Postoperative Analgesia After Knee Surgery: A Comparison of Three Different Concentrations of Ropivacaine for Continuous Femoral Nerve Blockade

Gerhard Brodner, MD, PhD*

Hartmut Buerkle, MD, PhD†

Hugo Van Aken, MD, PhD, FRCA, FANZCA‡

Roushan Lambert, MD§

Marie-Luise Schweppe-Hartenauer, MD§

Carola Wempe, MD‡

Wiebke Gogarten, MD, PhD‡

BACKGROUND: The most effective ropivacaine concentration for femoral infusion after total knee arthroplasty is currently ill defined. We designed the present study to compare ropivacaine in three different concentrations (0.1, 0.2, and 0.3%) to evaluate analgesic quality, when administered as a continuous infusion with frequent infusion adjustments in patients receiving a combined femoral and sciatic nerve block. Secondary aims were to evaluate side effects such as motor blockade, rehabilitation indices, and ropivacaine plasma concentrations.

METHODS: One hundred twenty-two patients undergoing total knee arthroplasty under combined general and regional anesthesia received femoral infusions of ropivacaine 0.1, 0.2, or 0.3%. Infusions were started after initial loading doses of 30 mL ropivacaine 0.5% into the femoral catheter and a sciatic catheter and were targeted to dynamic pain scores of 40 mm. Pain and side effects were assessed 1 h after tracheal extubation and on the first, second, third, fourth, and fifth postoperative days. Ropivacaine plasma concentrations were measured 24, 48, and 72 h after the start and 24 h after termination of femoral infusions in patients receiving ropivacaine 0.2% or 0.3%.

RESULTS: Ropivacaine 0.1% provided ineffective analgesia. Ropivacaine 0.2% and 0.3% provided equivalent analgesia. Maximum infusion rates were 15.39 and 13.77 mL/h for ropivacaine 0.2% and 0.3%, respectively. There were no significant differences in motor blockade, mobilization, or ropivacaine plasma concentrations, which remained below toxic levels throughout the study period.

CONCLUSION: Ropivacaine 0.2% and 0.3% were similar in terms of analgesic quality. Initial infusion rates should be adjusted to 15 mL/h to obtain effective analgesia.

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Studies evaluating the quality of analgesia provided by continuous femoral nerve blocks after knee surgery are still equivocal, with some reporting excellent analgesia while others describe less satisfactory results (1,2). Some of these discrepancies may be explained by differences in local anesthetics as well as by differences in the use of additional sciatic nerve blocks, and additional systemic analgesics prescribed. Although ropivacaine is frequently administered in a concentration of 0.2% (3,4), which is the standard commercial preparation, the most effective concentration in terms of analgesia and side effects is currently ill defined. In a previous study, no differences in pain scores, motor blockade, and ambulation between femoral infusions of ropivacaine 0.2% and 0.15% after total knee arthroplasty were described (5); however, higher concentrations of ropivacaine were not evaluated, leaving unanswered the question of whether increasing the concentrations will further enhance the quality of blocks. Additionally, most study protocols have applied fixed infusion rates of local anesthetics, whereas analgesia may be further improved by titrating the infusion rate according to the individual needs.

The current study was therefore designed to evaluate whether ropivacaine 0.3% is superior to ropivacaine 0.2% or 0.1% in terms of dynamic pain scores when infusion rates are individually titrated according to patient needs for postoperative continuous femoral blocks after knee surgery, and supplemented by intermittent sciatic nerve catheter injections. The primary aim was to evaluate the quality of analgesia during leg movement. Secondary aims were the evaluation of rehabilitation indices and side effects such as motor blockade in addition to determining the resulting plasma concentrations of ropivacaine.

From the *Department of Anesthesiology, Intensive Care and Pain Therapy, Fachklinik Hornheide, Münster, Germany; †Department of Anaesthesiology, Intensive Care and Pain Therapy, Memmingen Hospital, Memmingen, Germany; ‡Department of Anaesthesiology and Intensive Care, University Hospital of Münster, Münster, Germany; and §Department of Anaesthesia and Intensive Care, St. Josef Stift, Sendenhorst, Germany.

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Supported by AstraZeneca GmbH, Tinsdaler Weg 183, 22880 Wedel, Germany.

