ABSTRACT

Hip fractures are a persistent health problem especially post-operative with morbidity disability and mortality. The fascia iliaca nerve block (also called the fascia iliaca compartment nerve block) is considered an alternative to a femoral nerve or a lumbar plexus nerve block.

Objective: This study aims to evaluate the analgesic efficacy of ultrasound-guided fascia iliaca plane block after hip arthroplasty.

The Primary Outcome: average postoperative VAS pain scores.

Secondary Outcome: Time to first analgesic request; Postoperative analgesic consumption; Overall patient satisfaction with analgesia; Any adverse effects e.g., nausea, vomiting, pruritus, or urinary retention.

Patients and Methods: This Prospective randomized double-blinded clinical trial will be carried out in Tanta University Hospital in Orthopedic Surgery Department. The study included 60 adult patients aged > 25 years; ASA class I & II scheduled for total hip arthroplasty surgery.

Results: As regards, the first analgesic requirement of analgesic there were significant statistical increases in group I compared to group II. also, there were statistically significant decreases in total consumption of both paracetamol and pethidine in the group, however, There were significant statistical decreases in total pethidine consumption (mg) in group I compared to group II
Conclusion: FICB is safe and effective in improving postoperative pain after hip arthroplasty. It provides lower NRS, more hemodynamic stability, a longer time for 1st time of analgesics requirement ad a lower amount of total analgesic consumption within 1st 24 hours.

Keywords: Analgesic; ultrasound-Guided; Fascia iliaca block; hip Arthroplasty.

1. INTRODUCTION

Hip fractures are a persistent health problem especially post-operative with morbidity disability and mortality that may threaten patient recovery [1]. Side effects of anesthesia must be decreased to optimize patient's comfort, safety, and to ease rehabilitation [2]. General anaesthesia (GA), regional anaesthesia (RA), or a mix of the two are the most common anaesthetic options. Regional anaesthesia (RA) has been shown to minimise post-operative pain when compared to systemic analgesia in a recent systematic evaluation [3].

Many patients undergoing hip arthroplasty receive spinal anaesthesia, which is a frequent RA method [4]. In patients undergoing hip arthroplasty, opioids given to the spinal anaesthesia to prolong and improve postoperative pain relief are linked to lower postoperative analgesic needs [5]. Intrathecal opioids, on the other hand, are linked to a variety of adverse effects, including urine retention, nausea and vomiting, itching, and, most notably, respiratory depression. Such side effects can be inconvenient for the patient, cause delays in movement, healing, and eventual discharge, and can even be harmful in some cases [6].

Peripheral nerve blocking has been found to enhance pain scores and minimise painkiller usage in patients having hip arthroplasty [7]. Sensory blocking of the major nerves that give pain to the hip can be achieved with the fascia iliaca block. However, when administered 'blindly' using classic landmark procedures, the clinical success rates of this block are variable [8,9]. When compared to traditional procedures, using ultrasound to detect nerves during peripheral nerve blockade has been demonstrated to boost success rates, minimise block onset time, increase block length, reduce the amount of local anaesthetic required, and improve patient satisfaction [10,11].

The present research seeks evaluating the analgesic efficacy of ultrasound-guided fascia iliaca plane block after hip arthroplasty.

The primary outcome: Average postoperative VAS pain scores.

Secondary outcome: Time to first analgesic request; Postoperative analgesic consumption; Overall patient satisfaction with analgesia; Any adverse effects e.g. nausea, vomiting, pruritus, or urinary retention.

2. PATIENTS AND METHODS

The study will be carried out at Tanta University Hospital's Orthopaedic Surgery Department conducted a prospective randomised double-blind clinical trial.

Patient grouping: Sixty patients were classified at random to two equal groups (30 patients each) with ASA physical status I, II, III; Age > 25 years old of both sexes scheduled for hip arthroplasty; Competence to consent.

Group I: (Fascia iliaca group): Spinal anesthesia with hyperbaric bupivacaine of 10-15 mg, accustomed at the level of L2-L3 with intrathecal fentanyl 25 micrograms (0.5 ml). Ultrasound-guided fascia iliaca block using 2 mg/kg bupivacaine diluted to 30 ml with sterile saline.

Group II: Control group: Spinal anesthesia with hyperbaric bupivacaine of 10-15 mg with intrathecal fentanyl 25 micrograms (0.5 ml). Ultrasound-guided fascia iliaca injection with 30 ml of sterile saline was done.

