Postoperative pain relief after total hip arthroplasty: a randomized, double-blind comparison between intrathecal morphine and local infiltration analgesia

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Editor’s key points

- Good analgesia after total hip arthroplasty (THA) is an important factor in postoperative recovery.
- The ideal method with minimal side-effects and consistently good analgesia has yet to be established.
- This study assessed equivalence of periarticular infiltration with ropivacaine, ketorolac, and epinephrine to intrathecal morphine.
- Equivalence was demonstrated along with a lower incidence of side-effects from the infiltration technique.

Background. Postoperative pain after total hip arthroplasty (THA) can delay mobilization. This was assessed after intrathecal morphine (ITM) compared with local infiltration analgesia (LIA) using a non-inferiority design.

Methods. Eighty patients were recruited in this randomized, double-blind study. ITM 0.1 mg (Group ITM) or periarticular local anaesthetic (ropivacaine 300 mg) + ketorolac 30 mg + epinephrine 0.5 mg (total volume 151.5 ml) (Group LIA) were compared. After 24 h, 22 ml of saline (Group ITM) or ropivacaine (150 mg) + ketorolac (30 mg) + epinephrine (0.1 mg) (Group LIA) were injected via a catheter. After operation, rescue analgesic consumption, pain intensity, and home-readiness were measured.

Results. Morphine consumption was equivalent, median difference 0 mg (95% confidence interval –4 to 4.5) between the groups at 0–24 h. During 24–48 h, it was lower in Group LIA (3 mg, 0–60 mg, median, range) compared with Group ITM (10 mg, 0–81 mg) (P<0.01). Lower pain scores were recorded at rest at 8 h in Group ITM (P<0.01), but in Group LIA on standing and mobilization, at 24–48 h (P<0.01). Paracetamol and tramadol consumption was lower in Group LIA (P<0.05 and 0.05, respectively) as was pruritus, nausea, and vomiting (P<0.05).

Conclusion. Lower pain intensity was recorded early after surgery in ITM group but later, analgesic consumption, pain intensity on mobilization, and side-effects were lower in patients receiving LIA. LIA is a good alternative to ITM in patients undergoing THA.

Keywords: analgesic techniques, infiltration; pain, postoperative; surgery, orthopaedic

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Postoperative pain after total hip arthroplasty (THA) is often considered moderate to severe. This can influence postoperative recovery and result in delayed mobilization and prolonged hospitalization. An optimal method for alleviation of pain is needed. Traditionally, this has been managed by epidural analgesia, peripheral nerve blocks, and parenteral or spinal opioids. Although epidural analgesia is efficacious, side-effects and some rare but major complications have questioned its routine use, specifically in the elderly. Peripheral nerve blocks provide good analgesia, but in order to effectively control pain, it may be necessary to block the femoral, lateral cutaneous, and obturator nerves, which can be technically demanding, time-consuming and may result in residual motor block. Parenteral and spinal opioids are associated with minor but troublesome side-effects. This has led to a search for new strategies for pain management after THA.

Local infiltration analgesia (LIA) was first used in Australia and is efficacious during knee surgery. It is based on a systematic infiltration of a mixture of a long-acting local anaesthetic (ropivacaine), a non-steroidal anti-inflammatory drug (ketorolac), and epinephrine into the tissue around the surgical field to achieve satisfactory pain control with little physiological disturbance. A catheter is left in situ, and effective pain relief with early mobilization and reduced hospital stay have been reported, but the results have not been universally positive.

The primary aim of this study was to evaluate whether intra-operative administration of ropivacaine, ketorolac, and epinephrine into the operating field during THA will provide similar analgesia compared with intrathecal morphine (ITM).

Methods

The Regional Ethics Committee and the Swedish Medical Products Agency in Uppsala approved this study before patient...
recruitment. It was registered in an international database, Clinicaltrials.gov (identification number: NCT01281891), and externally monitored by an independent organization for quality control and conducted in accordance with Good Clinical Practice. The study was performed at the Departments of Anaesthesiology and Intensive Care, and Orthopaedic Surgery, University Hospital, Örebro, Sweden.