Address correspondence and reprint requests to Hugo Van Aken, MD, PhD, Department of Anaesthesiology and Intensive Care, Universitätsklinikum Münster, Albert-Schweitzer-Strasse 33, D-48149 Münster, Germany. Address e-mail to hva@uni-muenster.de.

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METHODS

After approval by the local ethics committee and written informed consent, 138 patients undergoing elective knee surgery were enrolled in this prospective, double-blind study. Sixteen patients who were approached during the enrollment period were subsequently excluded because they either decided not to participate ($n = 2$) or catheter placement was unsuccessful ($n = 14$).

Using random numbers, the remaining 122 patients were assigned to 1 of 3 groups receiving ropivacaine in concentrations of 0.1% (Group 1), 0.2% (Group 2), or 0.3% (Group 3) via a femoral catheter for postoperative analgesia.

The femoral nerve was identified by the inguinal paravascular approach using a stimulating needle set (19.5 G, 60 mm; polyamide catheter 20 G, 50 cm; Pajunk, Geisingen, Germany). The block was started with an output of 1 mA (0.5 ms at 2 Hz). Correct identification of the nerve was confirmed by quadriceps contraction with the nerve stimulator set at 0.5 mA (0.1 ms, 2 Hz). The catheter was introduced through the needle pointing cephalad and positioned 4–5 cm beyond the needle tip. A sciatic nerve catheter was then placed via the anterior approach (stimulating needle 19.5 G, 130 mm; polyamide catheter 20 G, 50 cm). Stimulation was considered acceptable when responses from the peroneal or tibial nerve were elicited (dorsiflexion or plantar flexion of the foot) at <0.5 mA (0.1 ms, 2 Hz). The catheter was positioned at a depth of 4–5 cm beyond the needle tip. Then, 30 mL ropivacaine 0.5% was administered through each catheter. Immediately after confirmation of both blocks by pinprick at the anterior knee and anterior foot, a continuous infusion of 10 mL/h of ropivacaine in the respective concentration for each group was started via the femoral catheter.

General anesthesia was induced with propofol (2 mg/kg), sufentanil (0.25 μg/kg) and *cis*-atracurium (0.1–0.12 mg/kg). After tracheal intubation, the lungs were ventilated with 30% oxygen in air. Anesthesia was maintained with propofol (100–170 $\mu g \cdot kg^{-1} \cdot min^{-1}$) and monitored using standard clinical methods. Supplementation with sufentanil, infusions, and transfusions was left to the discretion of the attending anesthesiologist.

Members of the acute pain service who were unaware of the ropivacaine concentrations administered visited all patients at least twice daily and adjusted pain treatment to the patients' individual needs using a modified up and down method. The treatment goal was a dynamic pain score (knee flexion, extension) of 40 mm on a visual analog scale (VAS) with 0 mm representing no pain and 100 mm indicating the worst pain imaginable. If patients scored <40 mm, femoral infusions were reduced in steps of 5 mL/h. If patients scored >40 mm, these infusions were increased in steps of 5 mL/h without an additional bolus via the femoral catheter. In addition, pain in different segments of the knee was assessed. If pain in the posterior segment exceeded a VAS score of 40 mm, a bolus of 10 mL of the study medication was administered via the sciatic catheter. Continuous infusions via the sciatic catheter were avoided in order not to obscure sciatic nerve damage or postoperative compartment syndrome. The effect of all interventions was assessed 2 h later and the protocol was repeated until patients scored 40 mm. This method was used to evaluate the minimum effective infusion rate for each group. Bolus doses of subcutaneous morphine were allowed as rescue medication.

Femoral catheters were removed if the patients in whom infusions were completely stopped did not request further infusions for ≥6 h and sciatic catheters were withdrawn in patients not requiring boluses over 24 h. In patients with indwelling femoral catheters on the fourth postoperative day, infusions were reduced by 50%. On the fifth postoperative morning, all infusions were terminated, catheters were removed, and the patients were treated according to the intensity of pain with IV dipyrone.

