Combination of femoral triangle block and infiltration between the popliteal artery and the capsule of the posterior knee (iPACK) versus local infiltration analgesia for analgesia after anterior cruciate ligament reconstruction: a randomized controlled triple-blinded trial

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ABSTRACT

Background and objectives Femoral triangle block and local infiltration analgesia are two effective analgesic techniques after anterior cruciate ligament reconstruction. Recently, the iPACK block (infiltration between the popliteal artery and the capsule of the posterior knee) has been described to relieve posterior knee pain. This randomized controlled triple-blinded trial tested the hypothesis that the combination of femoral triangle block and iPACK provides superior analgesia to local infiltration analgesia after anterior cruciate ligament reconstruction.

Methods Sixty patients undergoing anterior cruciate ligament reconstruction received general anesthesia and were randomly allocated to two groups: femoral triangle block and iPACK under ultrasound guidance or local infiltration analgesia. For each group, a total of 160 mg of ropivacaine was injected. Postoperative pain treatment followed a predefined protocol with intravenous morphine patient-controlled analgesia, acetaminophen, and ibuprofen. The primary outcome was cumulative intravenous morphine consumption at 24 hours postoperatively. Secondary pain-related outcomes included pain scores (Numeric Rating Scale out of 10) measured at 2 and 24 hours postoperatively. Functional outcomes, such as range of motion and quadriceps strength, were also recorded at 24 postoperative hours, and at 4 and 8 postoperative months.

Results Cumulative intravenous morphine consumption at 24 hours postoperatively was significantly reduced in the femoral triangle block and iPACK group (femoral triangle block and iPACK: 9.7 mg (95% CI: 6.7 to 12.7); local infiltration analgesia: 17.0 mg (95% CI: 11.1 to 23.0), p=0.03). Other pain-related and functional-related outcomes were similar between groups.

Conclusions The combination of femoral triangle block and iPACK reduces intravenous morphine consumption during the first 24 hours after anterior cruciate ligament reconstruction, when compared with local infiltration analgesia, without effect on other pain-related, early, or late functional-related outcomes.

Trial registration number ClinicalTrials.gov Registry (NCT03680716).

INTRODUCTION

Regional anesthesia represents a valuable contribution to adequate pain relief after anterior cruciate ligament (ACL) reconstruction, although its contribution to early rehabilitation is unclear.[1] Several regional anesthetic techniques are available for this indication, including the femoral nerve block,[2–4] the adductor canal block,[5] the femoral triangle block,[6] or periarticular and intra-articular infiltration of the knee joint, otherwise referred to as local infiltration analgesia (LIA).[7–9] Whereas the femoral nerve block is increasingly avoided due to associated quadriceps muscle weakness, a recent randomized controlled trial of 104 patients concluded that adductor canal block and LIA were equivalent in providing postoperative analgesia after ACL reconstruction. Furthermore, no differences in functional outcomes measured within 48 postoperative hours or at 4 and 8 postoperative months were found between these interventions.[5] Of note, while both the adductor canal and femoral triangle blocks include the saphenous nerve, the femoral triangle block (FTB) has the additional advantage of blocking the medial retinacular nerve, which is the terminal branch to the medial vastus muscle, and which is an additional contributor to nociceptive conduction after knee surgery.[6]

Recently, a novel ultrasound-guided regional technique has been described, called iPACK. This block consists of local anesthetic infiltration in the space between the popliteal artery and the capsule of the knee, with the goal of providing analgesia for the posterior aspect of the knee.[10] Indeed, a cadaver study demonstrated that the iPACK technique consistently results in the diffusion of dye towards the inferior branches of the tibial nerve and the genicular branch of the obturator nerve.[11] While several publications reported enthusiastic analgesic results with this technique in patients undergoing

