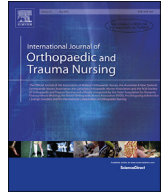




Contents lists available at ScienceDirect

International Journal of Orthopaedic and Trauma Nursing

journal homepage: <http://www.journals.elsevier.com/international-journal-of-orthopaedic-and-trauma-nursing>

The efficacy of high volume of local infiltration analgesia for postoperative pain relief after total hip arthroplasty under general anaesthesia - A randomised controlled trial

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ARTICLE INFO

Article history:

Received 24 July 2017

Received in revised form

6 October 2017

Accepted 27 October 2017

Keywords:

Anaesthesia

Total hip arthroplasty

LIA

Nursing

ABSTRACT

Background and aim: Research regarding patients undergoing total hip arthroplasty (THA) has shown no significant difference in postoperative pain with or without the use of local infiltration analgesia (LIA). The aim was to evaluate whether intra-operative LIA with Ropivacaine in patients undergoing THA under general anaesthesia reduces postoperative pain.

Method: A randomised, placebo-controlled trial. Forty patients undergoing elective primary THA under general anaesthesia were allocated to an intervention group (RG) who received 150 ml of LIA or a placebo group (CG) who received 150 ml of saline solution.

Results: There were no differences in demographic data or duration of anaesthesia. The total mean dose of morphine given was 16 ± 12 mg (RG) and 13 ± 9 mg (CG) ($p=0.238$). Pain scores (Numeric rating scale, NRS) on arrival at the PACU (time 0) were *Md* 1 in the RG group vs *Md* 5 in the CG group ($p = 0.026$). During the first 2 h the *Md* NRS values in the RG group were ≤ 3 whereas the *Md* values in the CG were ≥ 3 . No significant differences in NRS were found at 1–6 h after arrival at the PACU.

Conclusion: Our study suggests that there is a positive effect of LIA on pain scores within the first hour postoperatively in patients undergoing elective primary THA under general anaesthesia.

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Introduction

Total hip arthroplasties (THA) are increasing in number due to the increased aging population. In 2015 according to the Swedish hip arthroplasty register 16609 patients received a THA compared to six patients in 1967. THA is considered major surgery and can either be performed under spinal or general anaesthesia. Spinal anaesthesia itself has the positive physiological effect of the providing afferent blockade with better initial pain relief (Harsten et al., 2013a; 2015; Kehlet, 2013), but at the potential cost of reduced capability for early postoperative mobilization. Early mobilization is very important for the fast-track recovery concept and this key point is hindered by the long-lasting motor block after spinal anaesthesia (Kehlet, 2013; Kehlet and Söballe, 2010; Husted et al., 2011, 2012).

Local infiltration analgesia (LIA), after total knee arthroplasty significantly decreases postoperative pain in patients who have undergone general anaesthesia compared to spinal anaesthesia (Harsten et al., 2013a; Harsten et al., 2013b). However, LIA given to patients having hip replacements did not improve postoperative pain after either general or spinal anaesthesia in studies by Dobie et al. (2012) or Kehlet (2013). The postoperative analgesic effect of spinal anaesthesia lasts up to 4 h depending on the drugs used and therefore the effect of single-dose LIA has a questionable role during these first few hours postoperatively. This agrees with Lunn et al. (2011) study on intraoperative local infiltration analgesia for early analgesia after total hip arthroplasty and LIA was not recommended in THA. However, there is some controversy over this finding since Narinder (2016) concluded in his later review that the technique of LIA was an effective method even for THA.

Former studies have demonstrated that LIA does not improve postoperative pain relief after THA under general anaesthesia (Solovyova et al., 2013; Zoric et al., 2014). The authors in both trials used a lower volume of local anaesthetics (50 ml and 80 ml). A

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recent modification of the technique is *high-volume* (up to 150 ml) LIA, as developed by Kerr and Kohan (2008) for lower extremity joint replacement surgery. Lunn et al. (2011) compared high volume LIA and a placebo in THA, however in their study all the patients received spinal anaesthesia. So efficacy of LIA even after spinal anaesthesia is controversial and the initial positive observations with LIA have had to be modified based on subsequent results from well-performed randomised, double-blind, placebo-controlled, procedure specific studies. In this randomised, double-blind study, we compared the analgesic effects of a single high dose of LIA with Ropivacaine alone after THA under general anaesthesia compared to placebo.

The subjective nature of pain

Experiences of pain after physical trauma, such as surgery, are subjective and vary among individuals (Coghill et al., 2003). The individual variation may be due to past experiences and/or future predictions that may be important for perceived pain experiences (Posner et al., 1980). In anticipated pain, positive expectations such as a high level of safety in terms of operating outcome can reduce the subjective experience of pain, while negative expectations associated with uncertain outcomes can impact pain perception negatively. The modulation of pain-related activation by expectations is therefore related to the subjective expectation of pain magnitude supporting a mental representation of forthcoming pain (Koyama et al., 2004).