Beginning 1 h after tracheal extubation, an independent investigator, who was not a member of the acute pain service, recorded the study data every morning for 5 days to ensure a thorough evaluation at identical time points. This investigator evaluated knee pain at rest (overall, ventral, lateral, medial, and dorsal aspects) and dynamic knee pain during extension, flexion, and femoral adduction. Satisfaction was rated as: 1 = excellent; 2 = good; 3 = moderate; 4 = insufficient; 5 = poor; mobilization was scored as: 1 = able to move without restriction; 2 = able to move outside the bed for a limited time – with attendant–; 3 = able to sit outside the bed; 4 = bed rest; and motor blockade was assessed with a modified Bromage-score (6): normal function = 0; impaired function >0. Additionally, the degree of knee flexion and extension was measured. Drug dosage was calculated from daily cumulative volumes administered via the femoral and sciatic catheters. Rescue morphine was also recorded.

Demographic variables, medical history, physical status, medication, duration of surgery and anesthesia, blood loss, fluid balance, transfusions, and length of hospital stay were recorded in a standardized protocol.

Plasma levels of ropivacaine and α1-acid glycoprotein were also measured. Blood (10 mL) was sampled at 24, 48, and 72 h after the start and 24 h after the termination of the femoral infusion, and plasma samples were stored at −80°C until assays were performed. For total and free ropivacaine concentration measurements, high-performance liquid chromatography was used. α1-acid glycoprotein was analyzed by immunonephelometry.

The primary outcome was dynamic knee pain. In previous studies, we observed a high variability of VAS-scores with standard deviations of 20–40 and these scores were highly correlated with a 4-point

numeric rating scale (7,8). This indicates that patients cluster the VAS-scores into several distinct categories representing different degrees of pain. Assuming a standard deviation of 30, we consider a difference of 15 VAS-points as a significant difference between two of such clusters. According to the criteria defined by Cohen (9), these parameters correspond to a medium effect size. The study was designed to detect a medium effect size of $f = 0.25$ (significance level: $\alpha = 0.05$, statistical power: $1 - \beta = 0.8$, sample size: $n = 159$) in VAS scores. The ethics committee advised performing a statistical interim analysis after 20 patients in each group, and an *a priori* decision was made to stop the allocation to any group in which significantly increased pain scores were observed. If one of the groups had to be excluded from further study, the power analysis with two groups resulted in a sample size of 51 patients per group. Plasma concentrations were analyzed in a randomized subsample (by random numbers) of 10 patients in each group (effect size: $f = 0.6$). Statistical tests were performed as an intention-to-treat analysis using the Statistical Package for the Social Sciences (SPSS 12.0; SPSS, Chicago, 2005). Nominal variables were described as relative and absolute frequencies; differences among groups were assessed by χ^2 tests or Fisher's exact tests if matched cells were rare (expected frequencies <5). Ordinal variables were reported as medians and interquartile ranges, metric variables were described as means and standard deviation. Pearson correlation coefficients were calculated to evaluate covariation; Kruskall–Wallis tests, *U*-tests, *t*-tests, or repeated-measures analyses of variance were used to compare groups.

RESULTS

Of the 122 patients included in the study, one patient of Group 1 had to be excluded due to femoral catheter dislocation. Because of limited analgesia, despite increasing infusion rates, four more catheter dislocations were suspected in one patient of Group 2 and three patients of Group 3. The data of all patients were included in the statistical analyses.

The interim analysis revealed significantly less satisfaction with the quality of analgesia in patients allocated to Group 1 (1 h after surgery: Group 1 vs 2: mean difference = 0.60 confidence interval: 0.04–1.2, $P = 0.04$; first postoperative morning: Group 1 vs 2: mean difference = 0.63, confidence interval: 0.03–1.2, $P = 0.04$, Group 1 vs 3: mean difference = 0.65, confidence interval: 0.08–1.2, $P = 0.03$) despite higher infusion rates and higher supplemental boluses via the sciatic catheter. VAS scores were significantly increased 1 h after surgery (knee extension, Group 1 vs 2: mean difference = 31.9, confidence interval: 10.4–53.5, $P = 0.01$; Group 1 vs 3: mean difference = 41.4, confidence interval: 21.6–61.7, $P = 0.000$) and on the first morning (Group 1 vs 3: mean difference = 20.6 confidence interval: 1.4–39.8, $P = 0.04$). Further enrollment to Group 1 was therefore discontinued according to the study protocol.

