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Original Research Article

Patient-reported outcomes after femoral nerve block versus periarticular injections in patients undergoing total knee arthroplasty: A randomized controlled study

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ABSTRACT

Background: Total Knee Arthroplasty (TKA) is one of the most advanced surgical solutions for pain relief and mobility improvement in patients with end stage osteoarthritis. TKA patients experience severe postoperative pain. Recently, peripheral nerve blockade and Peri or intra-articular injections have been used successfully with fewer side effects when compared to the conventional analgesic techniques. Measuring quality of recovery (QoR) using QoR-15 scale is considered as an accepted and efficient scale for clarification the success of surgery and anaesthesia.

Materials and Methods: One hundred and thirty adult patients scheduled for TKA were randomized into 2 groups: Femoral nerve block (FNB) group and periarticular injections (PAI) group. All patients completed the QoR before or on the day of surgery and at the end of the first post-operative day. Postoperative pain scores, opioid consumption and adverse effects of the drugs and techniques were also measured.

Results: Periarticular injections resulted in better analgesia at rest and on movement and less postoperative morphine consumption during the first 24 h postoperatively when compared to femoral nerve block. Global QoR-15 score was significantly higher in PAI when compared to FNB group.

Conclusion: Periarticular injection of local anesthetics provides better quality of recovery and sufficient level of analgesia than does single shot femoral nerve block for patients undergoing total knee arthroplasty in early postoperative period.

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1. Introduction

Total Knee Arthroplasty (TKA) is one of the most advanced surgical solutions for pain relief and mobility improvement in patients with end stage osteoarthritis.¹ As the number of TKAs performed worldwide in the last few years increased significantly, the surgical and anesthetic techniques used for these procedures changed overtime.² TKA patients experience severe postoperative pain. Failure to suppress that pain interferes with early postoperative patient's ambulation and rapid rehabilitation, which are important for success of the surgery and rapid hospital

discharge.³ In the past, postoperative analgesia following TKA was achieved by either intravenous-patient controlled analgesia (PCA) or epidural analgesia. Each technique has obvious advantages and disadvantages, for example, opioids does not usually provide adequate analgesia and often cause sedation, nausea or vomiting and delayed bowel movement. Epidural analgesia provides superior analgesia but is associated with hypotension, urinary retention and muscle weakness that delay early ambulation.⁴ Recently, other analgesic techniques like peripheral nerve blockade, commonly used are femoral nerve block or Adductor canal block and Peri or intra-articular injections have been used successfully with fewer side effects when compared to the conventional analgesic techniques.⁵

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Although several studies have evaluated different types of peripheral nerve blocks and local periarticular injections, most of them didn't focus on measuring the effectiveness of interventions intended to improve the patient experience after anaesthesia and surgery. These interventions are strongly affecting the quality of recovery and patient satisfaction in the immediate postoperative period.⁶

The outcomes of a clinical intervention obtained by the patient i.e. patient-reported outcomes (PROs) seem to be very important in the coming years than any other outcomes. Unlike that seen for traditional outcomes of mortality and morbidity, the effect of postoperative analgesia on patient-reported outcomes is dependent on patient's subjective assessment of multiple outcomes that are not only related to the level of the analgesia provided but also by the presence of any analgesic side effects or complications.⁷

The presence or absence of side effects and the efficacy of postoperative analgesia are extremely important components of the four patient-reported outcomes; analgesia, health related quality of life, postoperative quality of recovery and patient satisfaction.⁸ Measuring quality of recovery (QoR) from the patient's perspective could be achieved with several QoR scales.⁹ QoR-40 scale is the most comprehensive global measure of a patient's overall health status with score range from 40 to 200. The QoR-15 scale with a score range from 0 to 150 was developed later and undergone repeat and external validation, confirming its perfect reliability and responsiveness in the post-operative period.¹⁰

The primary objective of this study was to compare two different analgesic techniques (femoral nerve block versus periarticular injection) on the postoperative quality of recovery and analgesia for patients undergoing total knee arthroplasty. Secondary outcomes for the study included postoperative pain scores, opioid consumption and adverse effects of the drugs and techniques.

2. Materials and Methods

This randomized, controlled, clinical trial was approved by the research ethics committee of faculty of medicine and was registered in Pan African Clinical Trial Registry (PACTR 201907657139393), date of registration 22 February 2019. Written informed consent was obtained from all study participants.

