±1.24	27.82±1.53	28.31±1.52	0>0.05
Side (right/left), n	17/13	14/16	12/18	0>0.05
ASA class, n (%)				
I	16 (53.3)	19 (63.3)	17 (56.6)	0>0.05
II	14 (46.6)	11 (36.6)	13 (43.3)	
Hospital length of stay, mean±SD	4.36±0.52	4.22±0.41	4.16±0.39	>0.05

BMI: body mass index; ASA: American Society of Anesthesiologists.

Table 2. Visual analogue scale values for all groups

VAS values	Group 1	Group 2	Group 3	p
30 min, mean±SD	65.21±9.46	51.86±5.96*	29.33±8.55‡	0<0.001[a]
1 h, mean±SD	64.43±9.32	47.26±4.77*	31.66±7.37‡	0<0.001[a]
2 h, mean±SD	61.46±8.62	48.33±4.66*	30.83±6.76‡	0<0.001[a]
4 h, mean±SD	64.72±8.91	47.53±4.35*	34.36±6.64‡	0<0.001[a]
6 h, mean±SD	63.56±9.73	44.91±4.12*	41.83±6.71[n.s.]	0<0.001[a]

[a]Repeated-measures analysis of variance within the each evaluation time.
*Significant difference between groups 1 and 2.
‡Significant difference between groups 2 and 3.
[n.s.]: non-significant; VAS: visual analogue scale

We did not observe any complications due to periarticular and incisional bupivacaine injections in our study. No infection was encountered. No patient developed any side effects.

Discussion

In this study, we aimed to determine the effectiveness of combined periarticular and incisional injections of bupivacaine for post-operative pain after TKA by analyzing VAS scores at 30 min and 1, 2, 4, and 6 h post-operatively. We hypothesized that administering combined periarticular and incisional injections of bupivacaine was more effective than periarticular injection alone on post-operative pain after TKA. The main results of this study are as follows. First, periarticular and incisional injections of bupivacaine, when used concurrently, provide effective post-operative pain control after TKA. Thus, the VAS scores during the first 4 h were lower in group 3 than in the other groups. Second, although there were no statistically significance differences in the VAS values between groups 2 and 3 at 6 h, the values were lower than those in the control group, and the difference was statistically significant. Third, periarticular and incisional injections of bupivacaine appear to be more effective treatment methods than periarticular injection alone for post-operative pain after TKA. Fourth, to our knowledge, no study has yet examined and compared both methods.

Severe pain following TKA may be related to bone or soft tissue trauma or hyperperfusion following tourniquet release. Surgical difficulty in TKA has also been found to be related to post-operative pain and related to bone loss, severe deformity, flexion contracture, and poor range (13). Periarticular and incisional injections with multimodal drugs is a simple and safe method that should be considered to effectively reduce the pain of patients after TKA (14). The periarticular injection technique for reduction of post-operative pain following TKA has been reported and has demonstrated good results (15). Several studies have shown that incisional injections increase the effectiveness of periarticular injections (12, 13). Busch et al. reported a decreased requirement of patient-controlled analgesia at 12 h post-operatively and a lower pain score in total knee replacement patients who received a perioperative periarticular injection compared with patients who did not receive an injection (13). These studies have explored periarticular and incisional injections used together with local anesthetics, anti-inflammatories, and corticosteroids. Due to the additive effects of these drugs, the duration of post-operative analgesic effects is long (12, 13, 16, 17). However, studies have shown that the combined use of local anesthetics and NSAIDs may prolong the analgesic effect but may cause NSAID-induced digestive tract and kidney damage (14, 18). In addition, corticosteroids have strong anti-inflammatory effects; bupivacaine combined with dexamethasone prolongs the effect of local anesthetics. Although prolongation of the effect time is a positive, the use of perineural and/or infiltratif glucocorticoids causes a low rate of permanent neurological complications and elevation of blood glucose. In addition, it may increase the risk of surgical site infection in diabetic patients (18, 19). To avoid these side effects mentioned above, in this study, the first report in English literature, we applied bupivacaine alone. The half-life of bupivacaine is approximately 3 h, and the duration of action after infiltration is 4–6 h (20). Therefore, we thought that follow-up in the first 6 h could be appropriate for this study.

Effective post-operative analgesia management in the early post-operative period after TKA is crucial to early functional results and patient satisfaction. Moreover, it affects patients' ability to return to work and social activities. The sources of pain are both intra-articular and capsular structures, as the trauma stimulates free nerve endings and afferent nociceptors, after which inflammatory factors such as bradykinin, histamine, and serotonin are released from the damaged cells. Additional infiltration of the adjacent capsular area with local anesthetics helps to block nociception (21). Surgical trauma during a TKA modifies the responsiveness of the nervous system in 2 ways: peripheral sensitization reduces the threshold of afferent nociceptive neurons, and central sensitization increases the excitability of spinal neurons (22). Nociceptive activity with the establishment of primary hyperalgesia and tissue mediators of pain and inflammation diffuse the pain by involving areas away from the skin incisions (23). Most post-operative pain is caused by surgical tissue injury. An incisional bupivacaine injection prevents nociceptive impulses from reaching the central nervous system (24). According to our results, this study showed that the synergistic effect of periarticular and incisional injections provides more effective analgesia than periarticular injection alone by blocking the source of pain in the subcutaneous layer and intra-articular and capsular areas.

Epidural analgesia and peripheral nerve blocks have been reported to control pain with good efficacy after TKA. Although these techniques are widely used, each has both local and systemic side effects, including diminished muscle control, nerve damage, and local infection (25); in addition, these procedures increase the operating time and require a well-trained physician (10, 15). In our study, periarticular and incisional injections were easy to perform, effective, safe, caused no complications, provided good muscle control, and effectively reduced pain in the first 4 h post-operatively; these injections do not increase operating time compared with other perioperative analgesic procedures.

There are several limitations to our study. First, we did not measure the plasma concentration of bupivacaine. Second, the VAS did not focus separately on rest pain and motion pain. Third, long-term results such as post-operative knee range of motion and late complications were not evaluated.

In conclusion, the results of our study demonstrated that combined periarticular and incisional injections of bupivacaine provide more effective post-operative analgesia than periarticular injection alone during the first 4 h following TKA. This is the first report in the English literature to use combined periarticular and incisional injections of bupivacaine for post-operative pain after TKA. Further larger, prospective, randomized comparative studies using bupivacaine in both periarticular and incisional injections are needed to confirm our results.

Ethics Committee Approval: Ethics committee approval was received for this study from the Local Research Ethics Committee of the Harran University (approval number: 74059997.050.01.04/197).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Author Contributions: Concept - N.A; Design - M.A.A., C.E.; Supervision - M.A.K., O.B., E.B.; Resources - N.A., B.S.; Materials - M.A.K, E.B., O.B.; Data Collection and/or Processing - C.E., M.A.A.; Analysis and/or Interpretation - N.A., M.A.A.; Literature Search - N.A., M.A.A.; Writing Manuscript - M.A.A.

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