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Peripheral Regional Analgesia with Femoral Catheter *versus* Intravenous Patient Controlled Analgesia after Total Knee Arthroplasty: A Prospective Randomized Study

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A B S T R A C T

The aim of this study is to compare the effects of femoral analgesia (FA) with 0.25% levobupivacain and intravenous patient controlled analgesia (PCA) with morphine on postoperative pain assessed by a visual-analog scale (VAS) score and their complications during the first 24 postoperative hours after the a total knee arthroplasty in a prospective randomized study. Secondary outcomes included: morphine use, patient satisfaction, complication of analgesia and duration of hospital stay. We analyzed 71 patients with an ASA score of II or III. The patients were randomized into two groups: group PCA (n=36) was given the PCA pump, which contained morphine; and group FA (n=35) was given first a bolus dose, then a continuous infusion 0.25% levobupivacain via a femoral catheter. The assessment of VAS was performed every 2 hours. There were no differences between the PCA and FA groups regarding demographic characteristics, operation duration, ASA score distribution, duration of hospital stay and satisfaction with analgesia (although there were more satisfied patients in the FA group). Significant differences were noted in the quantity of morphine used (higher values were in the PCA group; p<0.001). More complications were recorded in PCA group (p<0.001). The VAS score was lower in the FA group (p<0.001). The highest difference occurred 4 hours after the operation, with the PCA group having significantly higher VAS score values compared to the FA group. Femoral analgesia leads to a stronger pain relief with less side effects, less morphine use and more patient satisfaction than intravenous PCA with morphine.

Key words: *total knee arthroplasty, femoral nerve block, patient controlled analgesia, morphine, levobupivacain*

Introduction

The implantation of total knee prosthesis is deemed to be one of the most painful procedures in orthopedic surgery[1]. Inadequate control of postoperative pain is associated with poor patient recovery, longer rehabilitation, extended hospital stay and higher cost of treatment. Uncontrolled pain leads to hormonal-metabolic stress response as well as to inflammatory response, which both have negative effects on other organ systems[2]. The patients who undergo total knee arthroplasty are usually in the older age group with a decreased cardiac reserve and incipient impairments of other vital organ systems. This older age group also has an increased sensitivity to medications[19].

For postoperative analgesia, it is necessary to choose the method and analgesic that has minimal side effects. Postoperative analgesia is achieved using various methods, such as intravenous analgesia, patient controlled analgesia (PCA)[3], central neural analgesia (epidural analgesia)[4], and peripheral regional analgesia of the lumbar plexus[5]. A multimodal approach of balanced analgesia certainly has its place in orthopedic surgery[6]. Peripheral regional analgesia is the method of choice for postoperative analgesia after painful orthopedic surgery procedures[7]. Unlike PCA, peripheral regional analgesia requires that practitioners have appropriate experience.

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The aim of this randomized prospective study was to compare the effects and complications of two analgesic techniques: femoral nerve catheter analgesia and patient control analgesia with morphin after the total knee arthroplasty (TKA).

The primary end point was the assessment of postoperative analgesia using the visual analog scale (VAS scoring; 0=no pain, 10=worst pain) at rest and in motion.

Secondary end points included: morphine use, degrees of knee flexion on the second postoperative day (2POD), patient satisfaction (satisfied or not satisfied) with analgesia, complications of analgesia and duration of hospital stay.

Materials and Methods

The Ethics Committee of the University of Traumatology Zagreb approved the study and all 80 patients gave a written informed consent to participate. The 80 patients with ASA scores II and III were selected for the elective TKA surgery in spinal anesthesia. The participants were randomized into two groups: group FA (44 patients) and group PCA (36 patients) using statistical software MedCalc for Windows (v.11.0, www.medcalc.be).

Nine patients were excluded from the study because their femoral catheter fell out (Figure 1).

In order to be excluded from the study, the patients had to meet at least one the following criteria: previous vascular surgery in the region of femoral veins or arteries, confirmed coagulopathy, local infection, hepatic and renal insufficiency, dementia, body mass index (BMI) >30 kg/m^2, allergy to local anesthetics, morphine and non-steroid anti inflamatory drugs, a previously diagnosed neurologic deficit and an ASA score>III.