The sample size was calculated using G Power software at α error probability of 0.05 and power of 80% with equal allocation ratio and a medium effect size between groups (0.5). It yields a minimum of 64 eligible patients in each group.

It was planned to recruit 65 patients to each group. Eligible patients were American Society of Anesthesiologists (ASA) physical status grade I-III, able to understand and communicate with the anesthetists and an age between 40-80 years. Patients with previous major

knee surgery to the same side, overweight (BMI >35), Rheumatoid arthritis, chronic opioid use (more than 3 months), hepatic or renal failure, allergy to any of the drug used in this study and history of any psychiatric disease that could affect perception of pain or communication with the medical staff were excluded from the study. Anesthesia and surgery for all patients were conducted by the same team of anesthesiologists and orthopedists. Surgical intervention was the same for all patients included mid vastus approach, patellar resurfacing and cemented posterior stabilizing prosthesis (Zimmer, USA).

All procedures were done without tourniquet and without negative suction device. Randomization of patients was done using computer generated methods into 2 groups (65 each): Femoral nerve block (FNB) group and periarticular injections (PAI) group. Group assignments were sealed in sequentially numbered opaque envelopes that were opened after patient inclusion in the study before any anesthetic interference. All patients were asked to complete the validated Arabic translation of patient reported 15-items quality of recovery (QoR-15) questionnaire before or on the day of surgery. The questionnaire was adequately explained to all patients to confirm proper understanding of all questions. General anesthesia was applied for all patients in both groups. Two hours before the surgery, all patients were premedicated with oral 300 mg gabapentin and 1000 mg acetaminophen.

In the femoral nerve block group, an ultrasound guided single shot femoral nerve block was given by a qualified anesthetist just before induction of general anesthesia, where patient stayed in supine position. Linear transducer (6 to 18 MHZ) (Sonosite 11: Sonosite inc, Washington, USA) was placed transversely to identify the femoral nerve just lateral to the femoral artery. 20-gauge blunt bevel needle (B Braun, Germany) was inserted slowly in plane approach from the lateral aspect of the ultrasound probe and advanced toward femoral nerve to be below fascia iliaca or between the two layers of fascia iliaca. After careful aspiration, 1 ml of local anesthetics was injected to confirm proper needle placement, this was followed by single shot of 30 ml of bupivacaine 0.25% with adrenaline 1:200,000.

In periarticular injections group, under a complete aseptic technique the scrub nurse prepared the local anesthetic cocktail and gave it to the same orthopedic surgeon that performed the techniques for all cases. The cocktail consisted of 200 mg 0.5% bupivacaine, 5 mg morphine and 200 μ g epinephrine mixed with sterile normal saline solution to ultimately make up a combined volume of 50 ml. the cocktail was injected at 3 stages according to Kerr et al. technique¹¹ in calculated doses as follows: in 50 ml syringe and 10 cm long 18 gauges spinal needle was used. Injections were done using a moving needle technique to avoid depositing large volume of the drugs, 10 ml of the cocktail was injected subcutaneously at the operative side

before skin incision.

Following posterior release and femoral and tibial cuts with knee flexed to 90 degree for better visualization of the posterior capsule and before bone cementation. A volume of 30 ml of the cocktail was injected as infiltration anesthesia to sites posterior to the articular capsule near the incised part, namely the vastus intermedius, vastus lateralis, and lateral collateral ligament.

At the end of the operation and prior to closure of the wound, the remaining 10 ml of the cocktail was injected intra-articular. After awaking from general anesthesia patients were transferred to their rooms. A standardized postoperative analgesic regimen, consisting of regular IV acetaminophen 1 gm every 6 h and IV ketorolac 30 mg every 8 h. In the ward, well-trained nurses blinded to the investigation were asked to record pain level in each patient over the 10 cm visual analog scale (VAS) at postoperative 1,3,6,12,18 and 24 h during rest and mobilization (passive flexion to 30 degrees).

Patient controlled analgesia (PCA) device which delivered morphine as a 1-mg bolus, with a lockout time of 10 min was delivered to all patients and was continued postoperatively for 24 h. Patients with VAS score >4 at any point of time received 0.05 mg/kg IV bolus morphine. The total amount of the first 24 h morphine consumption and the presence of adverse effects related to drugs or technique were recorded during the first postoperative 24 h. At the end of first postoperative day all patients were asked again to complete the validated Arabic translation of patient reported 15-items quality of recovery (QoR-15) questionnaire.

