

Comparison of Combined Intrathecal Morphine and Sonar-guided Single-shot Femoral Nerve Block vs. Either Technique Alone for Postoperative Analgesia in Patients Undergoing Total Knee Replacement Surgery

Ashraf Amin Mohamed¹, Hatem Hassan Maghraby² and Hala Saad Abdel-Ghaffar^{2*}

¹Anesthesia and Intensive Care and Pain Management Department, South Egypt Cancer institute, Assiut University, Egypt

²Anesthesia and Intensive Care Department, Faculty of Medicine, Assiut University, Egypt

Abstract

Background: Postoperative pain associated with total knee replacement surgery (TKR) is considerable and requires adequate analgesia.

Objectives: To study the additive effect of femoral nerve block (FNB) and 0.2 mg intrathecal morphine (ITM) compared with either technique alone for postoperative analgesia in patients undergoing (TKR) under spinal anesthesia.

Design: Prospective double-blind randomized comparative study.

Setting: University hospital.

Methods: Sixty ASA I-III subjects undergoing unilateral TKR were enrolled in a randomized, parallel group, double-blind study receiving 15 mg hyperbaric bupivacaine spinal anesthesia plus 0.2 mg ITM (Group M), FNB (Group F), or 0.2 mg ITM and FNB (Group MF) for postoperative analgesia. Assessment parameters included; postoperative morphine PCA consumption in first 48 h postoperative, time to first request for rescue analgesia, pain scores, length of hospital stay and adverse effects.

Results: The time to the first administration of rescue intravenous morphine PCA, was longer in the MF group (8.21 ± 0.85 h) compared with the M (6.31 ± 1.45 h, $P < 0.001$) and F (4.99 ± 1.0 h, $P < 0.001$) groups. Morphine consumption was lower in MF group [6.3 ± 0.47 (6-7) mg] vs. [11.2 ± 1.32 (9-14) mg] and [13.75 ± 0.72 (13-15) mg] in M and F groups, respectively ($P < 0.001$). From the fourth till the 48th h postoperatively, VAS scores were significantly decreased in the FM group compared with M and F groups ($p < 0.001$). There were no recorded differences among groups in the length of hospital stay or postoperative adverse effects.

Limitations: This study is limited by its small sample size.

Conclusion: The combination of 0.2 mg ITM and single-shot FNB provided superior postoperative analgesia after TKR compared with either technique alone.

Keywords: Analgesic techniques; Intrathecal morphine; Femoral nerve block; Pain; Postoperative; Surgery; Orthopedic

Introduction

End stage knee arthritis is commonly treated with total knee replacement (TKR). As the population ages, the frequency of this surgery proportionally increases [1] bringing with it the challenge of managing older patients with frequent comorbid diseases and increased risk of complications. Poorly controlled pain immediately after surgery is still a key issue for this procedure that may influence the patient's participation in physiotherapy, time to discharge from hospital, and the long-term outcome. Optimal postoperative analgesia can lead to early mobilization, ambulation, and return to a normalized gait pattern. Traditionally, this has been managed by epidural analgesia, peripheral nerve blocks and parenteral or spinal opioids [2]. Multimodal analgesia protocols for TKR have been effective in decreasing requirements for narcotic medications in the early postoperative period. Consequently, decreasing the opioid adverse effects that can slow down rehabilitation such as nausea, vomiting, hypotension, respiratory depression, and constipation [3,4].

The efficacy of femoral nerve block (FNB) as a part of a multimodal analgesic protocol has been well documented [3-6]. FNB has been shown to decrease opioid use, improve postoperative

pain scores, and decrease length of stay while avoiding many of complications associated with other techniques such as continuous epidural analgesia or intrathecal opioids [6]. We hypothesized that the combination of single-shot ultrasound-guided FNB and low dose intrathecal morphine (0.2 mg ITM) would improve the quality of postoperative pain control and decrease side effects of systemic opioid use. So, we designed this study to demonstrate the additive effect of combined femoral nerve block (FNB) and 0.2 mg intrathecal morphine (ITM) compared with either technique alone for postoperative analgesia in patients undergoing unilateral (TKR) under spinal anesthesia.