A total of 80 patients, age 50–85 yr, ASA physical status I–II, undergoing elective THA were included in this prospective, randomized, double-blind, parallel-group study. A CONSORT diagram is shown in Figure 1. Written and verbal informed consent was obtained from each patient before inclusion. Exclusion criteria were patients with chronic pain or taking chronic opioid medication, known allergy to the medications used, contraindications to performing regional anaesthesia and unable to follow verbal or written instructions.

The patients were randomized to one of the two groups according to a computer-generated randomization sequence: intrathecal morphine (Group ITM) and local infiltration analgesia (Group LIA).

Preoperative preparation

The patients were informed about surgery, anaesthesia, postoperative pain management, patient-controlled analgesia (PCA) pump, and physiotherapy including the time-to-up-and-go (TUG) test. In addition, a preoperative pain score was obtained using a numeric rating scale (NRS), where 1=no pain and 10=worst imaginable pain. Dalteparin 5000 IU s.c. was administered on the evening before surgery and once each day for a period of 10 days for prophylaxis against deep vein thrombosis.

Randomization and blinding

The Hospital Pharmacy performed the randomization. The study drugs were prepared, labelled, and blinded to all except the Hospital Pharmacy, and blinding was maintained until the end of the study. Drugs for periarticular injection on postoperative day 1 were kept in a refrigerator until administration.

Anaesthesia

All patients received a mixture of midazolam 0.03 mg kg⁻¹ orally before surgery and at 8, 16, and 24 h after operation. Spinal anaesthesia was performed in the sitting position, using a 27-G spinal needle. All patients received bupivacaine plain 5 mg ml⁻¹ (17.5 mg = 3.5 ml) injected intrathecally. In addition, patients randomized to Group ITM received preservative-free morphine 0.1 mg (0.25 ml) and patients randomized to Group LIA received an equivalent amount of normal saline (0.25 ml). Total volume of intrathecal injectate was therefore 3.75 ml for each patient. When needed, i.v. propofol was administered during surgery for sedation.

Perioperative management

THA was performed in a standardized way according to usual practice at Örebro University Hospital, Sweden. During surgery, patients in Group LIA received a total volume of 151.5 ml of a mixture consisting of a long-acting local anaesthetic (ropivacaine 2 mg ml⁻¹=150 ml), a non-steroidal anti-inflammatory drug (ketorolac 30 mg ml⁻¹=1 ml), and epinephrine (1 mg ml⁻¹=0.5 ml) injected into the periarticular tissues in the following way: the first injection was made around the cup of the acetabulum when it was in place. The surgeons were careful to avoid injecting into the sciatic nerve. When the femur component was fixed, the analgesic mixture was injected into the rotators, on the medial side of their attachment to the femur. The last injection was made subcutaneously and around the catheter. At each of these three sites, ~50 ml was injected. Patients in Group ITM received a similar volume (151.5 ml) of normal saline in a similar way. At the end of surgery, a multi-hole catheter, InfiltraLong 600° (19G×600 mm, Pajunk, Geisingen, Germany), was tunnelled ~8–10 cm from the incision and placed intra-articularly, in a way that it did not get caught within the joint cavity when withdrawing and connected to a bacterial filter under sterile conditions.

After surgery, the patients were transferred to the postanaesthesia care unit (PACU) and, after a 4 h observation period, to the orthopaedic ward. After 24 h, the following solution was injected periarticularly via a multi-holed catheter by a doctor who was blinded to the injectate: Group LIA received 20 ml ropivacaine (7.5 mg ml⁻¹), 1 ml ketorolac (30 mg ml⁻¹), and 1 ml epinephrine (0.1 mg ml⁻¹) (total 22 ml) and Group ITM received 22 ml saline. Thereafter, the catheter was removed and its tip sent for culture and sensitivity.

Pain management

All patients received 1 g paracetamol orally four times a day, starting on the morning of surgery and until home discharge. A PCA morphine pump (programmed to give 1 mg bolus dose, 6 min lock-out time, maximum 10 mg h⁻¹) was connected i.v., and served as rescue medication when pain >3 on the NRS. After 48 h, the PCA pump was discontinued and tramadol 50 mg given orally up to four times a day, as rescue medication for pain management.

