Addition of femoral 3-in-1 blockade to intra-articular ropivacaine 0.2% does not reduce analgesic requirements following arthroscopic knee surgery

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Purpose: To test the hypothesis that the addition of a preincisional femoral 3-in-1 block to intra-articular instillation with ropivacaine 0.2% at the end of surgery improves postoperative pain control in patients undergoing arthroscopic anterior cruciate ligament reconstruction (ACLR) under general anesthesia.

Methods: In a prospective, randomized, placebo-controlled, double-blind trial, we studied 44 patients scheduled for inpatient ACLR. Prior to incision, the treatment group (n = 22) received a femoral 3-in-1 block with 40 ml ropivacaine 0.2%, augmented by infiltrations of the lateral and anteromedial incisions with 20 ml ropivacaine 0.2% at the end of the procedure. The control group (n = 22) received saline 0.9% instead of ropivacaine. All patients received an intra-articular instillation with 30 ml ropivacaine 0.2% at the end of surgery. The primary efficacy variable was 24 hr morphine consumption postoperatively standardized by weight, administered intravenously via a patient-controlled analgesia (PCA) pump.

Results: There was no difference between both groups in 24 hr PCA morphine consumption postoperatively (control, 0.45 ± 0.44 [mean ± SD] $mg \cdot kg^{-1}$; treatment, 0.37 ± 0.50 $mg \cdot kg^{-1}$; $P = 0.55$). No difference was found in postoperative visual analog scale pain scores, adverse events, or vital signs. In the treatment group, R = 10/22 patients did not require postoperative morphine compared with R = 6/22 in the control group ($P = 0.35$).

Conclusion: We found no effect of a femoral 3-in-1 block with ropivacaine 0.2% on postoperative analgesic consumption, compared to intra-articular instillation with ropivacaine 0.2% alone, in patients undergoing ACLR under general anesthesia.

Objectif : Vérifier l'hypothèse selon laquelle l'addition, avant l'incision, d'un blocage fémoral 3 en 1 à l'instillation intra- articulaire de ropivacaïne 0,2 % de fin d'opération, améliore le soulagement de la douleur postopératoire chez les patients qui subissent une reconstruction arthroscopique du ligament croisé antéro-externe (RLCA) sous anesthésie générale.

Méthode : Il s'agit d'un essai prospectif randomisé en double insu contre placebo concernant 44 patients qui subissent une RLCA élective en chirurgie ambulatoire. Avant l'incision, le groupe traité (n = 22) a reçu un bloc fémoral 3 en 1 de 40 ml de ropivacaïne 0,2 %, augmenté par des infiltrations des incisions latérale et antéromédiane de 20 ml de ropivacaïne 0,2 % à la fin de l'intervention. Le groupe témoin (n = 22) a reçu une solution salée à 0,9 %. Tous les patients ont reçu une instillation intra-articulaire de 30 ml de ropivacaïne 0,2 % à la fin de l'opération. La principale variable d'efficacité a été la demande de morphine postopératoire à 24 h, uniformisée selon le poids, dont l'administration intraveineuse s'est faite à l'aide d'une pompe d'analgésie contrôlée par le patient (ACP).

Résultats : La demande postopératoire de morphine ACP à 24 h n'a pas présenté de différence intergroupe (témoin, 0,45 ± 0,44 [moyenne ± écart type]$mg \cdot kg^{-1}$; traitement, 0,37 ± 0,50 $mg \cdot kg^{-1}$; $P = 0,55$), ni les seuils de douleur postopératoire, selon l'échelle visuelle analogue, les effets secondaires et les signes vitaux. Dans le groupe de traitement, 10/22 patients n'ont pas demandé de morphine postopératoire et 6/22 dans le groupe témoin ($P = 0,35$).

Conclusion : Nous n'avons pas noté d'effet du blocage fémoral 3 en 1 de ropivacaïne 0,2 % sur la demande postopératoire d'analgésique, comparé à l'instillation intra-articulaire de ropivacaïne 0,2 % seule, chez des patients qui subissent une RLCA sous anesthésie générale.