2.1. Data analysis

Data was entered and analyzed using statistical package for social science version 22 (SPSS). Quantitative data were test for normality using Shapiro Wilk test. Comparison between groups regarding quantitative normal data was done using student t test. Paired comparison was done using paired t test. Significance was judged at 5% level of significance.

3. Results

There was no difference in the demographics, as summarized in Table 1. VAS score at rest and mobilization was measured at 1 hour, 3 hours, 6 hours, 12 hours, 18 hours and 24 hours after surgery. There is no statistically significant difference of pain scores at rest in the two groups at 6 hour and p values are more than 0.05.

On the contrary, in group I VAS score at rest, at 1 hour, 3 hours, 12 hours, 18 hours and 24 hours after surgery showed statistically significant decrease when compared to group II ($P < 0.05$) (Figure 1).

In the same way, when VAS score at mobilization was measured at 12 hours, there was no statistically significant difference in the two groups, while at 1 hours, 3 hours

and 6 hours after surgery, group I showed statistically significant decrease when compared to group II ($P < 0.05$). At 18 hours and 24 hours group II showed statistically significant decrease when compared to group I ($P < 0.05$) (Figure 2). Patients undergoing peri articular injections showed reduction of total amount of 24 h morphine consumption (6.63 ± 1.89) in comparison to FNB group (8.15 ± 1.64) this result was found statistically significant ($P < 0.05$).

Before operation, there was no statistically significant difference between studied groups regarding the mean QOR score however, the mean postoperative score was significantly lower among the group received femoral nerve block as compared to those received periarticular injection of local anesthetics as ($p < 0.001$).

In the current study, significant high scores in the postoperative QOR among group 2 in the areas of hygiene, return to work, moderate pain and anxiety as $p = 0.003$, <0.001 , <0.001 and 0.04 respectively. On the other hand, no significant difference between groups regarding other parameters (Table 2, Figure 3).

4. Discussion

This randomized controlled clinical trial reported that periarticular injections of 50 ml solution that contains 200 mg 0.5% bupivacaine, 5 mg morphine and 200 μ g epinephrine resulted in better analgesia at rest and on movement during the second half of first 24 hours postoperatively when compared with single shot of 30 ml bupivacaine 0.25% with epinephrine 1:200,000. Moreover, periarticular injections PAI group confirmed less postoperative morphine consumption when compared to femoral nerve block (FNB) group. However, in both groups there were no incidence of opioid related side effects, and this may be due to low total amounts of morphine consumption secondary to satisfactory analgesia.¹²

These results could be explained as knee innervation involves multi nerve terminals arising from the femoral nerve and also from the sciatic nerve that probably responsible for posterior knee capsule innervation. It is believed that sciatic innervation plays an important role in pain modulation during the early postoperative period.¹³ The excellent influence of PAI in pain control during the early postoperative period may be attributed to the effectiveness of this technique to anesthetize the entire compartments with local anesthetics including the posterior knee compartment while the FNB did not have the same effect in the posterior knee compartment.¹⁴ In the present study, we used Kerr et al. technique¹¹ for PAI of local anesthetics, it is 3 stages local infiltration technique based on uniformly injection of local anesthetics, epinephrine and morphine around all structures subjected to surgical trauma and was done with the same professional orthopedic surgeon for all cases. It has been confirmed that PAI is more

Table 1: Baseline characteristics of studied groups

	Femoral nerve block (n=65)	Per-articular injection of local anesthetics (n=65)	P value
Age			
Min-max	48-77	51-78	0.74
Mean \pm SD	62.88 \pm 7.20	62.97 \pm 6.36	
Sex			
Male	30(46.2)	30(46.2)	1
Female	35(53.8)	35(53.8)	
BMI Min-max Mean \pm SD	21-34 27.62 \pm 3.21	21-33 27.4 \pm 3.39	0.94
Min-max	21-34	21-33	0.94
Mean \pm SD	27.62 \pm 3.21	27.4 \pm 3.39	
ASA score			
I	15(23.3)	14(21.5)	0.833.
II	50(72.7)	51(78.5)	

Student t test was used for comparison of age and BMI. Chi square test was used for comparison of sex and ASA score.