Table 1. Final Analysis: Demographic Data, Physical Condition, and Intraoperative Characteristics

	Group 2 n = 51		Group 3 n = 51	
Variable	Mean	SD	Mean	SD
Age (y)	62.2	12.23	63.2	8.41
Weight (kg)	87.8	13.98	86.2	12.91
Height (cm)	171.8	8.31	170.1	8.91
Duration of anesthesia (min)	150.8	24.52	146.3	21.35
Duration of surgery (min)	107.4	24.15	101.0	22.45
Hospital stay (days)	22.1	4.10	22.4	3.44
Sex (male/female)	23/28		20/31	
ASA physical status (I/II/III/IV)	3/31/16/1		4/28/19/0	

Values are presented as means with standard deviation (SD) or absolute frequency. ASA, American Society of Anesthesiologists.

Group 2: patients with femoral ropivacaine 0.2%. Group 3: patients with femoral ropivacaine 0.3%.

No significant differences among groups in any variables (t-test, χ^2, Fisher's exact test).

A total of 102 patients allocated to Groups 2 and 3 were included in the final analysis. Demographic data, physical condition, and intraoperative characteristics were comparable between both groups (Table 1). Median length of hospital stay was approximately 3 wk and determined by local policy.

Femoral catheters were primarily needed during the first 2 days. After this period, 40 (77%) catheters in Group 2 and 39 (75%) in Group 3 had been removed. There were no significant differences in the changes of infusion rates between Groups 2 and 3. During the first postoperative hour, no patient had a decrease of the initial infusion rate of 10 mL/h. This rate was maintained in 14 patients (27.4%) of Group 2 and in 19 (37.5%) patients of Group 3. It had to be increased by 5 or 10 mL/h in 37 (72.5%) and 32 (62.8%) of the patients of Groups 2 and 3 until the first postoperative morning. This increase could be reversed within 24 h in 7 (18.9%) patients of Group 2 and in 9 (28.1%) patients of Group 3. Until the first postoperative morning, the initial infusion rate of 10 mL/h was decreased by 5 mL/h in 4 (7.8%) patients of Group 2 but not in Group 3. None of the patients with a decreased infusion rate had their infusion rate subsequently increased again.

The median Bromage score in both groups was 0 from the end of the stay in the recovery room, and the median mobilization score was 2 after 5 days. The degrees of knee extension and flexion on the fifth postoperative day were comparable (extension: Group 2: 7.38 degree, Group 3: 6.90 degree flexion: Group 2: 72.02 degree, Group 3: 74.12 degree).

Cumulative drug dosages and VAS-pain scores are reported for the first two postoperative days, when most catheters were still in place. Femoral, sciatic, and

Table 2. Final Analysis: Drug Dosage and Supplementary Drugs After Femoral Block Final Analysis

Variable	Treatment	1 hour Mean/SD	POD 1 Mean/SD	POD 2 Mean/SD	Between subjects F (p)	Within subjects: Time F (p)	Within subjects: Interaction F (p)
Maximum infusion rate of femoral ropivacaine (mL/h)	Group 2	14.39/2.94	13.54/4.47	11.09/4.43	.01 (.92)	35.12 (.000)	4.46 (.01)
	Group 3	13.77/2.90	13.25/2.90	12.17/3.23			
Cumulative dosage of femoral ropivacaine (mg)	Group 2	282.11/142.96	964.48/248.72	1539.08/343.53	59.65 (.000)	1467.01 (.000)	55.32 (.000)
	Group 3	400.63/245.27	1355.25/379.47	2250.95/510.48			
Dosage of sciatic ropivacaine (mg/d)	Group 2	32.86/25.99	21.05/22.59	6.67/11.55	6.83 (.01)	40.07 (.000)	.13 (.88)
	Group 3	42.20/37.00	30.00/31.02	13.00/14.99			
Supplementary morphine s.c. (mg/d)	Group 2	7.14/7.56	4.64/6.60	2.32/5.04	.13 (.72)	20.23 (.000)	.11 (.90)
	Group 3	6.52/6.83	4.70/7.22	2.00/4.43			

Repeated-measures analysis of variance: values are presented as means and standard deviation (SD), F-term (F), probability (p).

1 hour: 1 hour after surgery. POD 1: 1st postoperative day. POD 2: 2nd postoperative day.