Table 1 Patient characteristics

	FTB and iPACK group	LIA group	P value*†
Sample size, n	28	28	
Sex, n (%)			0.57
Male	20 (71)	18 (64)	
Female	8 (29)	10 (36)	
Mean age (95% CI) in years	32 (28 to 37)	35 (30 to 40)	0.45
Mean height (95% CI) in cm	176 (173 to 179)	173 (170 to 177)	0.17
Mean weight (95% CI) in kg	78 (73 to 84)	74 (70 to 78)	0.22
Mean body mass index (95% CI) in kg/m^2	25 (24 to 26)	25 (23 to 26)	0.67
ASA, n (%)			0.37
I	22 (79)	19 (68)	
II	6 (21)	9 (32)	
Mean duration of surgery (95% CI) in min	163 (145 to 180)	172 (154 to 191)	0.45

*P value compares FTB and iPACK versus LIA.
†Student's t-test used to compare means and Fisher's exact test used to compare proportions.
ASA, American Society of Anesthesiologists; FTB, femoral triangle block; iPACK, infiltration between popliteal artery and capsule of the knee; LIA, local infiltration analgesia.

total knee arthroplasty,[12 13] none investigated the impact on functional outcomes.

Given that the iPACK might confer additional analgesia, when combined with FTB, and as there are no data in patients undergoing ACL reconstruction, we conducted this randomized controlled triple-blinded trial to test the hypothesis that the combination of FTB and iPACK provides superior analgesia to LIA after ACL reconstruction. Furthermore, we include particular attention to secondary outcomes of early and late functional-related effects.

METHODS

Recruitment and randomization

In reporting this investigation, we followed the Consolidated Standards of Reporting Trials guidelines.[14] All patients 18 years or older, who were scheduled to undergo elective primary ACL reconstruction between October 2018 and March 2020 at the University Hospital of Lausanne, were eligible to participate. Exclusion criteria were existing femoral nerve deficit or pre-existing peripheral neuropathy, chronic pain diagnosis, pregnancy, or identified contraindications to peripheral nerve block (eg, local anesthetic allergy, coagulopathy, or infection at the block site). After appropriate written and informed consent, subjects were randomly allocated on the day of surgery to either the FTB and iPACK group or the LIA group. This process employed a computer-generated randomization table in blocks of 10. Group assignments were concealed within a sealed opaque envelope.

Intraoperative procedure

All patients received a standard general anesthetic including routine application of physiologic monitors. Anesthesia was induced with sufentanil 0.1 μg/kg intravenously and propofol 2–4 mg/kg intravenously. Endotracheal intubation was then performed following a dose of rocuronium 0.6 mg/kg intravenously. Anesthesia was maintained by application of 1.6%–2.4% inhaled sevoflurane in a 40:60 mixture of oxygen and air. Positive pressure ventilation was applied, with ventilation parameters set to maintain an end-tidal CO_2 of 35–40 mm Hg. Sufentanil 2.5–5.0 µg intravenously was given to treat blood pressure or heart rate increases of more than 15% above preinduction values. Our routine local practice includes the administration of magnesium sulfate and all patients received 50 mg/kg intravenously[15] in addition to dexamethasone 0.15 mg/kg intravenously,[16] at the beginning of surgery. Ketorolac 30 mg, acetaminophen 1 g, and ondansetron 4 mg were provided intravenously as components of multimodal analgesia and antiemetic prophylaxis at the end of the procedure. All surgical operations were performed with a tourniquet (pressure at 280 mm Hg) by two surgeons (RM and THNN) who harvested gracilis and semitendinosis hamstring tendons for a four-strand single bundle ACL reconstruction. In addition to arthroscopic portals, a two-incision approach was used to drill tunnels for tibial and femoral fixation of the graft, as previously described.[5] A modified Lemaire procedure was performed for extra-articular tenodesis of the anterolateral complex in all cases as follows. Through the lateral approach used for the femoral tunnel, a strip (8×60 mm) of the iliotibial band was incised originating from Gerdy's tubercle and proximally detached. The graft was then passed under the fibular collateral ligament and fixed on the femur 10 mm proximal and 10 mm posterior to the lateral epicondyle using a non-absorbable anchor. Concomitant meniscal resection or repair was undertaken when necessary. Repair was performed by an inside-out or outside-in technique, through a separate 5 cm long posteromedial or posterolateral approach. Prior to extubation, muscle relaxation was antagonized with neostigmine 50 µg/kg and glycopyrrolate 5–10 µg/kg.