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ARTHROSCOPIC anterior cruciate ligament reconstruction (ACLR) is a common procedure that is frequently associated with considerable postoperative pain.[1,2] When managed with opioids, pain relief is often unsatisfactory, and untoward effects such as nausea, vomiting, and urinary retention delay recovery and prolong in-hospital stay.[1,3,4] Several reports indicate that postoperative pain following a variety of lower limb procedures including ACLR may be reduced by regional anesthetic approaches to the lumbar plexus and femoral nerve.[1,5,6] In a recent uncontrolled study,[7] the need for administering opioids following ACLR under general anesthesia was eliminated in 92% of patients receiving a "femoral 3-in-1 block," the inguinal paravascular approach to lumbar plexus blockade first described by Winnie *et al.* 1973.[8] No controlled study has evaluated the efficacy of a femoral 3-in-1 block for postoperative analgesia following ACLR. The recently introduced long-acting aminoamide, ropivacaine, appears to be an attractive choice for this application, due to its potential to achieve a higher sensory-motor block separation[9] at a lower level of systemic toxicity[10] as compared to bupivacaine. However, ropivacaine has not been studied in femoral 3-in-1 blockade. We conducted a randomized controlled trial to test the hypothesis that the addition of a preincisional femoral 3-in-1 block with ropivacaine 0.2%[11] (augmented by peri-incisional infiltrations of the knee) to standard intra-articular local anesthetic instillation at the end of surgery[2,12–17] improves postoperative pain control in patients undergoing ACLR under general anesthesia.

Methods

With approval of the institutional human research committee, we conducted a prospective, randomized, placebo-controlled, double-blind trial at a single centre (Vancouver Hospital & Health Sciences Centre, University of British Columbia Site). After obtaining written informed consent, 44 male or female patients (aged 19 to 45 yr and ASA physical status I) scheduled for inpatient ACLR were assigned to one of two parallel groups. Patients were excluded if there was a history of sensitivity to local anesthetics of the amide type, acetaminophen, or opioids; regular treatment with analgesics, sedatives or any other medication with central nervous system effects; suspected alcohol, drug, or medication abuse; inability to comply with study procedures; or tendency to bleed. Also excluded were women who could not rule out the possibility that they were pregnant and patients who had previously been included in this study. Patients were allocated to the groups in blocks of four using a computer generated randomization list.

All patients received a standardized general anesthetic with 0.01–0.03 $mg \cdot kg^{-1}$ midazolam *iv*, 1.5 $\mu g \cdot kg^{-1}$ fentanyl *iv* over the duration of anesthesia, 2–3 $mg \cdot kg^{-1}$ propofol *iv* as required, and nitrous oxide 70% with isoflurane 0.5–2% in oxygen through a laryngeal mask airway. Prior to surgical incision, the treatment group received a femoral 3-in-1 block with 40 ml ropivacaine 0.2% (Figure) using the classic inguinal paravascular approach described by Winnie *et al.*[8] The solution for the block was injected after correct placement of the regional block needle (22G × 2.5" insulated short bevel needle; Preferred Medical Products, Thorold, Ontario, Canada or 22G 1½" Regional Block Needle; Becton Dickinson and Company, Franklin Lakes, NJ, USA) in the fascial sheath of the femoral nerve was confirmed by eliciting quadriceps muscle twitches with a peripheral nerve stimulator (Model NS-2CA/DX, Life-Tech, Inc., Houston, TX, USA or Nerve Finder®, Regional Master Corp., Miami, FL, USA) at < 0.5 mA. All patients subsequently underwent ACLR utilizing hamstring tendon (semitendinosus and gracilis muscle) autografts with a tibial bone tunnel and "over the top" femoral placement. The surgical technique was identical for all patients. A tourniquet was used in all cases. At the end of surgery, the femoral 3-in-1 block was augmented by additional infiltration of the lateral surgical incision at the site of staple insertion over the lateral femoral condyle and the anteromedial incision at the site of the origin of the semitendinosus and gracilis tendons (which receive sensory innervation by the sciatic nerve). For these peri-incisional infiltrations, 20 ml (10 + 10 ml) ropivacaine 0.2% were administered by the surgeon. The control group received saline 0.9% instead of ropivacaine; appearance of the solutions and vials was identical for ropivacaine and saline. All 44 patients received an intra-articular instillation of the knee with 30 ml ropivacaine 0.2% at the end of surgery (Figure); no drainage tubes were inserted.

After completion of the procedure, postoperative pain was assessed in the postanesthesia care unit (PACU) using a 100 mm visual analog scale (VAS; no pain = 0 mm, worst pain imaginable = 100 mm [Biomedical Engineering, Flinders Medical Centre, Bedford Park, S.A., Australia]). When VAS scores remained ≤ 50 mm, acetaminophen 300 mg with codeine 30 mg was given (one to two tablets *po* every three to four hours as needed). At VAS scores > 50 mm,[18] or when pain relief was inadequate as judged by the patient, intravenous morphine was started, administered via a patient-controlled analgesia (PCA) pump