Standard monitoring was used throughout the procedure (including noninvasive arterial blood pressure, electrocardiography, heart rate and oxygen saturation).

The femoral catheter was set before the spinal anesthesia with patients in the supine position, with a nerve stimulator (Stimuplex HNS 11,B.Braun,Germany) set to deliver a stimulus at a frequency of 2Hz and duration of 0.1 ms. The intensity of the current, initially set to 1.2 mA, was gradually decreased to 0.3 mA (<0.5 mA) while the stimulation of the femoral nerve was maintained.

The puncture site was located 5 cm caudal to the inguinal ligament and one centimeter lateral to the femoral artery and then advanced in a lateral and posterior direction just distal to the inguinal ligament. The femoral nerve was identified by contractions of the quadriceps muscle, referred to as the »dancing« patella. The femoral nerve catheter was inserted from 5–10 cm beyond the tip of the needle in a cephalad direction (Contiplex Tuohy 18G, B.Braun, Germany). Fixation of the femoral catheter was performed by LockIt Plus™ (Smiths; Catheter Securement Device).

One anesthesiologist who was trained in the techniques of regional anesthesia set the femoral catether. The time required for setting one femoral catheter was 10 minutes (median; interquartile range 8.5–10 min). All the catheters were left in place for 48 hours.

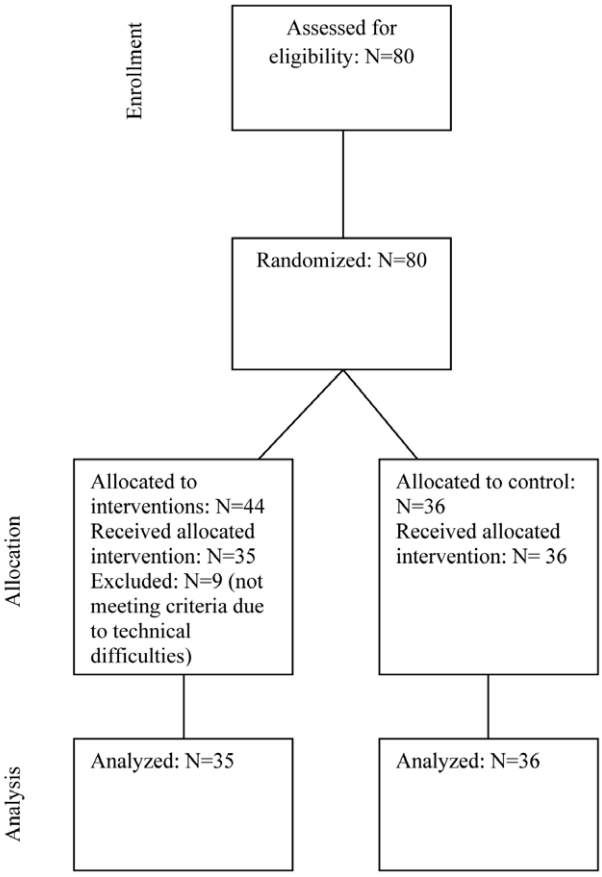

Fig. 1. CONSORT diagram: showing the flow of patient throughout study.

The patients received premedication consisting of midazolam per os at a concentration of 0.1mg/kg. All patients were anesthetized using spinal anesthesia with 3mL of 0.5% levobupivacain in the region of L3/L4 or L4/L5 segments. Intraoperatively, the patients were sedated with 2.5–5mg midazolam intravenous and fentanyl in doses of 1–2ug/kg.

Data on baseline demographic characteristics (age, sex), BMI and ASA score were collected. Furthermore, the duration of surgical procedure and the duration of tourniquet application were assessed.