Regional procedures

After induction, an experienced staff regional anesthesiologist, or a directly supervised regional anesthesia fellow, performed the FTB and iPACK under ultrasound guidance, for patients allocated to this group. First, the FTB was performed following previously published descriptions[17]: the mid-thigh site was identified, defined as the midpoint between the anterior superior iliac spine and the base of the patella, and was prepared with a solution of chlorhexidine 2% in isopropyl alcohol 70%. Under sterile conditions, a high-frequency linear array transducer (18-6 MHz, HF Linear Array 8870, BK Ultrasound, Peabody, Massachusetts, USA) was placed on the medial, mid-thigh to permit visualization of the superficial femoral artery in short axis. A 21-gage 50 mm insulated facet tip needle (SonoLong NanoLine cannula; Pajunk, Geisingen, Germany) was then inserted in-plane with the ultrasound beam, from a lateral to medial direction. The needle tip was advanced under direct ultrasound guidance to the superolateral corner of the artery, just below the sartorius muscle. Given that the saphenous nerve may be difficult to identify, the needle was targeted to the triangular hyperechoic region lateral to the artery, defined by the sartorius muscle superficially, and the vastus medialis muscle laterally.[5] A small amount (1–2 mL) of dextrose 5% was used for needle tip hydrolocation at the discretion of the operator. Once the needle tip was satisfactorily positioned, 20 mL of ropivacaine 0.5% was injected, in slow 5 mL increments, with intermittent aspiration to prevent intravascular injection. Adequate spread of local anesthetics around the saphenous nerve was observed in a caudocephalad direction. The iPACK was then performed on a bent knee following sterilization of the lower third of the lateral and posterior thigh. The probe was placed in a transverse position proximal to the popliteal crease to visualize the popliteal artery in short axis and a 21-gage 100 mm insulated facet tip needle (SonoLong NanoLine

Table 2 Pain-related outcomes

	FTB and iPACK group	LIA group	P value*†
2 postoperative hours in PACU			
Mean resting pain score (95% CI) in NRS	1.7 (1.1 to 2.3)	1.9 (1.3 to 2.4)	0.69
Mean i.v. morphine consumption (95% CI) in mg	4.4 (2.9 to 6.0)	4.9 (3.4 to 6.5)	0.64
Presence of PONV, n (%)			0.29
Yes	3 (11)	1 (4)	
No	25 (89)	27 (96)	
24 postoperative hours			
Mean resting pain score (95% CI) in NRS	1.3 (0.9 to 1.7)	1.3 (0.7 to 2.0)	0.92
Mean dynamic pain score (95% CI) in NRS	3.2 (2.4 to 3.9)	3.7 (2.8 to 4.6)	0.38
Mean i.v. morphine consumption between 2 and 24 postoperative hours (95% CI) in mg	5.3 (3.1 to 7.5)	12.1 (6.9 to 17.2)	0.02
Presence of PONV, n (%)			0.67
Yes	3 (11)	2 (7)	
No	25 (89)	26 (93)	

*P value compares FTB and iPACK versus LIA.
†Student's t-test used to compare means and Fisher's exact test used to compare proportions.
FTB, femoral triangle block; iPACK, infiltration between popliteal artery and capsule of the knee; i.v., intravenous; LIA, local infiltration analgesia; NRS, Numeric Rating Scale from 0 to 10; PACU, postanesthetic care unit; PONV, postoperative nausea and vomiting.

cannula; Pajunk, Geisingen, Germany) was inserted in-plane with the ultrasound beam, in a lateral to medial direction, between the vessels and the posterior capsule. Thirty mL of ropivacaine 0.2% was injected in the space between the popliteal artery and the posterior capsule of the knee under ultrasound guidance, in 5 mL increments, while simultaneously withdrawing the needle slowly.[12] The distribution of local anesthetic was continuously observed superficial to the posterior capsule.