***Corresponding author:** Hala S Abdel-Ghaffar, Anesthesia and intensive care department, Faculty of Medicine, Assiut university, Assiut, Egypt, Tel: 20882 01003812011; Fax: 2088 2333327; E-mail: hallasaad@yahoo.com

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Patients and Methods

Patients

After obtaining an ethical committee approval and written informed consent, patients (aged 60-85 years) who met the ASA physical status I-III, scheduled for elective single TKR surgery were enrolled in this prospective randomized double-blind parallel-group study. Excluded from the study patients with; previous surgery to the same knee, history of significant hepatic, renal or cardiac disease, rheumatoid arthritis, immunological depression, peripheral neuropathy, contraindications to nerve blocks (coagulation defects, infection at puncture site) and allergy to study drugs. Patients were also excluded if they were taking opioids or steroids or if they had a history of stroke or psychiatric disease that could affect the perception of pain. Preoperatively, patients were taught in how to evaluate their pain intensity using the Visual Analogue Pain scale (VAS) score ranging from 0 to 10 (with Zero=no pain and 10=the worst pain imaginable) and how to use the patient controlled analgesia device (PCA).

Randomization and blinding

According to a computer-generated randomization tables, patients were randomly assigned to three groups of 20 patients each;

Group M: Patients received intrathecal hyperbaric bupivacaine 15 mg and intrathecal 0.2 mg morphine.

Group F: Patients received intrathecal hyperbaric bupivacaine 15 mg and sonar-guided single-shot femoral nerve block.

Group MF: Patients received intrathecal hyperbaric bupivacaine 15 mg, intrathecal 0.2 mg morphine and sonar-guided femoral nerve block.

The attending anesthesiologist, surgeon and patient care giver or data collection personnel were blinded to the patient group assignment.

Anesthesia

Monitoring included; pulse oximeter, ECG, and non-invasive arterial pressure. Before the blocks, all patients received i.v. midazolam 2 mg plus fentanyl 50 µg titrated to produce sedation while maintaining verbal contact. The anesthetic technique was standardized in the three groups. After an i.v. preload with 500 ml of 0.9% NaCl solution, under aseptic sterilization and local anesthesia of skin (3 ml of lidocaine 2%), spinal block was performed in the sitting position with a 25 or 27 G Whitacre spinal needle inserted at the L2-L3 or L3-L4 intervertebral space. After clear free flow of cerebrospinal fluid, 15 mg hyperbaric bupivacaine (Marcaïne®, Spinal Heavy 0.5%, Astra Zeneca) was administered to achieve sensory block (to cold and pinprick) to the 10th thoracic dermatome or above. In addition, patients randomized to Groups M and MF received preservative-free morphine 0.2 mg (0.25 ml) and patients randomized to Group F received an equivalent amount of normal saline (0.25 ml). Lactated Ringer's solution was administered during the surgery at an hourly rate of 6-8 ml/kg. Hypotension (>20% decrease in mean arterial pressure) was treated with i.v. bolus doses of 10 mg of ephedrine. Intraoperative oxygen therapy (30% oxygen mask) was provided to all patients. One dose of 2 g of cefazolin (GlaxoSmith Kline, England) was given i.v. 30 min before surgery and then every 8 h for a total of three doses. A pneumatic tourniquet was positioned on the thigh before surgery and inflated to 250 mm Hg. All patients were catheterized and the urinary catheter was left in situ for 24 h.

