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Effect of local anesthetic wound infiltration on acute pain and bleeding after primary Total Hip Arthroplasty: the EDIPO randomized controlled study

(EDIPO, effects of local anesthetic infiltration in THA)

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## **Abstract**

**Purpose.** Total Hip Arthroplasty (THA) is considered as a painful and bleeding procedure. The aim of the study was to determine if Local Infiltration Analgesia (LIA) (with long-acting local anesthetics and epinephrine) during THA could reduce acute postoperative pain, improved early recovery and per and post-operative bleeding.

**Methods.** 150 patients scheduled for primary THA were randomized into two groups. The treatment group received LIA (ropivacaine with epinephrine) whereas the control group had no infiltration. Pain intensity was measured with a Visual Analogue Scale (VAS) scores for the duration of hospital stay, and pain-killer's consumption. Length of hospital stay, time to get out of bed alone, and the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index at 3, 6 and 12 months were recorded to evaluate recovery. Per and post-operative bleeding were evaluated through direct and indirect criteria (operative bleeding measure, hemoglobin, estimation of uncompensated blood loss and red blood cells transfusion).

**Results.** Patients with LIA had significantly less pain during the first 24 hours ( $p=0.04$ ). No significant differences were found in terms of pain-killer's consumption ( $p=0.57$ ), early and delayed recovery, or bleeding between the 2 groups.

**Conclusions.** Operative wound infiltration of LIA reduce acute pain after primary THA, but probably did not change recovery result and had no effect on per and post-operative bleedings.

**Keywords.** LIA, THA, bleeding, pain management.

## **Introduction**

Total Hip Arthroplasty (THA) is one of the most frequent surgical procedure in Western countries[1], but is also known to be painful in the postoperative period[2] that could prolong hospital stay, delay recovery, and moreover promote chronic pain[3, 4].

As a consequence, for over the past, many postoperative pain management therapies have been developed and in particular with Local Infiltration Analgesia (LIA) (surgical wound or peri-articular infiltration)[5, 6].

The theoretical benefits of local anesthetics are to block pain conduction at its origin, without any systemic side effects or inhibiting muscle action.

Nevertheless, randomized studies found in the literature are not totally consistent with results on pain control, early functional recovery and hospital stay[7, 8] neither on complications[9].

Furthermore, LIA are sometimes prepared with adjuvant like epinephrine that has a vaso-constrictive action, but LIA's effect on blood loss after THA has never been reported.

The purpose of the EDIPO study was to investigate if LIA (with long-acting local anesthetics and epinephrine) during THA could significantly improve acute postoperative pain control, early recovery, and per and post operative bleeding.

## **Materials and Methods**

The EDIPO study was a single-blinded randomized controlled trial, achieved in a University Hospital Center during 18 months. It has been approved by national health authority (AFFSAPS) and registered in clinicaltrials.gov as a phase 2/3 interventional trial (NCT00980616).

### **Patients and randomization**

We recruited 150 patients ages 50 to 85 years old, with degenerative or rheumatoid arthritis undergoing primary THA. Exclusion criteria included refusal or lack of mental ability to provide informed written consent, previous surgery of the hip joint or femoral neck fracture, known history of intolerance or allergy to the drugs used in the study and general contra-indication to surgery. Eligible patients were randomized with a computer-generated sequence and assigned, the day before the procedure, to the study group (75) or to the control group (75). Characteristics of the 2 groups were similar (Table 1). Patients were blind (and so were the physiotherapist and nurse) regarding the allocation group. All included patients received allocated intervention. None was excluded during the hospitalization period. Seven percent of the patients were not analyzed at the study end (Fig. 1).

### **Anesthesia**

All patients underwent a general anesthesia with a standardized anesthetic protocol (combination of hypnotic, opioid and curare), combined with prophylactic intravenous (IV) antibiotics as recommended by our Anesthesiologist Society (SFAR)[10].

