### Cover Page



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# Chapter 2

Femoral nerve block using ropivacaine 0.025%, 0.05% and 0.1%: effects on the rehabilitation programmes following total knee arthroplasty: a pilot study

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#### **ABSTRACT**

Femoral nerve blockade is recommended for analgesia following total knee arthroplasty. Following implementation of this type of postoperative analgesia in our hospital we found that active mobilization the day after surgery, may be difficult due to insufficient quadriceps muscle strength. We therefore designed a pilot study comparing the effect of ropivacaine 0.1%, 0.05% or 0.025% on the patient's postoperative rehabilitation and analgesia. Three groups of 12 patients received bolus doses of ropivacaine via their femoral nerve catheters for postoperative analgesia. The ability to actively mobilize, quadriceps muscle strength, pain VAS-scores and patient's satisfaction were measured during the first three postoperative days. There were no significant differences in the patient's ability to actively mobilize and the pain VAS-scores. The overall satisfaction of the patients with the pain treatment was significantly better (p=0.049) in the 0.1% compared with the 0.025% group. This pilot study demonstrated no advantage associated with the use of a ropivacaine concentration less than 0.1%.

#### INTRODUCTION

Adequate postoperative pain control is important for rapid and optimal rehabilitation following total knee arthroplasty (TKA).1 A multimodal approach for postoperative pain management that reduces nociception at a local, spinal and cerebral level is recommended, because it achieves better pain control and less side effects than when a single modality (i.e. opioids) is used.<sup>2-3</sup> In recent years several studies have indicated the beneficial effect of a femoral nerve blockade as part of a multimodal analgesia regime on postoperative pain and passive joint function following TKA.<sup>4-6</sup> However, after incorporation of a femoral nerve catheter for bolus doses of 10 mL ropivacaine 0.1% in our postoperative pain protocol for TKA we received feedback from the nurses and physiotherapists that although analgesia appeared to be improved, a greater number of patients were unable to mobilize (i.e. walk) the day following surgery due to inadequate quadriceps muscle strength and diminished proprioception (i.e. sensation of joint position). Femoral nerve blockade produces a motor and sensory block of the anterior thigh muscles, i.e. quadriceps femoris, pectineous muscle, iliopsoas muscle and sartorius muscle and the skin on the anteromedial aspect of the thigh and knee. These factors may cause decreased muscle power and diminished proprioception and therefore interfere with the fast-track rehabilitation programme after TKA used in our institution. In this programme, patients are mobilised the morning after surgery and they follow an active rehabilitation schedule, which enables patients to be discharged home on the morning of the 5<sup>th</sup> postoperative day.

On the assumption that decreasing the concentration of ropivacaine used for femoral nerve blockade may improve the patient's ability to follow the fast-track rehabilitation programme after TKA, we designed a pilot study using 0.1%, 0.05% or 0.025% ropivacaine bolus doses postoperatively. The purpose of this pilot study was to identify an optimal concentration of ropivacaine that provides good analgesia and patient's satisfaction following TKA, whilst not interfering with the active mobilisation program.

#### METHODS

The local Ethical Committee approved the study. Patients scheduled for TKA, aged between 18-80 years, without allergic or other contra-indications to the medication used in this study, were selected. Eligible patients, received verbal and written information on the study. One week before the scheduled surgery the patients gave written informed consent.

Approximately 1hr prior to surgery the attending anaesthetist inserted a perineural femoral catheter (Pajunk with stimulating tip, Plastimed Benelux B.V., Velserbroek, The Netherlands) and administered 20 mL ropivacaine 0.2% using this catheter. Following confirmation of correct catheter position by the loss of skin sensibility and quadriceps weakness, 36 patients were randomly allocated, by the use of sealed envelopes, to one of three equally sized groups (i.e. 0.1%, 0.05% or 0.025% ropivacaine). The ward received blinded study medication for the postoperative bolus injections of ropivacaine in a 100 mL bottle with only the patient's name and study number on it. Patients and investigators were blinded to the concentration of ropivacaine administered in the bolus injections on the ward.