Mobilization and home-readiness

The first attempt to mobilization was made ~40 min after the periarticular injection of study medication/saline, 24 h after surgery. The patient was asked to stand up and walk 10 steps. If unsuccessful, another attempt was made to mobilize the patient every 12 h until the patient could walk 10 steps. If the 12 h period was after 9 pm, the next attempt was made on the following morning. Thereafter, mobilization was quantified using the TUG test until discharge.

The patient was considered to be home-ready when the following discharge criteria were fulfilled: mild pain (NRS <3) sufficiently controlled by oral analgesics, ability to walk with elbow crutches, ability to eat and drink without nausea or vomiting, and no signs of any surgical complications. After discharge, the patients were asked to register pain and analgesic consumption during the first 7 postoperative days in a diary that was sent home with all patients.
Recordings and measurements

The following recordings were made:

**Home-readiness:** when home discharge criteria were fulfilled (see above).

**Pain:** before operation and at 1, 4, 8, 12, 24, 36, and 48 h after operation, and subsequently every 24 h up to 7 days. Pain was assessed both at rest and on mobilization (after walking 10 steps).

**Analgesic consumption:** morphine consumption was recorded during 0–4, 4–24, and 24–48 h after operation. Rescue oral analgesic consumption was recorded once each day during 3–7 days in a diary.

**Side-effects and complications:** all side-effects and intra- and postoperative complications were recorded.

**Surgical outcomes:** TUG test was performed once a day from postoperative day 1 until the patient was ready to be discharged home. Patient satisfaction during the first 24 postoperative hours and after 7 days was rated according to a satisfaction score: 1 = poor, 2 = satisfactory, 3 = good, and 4 = excellent.

**Statistics**

**Power calculation**

The number of patients who were recruited into the study was calculated using a non-inferiority hypothesis with a one-sided
2.5% level of significance which is the same as two-sided of 5% level; to assess non-inferiority 95% confidence interval (CI) was calculated. The primary endpoint was total rescue morphine consumption during 0–24 h after operation. Previous studies have found that morphine consumption was 3–11 mg during 0–24 h in patients receiving 0.1 mg morphine intrathecally\(^1\)\(^1\)\(^3\) and our own pilot study on six patients found it to be 0–26 mg. Therefore, assuming that the total morphine consumption in the ITM group is 5 mg [standard deviation (so) 7.8 mg], a difference between the groups of <5 mg was considered to be equivalent. Using unpaired t-test and assuming α of 5% and statistical power of 80%, we calculated that we would need a total of 80 patients (40 in each group). Continuous variables were summarized with mean and SD and analysed using unpaired t-test if symmetric distributed, otherwise summarized with median and range, and analysed with Mann–Whitney U-test. Mean differences between groups with 95% CI were calculated from unpaired t-test and median differences with 95% CI by the method of Hodges–Lehmann. As data on pain intensity were missing on some occasions, a mixed model with autoregressive correlation structure for time was used. Multiple comparisons between the study groups on each time point were adjusted using the Bonferroni correction and P-values shown are corrected values. Side-effects and complications were analysed using the χ\(^2\) test or Fischer exact test when appropriate. P-values <0.05 were considered to be statistically significant. All statistical analyses were done using SPSS version 17 or STATA release 11.

**Results**

A total of 80 patients met all inclusion criteria and none of the exclusion criteria. Of these, two patients were excluded, one in each group: one patient decided not to participate in the study after initial randomization (Group ITM) and in the other patient, spinal anaesthesia failed to achieve adequate block for surgery (Group LIA). Patient characteristic data and intra-operative characteristics are given in Table 1. The patients in the two groups were well matched and data were similar between the two groups.