Group 2: patients with femoral ropivacaine 0.2%. Group 3: patients with femoral ropivacaine 0.3%.

Table 3. VAS-Pain Scores

	Group 2 (n = 51) Mean (SD)	Group 3 (n = 51) Mean (SD)	Mean diff (95% CI)
Dynamic pain: knee flexion			
1 hour	52.3 (31.7)	56.7 (30.2)	−4.4 (−16.8–7.9)
POD 1	45.0 (24.7)	46.2 (24.2)	−1.2 (−11.0–8.6)
POD 2	43.5 (23.6)	49.3 (25.5)	−5.8 (−15.6–4.0)
Dynamic pain: knee extension			
1 hour	39.6 (33.0)	44.0 (33.3)	−4.4 (−17.6–8.8)
POD 1	35.1 (27.3)	36.7 (27.2)	−1.6 (−12.4–9.3)
POD 2	32.0 (25.9)	39.4 (26.3)	−7.4 (−17.8–3.1)
Dynamic pain: femur adduction			
1 hour	38.5 (30.3)	42.4 (27.2)	−3.8 (−15.3–7.7)
POD 1	32.2 (22.6)	30.1 (19.2)	2.1 (−6.3–10.5)
POD 2	25.6 (21.4)	26.2 (19.6)	−0.6 (−8.8–7.6)
Overall knee pain at rest			
1 hour	40.7 (29.9)	41.9 (27.7)	−1.2 (−12.2–9.8)
POD 1	28.7 (16.0)	26.9 (16.4)	1.8 (−4.6–8.2)
POD 2	25.2 (24.9)	21.5 (14.8)	3.7 (−4.4–11.4)
Posterior knee pain at rest			
1 hour	25.4 (24.8)	27.1 (26.0)	−1.7 (−11.7–8.4)
POD 1	24.9 (19.8)	16.9 (16.0)	8.0 (0.9–8.4)*
POD 2	21.3 (21.3)	14.5 (15.3)	6.8 (−0.6–14.2)

Group 2: patients with femoral ropivacaine 0.2%. Group 3: patients with femoral ropivacaine 0.3%.

1 hour: 1 hour after extubation. POD 1: first postoperative day. POD 2: second postoperative day.

Mean: Mean score SD: standard deviation. Mean Diff: Mean difference. 95 % CI: 95 % confidence interval of differences (lower − upper limit).

There were no significant differences between groups except posterior knee pain at rest on the first postoperative day.

* p = .03.

rescue drug consumption decreased during the observation period; however, femoral and sciatic drug dosage was significantly higher in Group 3 (Table 2). Pain scores in different segments of the knee during rest correlated significantly with overall knee pain (r_{min} = 0.59, r_{max} = 0.89) and pain scores during flexion, extension, and femur adduction were significantly intercorrelated (r_{min} = 0.66, r_{max} = 0.87). Pain scores in Groups 2 and 3 were comparable, only on the first postoperative morning was posterior knee pain at rest lower in Group 3 (Table 3).

Both groups were satisfied with their pain therapy (first postoperative day: Group 2: mean = 1.8, SD = 0.61; Group 3: mean = 1.65, SD = 0.63; second postoperative day: Group 2: mean = 1.65, SD = 0.75; Group 3: mean = 1.73, SD = 0.67), neither central nervous nor cardiac complications were observed.

Plasma concentrations were measured in 10 patients in Groups 2 and 3, respectively (Fig. 1). Ropivacaine concentration increase was more pronounced in Group 2. Maximum total ropivacaine concentrations were 0.38 μg/mL in Group 2 and 0.32 μg/mL in