Patients had the option of either general anaesthesia or spinal analgesia. Patients preferring general anaesthesia received propofol 1.5-2.5 mg.kg<sup>-1</sup> and fentanyl 0.02 mg.kg<sup>-1</sup> for induction. Atracurium 0.3-0.5 mg.kg<sup>-1</sup> was used to facilitate tracheal intubation. The patients' lungs were mechanically ventilated using oxygen (40-60%) in air and sevoflurane at an end-tidal concentration of approximately 1.8%. At the discretion of the anaesthetist additional doses of fentanyl could be administered to suppress responses of the patient indicating inadequate anaesthesia. For spinal analgesia 15-20 mg bupivacaine 0.5% was administered at the interspace L2-3 or L3-4 using a 27-gauge 3.5-inch Whitacre spinal needle and a midline approach with the patient in a sitting position.

During the study period all patients received acetaminophen 1g four times daily, starting approximately 1hr before surgery and celecoxib 200 mg once daily, started in the recovery room. On arrival in the recovery room a continuous infusion of ropivacaine 0.1% 5mL.h<sup>-1</sup> via the femoral catheter was started and was infused until 06.00 the following morning to ensure good analgesia during the first night after surgery. At 06.00 the infusion was discontinued and the patients received bolus injections of 10 mL ropivacaine at a concentration according to their study group (i.e. 0.1%, 0.05% or 0.025%). Four bolus injections were given on fixed times, i.e. first postoperative day at 06.00 (after discontinuation of the continuous infusion), 11.00 (after mobilisation by the physiotherapist) and 22.00 and the second postoperative day at 06.00, to achieve a basic level of analgesia together with the acetaminophen and celecoxib. Apart from these fixed bolus injections, extra 10 mL doses of ropivacaine with a minimum time interval between doses of 30 min were given on patient request. If two consecutive doses of ropivacaine did not achieve adequate pain relief, 15 mg piritramide intramuscularly was administered as rescue medication. In the morning of the third postoperative day the femoral catheter was removed.

One week before the scheduled surgery basic measurements of pain (VAS, a 100 mm horizontal line with the words 'no pain' at the left and 'worst possible pain' on the right) and quadriceps muscle strength were performed. Quadriceps muscle strength was measured by the physiotherapist using two methods: a qualitative measurement using a 6-point numerical rating scale (MRC scale<sup>7</sup>, Table 1) and a quantitative method for knee extension using a hand-held isometric force dynamometer (microFET2®, Hoggan Health Industries Inc., USA). The quantitative measurements of quadriceps muscle strength during the study were reported as a percentage of the baseline measurements 1 week before surgery.

**Table 1** Qualitative 6-point rating of quadriceps muscle strength (MRC)<sup>7</sup>

Level	Grading
0	No muscle action
1	Flicker of movement
2	Unable to overcome gravity
3	Able to overcome gravity
4	Able to overcome gravity and moderate resistance
5	Assessor unable to manually overcome the muscle power

Qualitative 6-point rating of quadriceps muscle strength

In the first two postoperative days the physiotherapist visited the patients at approximately 10.00 and 14.30, the third day at 10.00 and the fourth day at 14.30 to measure the muscle strength and to determine if the patient had adequate muscle strength and sufficient proprioception to safely start the active training program. If patients had a MRC <3 or an inadequate sense of joint position they were not allowed to walk but followed a training programme in bed. At these time points the physiotherapist also tested the patient's ability to passively flex the operated knee >90°. The rehabilitation programme after TKA, used in our institution, aimed at the rapid achievement of a functional level of recovery that enables patients to leave the hospital on the fifth postoperative day. The minimal discharge criteria were 40m walking with two crutches and ascending and descending stairs consisting of 12 steps using one crutch and the handrail.

During the physiotherapy visits the patients recorded a pain VAS score at rest and on flexion of the knee in a diary. They also recorded a daily satisfaction score with the pain treatment (VAS, on a 100 mm horizontal line for satisfaction with the words 'extremely dissatisfied' at the left and 'excellent' on the right) for the first three postoperative days. The nursing staff recorded the use of rescue medication (piritramide) in the diary.

#### Statistics

Our primary aim was to reduce the number of patients not able to participate in active mobilisation due to insufficient muscle power defined as a MRC score <3, while still maintaining an adequate pain relief. Previous testing indicated a mean (SD) MRC of 2.2 (1.02) the day after surgery while using ropivacaine 0.1%. A sample size of 12 per group was calculated to detect a clinical relevant increase of the mean MRC of 1.5 between the groups at a two-sided 0.05 significant level with a power of 80%.