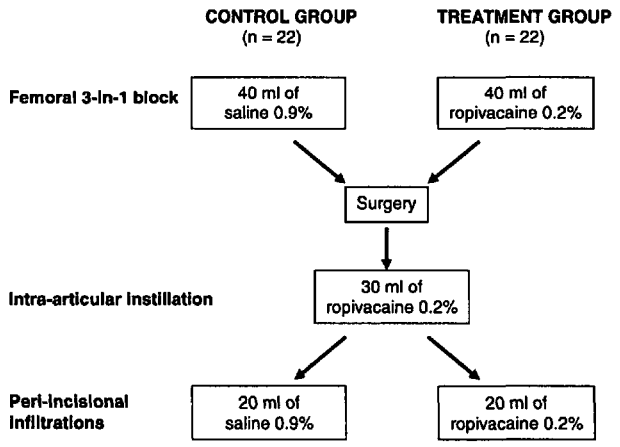

FIGURE Treatment interventions

(LifeCare® PCA Plus II Infuser Model 4100, Abbott Laboratories, North Chicago, IL, USA; loading dose [given via syringe], 2–4 mg/5 min; incremental dose, 1–3 mg; lockout time, 6–10 min; maximal dose over 4 hr, 45 mg). All patients received supplemental external cryotherapy to the knee postoperatively by way of a Cryo/Cuff™ (Aircast, Inc., Summit, NJ, USA) or ice packs.[2,15,19–21] Patients were discharged home according to normal hospital procedures when they were mentally clear and cooperative, were able to void, were afebrile and had stable vital signs, tolerated oral nutrition, had satisfactory pain control on oral analgesics, and were able to ambulate with crutches. The primary efficacy variable was postoperative PCA morphine consumption over 24 hr standardized by body weight (initial loading dose administered via syringe included). Secondary variables included postoperative consumption of acetaminophen with codeine over 24 hr, VAS pain scores at rest and following mobilization, blood pressure, heart rate, and the incidences of nausea, vomiting, pruritus, urinary retention, and orthostatic hypotension at 1, 2, 4, 6, 8, 12, 16, 20, and 24 hr following completion of surgery. The times to readiness for discharge from the PACU according to the Aldrete scoring system[22] and the times of discharge from the hospital were recorded and compared between both groups. Strict blinding of all investigators was maintained throughout the study: all data were recorded by personnel unaware of the treatment allocation and patients were not assessed for sensory or motor blockade following the block. All patients were followed up two to eight weeks after hospital discharge by telephone interview that included questioning on the occurrence of neuropraxia.

Statistical analyses were completed on an intention-to-treat basis unless specified otherwise. Morphine consumption over 24 hr, using PCA, and acetaminophen with codeine consumption over 24 hr were analyzed using analysis of variance and the Wilcoxon rank sum test for robustness. Postoperative VAS scores at rest and following mobilization were analyzed using repeated measures analysis. Categorical data were analyzed using Fisher's exact test. Blood pressure and heart rate were analyzed by repeated measures analysis after replacing values with the last value carried forward methodology. All statistical tests were two-tailed and comparisons were declared statistically significant when $P < 0.05$.

Based on the data from a previous pilot study conducted at our centre, the target sample size for the trial was projected to detect a minimum important difference of 20 mg in total morphine consumption over 24 hr between the groups. In order to have 90% power and a type I error of 5%, a sample of n = 22 valid patients per group was required, assuming equal variances and approximately normal distributions of the groups. If the assumptions of the t test on which this calculation was performed were shown not to hold, an equivalent non-parametric test would provide no less than 95% efficiency.

Results

Twenty two patients were enrolled in each of the two groups. All 44 patients were valid for intention-to-treat analysis. The male to female ratio was 13:9 in the control group and 17:5 in the treatment group. Other patient demographics were statistically similar in both groups, as were preoperative baseline vital signs and the duration of surgery (Table I). There were no differences between the groups in the doses of agents used for general anesthesia (data not shown).

No difference was found between the control group and the treatment group in PCA morphine consumption over 24 hr (standardized by body weight or expressed as total cumulative dose in mg) or acetaminophen with codeine consumption over 24 hr (Table II). More patients in the treatment group never required any PCA morphine postoperatively than in the control group (*cf.* Methods) but the difference was not statistically significant (Table III). When those patients that did not require morphine were excluded from the analysis, no difference in 24 hr morphine consumption was found between groups (Table IV). Also, there were no differences earlier in the postoperative course, e.g., at six or 12 hr following completion of surgery (data not shown).

There was no difference between groups in postoperative VAS pain scores at rest, blood pressure/heart

TABLE I Patient demographics, preoperative vital signs, and surgical data.