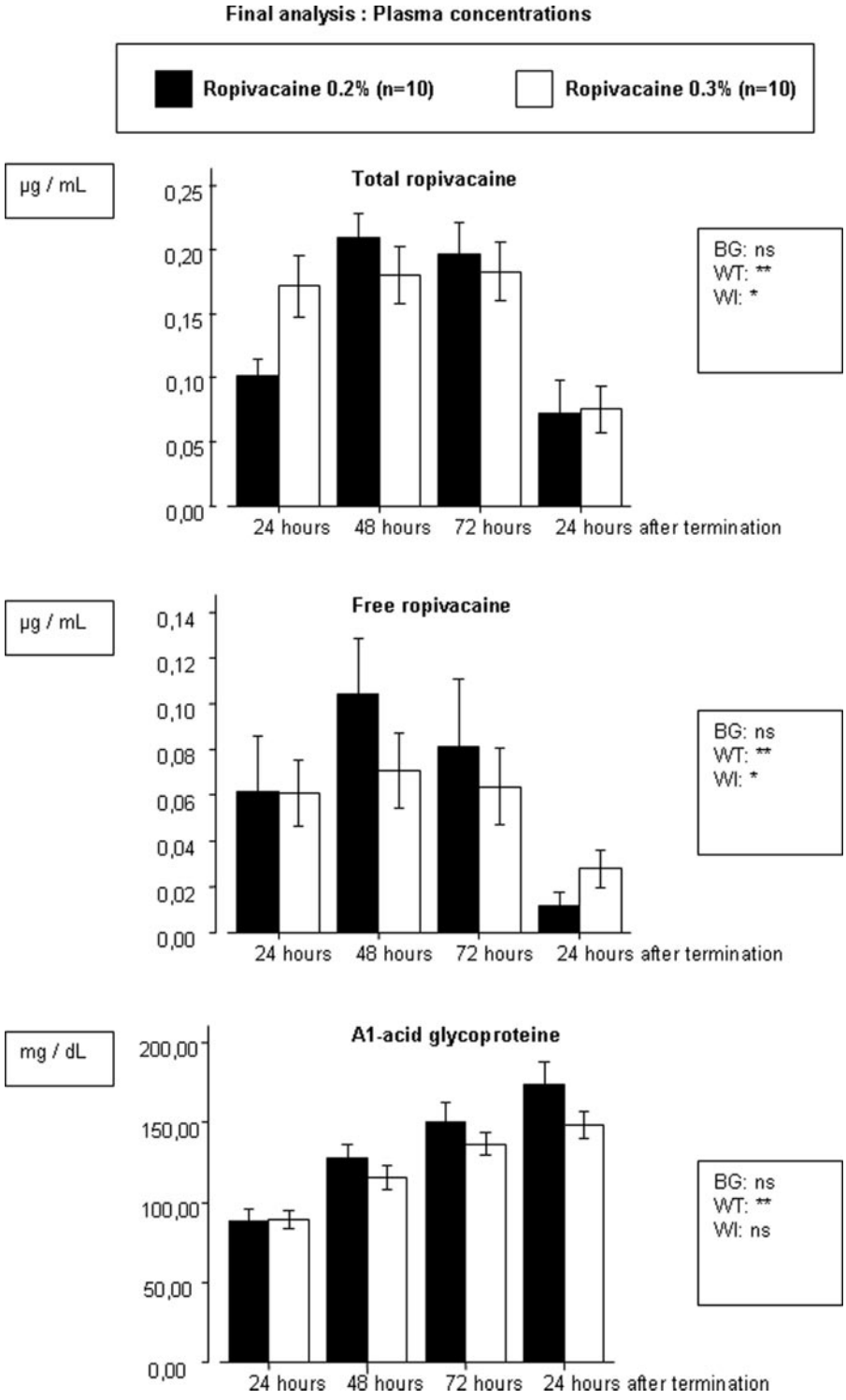

Figure 1. Final analysis: Plasma concentrations are presented as mean scores and standard error of the mean. 24 h: 24 h after the start of the continuous infusion, 48 h: 48 h after the start of the continuous infusion, 72 h: 72 h after the start of the continuous infusion, 24 h after termination: 24 h after termination of the continuous infusion. Repeated measures analysis of variance: BG, between groups effect; WT, within groups effect for time; WI, within groups effect for interaction; ns, not significant. $^{*}P < 0.05$, $^{**}P < 0.01$.

Group 3. Maximum concentrations of free ropivacaine were 0.20 µg/mL in Group 2 and 0.17 µg/mL in Group 3. Total ropivacaine levels remained stable during the continuous infusion, but decreased significantly 24 h after termination of the infusion. α1-acid glycoprotein increased postoperatively in all patients.

