Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jor

Original Article

Continuous intraarticular and periarticular levobupivacaine for management of pain relief after total knee arthroplasty: A prospective randomized, double-blind pilot study

A. Di Francesco [a], S. Flamini [a], R. Pizzoferrato [a], P. Fusco [b], A. Paglia [c,*]

[a] Department of Orthopaedic Surgery, San Salvatore Hospital, via Vetoio, N° 1, 67100 L'Aquila, Italy
[b] Department of Anesthesiology, San Salvatore Hospital, via Vetoio, N° 1, 67100 L'Aquila, Italy
[c] University of Study L'Aquila, Department of Orthopaedic Surgery, San Salvatore Hospital, via Vetoio, N° 1, 67100 L'Aquila, Italy

ARTICLE INFO

Article history:
Received 28 October 2015
Accepted 15 February 2016
Available online 25 March 2016

Keywords:
Pain-control infusion pumps (PCIP)
Levobupivacaine
Postoperative outcomes
Total knee arthroplasty

ABSTRACT

Background: Total knee arthroplasty (TKA) can result in major postoperative pain which can impact the recovery and rehabilitation of patients and for this reason the use of a pain-control infusion pumps (PCIP) enhances analgesia for TKA.
Purpose: To investigate whether a PCIP of levobupivacaine would reduce pain in patients following TKA.
Methods: This was a prospective, randomized, controlled study conducted in 55 patients. Criteria for participation were unilateral TKA for osteoarthritis and no allergies to levobupivacaine. The primary outcomes measured were postoperative pain intensity on Visual Analogue Scale (VAS) score measured at 24 h and 48 h. Other measures included amount of narcotics, presence of adverse events, and length of hospital stay.
Results: PCIP-treated patients ($n = 28$) showed significant reductions in VAS score at any time *versus* control ($p < 0.01$). Amount of narcotics, presence of adverse events, and length of hospital stay were significantly less with the PCIP *versus* control (each $p < 0.01$).
Conclusion: The use of a mix of levobupivacaina, ketoral-trometamina, and adrenalin provides a safe and effective means in post-operative pain relief in patients undergoing TKA.
Level of evidence: Level II therapeutic study.

1. Introduction

Orthopedic surgery is reportedly among the most painful surgical procedures.[5] Surgical damage following major orthopedic surgery often involves a large, deep incision with considerable tissue dissection and muscle, bone, and vascular exposure.

Total knee arthroplasty (TKA) is billed as a pain relieving procedure, but patients experience immense discomfort in the

* Corresponding author.
E-mail address: a_paglia@live.it (A. Paglia).
http://dx.doi.org/10.1016/j.jor.2016.02.003

immediate postoperative period to attain this benefit. High postoperative pain levels decrease knee range of motion, increase narcotic analgesic use, and increase hospital length of stay.[8]

The growing trend toward quicker recovery following orthopedic procedures has stimulated the development of a variety of techniques focused on improving postoperative pain management. Postoperative pain relief after TKA can be achieved by a variety of techniques such as intravenous analgesia, epidural analgesia, and peripheral nerve block techniques.

Hoenecke et al.[7] found that postoperative pain was decreased (4.0 *versus* 2.7 on a scale of 0–10) and narcotic use was reduced by 37% after ACL reconstruction using a continuous, 48 h intraarticular infusion of bupivacaine. Knee range of motion (100° *versus* 70° at discharge) and hospital stay (7 days *versus* 9 days) have also been shown to improve with continuous infusions of ropivacaine and morphine in a non-randomized trial of primary total knee replacements.[12]

There is a paucity of literature on continuous intraarticular bupivacaine infusion in the primary TKA population, with no published randomized controlled trials. We chose to conduct a randomized controlled trial (RCT) pilot study to assess the efficacy of a 48-h continuous infusion of intraarticular levobupivacaine *versus* placebo in decreasing morphine consumption and postoperative pain levels following primary TKA.

The aim of this study was to evaluate the efficacy of intra- and extraarticular anesthetic infusion in patients undergoing TKA by determining postoperative (1) pain, (2) narcotic consumption, and (3) leg of hospital stay.