After the sensory recovery from spinal anesthesia and when the patients complained of pain, group FA was given first a bolus dose of 8 ml 0.25%levobupivacain, then 5–6 mL *per* hour of 0.25% levobupivacain via a femoral catheter in addition to the intravenous dose of morphine: 5mg (patient weight <60kg) or 10 mg (patient weight >60 kg) if pain in the posterior part of the knee was higher than 3 points. Group PCA was given the patient controlled analgesia (PCA) pump, which contained morphine (concentration 1mg/ml; »basal rate« 3 mg/h, bolus upon request 2 mg, with »lock out« interval of 8 minutes). Both groups received diclofenac 75 mg intravenous every 12 hours. A VAS score of lower than or equal to 3 was considered good analgesia.

The primary outcome was assessment of analgesia using VAS scoring (0=no pain; 10=worst pain). It was performed within the first 24 postoperative hours, every 2 hours in resting position and during movement after the reversion of spinal anesthesia during the patient's stay in the Intensive Care Unit (ICU). The assessment of the level of sedation was done within the first 24 postoperative hours by using the following scale: 1 – awake and oriented; 2 – sleepy, responds to a call; 3 – responds to a call with difficulties, but responds to painful stimuli.

We monitored: cardiovascular (heart rhythm disorders--supraventricular or ventricular disorders and hemodynamic instability-drops of blood pressure of more the 20% of starting values) and gastrointestinal (nausea, vomiting) complications of analgesia during the first 24 postoperative hours of each patient's stay in the ICU; urinary retention; patient satisfaction with analgesia (satisfied or not satisfied); morphine use; degrees of knee flexion on the second postoperative day (2 POD); and duration of hospital stay. The VAS scores were assessed by persons who were not involved in setting the femoral nerve catheter.

Statistical methods

Power analyses were performed for repeated measures (power 0.95; Effect size dz 0.5; a error probability 0,05; two tailed) with minimal total samples of 35 participants per group.

Data were shown in tables and graphs. The Smirnov--Kolmogorov test was performed to analyze the quantitative data distribution and the appropriate non-parametric test (Mann-Whitney U test) was used to analyze differences between group PCA and group FA. Related measures (differences in VAS score over time) for both groups were assessed with the Friedman test. Differences in categorical data were analyzed with the chi-square test with a continuity correction for 2x2 tables. All p values under 0.05 were considered significant. Statistical analyses were performed using MedCalc for Windows, version 11.0 (MedCalc Software, Mariakerke, Belgium)

Results

The only non-significant difference in postoperative VAS scores between the groups was observed 2 hours after operation. All other VAS scores in rest and motion differ significantly ($p<0.001$). The highest difference is 4 hours after the operation when group PCA had significantly higher VAS scores as compared to group FA (Table 1). Dynamics of VAS scores regarding measuring time

TABLE 1
DIFFERENCES IN VAS SCORE IN REST AND MOTION BETWEEN PCA AND GROUP FA REGARDING TIME AFTER OPERATION: MANN-WHITNEY U TEST

	Group		
	PCA (N=36) Median (interquartile range)	FA (N=35) Median (interquartile range)	p
VAS score after 2h: resting	2.0 (1.3–3.0)	2.0 (2.0–3.0)	0.238
VAS score after 4h: resting	7.0 (6.3–8.0)	3.0 (3.0–4.0)	<0.001
VAS score after 6h: resting	5.0 (5.0–6.0)	4.0 (4.0–4.0)	<0.001
VAS score after 8h: resting	5.0 (4.0–6.0)	4.0 (4.0–4.0)	<0.001
VAS score after 10h: resting	5.0 (4.0–5.0)	4.0 (4.0–4.0)	<0.001
VAS score after 12h: resting	4.0 (4.0–5.0)	3.0 (3.0–4.0)	<0.001
VAS score after 14h: resting	4.0 (4.0–4.0)	2.0 (2.0–3.0)	<0.001
VAS score after 16h: resting	4.0 (4.0–4.0)	2.0 (2.0–2.0)	<0.001
VAS score after 18h: resting	4.0 (3.3–4.0)	2.0 (2.0–2.0)	<0.001
VAS score after 20h: resting	3.0 (2.0–4.0)	2.0 (2.0–2.0)	<0.001
VAS score after 24h: resting	3.0 (2.0–4.0)	2.0 (2.0–2.0)	<0.001
VAS score after 2h: motion	2.5 (1.8–4.0)	2.0 (2.0–3.0)	0.125
VAS score after 4h: motion	8.0 (7.3–9.0)	4.0 (3.0–4.0)	<0.001
VAS score after 6h: motion	6.0 (6.0–8.0)	4.0 (4.0–5.0)	<0.001
VAS score after 8h: motion	6.0 (5.0–7.0)	5.0 (4.0–5.0)	<0.001
VAS score after 10h: motion	5.0 (5.0–6.0)	4.0 (4.0–5.0)	<0.001
VAS score after 12h: motion	5.0 (4.0–5.0)	3.0 (3.0–3.0)	<0.001
VAS score after 14h: motion	5.0 (4.0–5.0)	3.0 (3.0–3.0)	<0.001
VAS score after 16h: motion	4.0 (4.0–5.0)	3.0 (3.0–3.0)	<0.001
VAS score after 18h:motion	4.0 (4.0–5.0)	2.0 (2.0–2.0)	<0.001
VAS score after 20h: motion	4.0 (3.0–4.0)	2.0 (2.0–2.0)	<0.001
VAS score after 24h: motion	4.0 (3.0–4.0)	2.0 (2.0–2.0)	<0.001