DISCUSSION

In the present study, ropivacaine 0.2% and 0.3% provided similar analgesia, whereas ropivacaine 0.1% provided insufficient pain relief. The study was designed to evaluate a between-group difference of 15 VAS points. One could argue that this difference is inadequate, and that the study might be underpowered to detect lower but potentially relevant effects. However, all mean differences in dynamic pain scores between Groups 2 and 3 were far beyond this predefined level; 11 of the 15 reported mean differences in Table 3 amount to <5 VAS points. On the other hand, the significant differences between

Group1 versus Groups 2 and 3 are in the range of 30 and more VAS points, which is twice the predefined meaningful difference. Thus, according to these results, the study did not exclude possibly relevant differences due to insufficient statistical power. Plasma levels of total and free ropivacaine did not increase further after 48 h, indicating that a plateau had been reached.

Although ropivacaine 0.2% is frequently used for postoperative analgesia, the most appropriate concentration and infusion rates via a femoral nerve catheter have never been completely studied, but are rather chosen by institutional preferences and availability of commercial solutions. Current reports on ropivacaine infusions range from 5 to 12 mL/h, with or without the ability to administer additional boluses via a patient-controlled analgesia (PCA) device (4,10,11). The initial infusion rate of 10 mL/h thus lies within the range of previously published reports. In most of these studies, infusion rates were fixed and not titrated according to individual patients' needs. The present study was therefore designed to overcome some of these limitations, with a special focus on frequent adjustments of infusion rates titrated to achieve a dynamic VAS score of 40 mm. In most patients, infusion rates had to be increased by 5–10 mL/h in order to provide sufficient pain relief, indicating that currently chosen infusion rates may be too low, if additional boluses are not administered. In addition to a lack of a sciatic nerve block, this may, in part, explain why a larger consumption of additional analgesics has been observed in patients receiving femoral nerve blocks as opposed to epidural analgesia (12).

In order to perform clinically meaningful changes in the infusion rate, adjustments were chosen in steps of 5 mL/h, which are slightly larger than the steps used in a previous up and down sequential allocation method study (11). These steps would reduce the initial dose by 50%; nevertheless, doses as low as 5 mL/h have been reported to provide analgesia after total knee replacement and were thus considered safe in terms of efficacy (11). Casati et al. (13) reported a minimum local anesthetic volume of 15 mL ropivacaine, supporting our finding that 5–10 mL/h may be insufficient.

A major limitation of this study design is that the low initial infusion rates of 10 mL/h provided insufficient analgesia in patients receiving ropivacaine 0.1%. Although infusion rates were adjusted according to the study protocol, these steps were probably too small and too slow to provide a sufficient dose of ropivacaine in a timely manner. This may explain the high failure rate with ropivacaine 0.1%, while ropivacaine 0.15% was reported to be indiscernible from ropivacaine 0.2% by others (5).

The addition of a bolus at the time of infusion adjustments may have yielded different results, as it was previously shown that boluses via a femoral nerve catheter significantly enhance the quality of analgesia. Singelyn et al. (14) demonstrated that maintenance analgesia via a femoral nerve block was superior, if the local anesthetic was delivered via PCA boluses, only when compared to continuous infusions, while reducing the amount of local anesthetic consumed. Similar results have been obtained with neuraxial blockade (15). We did not combine boluses with changes in infusion rates in order to avoid confounding effects.

Continuous femoral infusions of 12 mL ropivacaine 0.2% resulted in maximum plasma concentrations of 2.631 μg/mL after 48 h (15). In the present study, the maximum concentrations were 0.32 μg/mL (Group 2) and 0.38 μg/mL (Group 3). This result may be explained by differences in drug dosage: in the present study, infusion was targeted to a specific pain level and the infusion rate was decreased in patients with lower pain scores. Thus, drug dosage was lower compared with studies with fixed infusions in which the infusion rate was not reduced in patients scoring below a predefined pain level. This broad variability has also been observed in other studies (16). Toxic plasma levels of ropivacaine in humans are not well-defined and depend on the injection site, absorption time, protein-binding capacity, and elimination. Ropivacaine remained stable during prolonged continuous infusions with low plasma concentrations and with no relevant differences among the groups.

In summary, the present study shows that ropivacaine 0.2% and 0.3% provided effective analgesia in femoral nerve blocks when administered as a continuous infusion. If continuous infusions are administered as opposed to PCA boluses, infusion rates should be set higher than in previous reports in order to obtain a sufficient level of analgesia.

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