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Original article

Peri-articular local infiltration analgesia versus femoral nerve block for postoperative pain control following anterior cruciate ligament reconstruction: Prospective, comparative, non-inferiority study

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ABSTRACT

Introduction: Femoral nerve block (FNB) is considered as a major advance in anterior cruciate ligament (ACL) reconstruction as it reduces the need for parenteral opioids. However, the incidence of transient or even permanent neurological deficits due to the FNB is estimated at 1.94% after knee surgery. The primary objective of this study was to compare local infiltration analgesia (LIA) to FNB during ACL reconstruction procedures. The study hypothesis was that LIA was not less effective than FNB on early postoperative pain.

Patients and methods: A retrospective analysis of data collected prospectively in the FAST cohort included a series of continuous patients who underwent primary repair for isolated ACL with a hamstring graft in 2013–2014. Changes in our anesthesia practices over time allowed us to form three successive groups: Group 1 – FNB, Group 2 – FNB + LIA, Group 3 – LIA only. Ultrasound-guided FNB was done pre-operatively. The LIA was done at the end of the procedure by the surgeon with systematic infiltration of all skin incisions and the hamstring donor site; no intra-articular injections were performed. The primary endpoint was the average early postoperative pain (Days 0–3) described by the patient on a visual analogue scale (0–10). Sample size calculation pointed to 36 subjects being needed per group for a non-inferiority study.

Results: The study involved 126 patients: G1 = 42, G2 = 38, G3 = 46. The patients were comparable at enrolment. The average early postoperative pain levels were 3.1 ± 2.4, 2.8 ± 2.0 and 2.5 ± 2.2, respectively ($P = 0.66$). A trend toward higher intake of tramadol was noted in the LIA group on D0 to D3, with a significant trend test on Day 1 ($P = 0.03$) and Day 2 ($P = 0.02$).

Conclusion: After reconstruction of isolated ACL tears with a hamstring graft, FNB is not more effective than LIA on patients' early postoperative pain. Patients who received a FNB consumed significantly less opioid-like analgesics.

Level of evidence: III – Prospective, comparative, non-randomized study.

1. Introduction

Anterior cruciate ligament (ACL) reconstruction is now mainly performed on an outpatient basis [1–3]. Multimodal analgesia consists of combining analgesic drugs and methods that have different but complementary actions, through additive or even synergistic interactions. The main objectives are early rehabilitation and reduction of chronic postoperative pain [4].

In this indication, femoral nerve block (FNB) is considered as a major advance; it is more effective than placebo [5] and reduces the need for parental opioids [6], which is an advantage for patients allergic to morphine. However, recent studies have found no proof of its effectiveness compared to other modes of analgesia [7,8]. In the USA, a survey of trends and demographics of patients undergoing ACL reconstruction found a significant increase in the percentage of patients operated under FNB, from 2% in 2004 to 8.3% in 2009 ($P < 0.001$) [9].

Many studies have reported a risk of nerve damage due to FNB, either due to direct trauma or neurotoxicity of the injected anesthetic agent. The incidence of transient or even permanent neurological deficits due to the FNB is estimated at 1.94% after knee surgery [10]. Luo et al. [11] found that FNB is associated with persistent strength deficits at 6 months after ACL reconstruction in pediatric and adolescent patients.

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A randomized, comparative study of 50 patients found no difference in the postoperative pain levels (4 h and morning of Day 1) after ACL reconstruction with bone-patellar tendon-bone graft between the FNB group and the group receiving an intra-articular injection of bupivacaine combined with oral analgesic agents [12]. A randomized, comparative study was performed by Kristensen et al. [13] with 60 patients who underwent ACL reconstruction with a hamstring graft: 30 received a FNB and 30 received local infiltration analgesia (LIA). This anesthetic procedure was combined in all patients with intra-articular injection of ropivacaine and epinephrine 2 min before the surgery. No significant difference in pain levels was found between the two groups at 0, 3, 24 and 48 h. Only a trend toward lower opioid consumption was noted in the FNB group.

The primary objective of our study was to compare LIA to FNB during ACL reconstruction using a hamstring graft. The study hypothesis was that LIA was not less effective than FNB on early postoperative pain.

2. Materials and methods

A prospective, longitudinal, single-center cohort study (French Prospective Anterior Cruciate Ligament Reconstruction Cohort Study (FAST), ClinicalTrials.gov Identifier: NCT02511158) was initiated in 2012 that included all the patients operated by four senior surgeons to repair an ACL tear. A comparative study based on a retrospective analysis of prospectively collected data was carried out. This study was approved by a national research ethics committee (Comité de Protection des Personnes IDF VI) and patient consent was collected.