For patients allocated to the LIA group, the surgeon proceeded with periarticular infiltration of local anesthetic at the end of surgery, following a previously described procedure.[5] Briefly, 80 mL of ropivacaine 0.2% was divided and injected in the empty space created after harvest of the gracilis and semitendinosis tendons, in the iliotibial band through the surgical exposure used for femoral tunnel drilling and for extra-articular tenodesis and in the subcutaneous tissue. Concentrations and volumes of local anesthetics were chosen for regional blocks and LIA so that patients of both groups received an equal total mass of ropivacaine (160 mg).

The patients, research assistant and physiotherapist collecting the data, as well as the statistician, were all blinded to group allocation.

Postoperative procedure

After surgery, patients were brought to phase I recovery. Patients were provided intravenous patient-controlled analgesia (PCA) of morphine with boluses of 2 mg available every 10 min and were instructed on the use of the PCA device. All patients received our institutional standard multimodal analgesic regimen of acetaminophen 1 g every 6 hours, and ibuprofen 400 mg every 8 hours. Antiemetic medications on the ward included ondansetron 4 mg intravenously and metoclopramide 10 mg intravenously as needed. In the morning of postoperative day 2, the intravenous PCA was discontinued.

Outcomes

The primary outcome was intravenous morphine consumption at 24 postoperative hours. Secondary outcomes were divided into pain-related, and early and late functional-related outcomes. Pain-related outcomes included intravenous morphine consumption at 2 postoperative hours in the postanesthetic care unit and between 2 and 24 postoperative hours; resting pain scores (Numeric Rating Scale (NRS), 0–10) at 2 and 24 postoperative hours; dynamic pain scores (NRS, 0–10) at 24 postoperative hours; and the incidences of postoperative nausea and vomiting, at 2 and 24 postoperative hours. Early functional-related outcomes were walking distance (m), range of motion (degrees) and quadriceps strength (ordinal scale of 1–5, with 5 being the maximal developed strength compared with the opposite side), measured at 24 postoperative hours. Late functional-related outcomes were range of motion (degrees), concentric quadriceps strength (Limb Symmetry Index or LSI, calculated as the mean value of the involved limb divided by the mean value of the uninvolved limb, expressed in percentage), concentric hamstring strength (LSI), Y balance test (LSI), Anterior Cruciate Ligament Return to Sport After Injury Scale, and the International Knee Documentation Committee Scale score measured at 4 and 8 postoperative months; these are the same functional outcomes as reported in our previous publication.[5] Finally, any procedure-related complications such as hematoma, infection, persistent new paresthesia or new hypoesthesia, neuropathic pain, weakness in the leg, or signs of chondrolysis were sought during the postoperative surgical visits.

Statistical analysis

Based on our previous publication,[5] the mean cumulative consumption of intravenous morphine at 24 postoperative hours was 17 mg with an SD of 8 mg for patients who received LIA. Assuming a 40% decrease in the FTB and iPACK group, an alpha error of 0.05 and a power of 80%, we calculated that 21 patients would be required for each group (total 42) in order to detect

Table 3 Early functional-related outcomes at 24 postoperative hours

	FTB and iPACK group	LIA group	P value*†
Mean walking distance (95% CI) in meters	64 (57 to 71)	73 (65 to 81)	0.10
Mean range of motion in flexion (95% CI) in degrees	77 (67 to 86)	74 (66 to 82)	0.64
Mean quadriceps muscle strength (95% CI) in ordinal scale, 1–5	2.7 (2.5 to 2.9)	2.8 (2.6 to 3.0)	0.59

*P value compares FTB and iPACK versus LIA.
†Student's t-test used to compare means.
FTB, femoral triangle block; iPACK, infiltration between popliteal artery and capsule of the knee; LIA, local infiltration analgesia.