### **Surgery and local infiltration technique**

Three senior surgeons performed all procedures through an antero-lateral approach, with a straight stem and a hemispherical pressfit acetabular cup (Avenir or PF stems with Cedior Cup, Zimmer, Warsaw, IN / Twinsys or CCA stems with RM cup, Mathys Ltd, Bettlach, Switzerland). Bone cement could be used for femoral implant depending on the quality of its primary stability. Single drainage was used for every patient.

For the treatment group, the local anesthetic mixture was prepared with 100 mL of saline solution containing 235 mg of ropivacaine and 0.5 mg of epinephrine. It was administered in 2 steps: just after opening the fascia, 50mL were infiltrated in the peri-articular muscles and joint capsule. Then the same volume was re-injected at the end of the procedure in the wound and in subcutaneous tissue. The control group received no infiltration.

### **Post-operative cares**

All patients were given the same pain management. They received paracetamol (1g , IV) 30 minutes before the end of the procedure, followed by an administration of paracetamol (1g every 6 hours, IV), ketoprofen (100mg twice a day, IV) and a patient controlled analgesia (PCA) (morphine 1 mg/ml, a 1 mg bolus dose and a 5 minute lock-out) for the first two days after surgery. After that, oral pain killers were systematically prescribed (paracetamol 1g + tramadol 50-100 mg, every 6 hours). If pain intensity was still more than 40 on the VAS pain scale, subcutaneous morphine (5-10 mg every 6 hours) was added.

Physical therapy protocol was the same for all patients. Immediate full weight bearing was allowed helping with walking canes. Quick mobilization was encouraged and assisted by physiotherapists.

### **Recordings and measurements**

#### *Pain relief and pain killer's consumption.*

During the first 24 hours after surgery, pain assessment was evaluated every 2 hours by trained nurses (single blinded) with a Visual Analogue Scale (VAS 100) at rest. Then the same evaluation was made twice a day for the duration of patient's hospital stay.

The PCA's use was measured after 48 hours and the entire pain killer's consumption (paracetamol, ketoprofen, and morphine) was evaluated at the end of the hospitalization.

#### *Functional recovery.*

We recorded the day of the first time the patient was able to go out of his bed alone and the length of stay. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was collected preoperatively (the day before surgery), and at 3 months and 12 months after THA.

#### *Bleeding evaluation.*

An evaluation (in milliliters) of operative bleeding (V) was done using the following formula:

$$V = (V2 - V1) + VD + M \times 1000/1060 = (V2 - V1) + VD + 0,943M$$

[V = operative bleeding volume, V1 = scrubbing fluids volume (saline solution, antiseptic solution...), V2 = collected fluids volume at procedure's end, VD = drainage volume, M = compresses (with blood) weight]

Hemoglobin (Hb [in g.dL]) and hematocrit (Ht [in percentage]) were measured before surgery and at days 1, 3, 6 and 9.

We calculated an estimation of uncompensated blood loss (V') (in milliliters) with the Mercuriali's formula[11]:

$$V' = \text{patient's blood volume} \times (Ht_{-1} - Ht_{+6})$$

Red blood cells transfusion was recorded (day and volume) if needed. The decision to perform to blood transfusion was based on hemoglobin and patient's clinical status, in regard with recommendations.

#### *Adverse events.*

Adverse events such as acute cardiac arrhythmia, surgical site infection, hypertension, hip dislocation or thromboembolic complications were observed for the duration of the study.

#### **Statistics**

Sample size was calculated based on the hypothesis of 30 units VAS-100 difference between treatment and control group, with a standard deviation of 10 units. With a type I error set at 5% and a type II error set at 10%, 75 subjects per group where necessary

Results are expressed as frequencies (percentages) for qualitative data and as mean  $\pm$  standard deviation for quantitative data. The results were analyzed by groups using the Chi-squared test (or Fisher's exact test when necessary) to compare qualitative data, and using the Student's t test (or Kruskal-Wallis's test when normality was not reached, normality assessed by the Shapiro-Wilk's test) to compare continuous data.

All tests were two-sided, and a p-value  $< 0.05$  was considered to be statistically significant.

Analyses were conducted using intention-to-treat and per protocols approaches. Statistical analysis was performed using Stata V12 (Stata Corp, College Station, Texas), and Excel 2007 (Microsoft, Redmond, WA, USA).