VAS – visual analog scale, PCA – patient controlled analgesia, FA – femoral analgesia

TABLE 2
SOCIO – DEMOGRAPHIC CHARACTERISTICS: MANN-WHITNEY U TEST AND CHI-SQUARE TEST

	Group		p
	PCA (N=36)	FA (N=35)	
Age (years): median (interquartile range)	70 (68–73)	69 (66–72)	0.358
Body mass index (kg/m2): median (interquartile range)	27.2 (25.0–29.0)	26.0 (24.5–27.3)	0.401
Female gender: N (%)*	18 (50.0%)	16 (45.7%)	0.901
ASA score III**: N (%)*	23 (63.9%)	16 (45.7%)	0.194

*χ^2-test with continuity correction for 2x2 table, **ASA score were only assessed as II or III

TABLE 3
CLINICAL DATA: MANN-WHITNEY U TEST AND CHI-SQUARE TEST

	Group		p
	PCA (N=36)	FA (N=35)	
Operation duration (min): median (interquartile range)	90.0 (65.0–98.8)	90.0 (80.0–110.0)	0.248
»Tourniquet« duration (min): median (interquartile range)	72.5 (65.0–95.0)	85.0 (80.0–95.0)	0.013
Morphine: median (interquartile range)	40.0 (40.0–40.0)	15.0 (5.0–20.0)	<0.001
Duration of hospitalisation (days): median (interquartile range)	12 (50.0%)	10 (45.7%)	0.891
Arrhythmias: N (%)*	2 (2.8%)	0 (0.0%)	0.486
Gastrointestinal complications: N (%)*	28 (77.8%)	0 (0.0%)	<0.001
Urinary retention: N (%)*	13 (18.3%)	0 (0.0%)	<0.001
Hemodynamic instability: N (%)*	21 (58.3%)	6 (17.1%)	<0.001
Moderate and highly sedated: N (%)*	32 (88.9%)	0 (0.0%)	<0.001
Satisfaction with analgesia: N (%)*	23 (65.7%)	29 (82.9%)	0.172
Flexion >60° (active motion,2 POD): N (%)*	10 (27.8%)	30 (85.7%)	<0.001

and groups are shown in Figure 2 and 3. Changes in postoperative values of VAS scores (from 2h to 24h) during resting and motion were significant ($p<0.001$) in both groups respectively.

There were no significant differences between group PCA and group FA regarding age, BMI, gender and ASA score distribution (Table 2); operation duration, duration of hospitalisation. Significant differences were noted only in the quantity of morphine used (higher values are in group PCA; $p<0.001$) and in duration of tourniquet application (longer use in group FA; $p=0.013$) (Table 3).