Table 2: Comparison between studied groups according to postoperative QOR scores in each domain

Postoperative QOR	(n=65) After surgery Mean \pm SD	Per-articular injection of local anesthetics (n=65) After surgery Mean \pm SD	P value (student t test)
Breathing	8.29 \pm 0.79	9.14 \pm 0.66	0.95
Food	8.92 \pm 0.79	9.14 \pm 0.66	1
Rest	6.83 \pm 0.74	6.75 \pm 0.68	0.54
Sleep	7.85 \pm 0.83	7.83 \pm 0.74	0.912
Hygiene	7.09 \pm 1.18	7.65 \pm 0.86	<0.003*
Communication	8.8 \pm 0.95	8.62 \pm 0.86	0.249.
Support	8.49 \pm 0.90	8.55 \pm 0.85	0.69
Feeling in control	7.63 \pm 0.89	7.63 \pm 0.86	0.187
Wellbeing	7.26 \pm 0.871	7.46 \pm 0.85	1
Return to work	6.0 \pm 0.87	7.52 \pm 0.81	<0.001*
Moderate pain	5.14 \pm 0.89	6.82 \pm 0.75	<0.001*
Severe pain	6.82 \pm 0.97	6.77 \pm 0.99	0.789
Nausea/vomiting	8.55 \pm 0.97	8.32 \pm 0.88	0.159
Anxiety	8.85 \pm 0.67	9.09 \pm 0.74	0.049*
Depressed	9.02 \pm 0.80	9.18 \pm 0.68	0.197
QOR score	113.74 \pm 6.08	117.83 \pm 4.71	<0.001*

*significant at p<0.05

superior to FNB in reducing early postoperative pain.¹⁵ We did not use a thigh tourniquet in the present study to avoid intraoperative ischemic nociception and so less pain perception and satisfactory analgesia was achieved for all subjects in the current study.¹⁶ Bupivacaine was chosen to be used as local anesthetics in this trial because it was proved to provide effective analgesia following TKA.¹⁷

Moghtadaei et al. agree with the results of the present study, they found that local infiltration anaesthesia was superior to FNB to reduce early postoperative pain and opioid consumption following TKA operations.¹⁸ Yun et al. also demonstrated in their meta-analysis better analgesia at rest and on movement in Local infiltration analgesia patients versus FNB patients in TKA patients.¹⁹ On the other hand, our results contrast with the results of Affas and colleagues who found equal analgesic efficacy of PAI when

compared with FNB in the first 24 h after surgery. However, these results might be explained by the fact that, in this one study, a continuous femoral nerve infusion was used instead of a single shot. Moreover, their mixture of local anesthetics did not contain morphine and contained 30 mg of ketorolac.²⁰ Carli et al. also demonstrated inferiority of PAI to continuous FNB as regards analgesia with increased PCA morphine consumption during postoperative period in PAI group. It should be noted that in this study, the continuous FNB group also received intra operative local anesthetic infiltration making the results are different.²¹ The current study showed that global QoR-15 score was significantly higher in PAI when compared to FNB group, subcomponents of the score (able to look after personal toilet and hygiene unaided, return to work or usual home activities, moderate pain, and feeling worried or