2. Materials and methods

This was a prospective, randomized, controlled trial conducted in 57 patients. All procedures took place at the same institution, San Salvatore Hospital L'Aquila, and were performed using the same standard surgical procedure. Criteria for participation were unilateral TKA for osteoarthritis and a preoperative hemoglobin level >13 g/dL. Patients with inflammatory arthritis, allergies to local anesthetic, and metals were excluded from the study. The study was approved by the local ethics committee and conducted according to the Declaration of Helsinki; the patients gave their informed consent prior to their inclusion. Between January 2010 and January 2012, 57 consecutive patients undergoing elective primary TKR for osteoarthritis at San Salvatore Hospital L'Aquila who met the inclusion criteria were enrolled. The sample size was calculated by a power analysis and participants were allocated to treatment group by the surgeon, using a computer-generated list of random numbers. The study dataset was derived from a randomized, double-blind study with approval of the local ethics committee and patients were followed up according to the pre-defined study protocol. The trial is registered at Hospital S. Salvatore L'Aquila (BCG:2656), and full details of the trial protocol can be found in the Department of Orthopaedic Surgery, San Salvatore Hospital, *via* Vetoio, N°1, 67100 L'Aquila, Italy.

We tested the hypothesis that the application of pain pump with a multihole catheter 19 Ga (length 15 cm) which instilled 10 cc/h for the first 30 h and 5 cc/h for the subsequent of a mix of levobupivacaina (200 mg), ketoral-trometamina (30 mg), and adrenalin (0.1 mg) for a total volume of 40 ml in the intra- and extraarticular prosthesis space reduces pain following TKA.

Both the treatment and control groups used a commercially available pain pump (Painfusor Catheter Baxter®).

The outcomes were postoperative pain score, narcotic consumption, knee motion all measured at 24 h, 48 h, 72 h, and length of hospital stay.

Low contact stress uncemented rotating platform prostheses (Depuy, Leeds, UK) without patellar resurfacing were used for all implants.

The TKA surgery was performed under a standardized spinal anesthetic with 10–15 mg of 0.75% or 0.5% plain bupivacaine and 20 μg of fentanyl. In addition, patients were sedated with intravenous midazolam and propofol titrated at the discretion of the case anesthesiologist.

2.1. *Surgical procedure*

All operations were performed in a bloodless field with use of a pneumatic tourniquet. In all cases, the drill hole created for the intramedullary guide rod was occluded with bone prior to implantation of the femoral component in order to reduce blood loss. After insertion of the prosthesis without cement, the tourniquet was deflated and hemostasis was achieved.

Before closure of the joint to all patients, a multihole catheter 19 Ga (Painfusor Catheter Baxter®) was placed in the intra- and extraarticular subfascial space for the infusion of the local anesthetic, the distal part of the catheter was adhered to the capsule, and the proximal was placed subcutaneously. The catheter was tested with a saline solution also to eliminate the air therein. The drains were positioned intraarticular space inside the joint.

All study patients received identical standard adjunctive pain control.

The rescue analgesic medication includes the following drugs: ketorolak 30 mf to a maximum dose of 120 md daily if NSR between 3 and 4 and in case of persistent pain or NSR >4, morphine hydrocloridre 5 mg subcutaneously repeated no earlier than one hour from the previous administration (maximum dose 10 mg in 8 h). In both patient groups, drains were used in the joint and connected to a high-vacuum, suction-drain bottle for 24 h. The knee joint was then closed in layers. All patients received low-molecular-weight heparin (4000 U.I. enoxaparin sodium) as thromboprophylaxis 12 h before the operation, and every 24 h postoperatively.

2.2. *Statistical analysis*

Data analyses were performed using the Student's *t*-test, the chi-squared test, and Pearson's correlation coefficient. A *p*-value of 0.05 or less was considered to be statistically significant for all analyses performed.

3. Results

Patients scheduled for unilateral TKA between January 2010 and January 2012 were included in this study. Of 57