Pain intensity at rest, on standing, and on walking is shown in Figure 2a–c. Patients in Group ITM had lower pain scores at 8 h compared with those in Group LIA at rest (P<0.01) (Fig. 2a) but subsequently, no differences were seen between the groups up to 48 h after operation. On standing and walking, patients in the LIA group had significantly lower pain intensity during 24–48 h (Fig. 2a and c) (P<0.01). No differences in NRS were found between the groups after 48 h. Rescue analgesic medication is given in Table 2. The primary hypothesis that PCA morphine consumption should not differ by >5 mg between the groups at 0–24 h was satisfied as the median difference was 0 mg (95% CI, −4 to 4.5), as the 95% CI did not include 5 mg. However, lower morphine consumption was found in Group LIA (3 mg, 0–60 mg; median, range) compared with Group ITM (10 mg, 0–81 mg) between 24 and 48 h (P=0.01). Paracetamol and tramadol consumption was lower in Group LIA compared with Group ITM (P=0.05 and 0.05, respectively) between 3 and 7 days (Table 2).

A lower incidence of postoperative side-effects such as nausea (P=0.02), vomiting (<0.01), and pruritus (<0.01) were seen in Group LIA compared with Group ITM during 4–24 h after operation (Table 3). However, patient satisfaction was similar between the groups.

No differences were found between the groups in functional recovery as assessed by the TUG test, time to first mobilization, and the length of hospital stay (LOS) (Table 4).

One patient in Group ITM had a positive culture but no clinical evidence of local or systemic infection. No other patients had any complications during the 7 days follow-up at home.

**Discussion**

In patients undergoing THA, we found that rescue analgesic consumption, pain intensity on mobilization, and side-effects such as nausea, vomiting, and pruritus were lower during 24–48 h when LIA was used, compared with ITM.

THA is commonly performed today in patients with hip osteoarthritis, an increasingly common problem in the western world.\(^1\)\(^4\) Early mobilization and short hospital stay are considered to be important endpoints of functional recovery. Several factors including poor postoperative pain relief can contribute towards delayed recovery and home discharge.\(^1\)\(^5\) Not only is good pain relief important for patient satisfaction, it also means that patients can be mobilized early and thereby return to normal body functions quickly. Pain on movement can be moderate to severe,\(^1\)\(^7\) which limits mobilization and reduces patient satisfaction. Therefore, it is important to achieve satisfactory pain relief during activity so that body functions return to normal as early as possible. Several methods are described in the literature including epidural analgesia,\(^6\) femoral nerve block,\(^1\)\(^6\) spinal morphine,\(^1\)\(^3\) and recently LIA.\(^1\)\(^7\)

We studied spinal morphine as a comparator as this method had been commonly used in Sweden. The analgesia achieved after 100 µg spinal morphine is usually satisfactory and lasts for up to 24 h,\(^18\) which means that it is cost-effective,
efficacious, and easily applied. However, side-effects such as pruritus, urinary retention, and nausea and vomiting have resulted in attempts to find other methods. We were therefore interested in assessing whether LIA could achieve similar analgesia as spinal morphine, without the side-effects mentioned above. As this was a non-inferiority study, we agreed that efficacy would be confirmed if the difference in morphine consumption between the groups was $5\text{ mg}$ during the first 24 postoperative hours. We found no difference in morphine consumption between the groups, which means that LIA is equi-efficacious. This is in contrast to the results of a recently published study where the authors found significantly lower oxycodone consumption in the ITM group. In contrast to our study, these authors used much lower doses of local anaesthetic in the LIA mixture (125 mg levobupivacaine vs 300 mg ropivacaine), their study was not double-blinded, primary endpoint was postoperative nausea and vomiting, and the rescue analgesic consumption was presented for the day of surgery, and it is unclear whether these results refer to 24 h analgesic consumption. In both studies, lower rescue morphine consumption was found in the LIA group compared with the ITM group during 24–48 h. In our present study, rescue analgesic consumption in the form of paracetamol and tramadol continued to be lower in the LIA group during 3–7 days in our study. Thus, patients having LIA injection have significantly lower rescue analgesic consumption up to 7 days after operation, which is a longer duration than the pharmacological action of the individual components of the mixture. This is an important finding and suggests that LIA is efficacious and over a longer period of time compared with spinal morphine, although this could be because of the injection of the LIA mixture, after 24 h.