Femoral nerve block

Patients in group F and group MF received a single-shot unilateral femoral nerve block before spinal anesthesia. An experienced anesthetist

performed the FNB using an S-Nerve machine (SonoSite Inc., Bothell, WA, USA). The patient was placed in the supine position. Skin asepsis and sterile draping were performed. A linear US probe (HFL 38, 13-6 MHz) was sheathed and placed on the inguinal crease with a slight anterior tilt. The femoral artery and the nerve were identified. A 5 cm needle (21G, Locoplex, Vygon, Ecouen, France) was inserted lateral to the probe and advanced by in-plane approach towards the femoral nerve under stimulation (Stimuplex, B Braun, Bethlehem, PA, USA). Direct visualization of the needle tip was maintained with ultrasound while inserting the needle, until optimal positioning of the needle tip was achieved within the fascial space as close as possible to the femoral nerve. The second target used for injection was an ipsilateral quadriceps contraction at 0.5 mA, (stimulator frequency at 2 Hz and pulse width of 0.1 s). Direct visualization of the needle tip was maintained with ultrasound while inserting and 20 ml 0.5% plain bupivacaine were slowly injected. The needle was repositioned to ensure circumferential perineural spread of the LA injection. Intraneural injection was avoided.

The femoral sensory block was assessed by testing the pinprick sensation along the medial aspect of the leg. The sensory block was graded as follows: grade 0=normal sharpness sensation (compared with the contralateral side); grade I=reduced sharpness or a non-sharp sensation (touch or pressure); grade II=unable to recognize pinprick sensation. For motor block assessment, the patient's knee was fully flexed, and the patient was then asked to extend it. The motor block was classified as follows: grade 0=normal muscle power; grade I= motor weakness; grade II=complete motor paralysis. The assessment was performed every 10 min until grade II sensory and motor blocks were achieved or to a maximum of 30 min. Spinal block was performed and surgery was started only after complete femoral nerve block had been clinically confirmed. Only patients with grade II sensory and motor femoral blocks within 30 min were included in the study.

Postoperative care

After surgery, the patients were transferred to the Post Anesthesia Care Unit (PACU), and after a 4 h observation period, to the orthopedic ward. At arrival at (PACU), all patients were connected to a patient-controlled analgesia (PCA) pump set-up to deliver incremental doses of 1 mg of morphine, with a lockout of 7 min and no background infusion. The PCA was discontinued 48 h after surgery, and all patients received Intravenous paracetamol 1 g every 6 h and diclofenac 50 mg intramuscular every 12 h as rescue medication for pain management. Patients with postoperative nausea and vomiting (PONV) received i.v. ondansetron 2-4 mg and i.v. dymenhydrate (Gravol) 50 mg as needed. All side-effects and intra and postoperative complications were recorded. Patients were assessed neurologically before hospital discharge and also during the physiotherapy visits for 3 weeks after operation. The patient was considered to be home-ready when the following discharge criteria were fulfilled: mild pain (VAS<3) sufficiently controlled by oral analgesics, ability to walk with elbow crutches, ability to eat and drink without nausea or vomiting, and no signs of any surgical complications.

Assessment parameters included

Patients' demographics and clinical characteristics (age, weight, sex, ASA class, operative time), postoperative VAS scores at rest (recorded at 2, 4, 6, 8, 12, 24 and 48 h after operation), time to first request for IV morphine PCA and total Morphine consumption during 0-4, 4-6, 6-8, 8-12, 12-24 and 24-48 h after operation, side effects and hospital length of stay.

Statistics

Power of the study

The primary end point was the total rescue PCA morphine consumption during the first 48 postoperative hours. Based on previous studies [6,7], 18 patients in each group would be required to detect a significant difference >40% in morphine consumption between the three studied groups with a power of 80% and at a significance level of 5%. To compensate for patients drop out, 60 patients were recruited.