Patient refusal; coagulopathy or infection at the block's position; allergy towards local anesthesia or opioid; significant peripheral neuropathy or neurological disorder altering the lower extremity, pregnancy; drug dependency; patient that cannot express his pain were excluded from our study.

Preoperative assessment was done by: history taking; clinical examination; laboratory investigations such as: CBC, bleeding time, clotting time, liver function tests, kidney function tests; make patient familiar with VAS (0: no pain to 10: intensive pain).

The following data were recorded: Demographic data: age, sex, body mass index, ASA, duration
of surgery; Vital signs: Mean arterial blood pressure (mmHg), heart rate (beats/minute) were monitored postoperatively at PACU, 6, 12, and 24 hr; duration of sensory and motor block.

2.1 Postoperative Pain was Assessed by a Visual Analog Scale

Postoperative pain was measured via a 10 cm marked visual analog scale (VAS) where zero means lack of pain and ten means extreme pain. The pain got assessed at PACU, 2, 6, 12, 24 after the operation. Patients scoring >7 in VAS score ≥ 4 while staying at the hospital were treated by I.V. paracetamol (maximum dose of 1 g every 6 h), starting in the postoperative ward and for 24 h postoperatively, if VAS scored > 7 pethidine was given at a dose of 30 mg as rescue analgesia.

2.2 Time of First Rescue Analgesia; Postoperative Analgesic Consumption

Overall patient satisfaction with analgesia was measured by a second anesthesiologist on a postoperative day using a 5-point verbal scale between levels of being very satisfied to very dissatisfied (1 for (very satisfied); 2 for (some-what satisfied); 3, for (neither satisfied nor dissatisfied); 4 for (some-what dissatisfied); 5 for (very dissatisfied) [12].

Any undesirable side effects during the time of the study were recorded (Manifestations of local Anesthetic toxicity, intravascular injection, hematoma, hypersensitivity to local anesthesia or opioids).

2.3 Statistical Analysis

We used the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC)'s Epi-Info software statistical package, Atlanta, Georgia, USA version 2002 to calculate the sample size at (N=45), 95% confidence limit and 80% power of the study. We also used the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) to analyze the gathered data. We documented the quantitative variables as mean ± standard deviation, while we used frequency and percentage for the qualitative data. P ≤ 0.05 was considered statistically significant.

3. RESULTS

Regarding HR comparison in both groups, at 6hrs. there was decreased HR in group I when compared to group II yet this difference appeared to be statically insignificant at PACU, at 2h, at 6h. While from 12 to 24h, HR showed a significant statistical decrease in group I in comparison to group II. For the mean arterial blood pressure (MAP) comparison in both groups, at PACU and 2h, we found no statistically significant difference. While from 6h to 24h, arterial blood pressure showed a significant statistical decrease in group I in comparison to group II.

Regarding the duration of sensory block, there was a significant statistical increase in group I in comparison to group II. While we found no significant statistical difference between both groups in duration of motor block.

Regarding VAS comparison in both groups, there was a decrease in group I compared to group II, yet the discovered difference was insignificant at PACU and 2h, but from 6h to 24h, VAS showed a statistically significant decrease in group I in comparison to group II (Table 1).

Regarding the first analgesic requirement of analgesic we discovered significant statistical upsurges in group I compared to group II. Also, we found statistically significant reductions in total consumption of both paracetamol and pethidine in the group. Even though, we discovered significant statistical declines in total pethidine consumption (mg) in group I compared to group II (Table 2).

In regards to patient satisfaction, our study reported a significant statistical rise in patient satisfaction score in group I in comparison to group II (Table 3).

4. DISCUSSION

Regarding VAS comparison in both groups, there was a decrease in group I compared to group II, yet the difference was insignificant at PACU and 2h, but from 6h to 24h, VAS showed a statistically significant decline in group I in comparison to group II.

In agreement with our study, Madabushi et al. [13] conducted a comparison between the analgesic efficacy of fascia iliaca block and the intravenous fentanyl. They discovered that the declining VAS scores was significantly appearing in the FICB group. They concluded that fascia iliaca block offers superior analgesia in comparison to IVF in patients with a femur fracture.
Table 1. VAS in both group