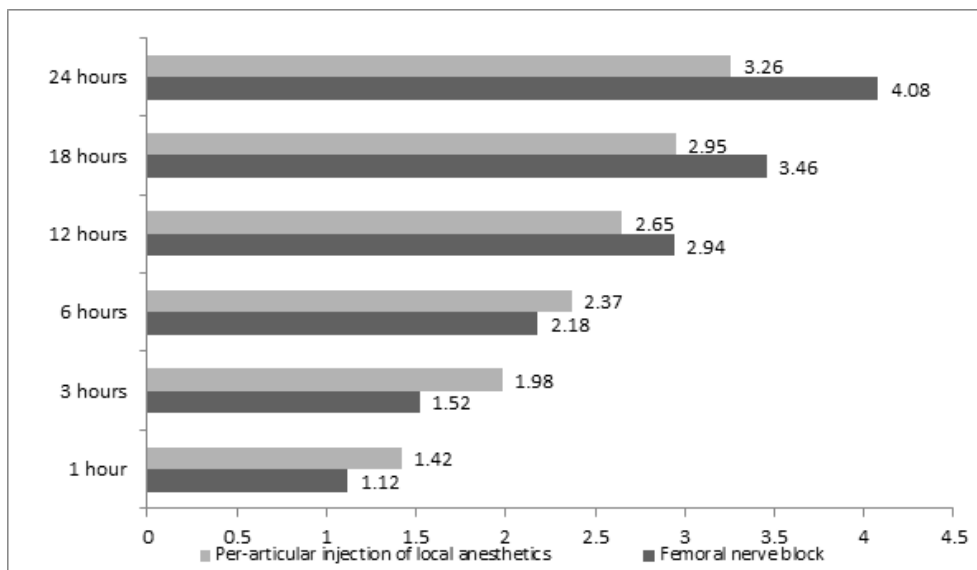


Fig. 1: Postoperative VAS scores at rest among the studied groups

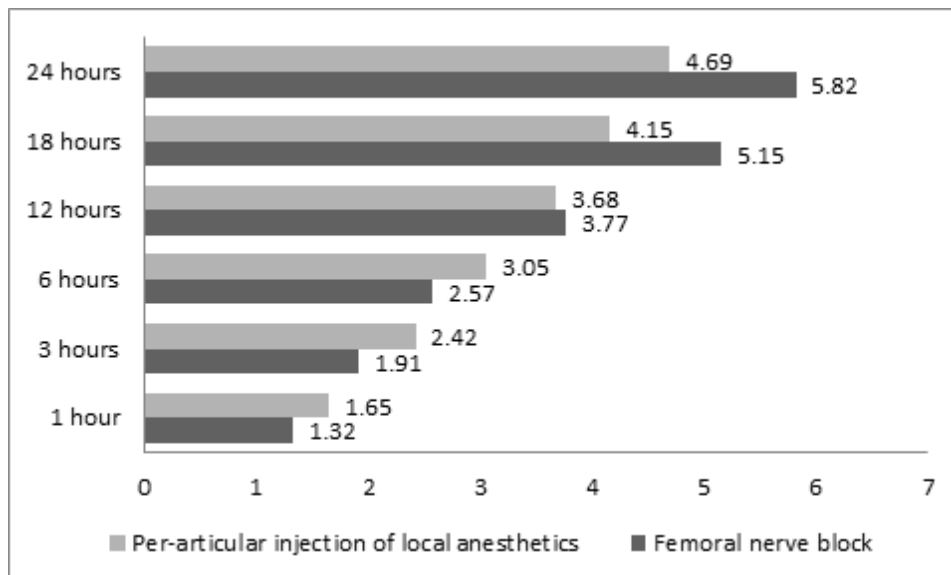


Fig. 2: Postoperative VAS scores with mobilization among the studied groups

anxious) were significantly high in PAI group and other subcomponents (having a feeling of general well-being and feeling depressed or sad) were comparable between the two groups, being more in PAI than FNB group.

Quality of life of surgical patient nowadays becomes anaesthesia's main concern. for many years, multiple parameters such as surgical site infection, duration of hospital stay, cardiovascular or pulmonary complications and major morbidity or mortality have been taken as research end-points after general or regional anaesthesia.²² Furthermore, postoperative pain and types and or amounts of analgesics used were the main and the only concern of

many studies without considering the reflection of these aspects on patient satisfaction. When evaluation of the early postoperative health condition takes place, quality of recovery is considered as one of the paramount parameters in this way.²³

The QoR-15 score is considered as an accepted and efficient scale for clarification the success of surgery and anaesthesia in the evaluation of quality of life and postoperative recovery²⁴ Ensuring high quality recovery entails effective control of several negative parameters such as pain, disturbed consciousness, nausea-vomiting and delayed ambulation as they induce anxiety and

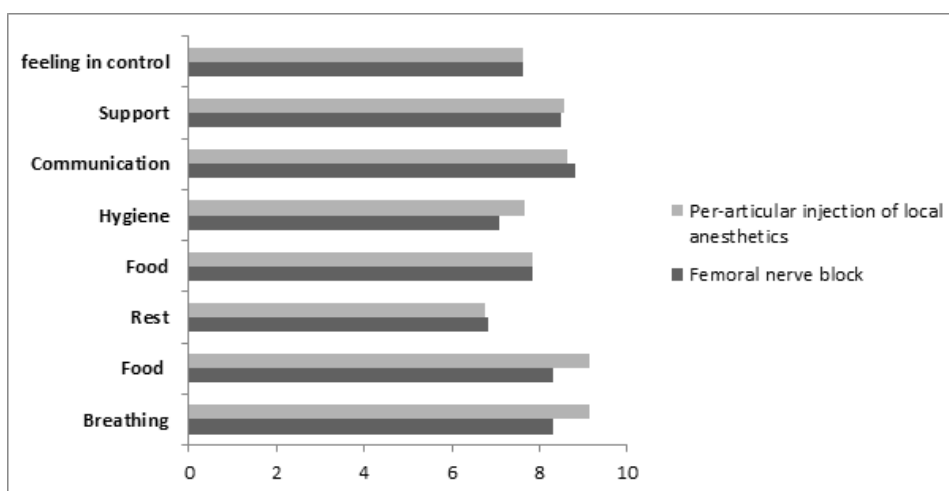


Fig. 3: Comparison between studied groups according to postoperative QOR scores in each domain