Additionally, LIA also significantly reduced pain intensity, specifically during standing and walking (dynamic pain) up to 48 h after operation. Although pain at rest was lower in the spinal morphine group at 8 h, at this time most patients are resting in bed and therefore the small difference in pain intensity at rest may not be of clinical importance. We had expected that the significantly lower pain on movement in the LIA group would have resulted in earlier mobilization and possibly quicker home-readiness, which we did not see, and this could depend on several factors. For instance, although patients in the spinal

### Table 2

Descriptive data of morphine, paracetamol and tramadol consumption. Values are shown as median (range). n, number of patients; Group ITM, intrathecal morphine; Group LIA, local infiltration analgesia

<table>
<thead>
<tr>
<th></th>
<th>Group ITM</th>
<th>n</th>
<th>Group LIA</th>
<th>n</th>
<th>Median difference LIA-ITM (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine i.v. (mg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>0–4 h after surgery</td>
<td>0 (0–10)</td>
<td>39</td>
<td>1 (0–27)</td>
<td>38</td>
<td>0 (0 to 1)</td>
<td>0.051</td>
</tr>
<tr>
<td>4–24 h</td>
<td>12 (0–77)</td>
<td>39</td>
<td>11 (0–55)</td>
<td>39</td>
<td>0 (−5 to 3)</td>
<td>0.845</td>
</tr>
<tr>
<td>0–24 h</td>
<td>13 (0–78)</td>
<td>39</td>
<td>12 (0–59)</td>
<td>39</td>
<td>0 (−4 to 4.5)</td>
<td>0.877</td>
</tr>
<tr>
<td>24–48 h</td>
<td>10 (0–81)</td>
<td>39</td>
<td>3 (0–60)</td>
<td>39</td>
<td>−4 (−9 to 1)</td>
<td>0.013</td>
</tr>
<tr>
<td>Paracetamol orally (g)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3–7 days after surgery</td>
<td>15 (0–25)</td>
<td>37</td>
<td>14 (1.5–20)</td>
<td>39</td>
<td>−2 (−5 to 0)</td>
<td>0.048</td>
</tr>
<tr>
<td>Tramadol orally (mg)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3–7 days after surgery</td>
<td>400 (0–1500)</td>
<td>37</td>
<td>50 (0–1000)</td>
<td>38</td>
<td>−100 (−400 to 0)</td>
<td>0.053</td>
</tr>
</tbody>
</table>

Fig 2 (a–c) Pain at rest (a), on standing (b), and on mobilization (c) is shown as a box plot during 0–72 h. NRS, numeric rating scale. Group ITM, intrathecal morphine; Group LIA, local infiltration analgesia. Circles and asterisks represent outliers. P-values refer to differences between the groups.
morphine group could be mobilized on the first postoperative day, this was achieved at the cost of higher pain intensity and a greater rescue analgesic consumption. Furthermore, early mobilization may be expected to result in improved performance on the TUG test when the patients were mobilized, which we did not observe. However, the TUG test may be influenced by several factors, which are not under the control of the investigator such as patient motivation and the time of the day when the test is conducted. We did not find this test to be sensitive in assessing ease of mobilization even in our earlier study.

The LOS has been considered to be an important endpoint when considering recovery. Although LOS was recorded in the present study, we believe that home-readiness is more accurate, and a more objective endpoint. For instance, the absence of relatives at home, long distance between home, and nearest medical facility and also the day of surgery in relation to the weekend may all influence LOS but not home-readiness. We measured the time to home-readiness based on objective criteria of well-defined endpoints. However, no differences were found between the groups. Delay in home-readiness could also be affected by postoperative side-effects and complications of the technique for pain management. Patients in the LIA group had a significantly lower incidence of nausea, vomiting, pruritus, and pain intensity. Despite these differences, the time to home-readiness was similar between the groups, which was somewhat surprising.