<table>
<thead>
<tr>
<th></th>
<th>PACU</th>
<th>2h</th>
<th>6h</th>
<th>12h</th>
<th>24h</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.57</td>
<td>2.57</td>
<td>3.53</td>
<td>4.57</td>
<td>5.57</td>
</tr>
<tr>
<td>SD</td>
<td>0.68</td>
<td>0.68</td>
<td>0.63</td>
<td>0.68</td>
<td>0.68</td>
</tr>
<tr>
<td>Median</td>
<td>1.0</td>
<td>2.0</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Range</td>
<td>1.0-3.0</td>
<td>2.0-4.0</td>
<td>3.0-5.0</td>
<td>4.0-6.0</td>
<td>5.0-7.0</td>
</tr>
<tr>
<td><strong>Group II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.90</td>
<td>2.90</td>
<td>5.50</td>
<td>6.53</td>
<td>7.53</td>
</tr>
<tr>
<td>SD</td>
<td>0.84</td>
<td>0.84</td>
<td>0.57</td>
<td>0.51</td>
<td>0.51</td>
</tr>
<tr>
<td>Median</td>
<td>2.0</td>
<td>3.0</td>
<td>5.0</td>
<td>7.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Range</td>
<td>1.0-3.0</td>
<td>2.0-4.0</td>
<td>5.0-7.0</td>
<td>6.0-7.0</td>
<td>7.0-8.0</td>
</tr>
<tr>
<td>P value (t-test)</td>
<td>0.097</td>
<td>0.098</td>
<td>0.000*</td>
<td>0.000*</td>
<td>0.000*</td>
</tr>
<tr>
<td>P value (MW test)</td>
<td>0.124#</td>
<td>0.124#</td>
<td>0.000*#</td>
<td>0.000*#</td>
<td>0.000*#</td>
</tr>
</tbody>
</table>

* denote significantly. SD; standard deviation

Table 2. Time of first analgesic requirement in both groups (in minutes)

<table>
<thead>
<tr>
<th></th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time of the first analgesic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>9.0</td>
<td>4.80</td>
</tr>
<tr>
<td>SD</td>
<td>3.67</td>
<td>1.86</td>
</tr>
<tr>
<td>P value</td>
<td>0.000*</td>
<td></td>
</tr>
<tr>
<td><strong>The total consumption of paracetamol</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>2.57</td>
<td>3.20</td>
</tr>
<tr>
<td>SD</td>
<td>0.68</td>
<td>0.66</td>
</tr>
<tr>
<td>P value</td>
<td>0.001*</td>
<td></td>
</tr>
<tr>
<td><strong>The total consumption of pethidine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.0</td>
<td>47.0</td>
</tr>
<tr>
<td>SD</td>
<td>9.15</td>
<td>17.05</td>
</tr>
<tr>
<td>P value</td>
<td>0.000*</td>
<td></td>
</tr>
</tbody>
</table>

* denote significantly. SD; standard deviation

Table 3. Patient satisfaction

<table>
<thead>
<tr>
<th></th>
<th>Group I</th>
<th>Group II (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>4.3</td>
<td>3.53</td>
</tr>
<tr>
<td>SD</td>
<td>0.651</td>
<td>0.507</td>
</tr>
<tr>
<td>P value</td>
<td>0.000*</td>
<td></td>
</tr>
</tbody>
</table>

In addition, Ghimire et al. [7] evaluated the viability and efficacy of fascia iliaca compartment block (FICB) and femoral nerve block (FNB) to decrease pain in patients undergoing proximal femoral fracture fixation procedures and reported that FICB was more effective in reducing pain than femoral nerve block (FNB).

Per our results, Krych et al. [14] evaluated the utility of multimodal analgesia with fascia iliaca blockade for acute pain control in patients having hip arthroscopy, they reported that multimodal analgesia with fascia iliaca blockade after hip arthroscopy appeared to be harmless and efficient. The quality of early postoperative analgesia of the fascia iliaca blockade appeared to be of high quality for pain relief.

Another study supports our results, by Wongswadiwat et al. [15], investigated the efficacy of fascia iliaca block for pain relief in post surgery. They discovered a statistically significant decrease in pain scores among the two groups. They concluded that the fascia iliaca block is efficient in controlling pain for at least 24 hours.

Also, Deniz et al. [16] compared the postoperative analgesic efficiency of an ultrasound-guided FICB and a 3 in 1 block in patients who had hip prosthesis surgery as a result of hip fracture and they observed a decrease in VAS values in both block groups. They believed that the ultrasound-guided 3 in 1 block where FICB are parts of multimodal
analgesic cure to facilitate postoperative analgesia in hip prosthesis operations.

Also in agreement with the present study, Desmet et al. [17], assessed patients scheduled for THA (longitudinal supra-inguinal FICB) compared to group C (control, no block) and found that there was a statistically significant reduction in pain scores postoperatively.

