Egyptian Journal of Anaesthesia xxx (xxxx) xxx–xxx

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Contents lists available at ScienceDirect

Egyptian Journal of Anaesthesia

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

Research article

Patient-controlled fascia iliaca compartment block versus fentanyl patient-controlled intravenous analgesia in patients undergoing femur fracture surgery☆,

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ARTICLE INFO

Keywords:
PCA
Fascia
Postoperative pain

ABSTRACT

Background and objectives: Postoperative pain relief is crucial in elderly, however, the use of opioids is limited owing to their potential side effects. We studied the effects of patient-controlled ultrasound guided fascia iliaca compartment block (FICB) with Levobupivacaine versus patient-controlled intravenous fentanyl on post-operative pain score in patients scheduled for fixation of femur fractures under general anesthesia.

Methods: 60 patients ASA physical status I and II undergoing elective fixation of fracture femur were enrolled in this randomized study into two groups. **Patient-controlled IV fentanyl group (PC-IVF):** patients received fentanyl 20 μg/ml solutions through a PCA pump programmed to give a basal infusion of 10 μ/h and bolus doses of 2 ml/dose with a 15 min lockout interval. **Patient-controlled fascia iliaca compartment analgesia (PC-FICA):** PCA was adjusted to deliver a continuous basal infusion of 4 ml/h levobupivacaine 0.125% and 2 ml demand boluses with a lockout interval of 15 min. Visual analogue score (VAS) and total postoperative rescue analgesic consumption were assessed.

Results: VAS scores were significantly lower in PC-FICA group compared to PC-IVF group at 1 h, 3 h and 6 h postoperative. 7 patients requested post-operative rescue analgesia in PC-FICA group compared to 19 patients in PC-IVF group. Total consumption of rescue analgesia was significantly decreased in PC-FICA group (31.4 ± 10.7 mg) compared to PC-IVF group (70.5 ± 20.4 mg) ($P < .05$).

Conclusion: PC-FICA provided a better quality of analgesia and decreased postoperative rescue analgesic requirement without increased side effects compared to PCA IV fentanyl.

Pan African Clinical Trial Registry: PACTR201512001367158

1. Introduction

Postoperative pain may not be managed properly in the elderly due to the potential adverse effects of opioid analgesics [1]. Effective pain management is essential for early mobility and hence subsequent hospital discharge [2].

Patient-controlled analgesia (PCA) allows patients to self-titrate required doses of analgesics according to their desired level of pain control using a programmable infusion pump. This adjusts the dose in order to maintain adequate analgesia individualized to the patient's needs [3]. PCA has been advocated an effective and safe technique for postoperative analgesia and is considered the "gold standard" for pain relief following major surgery [4].

The use of regional anesthetic techniques alleviates postoperative pain and avoids complications of opioids [5].

Fascia iliaca compartment block (FICB) is a regional block of lumbar plexus that involves the anterior thigh [6], if the injected local anesthetics are positioned posterior to the fascia iliaca, it diffuses to its internal layers then to the femoral, genitofemoral, lateral femoral cutaneous, and obturator nerves [7] which was radiologically confirmed later on [8].

It is an alternative to central neural block and can provide adequate unilateral analgesia with fewer adverse-effects than epidural analgesia [9]. FICB provided effective rapid onset analgesia following traumatic hip fractures in the elderly [10].

The aim of the current study was to compare the effects of patient-controlled ultrasound (US) guided fascia iliaca compartment analgesia (PC-FICA) with Levobupivacaine versus patient-controlled intravenous

☆ The work was attributed at Tanta University Hospital, Egypt.

Peer review under responsibility of Egyptian Society of Anesthesiologists.

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https://doi.org/10.1016/j.egja.2017.12.002
Received 8 September 2017; Received in revised form 3 December 2017; Accepted 21 December 2017

fentanyl (PC-IVF) on postoperative pain score in patients undergoing fixation of femur fractures under general anesthesia.

2. Patients and methods

After obtaining approval from the Institutional Review Board (code number: 30594/11/15), registration in the Pan African Clinical Trial Registry (PACTR201512001367158) and patients' informed written consent, a prospective randomized study was carried out in Orthopedic surgery department, Tanta University hospital on 60 adult patients aged 50–70 years, of either gender, with American Society of Anesthesiologists physical status (ASA) I–II undergoing elective fixation of fracture femur. The study duration was 6 months.