Significantly more complications were recorded in group PCA ($p<0.001$): 28 (77.8%) patients had gastrointestinal symptoms (nausea and vomiting), 13 (18.3%) had urinary retention, 21 (58.3%) had hemodynamic instability and 32 (88.9%) patients were moderately and highly sedated (response only to shouting or pain stimulus). There was no significant difference in heart rhythm disorders and in satisfaction with analgesia, although there were more satisfied patients in Group FA. Active motion (flexion over 60 degrees) occurred significantly more often in group FA, $p<0.001$ (Table 2).

Discussion

Our results suggest that patients from group FA had significantly lower VAS score (i.e. better postoperative analgesia) within the first 24 postoperative hours both at rest and in movement (Table 1), less morphine use and less side effects or complications compared with group PCA (Table 3). During the fourth postoperative hour the difference in VAS score between the groups had the greatest magnitude (Figure 2 and Figure 3). The use of morphine in group FA was reduced by 60% within the first 24 postoperative hours.

Results suggest that group PCA had a more heart rhythm disorders (2.8%) because they have significantly higher VAS scores and don't have adequate/suitable pain control. Morphine in combination with blood loss and hypovolemia in early postoperative time can lead to hemodinamic instabilility (group PCA 58.3%) and hypotension. Group FA had a more efficient early rehabilitation than group PCA. Early rehabilitation and mobilization after orthopedic surgical procedures is important, but limited by strong postoperative pain and muscular spasm[19]. Regional analgesic techniques contribute to better analgesia and quicker postoperative

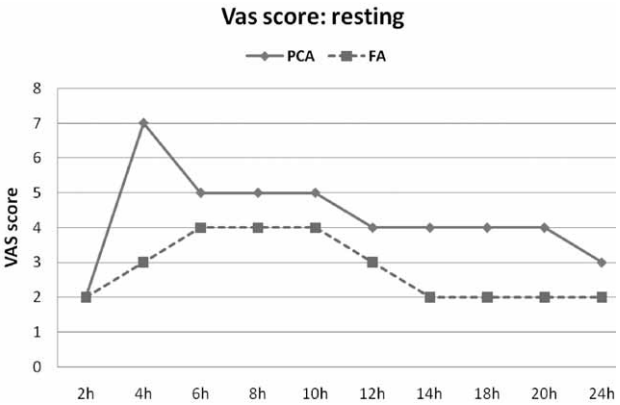

Fig. 2. Changes in VAS score at resting regarding measurement time.

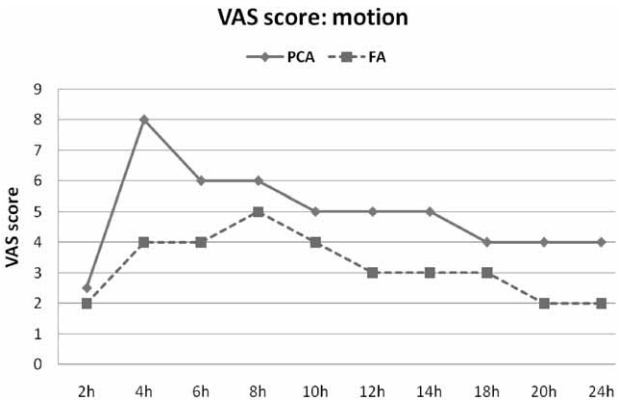

Fig. 3. Changes in VAS score in motion regarding measurement time.

rehabilitation[8,19]. There were no significant differences in the hospital stay length between the groups (p=0.96). despite better analgesia and less morphine use in group FA. The length of hospital stay did not depend on better or worse analgesia or on higher frequency of complications of analgesia. Nevertheless, it was associated with titration of the dose of oral anticoagulants and with early postoperative rehabilitation. Moreover, a common practice in public hospitals in transitional countries with inadequate economic strategy is to keep patients in the hospital for a rather long period of time, which may have contributed to the length of hospital stay in this study.

Potential limitations[9] of the femoral nerve block include toxicity of the local anesthetic and »block failure«. »Secondary analgesic block failure« after a successful block (migration of catheter or the top of catheter not being in the proximity of the nerve) is possible in the ranges from 10%[10] up to 40%[11]. The success of sensory and motor blocks, as well as postoperative analgesia, depend on the position of the catheter under the fascia iliaca.