## **Results**

### **Pain relief**

A significant difference in postoperative pain intensity (VAS) was found in treatment group, beginning at 4 h and continuing to 24 h after operation ( $2.39 \pm 1.51$  vs  $2.87 \pm 1.55$ ,  $p=0.04$ ) (Fig. 2). Twenty four hours after surgery there was a trend toward higher pain scores in control group however the difference was not statistically significant.

### **Pain killer's consumption**

There was a trend toward greater narcotic consumption in the control group but the difference was not statistically significant. The total dose of opioids was  $20.9 \pm 20.8$  mg in the treatment group and  $24.4 \pm 19.7$  mg in the control group ( $p=0.07$ ). During hospitalization, there

were no significant differences between the 2 groups in terms of pain killers consumption ( $p=0.57$ ). Furthermore an insignificant reduction in the use of PCA was observed in the treatment group compared to control group (20.1 vs 23.7 mg,  $p=0.06$ ).

### **Functional recovery**

Physical function evaluation results are developed in Table 2.

The WOMAC score significantly decreased after the surgery without any differences between the 2 groups ( $p=0.15$ ).

There were no significant differences for all criteria except for the ability to get out of bed alone ( $p=0.04$ ).

### **Adverse events**

There was no statistically significant difference in the incidence of complications between the two groups.

Symptoms of systemic toxicity of LIA were not observed in any patients. The frequency of nausea, vomiting, abdominal discomfort and dizziness was unaffected by the treatment modality throughout the study period.

Two septic complications were observed in treatment group (at day 15 and 28). They were treated by surgical debridement and irrigation and excluded from the study.

In the control group, one hip dislocation occurred and treated by acetabular cup revision at 6 months.

### **Bleeding evaluation**

Per-operative blood loss (V) was not significantly different between the two groups ( $654\pm 342\text{mL}$  for the treatment group vs  $702\pm 418\text{mL}$ ,  $p=0.44$ ).

Hemoglobin evolution was similar in the 2 groups for the duration of hospital stay (Table III).

Uncompensated blood loss (Mercuriali's formula) were not significantly different ( $p=0.32$ ), estimated at  $525\pm 228\text{mL}$  for the treatment group and  $486\pm 236\text{mL}$  for the control group.

Thirty five (23%) patients required blood transfusion at mean time of 1.5 days after surgery (from day 0 to day 7). They were 18 (24%) in treatment group and 17 (23%) in control group ( $p=0.92$ ).

## **Discussion**

The EDIPO randomized study showed that LIA (single dose) was a safe act during THA and significantly decreased patient's pain (VAS scores) in the first 24 hours. Nevertheless no significant differences were found in pain killer's consumption, functional recovery and hospital stay. Moreover our study reported for the first time, that epinephrine (held in the infiltration) did not significantly reduce THA's per and post-operative bleeding.

Our results on pain control are consistent with those in the literature illustrated by recent systematic reviews[12–17]. LIA is generally efficient on pain for the first 24 to 48

hours, which is the period usually considered by patients to be the worst in terms of pain management[2].

We choose a single dose of LIA (at the beginning and at the end of the surgery) because it is easy to do, reproducible, and probably safer than intraarticular catheter[15]. Moreover, Chen[18] suggests that a large bolus of LIA is more effective than a continuous infusion with wound catheter to control pain.

We noticed 2 cases of early deep infection in the treatment group (no significant difference with control group). Nevertheless, we can imagine that LIA could reduce this kind of complication. Free ropivacaine blood concentrations should have also been evaluated to confirm our clinical findings of no induce toxic adverse event. These findings confirm that LIA is a safe act.

Concerning analgesics consumption, our results showed that there was no significant difference between the 2 groups for each kind of pain killers. This could be easily explained for paracetamol and ketoprofen, because they are systematically prescribed (standard protocol's service) and given to all patients by "blinded" nurses (except if the patient refused it). Contrary to literature's trend[15, 17] we found an insignificant decrease for morphine consumption in the study group ( $p=0.07$ ), as the same for PCA use ( $p=0.06$ ).