Group	*Age (years)*	*Weight (kg)*	*Height (cm)*	*Heart rate (min^{-1})*	*Systolic blood pressure (mmHg)*	*Diastolic blood pressure (mmHg)*	*Duration of surgery (min)*	*n*
Control	28 ± 7	74 ± 11	174 ± 7	65 ± 9	119 ± 14	75 ± 11	52 ± 13	22
Treatment	31 ± 7	78 ± 11	176 ± 8	66 ± 10	119 ± 11	76 ± 11	55 ± 13	22

Data are given as mean ± SD.
No statistically significant difference between the groups was seen for any of the variables.

TABLE II Postoperative analgesic consumption.

Group	*PCA morphine consumption over 24 hr standardized by weight (mg/kg)*	*PCA morphine consumption over 24 hr (mg)*	*Acetaminophen/ codeine consumption over 24 hr (No. of tablets)**	*n*
Control	0.45 ± 0.44	31.0 ± 28.7	6.4 ± 3.1	22
Treatment	0.37 ± 0.50	27.7 ± 38.7	7.6 ± 4.8	22

Data are given as mean ± SD; PCA = patient-controlled analgesia.
No statistically significant difference between the groups was seen for any of the variables.
*One tablet contains 300 mg of acetaminophen and 30 mg of codeine.

TABLE III Number of patients not requiring morphine postoperatively.

Group	*No morphine required*	*Morphine required*	*n*
Control	6	16	22
Treatment	10	12	22

No statistically significant difference between the groups was seen (Fisher's exact test, $P = 0.35$).

rate (not shown), incidence of nausea, vomiting, pruritus, urinary retention, or orthostatic hypotension at 1, 2, 4, 6, 8, 12, 16, 20, and 24 hr following completion of surgery. Median VAS scores at rest ranged between 20–40 mm in the control group and 22–42 mm in the treatment group. The majority of patients were mobilized on postoperative day 1 before discharge according to normal hospital procedures. As a result, the VAS scores following mobilization were inapplicable in over 80% of the cases and thus excluded from the analysis. The most common adverse events during the first 24 hr following surgery were nausea, pruritus, orthostatic hypotension, vomiting, and urinary retention (Table V). One patient in the treatment group reported prolonged postoperative anesthesia in the area of distribution of the femoral nerve on the surgical side that lasted for four days but subsided completely. There were no incidents of persistent neuropraxia. No signs of systemic local anesthetic toxicity were observed. The times to readiness for discharge from the PACU according to the Aldrete scoring system[22] were similar for both groups (control group, 19.3 ± 10.9 min; treatment group, 16.9 ± 9.7 min; n = 22; $P = 0.44$), as were the times of discharge from the hospital (control group, 21.5 ± 3.4 hr; treatment group, 23.5 ± 7.9 hr; n = 22; $P = 0.28$).

Discussion

In this study, we found no effect on postoperative morphine consumption with the addition of preincisional femoral 3-in-1 block (augmented by peri-incisional infiltrations) with ropivacaine 0.2% compared with intra-articular instillation of the knee at the end of surgery with ropivacaine 0.2% in patients undergoing hamstring tendon autograft ACLR under general anesthesia. We also observed no difference in postoperative VAS pain scores, vital signs, incidence of adverse events, or time to readiness for discharge from PACU and time to hospital discharge between the groups studied.

This is the first randomized, controlled trial to assess the efficacy of a femoral 3-in-1 block to improve postoperative pain control in ACLR, and the first report on the use of ropivacaine for this purpose. Our results harmonize with those of Tierney *et al.*,[23] who conducted a randomized controlled trial to assess the use of a femoral nerve block with 20 ml bupivacaine

0.25% in patients undergoing open ligament reconstruction of the knee and found no effect on the total *im* analgesic dose in the first 12 hr postoperatively. In a recent report, Fournier *et al.*[24] similarly observed no reduction in analgesic requirements at 24 and 48 hr following prosthetic hip surgery by a preincisional femoral 3-in-1 block with 40 ml of bupivacaine 0.5% with epinephrine 1:200,000.