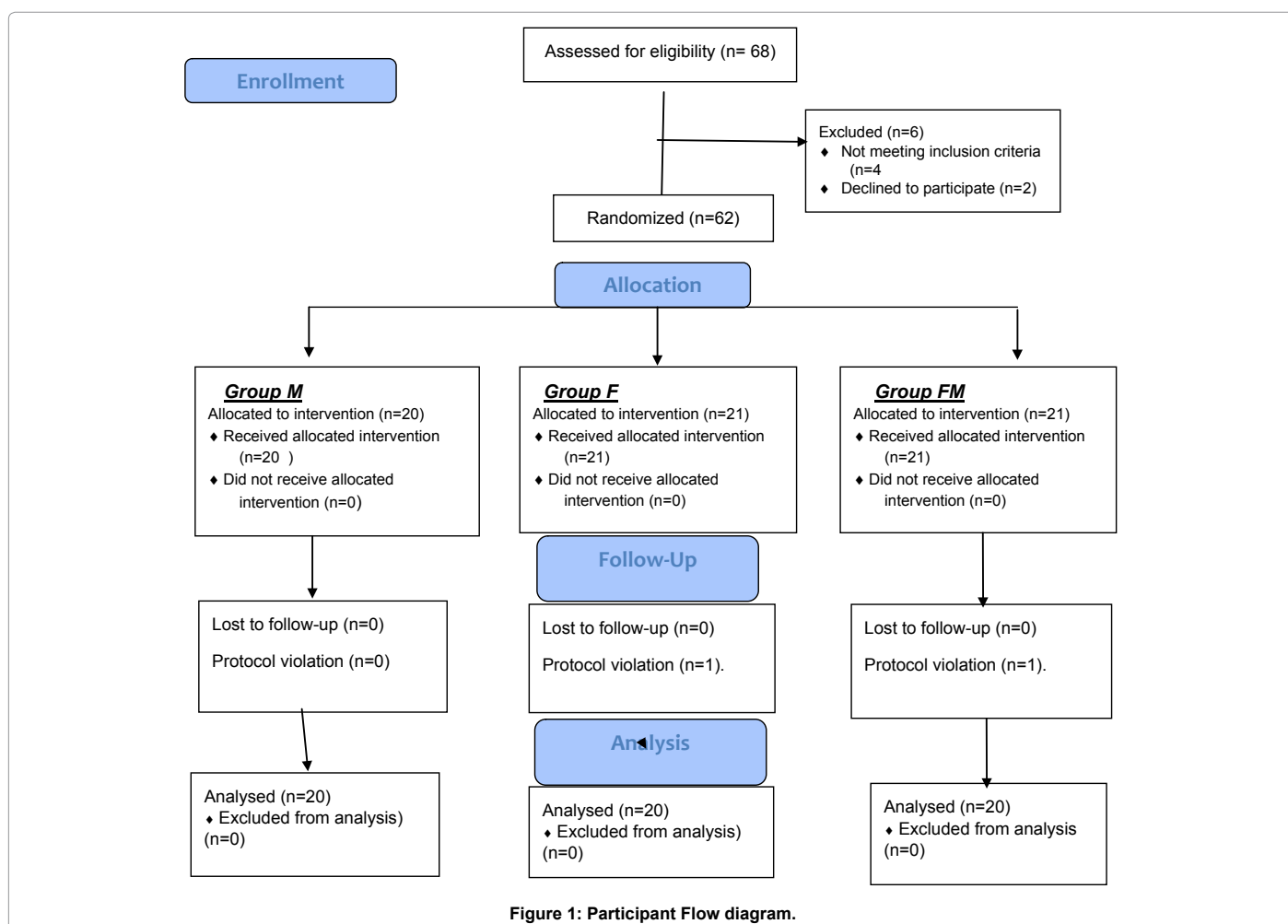
Data analysis

Distribution of baseline variables was assessed by the Shapiro-Wilk tests. Continuous variables were reported as mean (\pm SD) and were analyzed using the one-way analysis of variance test with post hoc

multiple comparisons. Categorical data were reported as numbers and percentages and were analyzed using the χ^2 test or Fisher exact test with the Bonferroni correction to calculate adjusted P-values. Nonparametric data such as pain scores were reported as median and inter-quartile range and were analyzed using the Mann-Whitney U-test. A P-value of <0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS statistics version 20 (SPSS Inc., Chicago, IL, USA).

Results

Sixty eight consecutive patients were assessed for eligibility and 62 were included. Two cases were excluded, and a total of 60 patients successfully completed the study (Figure 1). Baseline patient and surgical characteristics were reasonably balanced and data were similar among the three studied groups ($P > 0.05$, Tables 1 and 2).