Data are presented as mean  $\pm$  SD, median with interquartile ranges (IQR), numbers or percentages. Student's t-test was used for comparison of the means of continuous variables. One-way analysis of variance (ANOVA) was used for ordinal data (e.g. VAS-scores, patient's satisfaction with pain therapy), if indicated followed by a Kruskal-Wallis test. Categorical data (e.g. ASA physical status, type of anaesthesia) were analysed using chi-squared test with Yates correction or two-tailed Fisher's exact test where appropriate. A p-value <0.05 was considered statistically significant.

#### **RESULTS**

The groups were comparable for gender, age, body mass index, ASA physical status and type of anaesthesia (Table 2). Table 3 shows the qualitative and quantitative measurements of quadriceps muscle strength in the operated leg and the patient's ability to flex the knee. There were no significant differences in the number of patients per group with permission (MRC  $\geq$ 3) to active mobilise during the study period. In fact, more patients in the group 0.1% were able to mobilise on the first postoperative day (0.1%: 0.05%: 0.025% = 7: 6: 5, NS).

**Table 2** Demographic and anaesthetic characteristics

Group	0.025%	0.05%	0.1%
n (male/female)	12 (4/8)	12 (5/7)	12 (4/8)
Age (years)	68.5 (4.9)	68.3 (8.3)	71.5 (8.6)
Body mass index	28.3 (4.7)	29.9 (6.0)	29.1 (4.3)
ASA physical status I/II	4/8	2/10	5/7
Spinal/general	11/1	11/1	11/1

Data presented as mean (SD) or frequency data

Table 3 Measurements of quadriceps muscle strength and flexion of the knee

	Group	0.025%	0.05%	0.1%
Day 1				
10.00	MRC	2 (2-2.3)	3 (2-3)	2 (1.8-3)
	%	15 (22)	10 (15)	11 (13)
14.30	MRC	2.5 (2-3)	3 (2-3)	3 (2-3.3)
	%	21 (25)	22 (18)	23 (21)
Flexion	>90°	3/12	2/12	1/12
Day 2				
10.00	MRC	2.5 (2-3)	3 (2-3)	3 (2.8-3)
	%	11 (12)	16 (14)	30 (28)*
14.30	MRC	3 (2-3)	3 (2.5-3)	3 (2-3.3)
	%	21 (25)	25 (25)	30 (29)
Flexion	>90°	4/12	7/12	10/12*
Day 3				
10.00	MRC	3 (3-3)	3 (3-3)	3 (3-4)
	%	24 (19)	29 (19)	33 (25)
Flexion	>90°	7/12	8/12	10/12
Day 4				
14.30	MRC	3.5 (3-4)	3 (3-3.8)	3.5 (3-4)
	%	31 (20)	36 (31)	35 (21)
Flexion	>90°	8/12	10/12	12/12

<sup>\*</sup>Difference between 0.025% group and 0.1 group significant (p<0.04)

Qualitative measurements (MRC, median (IQR)), quantative measurements (expressed as mean % (SD) of the measurement 1 week before the surgery). Flexion is the number of patients with a passive range of motion of the operated knee >90°/total number of patients.

By the end of the third postoperative day all patients had permission to walk with a walking frame. The quantitative strength measurements in the operated leg declined sharply from the pre-operative values in all groups on the first postoperative day and recovered only partially (31-36%) (Table 3) in the days until discharge from the hospital. Apart from the first measurement (10.00) (Table 3) on the second day there were no significant differences in the quantitative power measurements between the groups. Except for the measurement at 10.00 on the first postoperative day (r=0.63, p=0.01), the Pearson correlation between the qualitative and quantitative strength measurements on the other data collection points was poor and not significant (r=0.20-0.26). From day 2 more patients in group 0.1% had a passive range of motion of the operated knee >90° compared with the other two groups. All patients in group 0.1% reached this milestone in the rehabilitation programme on the fourth postoperative day (Table 3). The difference in knee flexion between group 0.1% and

0.025% was significant on the second postoperative day. All patients achieved the discharge criteria on the fourth postoperative day and went home the following morning.