For patient's recovery evaluation, we choose simple and relevant criteria for everyday practice (day to get out of bed alone, length of hospital stay, WOMAC score). Study group patients were able to get out of bed significantly faster ( $3.1\pm 1.4$  vs  $3.5\pm 1.5$  days;  $p=0.04$ ) but this did not change hospital stay ( $p=0.51$ ) and WOMAC scores at 3 ( $p=0.29$ ) and 12 ( $p=0.80$ ) months. These conclusions may be explained by the initial short period (24-48 hours) of pain improvement found in patients with LIA. Literature is unclear with this point. Many authors find significant differences in favor of patients who received LIA[6, 15, 19] whereas others do not[14, 20].

To our knowledge this is the first prospective and randomized study that evaluate the effect of LIA on per and post-operative bleeding. We hypothesized that epinephrine (contained in LIA's mixture) could decrease bleedings because of its adrenergic effect (vasoconstriction). THA's bleeding evaluation is always difficult and only few studies reported results[21]. Our method could be criticized, nevertheless we chose multiple direct (operative bleeding volume, Hb) and indirect (Mercuriali's formula, red blood cells transfusion) measures currently used in literature[21, 22]. Finally, no significant differences were observed for any criteria between the 2 groups. In comparison, studies on LIA's effects in total knee arthroplasty are more frequent and relate significant improvements on bleeding[23] especially when Ketorolac is used in the mixture[24].

To conclude, the present study suggests that LIA can be used in pain management protocols for patients undergoing THA especially in patients with predictors for pain[25], because it is safe and improves early pain management (quick recovery). Nevertheless, LIA probably changes neither early and long term functional results nor per and post-operative bleeding.

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## **Conflict of Interest**

The authors declare no conflict of interest with this study.

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**Tables.**

	<b>Treatment Group (n=75)</b>	<b>Control Group (n=75)</b>	<b>P value</b>
<b>Sex (M/F)</b>	44/31	38/37	0.33
<b>BMI</b>	27.4	27.6	0.78
<b>Age (year)</b>	66.4	67.3	0.56
<b>Hemoglobin (g/dL)</b>	14.5	14.1	0.07
<b>Cemented/Uncemented stem</b>	30/45	27/48	0.61
<b>Etiology</b>			1
- <b>Hip osteoarthritis</b>	74	74	
- <b>Osteonecrosis</b>	1	0	
- <b>Secondary to ankylosing spondylarthritis</b>	0	1	
<b>Pre-operative WOMAC score</b>	53.1	56.4	0.16

**Table 1. Patients Characteristics (mean values).**

	<b>Treatment Group</b>	<b>Control Group</b>	<b>p-value</b>
<b>Pre-operative WOMAC score</b>	53.1	56.4	0.15
<b>WOMAC score at 3 months after surgery</b>	18.1	15.9	0.29
<b>WOMAC score at 12 months after surgery</b>	14.3	13.3	0.80
<b>Time to mobilization (days)</b>	1.8	1.9	0.51
<b>Time to get out of bed alone (days)</b>	3.1	3.5	<b>0.04</b>
<b>Length of hospital stay (days)</b>	7.5	7.6	0.51

**Table 2. Physical function evolution (mean values).**

	<b>Treatment Group</b> (n=75)	<b>Control Group</b> (n=75)	<b>P value</b>
<b>Pre-operative Hb</b>	14.5 (1.1)	14.1 (1.4)	0.07
<b>Hb at day 1</b>	11.7 (1.4)	11.4 (1.4)	0.22
<b>Hb at day 3</b>	10.8 (1.6)	10.8 (1.3)	0.91
<b>Hb at day 6</b>	10.6 (1.8)	10.5 (0.9)	0.34
<b>Hb at day 9</b>	10.9 (1.2)	10.7 (0.7)	0.62

**Table. 3. Hemoglobin evolution (mean values and standard deviations).**

**Figure legends.**

Figure 1. The flow diagram of patients through our study.

Figure 2. Post-operative VAS-100 pain scores of the 2 groups.