	M (n=20)		F (n=20)		MF (n=20)		P value
	Range	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	
Age (yr.)	61 -73	67.8 \pm 2.91	63-71	67.1 \pm 2.27	60-70	66.3 \pm 2.36	0.182 ^{ns}
Weight (kg)	67-85	77.05 \pm 5.07	70-95	80.9 \pm 7.32	75-85	79.35 \pm 2.87	0.085 ^{ns}
Height (cm)	158-177	165.5 \pm 5.98	160-177	166.1 \pm 4.88	162-175	166.95 \pm 3.97	0.657 ^{ns}
Duration of surgery (min)	110-121	115.3 \pm 3.59	110-122	114.65 \pm 4.12	108-122	115.1 \pm 4.3	0.872 ^{ns}
Hospital length of stay (days)	5-Mar	3.1 \pm 0.81	5-Mar	3.3 \pm 0.65	5-Mar	2.9 \pm 0.69	0.436 ^{ns}

Data are represented as mean \pm SD, ns indicates no significant difference ($p > 0.05$).

Table 1: Patient Demographics and Clinical Characteristics.

		M (n=20)		F (n=20)		MF (n=20)		P value
		No.	%	No.	%	No.	%	
Sex	Male	8	40	9	45	9	45	0.934 ^{ns}
	Female	12	60	11	55	11	55	
Side of surgery (R/L)		11/9	55/45	12/8	60/40	11/9	55/45	0.765 ^{ns}
ASA class	I	3	15	2	10	2	10	0.851 ^{ns}
	II	17	85	18	90	18	90	

Data are represented as number and percentage; R: right; L: left; ASA: Anesthesia risk according to American Society of Anesthesiologists; ns: indicates no significant difference (p>0.05)

Table 2: Patients' sex, side of surgery and ASA class.

	M (n=20)		F (n=20)		MF (n=20)		P value
	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	
Time to first request for PCA rescue analgesia (hr.)	4-8.1	6.31 ± 1.45	4-6.3	4.99 ± 1	6-9.1	8.21 ± 0.85	<0.001** P1<0.002 P2<0.001 P3<0.001

Data are represented as mean ± SD and range; **Significant difference between groups (P<0.01); P1: significance between M and F groups; P2: significance between M and MF groups. P3: significance between F and MF groups

Table 3: Time to first request for PCA rescue analgesia (hr).

Morphine consumption (mg)	M (n=20)		F (n=20)		MF (n=20)		P value
	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	
4 hours	0-1	0.2 ± 0.41	0-2	0.4 ± 0.68	0-0	0 ± 0	0.028*
6 hours	0-2	0.4 ± 0.6	0-3	1.7 ± 1.13	0-1	0.05 ± 0.22	<0.001**
8 hours	0-3	1.2 ± 0.83	4-Feb	3.2 ± 0.83	0-1	0.25 ± 0.44	<0.001**
12 hours	6-Apr	4.5 ± 0.61	7-Apr	5.75 ± 0.91	2-3	2.3 ± 0.47	<0.001**
24 hours	8-Jun	6.95 ± 0.76	12-Oct	10.95 ± 0.89	4-5	4.3 ± 0.47	<0.001**
48 hours	14-Sep	11.2 ± 1.32	13-15	13.75 ± 0.72	6-7	6.3 ± 0.47	<0.001**

Data are represented as mean ± SD and range; *Significant difference (p<0.05); **Significant difference (p<0.01)

Table 4: Cumulative morphine consumption (mg) in the first 48 hours postoperative.

Survival analysis of analgesia free time demonstrated a significant advantage of MF group over M and F groups (log rank P<0.001) (Figure 2). The mean duration of analgesic effect of the techniques used, as indicated by the time to the administration of first rescue intravenous morphine PCA, was longer in the MF group (8.21 ± 0.85 h, range: 6-9.1 h) compared with the M (6.31 ± 1.45 h, range: 4-8.1 h, P<0.001) and F (4.99 ± 1.0 h, 4-6.3 h, P<0.001) groups (Table 3).