In addition, Kumie et al. [8] measured the efficiency of fascia iliaca compartment nerve block as part of post-operative multimodal analgesia for femoral bone fracture. They discovered that the VAS pain scores have declined within the first 24 hours after surgery in the FICNB group in comparison to the control group (Non-FICNB). They recommended FICNB for post-operative analgesia for femoral bone fractures at the emergency department.

In agreement with this study, Gola et al. [18] evaluated the viability of FICB with nonopioid analgesics and patient-controlled analgesia (PCA), in the perioperative anesthetic management for elective total hip replacement. Gola’s team discovered that the pain score in FICB group was statistically significantly less than the control group. They concluded that FICB in elective THR cure is an efficient form of analgesia.

Also, Telletxea, [19] evaluated the efficacy of FICB in controlling pain after total hip replacement by assessing pain intensity for 24 hours post surgery. The team reported that the VAS scores in the postanaesthetic recovery unit had significantly different results in the 2 groups (FICB group and control, no block) with less scores in the FICB group.

In addition, Diakomi et al. [20] compared the efficiency of FICB to intravenous (IV) fentanyl for positioning hip fracture patients for SA. They reported that in comparison to the IVFE group, the FICB group had significantly less numeric rating pain scale scores in all instances after the analgesic intervention. They concluded that performing a FICB prior to positioning for SA provides superior pain management in comparison with IVFE administration, facilitates spinal performance, and yields satisfactory postoperative analgesia and wide patient acceptance, thus refining general quality and care effectiveness.

Huang et al. [21] assessed the analgesic effect of preoperative fascia iliaca block (FIB) on postoperative morphine equivalent dose (MED), pain level, as well as patient satisfaction for patients electing to undergo primary hip arthroscopic labral repair with osteochondroblastic. They support our result that there was insignificant difference in PACU, however in disagreement with our results that there was insignificant difference in VAS scores among patients getting the FIB and a no-block control group at 1 day post operation. This contrast can be explained by different times of measuring the VAS score (1st measurement was at 1 day)

Also in disagreement with our results, Glomset et al. [22] compared the effectiveness of ultrasound-guided fascia iliac block with intra-articular ropivacaine in curbing pain after hip arthroscopy and reported that there was insignificant difference in pain scores for the PACU among both the FIB and IAR groups which can be explained by they compared 2 blocks and at a different time of measurement (2 weeks, 6 weeks, and 3 months).

Also in opposition to this study Bang et al. [23] compared the opioid consumption among patients receiving PCA with and without FICB, Bang’s team discovered similarity in pain scores between both groups (FICB and non-FICB) this can be explained by small sample size (Twenty-two patients) and all patients received PCA either with block or not so the pain score was less but without significant difference.

As regards, time to first analgesic requirement there were significant statistical increases in group I in comparison to group II. As regards, the total consumption of both paracetamol and pethidine, there were statistically significant decreases in group I in comparison to group II.

Per our results, Stevens et al. [24] evaluated a modified fascia iliaca compartment block in unilateral total hip arthroplasty providing a morphine-sparing effect and found fewer opioid consumption on the first day. They concluded that a modified FICB made a significant morphine-sparing effect in unilateral total hip arthroplasty.

Also, Gola et al. [18] found that the total consumed dose of opioids, in the FICB group had statistically significantly less than the PCA control group.

Also, Kumie et al. [8], support our study that, the total analgesic ingesting of diclofenac got
decreased in the FICNB group than the control group, and the time for the first analgesic request has significantly prolonged.

In addition, Diakomi et al. [20] compared the efficiency of FICB to IV for positioning hip fracture patients for SA. They reported that in comparison to the IVFE group, the FICB group had less postoperative morphine ingesting, the time to first dose demand appeared to be lengthier.

In agreement with our study, Desmet et al. [17], showed that opioid ingesting at one day postoperatively was significantly less in group FICB in comparison to the non-FICB group.

In agreement, Madabushi et al. [13] reported that postoperative analgesic requirement was fewer in group FICB than IVF group. They concluded that fascia iliaca block offers reduced analgesia ingestion in comparison to IVF in patients suffering femur fracture.

Also, Deniz et al. [16] support our results that, opioids consumption was found to decrease in block groups.

Per our results, Krych et al. [14], reported that the fascia iliaca blockade had little opioid ingestion, high quality of pain relief. And no complications for patients who got the fascia iliaca blockade.

In agreement with our study, Bang et al. [23] found that amount of fentanyl required was low in the FICB group and the FICB has a significant opioid-sparing outcome in the first day after hemiarthroplasty and concluded that FICB is efficient for multimodal analgesia in hip surgery.