Table 4 Late functional-related outcomes

	FTB and iPACK group	LIA group	P value*†
4 postoperative months			
Mean range of motion in flexion (95% CI) in degrees	133 (129 to 136)	126 (114 to 138)	0.28
Mean concentric quadriceps strength (95% CI) in LSI, %	64 (57 to 72)	69 (64 to 75)	0.29
Mean concentric hamstring strength (95% CI) in LSI, %	77 (68 to 85)	73 (67 to 79)	0.47
Mean Y balance test (95% CI) in LSI, %	96 (93 to 99)	96 (93 to 100)	0.90
Mean ACL-RSI Scale (95% CI)	57 (47 to 67)	54 (45 to 63)	0.71
Mean IKDC score (95% CI)	62 (55 to 69)	61 (55 to 67)	0.77
8 postoperative months			
Mean range of motion in flexion (95% CI) in degrees	133 (127 to 139)	126 (116 to 135)	0.16
Mean concentric quadriceps strength (95% CI) in LSI, %	86 (77 to 95)	81 (72 to 89)	0.36
Mean concentric hamstring strength (95% CI) in LSI, %	89 (82 to 96)	87 (80 to 94)	0.72
Mean Y balance test (95% CI) in LSI, %	99 (94 to 103)	99 (96 to 103)	0.78
Mean ACL-RSI Scale (95% CI)	58 (34 to 81)	62 (45 to 78)	0.77
Mean IKDC score (95% CI)	65 (48 to 83)	68 (58 to 77)	0.79

LSI is calculated as the mean value of the involved limb divided by the mean value of the uninvolved limb, with the result multiplied by 100.
*P value compares FTB and iPACK versus LIA.
†Student's t-test used to compare means.
ACL-RSI Scale, Anterior Cruciate Ligament Return to Sport After Injury Scale; FTB, femoral triangle block; IKDC, International Knee Documentation Committee Scale; iPACK, infiltration between popliteal artery and capsule of the knee; LIA, local infiltration analgesia; LSI, Limb Symmetry Index.

a difference. Allowing for a 40% drop-out rate, we planned to recruit a total of 60 subjects.

Data were analysed on an intention-to-treat basis. Categorical variables are presented as frequencies, ordinal variables as medians and IQR and continuous variables as mean values with 95% CIs. Continuous parametric and non-parametric data were compared using the Student's t-test and Mann-Whitney U test, respectively. Categorical and dichotomous data were compared using the Fisher's exact test or Pearson test as appropriate. Significance was considered at $p<0.05$ based on a two-tailed probability. Statistical analysis was performed using the JMP V.14 statistical package (SAS Institute, Cary, North Carolina, USA).

RESULTS

Sixty patients were recruited and 56 completed the protocol to measurement of the primary outcome. Figure 1 describes the flow of patients during the trial and table 1 presents patient characteristics.

Cumulative intravenous morphine consumption at 24 postoperative hours was significantly reduced in the FTB and iPACK group (FTB and iPACK group: 9.7 mg (95% CI: 6.7 to 12.7); LIA group: 17.0 mg (95% CI: 11.1 to 23.0); p=0.03). The secondary pain-related outcomes were similar between groups (table 2), with the exception of intravenous morphine consumption between 2 and 24 postoperative hours, which favored the FTB and iPACK group.

Regarding the early (table 3) and late functional-related outcomes (table 4), no differences were found between groups. Finally, no hematoma, infection, persistent new paresthesia or new hypoesthesia, neuropathic pain, or leg weakness was reported by patients at the post-surgical follow-up visits. Similarly, no clinical evidence of chondrolysis was observed in any patient.