Our present study has several merits in design. It is a randomized, and all personnel including the surgeons, nurses and anaesthesiologists were fully blinded to group allocation thus avoiding any patient or observer bias. Secondly, several orthopaedic surgeons, anaesthesiologists, and nurses were involved in patient management, thus increasing the generalizability of our results.

**Study limitations**

The role of ketorolac in the analgesic cocktail has been questioned, specifically because of some reports that non-steroidal anti-inflammatory agents may delay bone healing. Although the evidence for the latter is poor, we are uncertain of a definite advantage of ketorolac. We know that local anaesthetics alone injected in large volumes does not provide analgesia of sufficient duration. However, whether ketorolac prolongs analgesia when injected peri-articularly compared with a similar dose injected i.v., remains uncertain. Because ketorolac was first described as a part of the LIA technique, we used it in this clinical study. Finally, the role of a catheter placed peri-articularly for pain management has been questioned because of the risk of infection. In several published studies using catheters, very few cases of major infectious complications have been reported. The advantage of prolonging pain relief seems to outweigh the risk of infection and therefore we continue to use it in our hospital. However, the exact placement of the catheter in relation to the hip joint remains unclear and unexplored, and future studies should be directed towards the determination of site of catheter placement.

In conclusion, we have shown that rescue analgesic consumption, pain intensity on mobilization, and side-effects such as nausea, vomiting, and pruritus are lower during

### Table 3 Side-effects and satisfaction. Values are shown as median (range) or n, number of patients; Group ITM, intrathecal morphine; Group LIA, local infiltration analgesia; satisfaction: 1 = poor, 2 = satisfactory, 3 = good, and 4 = excellent

<table>
<thead>
<tr>
<th></th>
<th>Group ITM</th>
<th>n</th>
<th>Group LIA</th>
<th>n</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>Nausea (n)</td>
<td>0–4 h postoperative</td>
<td>6</td>
<td>7</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>4–24 h</td>
<td>22</td>
<td>12</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>24–48 h</td>
<td>12</td>
<td>8</td>
<td>39</td>
<td>39</td>
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<tr>
<td>Vomiting (n)</td>
<td>0–4 h postoperative</td>
<td>7</td>
<td>3</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>4–24 h</td>
<td>15</td>
<td>4</td>
<td>39</td>
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<tr>
<td></td>
<td>24–48 h</td>
<td>5</td>
<td>2</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Pruritus (n)</td>
<td>0–4 h postoperative</td>
<td>6</td>
<td>2</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>4–24 h</td>
<td>11</td>
<td>1</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>24–48 h</td>
<td>3</td>
<td>2</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>1 h postoperative</td>
<td>4</td>
<td>4</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td></td>
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<td>3</td>
<td>3</td>
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<tr>
<td></td>
<td>24 h</td>
<td>3</td>
<td>3</td>
<td>39</td>
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</table>

### Table 4 Functional outcome. All results are shown as median (range). Group ITM, intrathecal morphine; Group LIA, local infiltration analgesia; n, number of patients; TUG, time-to-up-and-go test; time for mobilization, first attempt at mobilization. Please see text for details

<table>
<thead>
<tr>
<th></th>
<th>Group ITM median (range)</th>
<th>n</th>
<th>Group LIA median (range)</th>
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<th>P-value</th>
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<td>TUG test (s)</td>
<td>Preoperative</td>
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<td>(8–28)</td>
<td>39</td>
<td>14</td>
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<td>2 days postoperative</td>
<td>38</td>
<td>(18–75)</td>
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<td>38</td>
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<tr>
<td></td>
<td>3 days postoperative</td>
<td>27</td>
<td>(10–57)</td>
<td>32</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Time to mobilization (days)</td>
<td>1</td>
<td>(1–3)</td>
<td>39</td>
<td>1</td>
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<td></td>
<td>Home-readiness (days)</td>
<td>3</td>
<td>(2–5)</td>
<td>37</td>
<td>3</td>
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</table>
24–48 h in patients having LIA after THA compared with those receiving spinal morphine. This technique is therefore a good alternative to spinal morphine for postoperative pain management in patients undergoing total hip replacement.

Authors’ contributions


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Declaration of interest

None declared.

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