In contrast to our study, Huang et al. [21] documented insignificant difference in analgesic ingestion over 3 months post operation, this is explained by the different times of measurement (2 weeks, 6 weeks, and 3 months), and the lock did not give this control.

Also, Glomset et al. [22] described insignificant differences in total analgesic ingestion over 3 months post operation, this is explained by the different times of measurement (2 weeks, 6 weeks, and 3 months), and the lock did not give this control.

In addition, Behrends et al. [25] investigated whether a preoperative fascia iliaca block. They reported that there was insignificant difference in analgesic ingestion within the first day among both the FIB and saline placebo groups. This explained why all groups received intraarticular local anesthetic injection either with FICB or not. They used ultrasound-guided as us.

Regarding HR comparison in both groups, at 6hrs. There was decreased HR in group I in comparison to group II, yet this difference was statically insignificant at PACU, at 2h, at 6h. While from12 to 24h, HR showed a significant statistical rise in group II in comparison to group I. Regarding MAP comparison in both groups, at PACU and 2h, they showed no statistically significant difference. While from 6h to 24h, HR showed a significant statistical increase in group II in comparison to group I.

In agreement with us, Sana et al. [26] determined the efficacy of FICB for positioning during spinal anesthesia and to determine its efficacy for postoperative analgesia. They found a statistically significant difference among the control and intervention groups in MAP and heart rate during positioning at 30 minutes. The difference in Baseline Mean arterial pressure, Heart rate (Baseline as well as during positioning at 30 minutes) was not found to be statistically significant.

In contrast to our results, Ebshena and Wei [27] compared short-axis in-plane vs. long-axis in-plane techniques of ultrasound-guided continuous fascia iliaca compartment block. They reported insignificant difference in hemodynamic changes among both groups, which can be explained that both groups received the block by a different technique.

Regarding the duration of sensory block, they documented a significant statistical rise in group I comparing it to group II. While there was insignificant statistical difference between both groups in duration of motor block.

In agreement with us, Sana et al. [26] found statistically significant difference in the duration of sensory block.

In contrast to our study, Ebshena and Wei [27] found that the sensory and motor blocks showed similarity among both groups.

As regard patient satisfaction our study reported a significant statistical rise in patient satisfaction scores in group I compared to group II.
Per our results, Krych et al. [14] reported that multimodal analgesia with fascia iliaca blockade after hip arthroscopy is linked to high general patient satisfaction.

In addition, Diakomi et al. [20] compared the efficiency of FICB to IV for positioning hip fracture patients for SA. They reported that in comparison to the IVFE group, the FICB group showed patient satisfaction rates at greater level ($P < 0.001$) in the FICB group.

In addition, Gola et al. [18] found a greater rate of patient satisfaction with the analgesic treatment use.

As regard complication, there was hypotension, bradycardia, nausea & vomiting post dual puncture headache. There were statically insignificant differences.

In agreement with our study, Behrends et al. [25] showed no static difference between groups as regard side effects such as nausea, vomiting, or constipation when compared to the placebo group.

Also, Ebshena and Wei [27] reported there were statically insignificant differences between groups. There has been only one patient reporting the complication after the block.

Per our results, Krych et al. [14] reported that no difficulties were reported for patients getting the fascia iliaca blockade.

Also, Deniz et al. [16], support our results that, no adverse effect as nausea. In addition, Gola et al. [18] found insignificant differences in complication.

5. CONCLUSION

FICB is safe and effective in improving postoperative pain after hip arthroplasty. It provides lower NRS, more hemodynamic stability, a longer time for 1st time of analgesics requirement ad a lower amount of total analgesic consumption within 1st 24 hours.

6. RECOMMENDATION

1- The concurrent study recommends using FICB as an adjuvant to spinal block in hip arthroplasty.

2- Additional studies including a large number of patients are required for the generalization of these results.

3- Also, further studies assessment of different volumes and amounts of L.A.

DISCLAIMER

The products used for this research are commonly and predominantly used products in our area of research and country. There is no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by the personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

After receiving clearance from the institutional ethics committee, each patient signed an informed written consent form. All patient information will be kept private and confidential, with secret codes and individual files for each patient. The information was only used for current medical research. Any unforeseen dangers that arose throughout the research were promptly communicated to the participants and the Ethical Committee. To preserve participant privacy and data confidentiality, each patient was given an explanation of the study's aim as well as a secret code number.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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