Table 4 shows the postoperative cumulative morphine PCA consumption at each assessment period. Morphine consumption in the MF group was significantly lower in the 1st 48 h postoperative, compared with other groups, with the MF group consuming 6.3 ± 0.47 (6-7) mg compared with 11.2 ± 1.32 (9-14) mg and 13.75 ± 0.72 (13-15) mg in M and F groups, respectively (P<0.001). Patients in the F group exhibited the highest PCA morphine consumption compared with the M (P<0.001) and FM (P<0.001) groups.

The mean postoperative VAS pain scores were similar between the three studied groups in the 2nd h postoperative (Figure 3). However, from the fourth hour till the 48th h postoperatively, VAS scores were significantly decreased in the FM group compared with the M and F groups (p<0.001). Patients in the femoral group (F group) showed the highest pain scores compared with the M (P<0.001) and FM (P<0.001) groups.

Compared to the F group, patients in the M and MF groups showed a higher incidence of PONV and pruritus (P>0.05) (Table 5). No patient in the study presented with sedation, respiratory depression, pulmonary embolism or falls on starting ambulation. Also, there were no recorded wound-related complications or infections and the length of hospital stay was comparable between groups (Table 1).

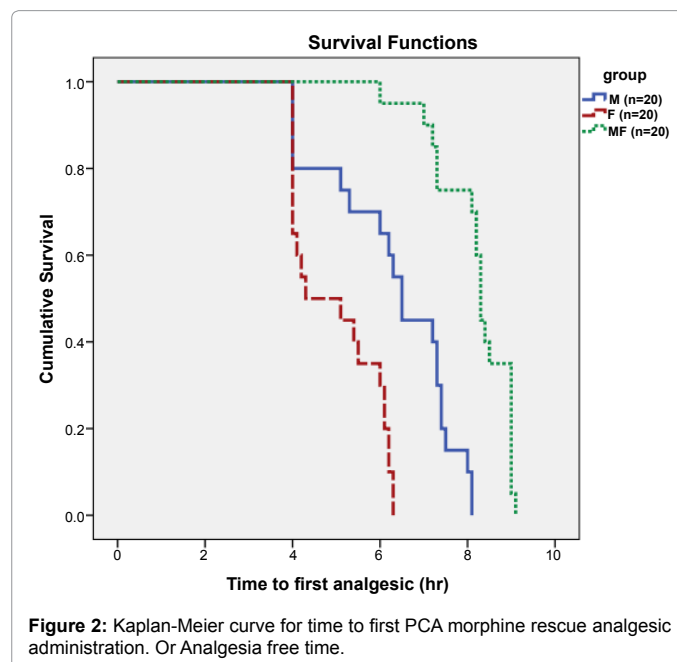


Figure 2: Kaplan-Meier curve for time to first PCA morphine rescue analgesic administration. Or Analgesia free time.

Discussion

In patients undergoing TKR, we found that the time to first request for rescue analgesia, cumulative PCA morphine consumption and pain scores were significantly lower during the first 48 h postoperative, when

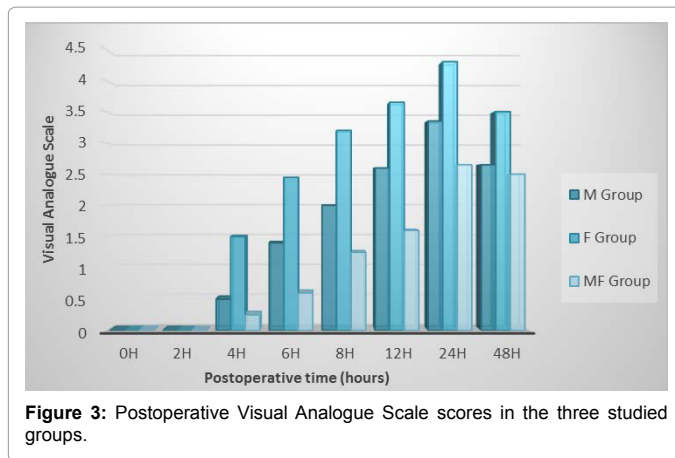


Figure 3: Postoperative Visual Analogue Scale scores in the three studied groups.

the combination of single-injection FNB and 0.2 mg ITM was used, compared with either technique alone.