We did not observe any catheter migrations within the first 24 postoperative hours in our patients. However, the position of the catheter was not checked by radiological methods. We did not notice any complications in the sense of toxic effect of local anesthetic or catheter related infections.

This study is subject to several methodological limitations. Firstly, the femoral catheter was inserted using a nerve stimulator, but without ultrasound control[12,13] because our anesthesiology unit does not have an ultrasound machine. Secondly, the assessment of pain and sensory analgesia was based on patients' subjective assessment using VAS score. We did not use the »pin prick test« or other objective methods to estimate sensory analgesia. Analgesia was assessed only within the first 24 postoperative hours during each patients' stay in the Intensive Care Unit which enabled adequate monitoring and control. Even this would not have been feasible at other hospital departments or units and consequently we did not evaluate analgesia over a longer period

It is necessary to investigate if there are significant differences in the intensity of analgesia and side-effects with respect to the concentration and type of local anesthetic (0.125%, 0.25% or 0.375% levobupivacain *vs*. bupivacain *vs*. ropivacain) in the elderly.

Femoral analgesia is significantly cheaper[14] than intravenous PCA with morphine (1,200 € *vs*. 2,800 € per patient in our study; the costs include the length of stay in the Intensive Care Unit, nurse's and anesthesiologist's work, analgesia-related complications, the material for delivery of analgesia PCA pump, nerve stimulator, femoral catheter and all the other devices) which is of great relevance for health care in South Eastern Europe where scarce financial resources dictate the choice of cheaper techniques without deleterious consequences on patients' health.

Conclusion

Femoral analgesia is an important part of multimodal balanced analgesia after TKA. Peripheral regional analgesia (peripheral nerve block) is a technique of choice for the postoperative analgesia after painful orthopedic surgery[7,20]. It contributes to a stronger analgesia and quicker postoperative rehabilitation[15] with less side-effects[16], less morphine use (»opiods sparing effect«)[17], more patient satisfaction and lower cost of treatment[19]. Our study confirmed the Procedure Specific Postoperative Pain Management (PROSPECT)[18] protocol for analgesia after TKA surgery

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PERIFERNA REGIONALA ANALGEZIJA *VERSUS* INTRAVENOZA »PATIENT CONTROLLED« ANALGEZIJA NAKON UGRADNJE TOTALNE PROTEZE KOLJENA: PROSPEKTIVNA, RANDOMIZIRANA STUDIJA

S A Ž E T A K

Cilj ove prospektivne, randomizirane studije je usporediti učinak femoralne analgezije (FA) 0,25% levobupivakainom i intavenozne »patient controlled« analgezije (PCA) morphinom na ishod poslijeoperacijske bol, kao i njihove komplikacije 24 h nakon ugradnje totalne proteze koljena. Sekundarni cilj uključuje: razliku u potrošnji morphina po grupama, zadovoljstvo bolesnika analgezijom, komplikacije analgezije, trajanje hospitalizacije. Analizirali smo 71 bolesnika, ASA II i III skora. Bolesnici su randomizirani u dvije grupe: grupa PCA (n=36) je analgezirana intravenoznom PCA morphinom; grupa FA (n=36) je analgezirana preko femoralnog katetera kontinuiranom infuzijom 0,25% levobupivakainom. Procjena VAS boli je vršena svaka 2 sata u mirovanju i pokretu. Nije bilo statistički značajne razlike među grupama u demografskim karakteristikama, trajanju operacije, ASA distribuciji, trajanju hospitalizacije i zadovoljstvu analgezijom (premda je grupa FA bila zadovoljnija). Statistički značajna razlika je bila u potrošnji morphina (veća potrošnja kod PCA grupe; $p<0,001$). Više komplikacije je bilo u grupi PCA ($p<0,001$). VAS je bio niži u grupi FA ($p<0,001$). Najveća razlika u VAS-u je bila 4 sata nakon operacije; grupa PCA je imala signifikantno veći VAS nego grupa FA. Femoralna analgezija doprinosi boljoj kontroli boli sa manje nuspojava, manjom potrošnjom morphina i većim zadovoljstvom bolesnika nego intravenozna PCA sa morphinom.