DISCUSSION

Based on 56 patients, this randomized controlled triple-blinded trial suggests that, in the setting of multimodal analgesia, the combination of FTB and iPACK reduces intravenous morphine consumption during the first 24 hours after ACL reconstruction, when compared with LIA, without effect on the other pain-related or early and late functional-related outcomes. It is noteworthy that the analgesic efficacy was identified between the 2nd and 24th postoperative hours, and not during the first 2 postoperative hours when patients reside in the postanesthetic care unit at our institution. Nurses in the postanesthetic care unit were indeed instructed to direct patients to self-administer PCA based on analgesic need. However, we cannot exclude that some administered doses based on established habits during patient recovery, which could explain the identical morphine consumption observed at 2 postoperative hours.

The lack of effect from the block combination on the other pain-related outcomes might be related to the standard multimodal analgesia regimen that we prescribed both intraoperatively and postoperatively. However, we consider this protocol to best represent the potential impact of these interventions in a real-world setting. While some physicians may consider the mean intravenous morphine difference between groups of 7 mg to be clinically negligible, we contend that there is significance in any opioid reduction.[18] In the setting of the current opioid crisis, we believe that interventions to further limit opiates consumption may represent benefits beyond the immediate surgical period,[19 20] particularly following report of surgery as a potential risk factor for chronic opioid use.[21] The combination of FTB and iPACK can therefore be argued to represent one option for adopting an opioid-sparing strategy.[22]

While never previously investigated in patients undergoing ACL reconstruction, the addition of iPACK to a block of the saphenous nerve in the adductor canal has been demonstrated to be an effective analgesic strategy in patients undergoing total knee arthroplasty,[13] compared with LIA.[12] Unfortunately, none of the prior trials examined functional outcomes beyond the immediate postoperative period after knee arthroplasty. We suggest that this represents an area of needed study to better understand the overall impact of these interventions. Indeed, we believe it is of importance to evaluate the effect of the different regional techniques on function in both the immediate and late postoperative period. In this trial, functional outcomes were equivalent between groups irrespective of analgesic technique, although the study was not designed to explore primarily these outcomes. Further, procedure times of the different interventions