Pain after TKR is considerable requiring adequate analgesia [8]. Moreover, movement is associated with moderate to severe pain [9], limiting patient mobilization and reducing his/her satisfaction. So, satisfactory pain relief during activity is important to return body functions to normal as early as possible. The commonly used analgesic techniques include; epidural analgesia [10], femoral nerve block [11], spinal morphine [7], and periarticular and intra-articular continuous local anesthetic infiltration [12].

Continuous femoral nerve block with dilute local anesthetic in the first 48 h postoperative has been demonstrated to provide decreased opioid use, improved postoperative pain scores, and decreased length of hospital stay while avoiding many of complications associated with other techniques such as continuous epidural analgesia [13-15]. However, continuous femoral nerve block analgesia will prevent early ambulation and increase the number of patient falls after surgery [16,17].

The effect of continuous femoral nerve block on early ambulation after major knee surgery is controversial. Although some authors have reported mean ambulation distances of 102 to 337 feet in the first 2 days after surgery [5,15,18], others note substantial limitations in early ambulation. Seet et al. [19], reported no ambulation until at least 60 hours after surgery. Similarly, Kandasami et al. reported that 70% of their patients were unable to mobilize until postoperative Day 2 [17]. YaDeau et al. reported 29% of patients who received FNB had buckling because of decreased quadriceps strength, whereas only 3% of patients who did not receive FNB had buckling [20]. In that study, patients who had quadriceps weakness were delayed in ambulation training exercises. All patients had adequate quadriceps strength by postoperative Day 2.

Physicians continue to use continuous FNBs for postoperative analgesia as a result of high patient satisfaction with the pain relief provided compared with traditional pain relief medications. By taking active steps to prevent in-hospital falls, including the use of a knee immobilizer for ambulation while the block is functioning, patients can benefit from the analgesia provided by the block and still ambulate early after major knee surgery.

Despite the prolonged analgesic effect of continuous FNB compared with single shot FNB used in this study, the safety profile of the single injection technique is superior. The period of maximum analgesic effect of single-shot FNB lies within the first 10 h postoperative, this period

usually, the patients lie in bed resting from the operation and usually start ambulation afterwards. By combining the pre-emptive Single-shot FNB with another analgesic modality, we can accentuate postoperative analgesia without affecting early patient mobilization efforts. The combination of low dose intrathecal morphine and single-shot FNB used in this study adequately controlled postoperative pain compared to either technique alone and for safety issues we instructed our patients to wear a knee immobilizer and ambulate supported during the early postoperative period.

The analgesia achieved after 200 µg spinal morphine is usually satisfactory and lasts more than 24 h [6], and the results in this study supports the superior efficacy of ITM over single-shot FNB. In accordance with our results, Frassanito et al. demonstrated that low dose of intrathecal morphine (100 µg) may be safe and more efficient than single-shot femoral nerve block for post-operative analgesia after total knee arthroplasty and that the analgesic efficacy of ITM (100 µg) lasted from 12 to 24 h postoperatively [6].

In this study patients in the femoral group reported higher postoperative pain scores and consumed more PCA morphine compared with the M and FM groups. The tendency of lower efficacy observed with femoral block may be due to; First, the fact that the posterior part of the knee is innervated by the sciatic nerve. Thus, a femoral block does not cover this area increasing the need for rescue systemic analgesics. Second, is the type of the FNB. We used single-shot FNB rather than continuous FNB.

Wang et al. reported that, patients with FNB had a shorter hospital stay than those who had not received the block [21]. These findings were also confirmed by Munin et al. [22]. In this study, we could not confirm a substantial reduction of hospital length of stay for patients received FNB. We measured the time to home-readiness based on objective criteria of well-defined endpoints [23] and no differences were found between the three studied groups.

In conclusion, Clinicians do their best to investigate more safe analgesic techniques and combinations of different analgesic modalities aiming at attaining the highest patient satisfaction with the least possible postoperative side effects and complications. The combination of 0.2 mg ITM and single-shot FNB used in this study provided superior postoperative analgesia after TKR compared with either technique alone.

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