This study included a continuous series of patients operated in 2013–2014 on an outpatient basis for primary reconstruction of an isolated ACL tear using a hamstring tendon graft. Excluded were patients operated during conventional hospitalization, revision surgeries, ACL tears associated with lateral collateral or posterior cruciate ligament tears, or reconstruction procedures done with the patellar tendon. Three successive groups were made up according to how the anesthetic procedures at our surgery center evolved over time: (1) FNB, (2) FNB + LIA and (3) LIA only.

2.1. Surgical technique

The repairs were performed arthroscopically using a semitendinosus and gracilis tendon graft (STG) or semitendinosus only (ST) [14], depending on surgeon preference.

2.2. Anesthetic protocol

The surgery was performed under spinal anesthesia or under general anesthesia if the patient refused spinal anesthesia.

Spinal anesthesia was carried out in the induction room with a conical 27G needle, either in lateral decubitus by slow injection of 2.5–3.5 ml hyperbaric bupivacaine 0.5%, or in a seated position with an injection of 3–4 ml of ropivacaine 0.5%. Patients were returned to the outpatient area 30–60 min after the surgical procedure while a sensory block of the surgical site was still in place.

Patients undergoing general anesthesia were not premedicated. Induction was carried out with propofol 2–3 mg/kg, sufentanil 0.2–0.3 μg/kg and atracurium besylate 0.5 mg/kg. Anesthesia was maintained with inhaled sevoflurane (1 MAC) in a 50/50 mixture of O_2/N_2O. Prophylactic anti-emetic treatment (dexamethasone 8 mg and ondansetron 4 mg) and analgesics (paracetamol 1 g and ketoprofen 100 mg if non-steroidal anti-inflammatory drugs are not contraindicated) were administered intravenously in all patients.

In the post-anesthesia care unit (PACU), morphine titration was performed if the patient had notable postoperative pain (VAS > 3/10). Patients were returned to the outpatient area once the modified Aldrete post-anesthetic recovery score was appropriate [15].

2.2.1. Femoral nerve block

The FNB was done before the surgical procedure by a senior anesthesiologist in the induction room with ultrasound guidance using 20 ml of ropivacain 0.475%.

2.2.2. Local infiltration anesthesia

LIA was performed toward the end of the procedure by the surgeon, before the incisions were closed. Three to four ampoules of 20 ml ropivacaine 2 mg/ml were used (depending on patient weight), with infiltration of all the skin incisions (1–2 ampoules) and the hamstring donor site (2 ampoules) in the medial compartment of the hamstring muscles. No intra-articular injections were done.

2.3. Analgesia protocol

The oral postoperative analgesia protocol was the same for all three groups. It was initiated immediately after the patient returned to the outpatient area: paracetamol 825 mg × 4/day, tramadol 37.5 mg × 4/day and naproxen 550 mg × 2/day combined with omeprazole 20 mg/day. A single dose of pregabalin (150 mg if patient > 75 kg and 75 mg if patient < 75 kg) was prescribed to every patient on the evening of the procedure. Morphine was not prescribed.

2.4. Endpoints

The primary endpoint was the mean intensity of early postoperative knee pain (D0 to D3) on a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worse imaginable pain). Secondary endpoints in the early postoperative period were waking up on the night of the procedure because of pain (yes/no), tramadol intake (yes/no) on D0 (evening and night) to D3, and signs of postoperative discomfort (nausea/vomiting, vertigo, malaise, anxiety, stomach pain – yes/no) between D0 and D3. At 6 months' follow-up, patients were invited to fill out the subjective IKDC [16] and KOOS [17] questionnaires and to indicate their overall level of satisfaction (very satisfied, satisfied, somewhat satisfied, not satisfied). The self-administered questionnaires were completed online by the patient using WebSurvey software.

2.5. Statistical analysis

The statistical analysis was performed with STATA v10 software. Sample size calculation was based on an alpha risk of 0.05, power of 0.80 and expected difference in early postoperative pain between the FNB and LIA groups of 1/10 with a standard deviation of 1.5/10, which corresponds to non-inferiority margins of −0.5 to 2.5/10. The number of patients needed per group was 36. The normality of the distributions was verified with the Shapiro–Wilk test and the homogeneity of variances with the Bartlett test. Quantitative variables were tested with Student's *t*-test; an analysis of variance (ANOVA) was used to perform multiple comparisons of the averages between the three groups. Qualitative variables were tested with the Chi-square test; a Cochran-Armitage trend test was used to look for changes (increase or decrease) between groups. The significance threshold was set at 0.05.