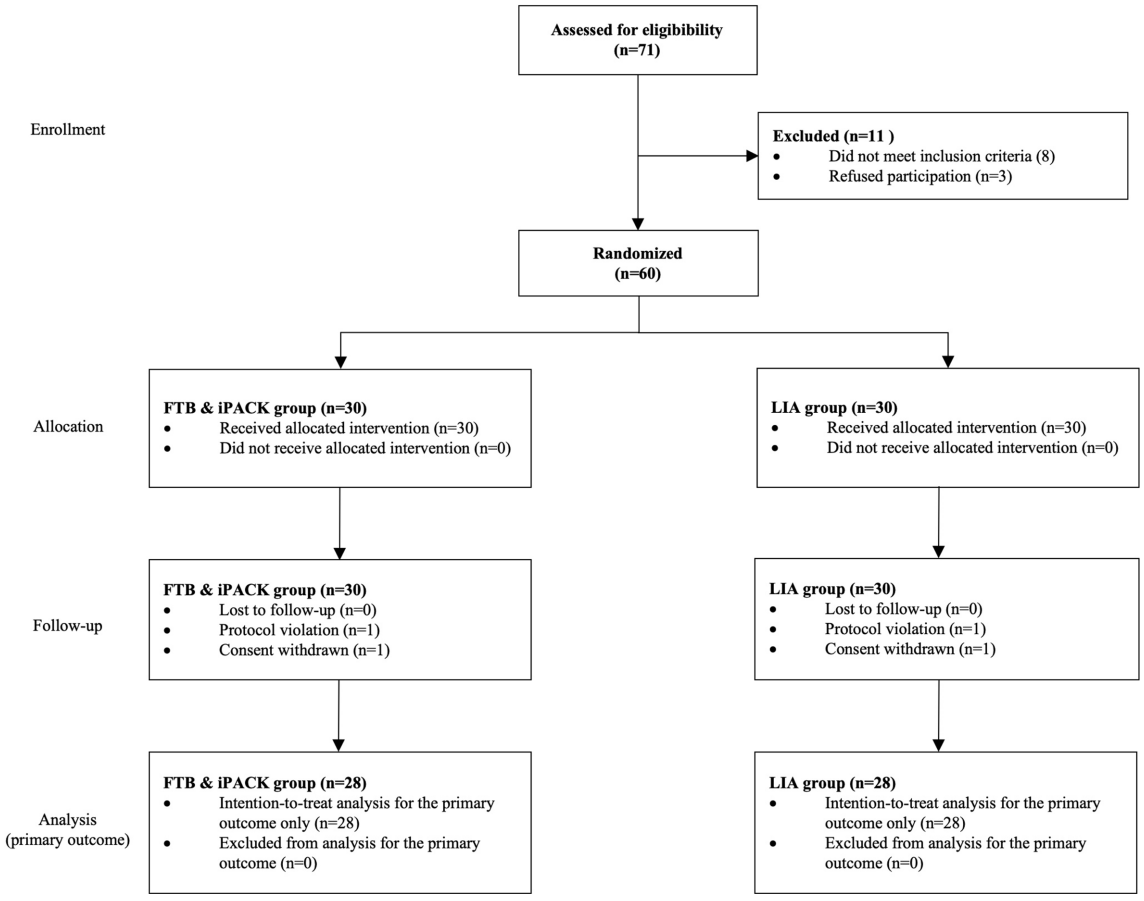

Figure 1 Flow of patients through trial. FTB, femoral triangle block; iPACK, infiltration between popliteal artery and capsule of the knee; LIA, local infiltration analgesia.

were not measured during our investigation, and one might argue that performing two regional blocks represents a practical drawback in a busy operating theater without parallel processing facilities.[1 23] While these differences in anesthetic and surgical times could be a topic of further clinical investigation, we believe that the benefit patients derive from improved analgesic care is worth this potential drawback in order to optimize comfort and postoperative recovery.

There may be debate among clinicians regarding the performance of LIA and some surgeons may argue that the technique employed here represents incomplete infiltration. In this study, our team elected to exclude intra-articular injection due to the theoretical risk of chondrolysis. It is noteworthy that this outcome has been reported only with continuous infusions of long-acting local anesthetics but that it was significant enough to necessitate partial knee arthroplasty in a case series of young patients.[24] Another potential limitation is that no adjuncts were combined with the LIA solution, as may be employed in some clinical practice. However, in the absence of established evidence for both the mechanism of action and a consensus on the types and doses of the adjuncts,[7] we elected to compare homogeneous solutions with an identical total mass of local anesthetic. However, some of these medications were administered as part of our routine, institutional multimodal analgesic regimen.[25 26] Further, while some anesthesiologists might choose remifentanil for intraoperative analgesia, we favored the administration of a longer acting opioid such as sufentanil in order to avoid the potential risk of secondary hyperalgesia which might contribute to increased postoperative opioid consumption.[19 20] Regarding our methodology, we elected not to blind the surgeons and the anesthesiologists performing the blocks due to logistical challenges with placebo blocks and our pharmacy; that said, we believe that the blinding of the patients, research assistant, physiotherapist and statistician was enough to minimize performance and detection biases. We also highlight two open questions that our protocol did not address, and which may warrant additional investigation. First, the potential addition of the iPACK block to LIA has the theoretical potential to improve the posterior coverage of this technique and could be compared with the FTB and iPACK technique from our investigation. Second, innervation of the gracilis and semitendinosis muscles by the anterior branch of the obturator and tibial nerves, respectively, might represent an additional target to optimize coverage of this surgical area. In particular, the addition of a block for the anterior branch of the obturator nerve might be considered in any future investigation to optimize this technique.

CONCLUSIONS

The combination of FTB and iPACK reduces intravenous morphine consumption during the first 24 hours after ACL reconstruction, when compared with LIA, without effect on other pain-related or early and late functional-related outcomes. This combination of blocks presents a potential option for an opioid-sparing analgesic strategy.

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Patient consent for publication Not required.

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