There were no significant differences in the median VAS scores for pain in rest and during flexion of the knee and the median VAS score for patient's satisfaction with the pain treatment between the groups on the separate data collection points (Table 4).

**Table 4** Median (IQR) VAS pain score in rest (VAS<sub>R</sub>) and knee flexion (VAS<sub>M</sub>) and patient's daily satisfaction with the pain treatment (VAS<sub>S</sub>, 0 = poor and 100 is excellent)

	Group	0.025%	0.05%	0.1%
1 week preo	<b>o</b>			
	VAS <sub>R</sub>	6 (5-42)	4 (3-7)	5 (4-17)
	VAS <sub>M</sub>	7 (6-37)	9 (3-35)	5 (2-52)
Day 1				
10.00	VAS <sub>R</sub>	36 (12-46)	40 (25-47)	34 (21-44)
	VAS <sub>M</sub>	38 (26-58)	41 (25-50)	36 (23-47)
	VAS	37 (20-75)	66 (54-73)	58 (46-81)
14.30	VAS <sub>R</sub>	17 (5-43)	11 (7-29)	13 (9-17)
	VAS <sub>M</sub>	29 (10-48)	27 (14-35)	22 (14-30)
Day 2				
10.00	$VAS_R$	31 (17-46)	20 (16-27)	22 (10-48)
	VAS <sub>M</sub>	37 (24-46)	40 (24-71)	37 (20-64)
	VAS <sub>s</sub>	45 (26-78)	70 (51-79)	79 (70-90)
14.30	VAS <sub>R</sub>	10 (5-15)	10 (5-21)	15 (7-17)
	VAS <sub>M</sub>	26 (19-35)	39 (18-60)	28 (24-43)
Day 3				
10.00	VAS <sub>R</sub>	11 (9-20)	15 (9-23)	12 (7-36)
	VAS <sub>M</sub>	24 (16-46)	20 (11-43)	38 (22-49)
	VAS <sub>s</sub>	70 (40-90)	73 (63-82)	83 (64-86)
Day 4				
	VAS <sub>R</sub>	10 (4-21)	16 (8-19)	15 (9-42)
	VAS <sub>M</sub>	24 (13-34)	42 (17-55)	25 (11-58)

There were no significant differences between the groups in VAS pain scores. VAS, over the whole study period (day 1-3) was significantly better in group 0.1% compared to group 0.025% (ANOVA, p=0.049).

However, the overall patient's satisfaction was consistently better in the group 0.1%. Measured over the entire study period (day 1-3) this difference was significant compared with the group 0.025% (Table 4). Moreover, the median number of extra bolus doses ropivacaine on request of the patient tended to be higher in the 0.025% group (NS, Table 5) and the mean decrease of the VAS score 30 min after the bolus injection was significantly

lower compared with the 0.1% group. Also the median (IQR) number of rescue piritramide injections were higher in patients of the 0.025% group compared with the 0.1% group, although this difference did not reach statistical significance (p=0.056).

**Table 5** Number of extra bolus doses ropivacaine, decrease in VAS pain scores 30 min after a bolus dose of ropivacaine and the number of rescue piritramide injections during the study

Group	0.025%	0.05%	0.1%	p (0.025% vs 0.1%)
Extra bolus doses	10 (6-11)	6 (4-11)	6 (5-8)	NS
Decrease VAS pain	8 (11.7)	13 (13.3)	16 (15.9)	0.01
Piritramide injections	2 (1-4)	0 (0-2)	1 (1-1)	0.056

The number of extra bolus doses ropivacaine presented as median (IQR), the decrease in VAS pain scores 30 min after a bolus dose of ropivacaine presented as mean (SD) and the median (IQR) number of rescue piritramide injections during the study (day 1-3).

#### DISCUSSION

In recent years several studies have indicated the beneficial effect of femoral nerve blockade on analgesia and the rehabilitation programme following TKA. 4-6,8-10 The principal aim of these studies was to detect improvement of postoperative pain control, reduction of opioid use and the associated side effects after TKA.