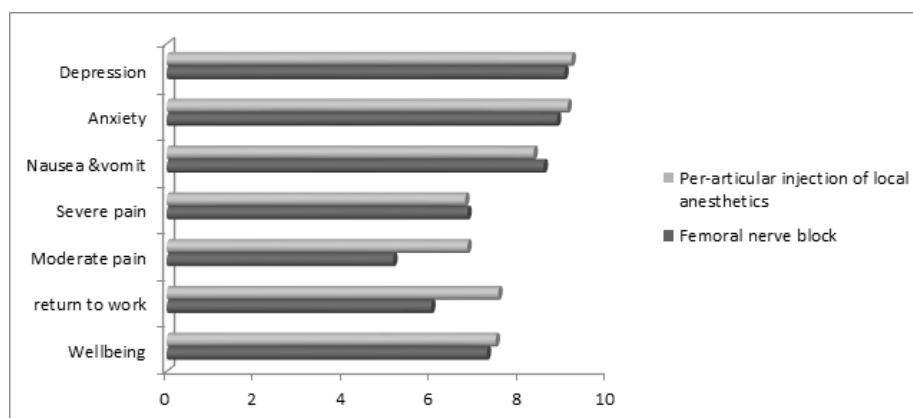


Fig. 4: Comparison between studied groups according to postoperative QOR scores in each domain

depression that eventually affect quality of recovery from anaesthesia.²⁵ We believe that high QoR-15 score in PAI could be attributed to the variation of postoperative pain between the two techniques used in the current study that affects patient reported outcomes. High grades of postoperative pain are always associated with diminished psychological and mental function, cognitive dysfunction, sleep disturbance, anxiety and delayed convalescence that affect patient orientation of assessment and finally quality of recovery.^{26,27}

Moreover, the inverse relationship between opioid consumption and quality of recovery was proven where patient who consumed less opioids had better quality of recovery scores.²⁸ On the other hand, PAI of the knee preserved motor function of the knee joint in comparison to FNB. This was accepted by the patient to feel early ability to ambulate and to return to work and usual home activities following surgery. This was reflected on patient self-confidence as well to look after personal toilet and hygiene unaided.²⁹ Putting all these together, early feeling

of independence of mobility together with adequate pain control promoting quick return to usual activities of daily living and therefore, enhancing sense of wellbeing, low anxiety and feeling of depression.¹¹

In the current study, no neurological or vascular complications were detected in both groups reflecting safety of both techniques. We believe that using ultrasound guided FNB and direct instillation of local anesthetics by the surgeon in PAI were the chief reason of safety in this trial. Adequate analgesia alone is not enough to ensure proper postoperative quality of recovery especially if there is no difference in pain scores between different techniques. Improved analgesia may be associated with increased complication or side effects related to the procedure used which in turn directly affects quality of recovery in immediate postoperative period.³⁰

Our findings as regards QoR-15 scores were comparable with the results of Castro-alves et al.,²⁸ they demonstrated influences of different anesthetic techniques on quality of recovery and confirmed the direct effect of postoperative

analgesia and opioid consumption on recovery scoring. Kanadli et al. also agree to the results of the present study, they reported the influence of adequate analgesia on quality of recovery when Compare the efficacy of femoral nerve block and fascia iliaca compartment block in patients with total knee arthroplasty.²⁴ The results of the current study contrast with those of Turan et al. who found no difference in postoperative quality of recovery among different analgesic regimens, however in their study quality of recovery was not assessed as a primary end point so it may have been under-powered to assess clinically significant differences in postoperative quality of recovery.³¹

5. Conclusion

Periarticular injection of local anesthetics provides better quality of recovery and sufficient level of analgesia than does single shot femoral nerve block for patients undergoing total knee arthroplasty in early postoperative period.

6. Source of Funding

Self fund.

7. Conflict of Interest

None.

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