In contrast to our findings is the 1984 study by Ringrose and Cross,[25] who reported a 40% reduction in *im* opioid administration in the first 24 postoperative hr following a femoral block with 20 ml bupivacaine 0.5% in patients undergoing "knee joint (anterior cruciate) reconstruction surgery". However, this trial was unblinded and patients likely received open knee ligament reconstructions utilizing bone-patellar tendon-bone autografts. In an uncontrolled study with patients undergoing both ACLR and ACLR combined with meniscal procedures, Edkin *et al.*[7] found the femoral 3-in-1 block useful for the relief of post-operative pain. In this report, 92% of patients did not receive any parenteral opioids following administration of a femoral 3-in-1 block combined with intra-articular local anesthetic injection, which is in contrast to our findings. However, aside from the fact that these observations were from an uncontrolled study, there were other major differences to our trial that render direct comparisons difficult. Firstly, the surgical techniques were different. In the study by Edkin *et al.*, middle-third patellar tendon autografts were used, whereas in our trial, the considerably less invasive technique utilizing semitendinosus and gracilis muscle tendon autografts was performed. Secondly, a different concentration, dose, and type of local anesthetic was employed. Edkin *et al.* used 2–3 $mg \cdot kg^{-1}$ bupivacaine 0.5%; in our study, 1.3–1.5 $mg \cdot kg^{-1}$ (80 mg) of ropivacaine 0.2%[11] were administered for the femoral 3-in-1 block. Thirdly, Edkin *et al.* administered the block postoperatively in the PACU, whereas it was performed prior to surgical incision in our study. Finally, different protocols for the management of postoperative pain were used. Although 92% of the patients of Edkin *et al.* were reported not to have required parenteral opioids, 75% received parenteral ketorolac and oral opioids to control postoperative pain. It is likely that the above differences contributed to differences in postoperative parenteral opioid consumption, and thus, the difference in outcome compared to our trial.

We cannot exclude the possibility that differences between the groups may have been detected had higher concentrations (e.g., 0.5% or 0.75% preparations) and higher total doses of ropivacaine been used.[26] It was noted that fewer patients in the treatment group required morphine than in the control group; although this difference was not statistically significant. Future studies are required to establish a dose-response relationship for the use of ropivacaine in femoral 3-in-1 blockade for postoperative analgesia.

It has to be emphasized, however, that all patients in this study (including those in the control group) received an intra-articular instillation with 30 ml ropivacaine 0.2% at the end of the procedure, in compliance with our standard institutional multimodal analgesic regimen. Postoperative pain following ACLR originates from a variety of anatomical sources,[27] which may include the site of the tendon cuts, the site of staple insertion, and the surgical incisions. The efficacy of intra-articular local anesthetic instillation of the knee for postoperative analgesia in ACLR is well established[2,12–17,27] and is a standard of practice at many institutions, including our centre. In the present study, no subsequent reduction in anal-

TABLE IV Postoperative morphine consumption (patients not requiring morphine excluded).

Group	*PCA morphine consumption over 24 hr standardized by weight ($mg \cdot kg^{-1}$)*	*PCA morphine consumption over 24 hr (mg)*	*n*
Control	0.62 ± 0.40	42.6 ± 25.0	16
Treatment	0.67 ± 0.51	50.8 ± 39.8	12

Data are given as mean ± SD; PCA = patient-controlled analgesia. No statistically significant difference between the groups was seen for either variable.

TABLE V Incidence of common adverse events.

Group	*Nausea*	*Pruritus*	*Orthostatic hypotension*	*Vomiting*	*Urinary retention*	*n*
Control	16	8	6	7	7	22
Treatment	13	9	8	5	2	22

Shown are the total cumulative in-hospital incidences during the first 24 hr following completion of surgery. Data are given as number of patients; each adverse event is reported only once for each patient.
No statistically significant difference between the groups was seen for any of the variables (Fisher's exact test, $P > 0.05$).

gesic requirements was observed when a femoral 3-in-1 block, augmented by additional local anesthetic infiltration of the lateral and anteromedial incisions (the sites of staple insertion and proximal cut of the semitendinosus and gracilis tendons, whose sensory supply includes sciatic fibres), was added to the intra-articular local anesthetic instillation.

Despite the fact that we observed no difference between the groups in postoperative adverse events, their incidence in the studied patient population was noteworthy; this was particularly the case for nausea. Although postanesthetic nausea cannot be easily separated from nausea specifically triggered by opiods, one may reasonably assume that the high incidence of nausea in this study is at least partially attributable to postoperative analgesic medication. Postoperative nausea and vomiting prolong in-hospital stay and increase costs. It has recently been reported that 58% of the cost associated with ACLR can be saved when in-hospital stay is shortened and this procedure is performed on an outpatient basis.[28] These findings further illustrate the need for optimization of perioperative care in ACLR.

In conclusion, our data do not support the routine addition of a preincisional femoral 3-in-1 block with ropivacaine 0.2% to standard intra-articular local anesthetic instillation of the knee for postoperative pain control in patients undergoing ACLR under general anesthesia. Pain control and prevention of adverse events following ACLR remain issues of clinical and pharmacoeconomical importance, and future studies will aid to further improve the management of these patients.

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