Although quadriceps muscle weakness is often mentioned as a potential disadvantage for early ambulation of the patient<sup>2,3,5,11</sup>, most studies do not comment further on this since their rehabilitation programmes in the first postoperative days were mostly in bed using a continuous passive motion machine and active walking was postponed until the second or third postoperative day or even later. 4-6,8-10 Salinas et al. also using the microFET® dynamometer, reported a quantitative decrease in quadriceps motor strength to 6 ± 16% from baseline motor strength in 17 healthy volunteers who had a continuous femoral block with ropivacaine 0.2% 10 mL.h-1 for 4 hours and an initial bolus injection of 10 mL lidocaine 1%. Eight hours after stopping the infusion they had recovered only to 58 ± 40% of their baseline power. Apart from the femoral nerve block itself, TKA surgery has a significant negative effect on quadriceps muscle strength of the operated leg.<sup>5,12</sup> In 14 consecutive patients after TKA without a postoperative regional technique in our institution the mean (SD) muscle strength in the operated leg declined to 33% (18) the day after surgery and recovered to 54% (30) on the fourth postoperative day (B.J.W. Thomassen, unpublished data). In the present study quantitative strength measurements declined to 15-23% of the baseline on the first postoperative day and recovered to 31-36% the day before discharge

(Table 3). There were no apparent differences in quantitative muscle strength between the groups and no indication of higher values in the groups with a lower concentration of ropivacaine that might become significant if we had included more patients in our study. Barrington et al. using the same 6-point rating scale for qualitative muscle strength measurement as in our study (Table 1), reported that only 6 of 53 patients had a score ≥3 on the first day after TKA in their femoral nerve block group using bupivacaine 0.2% at 0.1 mL.kg<sup>-1</sup>.h<sup>-1</sup> with a PCA bolus of 0.05 mL.kg<sup>-1</sup>.<sup>5</sup> They also found significantly greater quadriceps muscle blockade in their femoral nerve blockade group on the second postoperative day compared with the group of patients with epidural analgesia with a continuous infusion of ropivacaine 0.2% plus fentanyl. In the present study there were no significant differences in qualitative muscle strength measurements between the groups. However, this study was designed to detect a substantial difference in qualitative strength measurements and lacked the power to find smaller but probably clinically less relevant differences. The median qualitative strength score in all groups ranged between 2 and 3 (Table 3) on the first postoperative day and consequently only half of the patients had permission to actively mobilise with a walking frame that day. However, all patients with a slow start at ambulation made up the difference in the days thereafter and met the discharge criteria by the end of the fourth postoperative day.

In this study we used a qualitative 6 point rating scale (Table 1) and a quantitative (isometric muscle force dynamometer) method to evaluate quadriceps muscle strength and found a poor correlation between these two measurements. Zaric et al. in a study with epidural ropivacaine in 30 healthy volunteers also observed that qualitative strength measurements (modified 4-point Bromage scale) decreased far less and later than expected on basis of the quantitative measurements and at the recovery of the Bromage score from grade 1 to 0, only 22-40% of the muscle force for knee extension, assessed by the quantitative method, had recovered. However, they did find a close relationship between the sensory blockade (pinprick) and the quantitative strength measurements. Although the use of force dynamometry allows for more precise quadriceps strength measurements, than the normally used qualitative rating scale, caution in the interpretation of early postoperative measurements after TKA is warranted, because maximal isometric quadriceps contraction may be painful in the first postoperative days and lead to erroneously low values. 11,13,14

There were no significant differences between the groups in the VAS pain scores at rest and during flexion of the knee (Table 4). However, the patients in the 0.025% group tended to use more piritramide rescue medication and the VAS scores for satisfaction with the pain treatment were significantly better in the 0.1% group (Table 4). In view of the fact

that all patients met the discharge criteria on the end of the fourth postoperative day, although several of them could not participate in the active mobilisation (i.e. walking) in the first postoperative days, we consider to investigate the effect of a higher ropivacaine concentration (i.e. 0.15%, 0.2%) on our fast track rehabilitation programme, as these concentrations were reported as superior for analgesia and may not lead to a longer hospital stay.6,10

In conclusion, this pilot study indicated no apparent advantage in decreasing the concentration of ropivacaine administered as bolus injections via the femoral nerve catheter below 0.1% on the patient's ability to actively participate in the rehabilitation programme after TKA. In fact, the lowest studied concentration (i.e. 0.025%) resulted in a lower patient's satisfaction with the pain treatment, while not improving recovery after TKA.

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