The objective of this study was to assess the efficacy of a single-shot intraoperative periarticular Ropivacaine infiltration compared with placebo in THA under general anaesthesia.

Patients and methods

Patients

Patients scheduled for elective cemented THA in a hospital in southern Sweden during the period of February 1st – October 31st, 2016 were screened for eligibility. A total of 40 patients, physical status I–III according to the American Society of Anesthesiologists physical status classification system (ASA), undergoing elective THA were finally included in this prospective, randomised, double-blind, parallel-group study (Fig. 1). Written and verbal informed consent was obtained from each patient before inclusion. Exclusion criteria were patients with a lengthy increased opioid intake prior to surgery, known allergy to the medications used, <65 kg body-weight, obesity with body mass index > 35 and inability to follow verbal or written instructions.

Randomisation and blinding

Consort guidelines were used. The 40 patients were randomly allocated to one of two treatment groups, Ropivacaine Group (RG) and Control Group (CG) each comprising 20 patients, using computer-generated random numbers inserted into sealed envelopes marked 1–40. The randomisation envelope was opened in close proximity to the start of operation. The patients, surgeons, nurse anaesthetists, post-anaesthesia care unit (PACU) nurses and ward nurses were blinded to group allocation. The operating theatre nurses and auxiliary nurses were not blinded as they did not take part in patient care after completion of the operation. The randomisation key-list was opened only after having gathered and recorded the last patient's data. The people performing the analysis were not blinded to group allocation.

Study intervention

Preoperative preparation and anaesthesia. The patients were informed about surgery, anaesthesia, postoperative pain

management, patient controlled analgesia (PCA) pump and the numeric rating scale (NRS). In addition, a preoperative pain score was obtained using a NRS-11 where 0 = no pain and 10 = worst imaginable pain. There was no variance in intra-operative procedures/monitoring and anaesthesia between the groups. Target controlled infusion (TCI) with Propofol 10 mg/ml and Remifentanyl 50 µg/ml was the selected method of general anaesthesia.

Perioperative management. All patients received Cloxacillin (Ekvacillin) 1 g intravenously (i.v.) before surgery and at 4, 8, and 12 h after surgery. THA was performed in a lateral position according to usual practice at the hospital. Only cemented hip implants were used (Abdulkarim et al., 2013). In the study four specialist orthopaedic surgeons operated on the participants using the same technique, a posterior approach. These surgeons received the same information about the LIA technique as described by Kerr and Kohan (2008) and discussed the technique amongst themselves prior to commencing the trial.

During surgery, patients in RG received a total volume of 150 ml of a mixture consisting of a long-acting local anaesthetic (Ropivacaine 2 mg ml⁻¹ = 150 ml) injected into the periarticular tissues in the following way: the first injection around the cup of the acetabulum when it was in place. When the femur component was fixed, the analgesic mixture was injected into the surrounding tissue focusing on the joint capsule, the gluteal and the adductor muscles. The last injection was made subcutaneously (Kerr and Kohan, 2008). At each of these three sites, ~50 ml was injected. Patients in the CG received a similar volume (150 ml) of 0.9% saline (NaCl) in a similar way. After surgery, the patients were transferred to the PACU and after a 3–4 h period as routinely used at the hospital, to the orthopaedic ward.

Pain management

All patients received 1330 mg Paracetamol-modified release (Alvedon[®], GlaxoSmithKline Consumer Healthcare) orally three times a day, starting on the morning of surgery and continuing until discharge from the hospital. 200 mg of Celecoxib (Celebra[®], Pfizer) was given orally prior to surgery and repeated in 12 hourly intervals. Oxycodone 10 mg was given i.v. 30 min prior to extubating. If the patient in the PACU had an NRS score at rest ≥ 4, morphine 1 mg was repeatedly administered intravenously as often as needed until the NRS score was ≤ 3 prior to connecting the PCA device. All patients were provided with a PCA device programmed to deliver a morphine bolus of 2 mg, a lock-out of 10 min, and a maximum of 10 mg/h as a rescue medication for 24 h after the surgery. The starting point for the 24 h was the time of arrival at the PACU (time 0).

Study parameters

The following recordings were made by the nurses:

Pain score: Assessment with NRS scale before surgery, on arrival at the PACU (0) and at 1, 2, 3, 4 and 6 h after operation. A pain score was recorded while the patient was in bed, first at rest and secondly, during mobilization of the operated leg (elevation with a straight knee and 45-degree flexion of the hip). A third pain score was recorded after the patient walked 10 steps.

Analgesic consumption: morphine consumption was recorded during 0–24 h after operation. The successful demand to total demand ratio (SD/TD) of PCA morphine was recorded.

Statistics

The aim was to study if LIA was superior to placebo, with a null hypothesis of no difference between the two groups. A power analysis revealed that with a clinically relevant difference of 1.0 and an average standard deviation of 1.0 (Kendrick and Strout, 2005) on

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