The study methodology, instructions for use of PCA device and the Visual Analogue Scale (VAS) of pain, where zero score corresponds to no pain and 10 to the maximum or worst pain, were cleared to participants preoperatively.

Exclusion criteria: Patients were excluded if they suffered from any other concomitant fractures, neurological disease (Alzheimer, dementia), any contraindication to regional anesthesia (e.g. patient refusal, local infection or coagulopathy) or known allergy to the studied drugs.

Computer-generated randomization numbers were used to allocate patients into two groups using sealed opaque envelopes. The envelope was chosen by each patient which determined his group.

Group I: patient-controlled IV fentanyl group (PC-IVF): patients received fentanyl 20 μg/ml solutions through PCA pump programmed to deliver a basal infusion of 10 μ/h and bolus doses of 2 ml/dose with a 15 min lockout interval and a 4 h limit of 400–800 μ.

Group II: patient-controlled fascia iliaca compartment analgesia (PC-FICA): the PCA was adjusted to deliver a continuous basal infusion of 4 ml/h levobupivacaine 0.125% and demand boluses of 2 ml with a lockout interval of 15 min [11].

Patients were premedicated with 0.1 mg/kg oral midazolam, 60–90 min before surgery. Monitoring included 5 leads ECG, pulse oximetry, non-invasive blood pressure and capnography.

General anesthesia technique was standardized in all patients. Induction was done using IV propofol 2 mg/kg, fentanyl 1 μg/kg, cisatracurium 0.15 mg/kg, endotracheal intubation was performed, anesthesia was maintained with 1:1 O_2: air, 1.2–1.5% isoflurane and mechanical controlled ventilation was initiated with ventilator parameters set to maintain end-tidal carbon dioxide at 35–40 mmHg. IV fentanyl 0.5 μg/kg was administered to all patients every hour and if there is > 20% increase in heart rate or mean arterial blood pressure that may indicate inadequate analgesia. Intraoperative fentanyl consumption was recorded.

At the end of the surgical procedure, group II patients received an US-guided FICB [12]. The block was performed using a high-frequency 5–10 MHz linear transducer Sonosite Micromaxx (SonoSite, Inc. Bothell, WA). Firstly, sonographic visualization of the two fascial planes, the fascia lata and the fascia iliaca was performed as two hyperechoic lines, with the probe positioned on the thigh just inferior to the inguinal ligament in a transverse orientation and one-third of the distance between the pubic tubercle and the anterior superior iliac spine. A Tuohy needle (PERIFIX, B. BRAUN, Melsungen, Germany) was introduced percutaneously from lateral-to-medial then directed parallel to the transducer to allow continuous visualization of full needle length. The needle tip was visualized penetrating firstly the fascia lata and then the fascia iliaca and a 20 G catheter was introduced for about 15 cm past the needle tip then tunneled through the skin. A loading dose of 35 ml levobupivacaine 0.125% was injected. The catheter was removed after 48 h.

Perfalgan 1 g IV was administered to all patients before recovery. Basal infusion of PCA levobupivacaine and fentanyl were started in group I and II respectively before the patient woke up.

After extubation patients were admitted to Post Anesthesia Care Unit (PACU). Sensory and motor block were assessed in group II patients to verify successful FICB and to instruct patients against fall if quadriceps weakness occurred. Sensory block was assessed using pinprick over the sensory distribution of the femoral and lateral femoral cutaneous nerves (anterior and lateral aspect of the thigh respectively), and obturator nerve (medial and posterior aspect of the knee). Motor blockade was assessed using modified Bromage scale.

All patients with modified Aldrete-Kroulik recovery score [13] of more than 10 were instructed to start using the PCA pump (CADD-Legacy-PCA Pump, Model 6300, Smiths Medical, USA).

The postoperative pain was assessed over 24 h using VAS score at the time of PACU admission, 1 h, 3 h, 6 h, 12 h and 24 h postoperatively.

Rescue analgesia of 20 mg intravenous pethidine was given to patients in both groups if VAS ≥ 4 at rest, despite three consecutive PCA boluses.

Our primary outcome was the postoperative VAS score reduction. The secondary outcome was the total 24 h rescue analgesic consumption.

The occurrence of any adverse events including nausea, vomiting, hypotension, shivering, pruritus or depression of respiration was recorded. Local adverse effects at the site of the block such as hematoma were recorded. Nausea and vomiting were treated with ondansetron 4 mg IV. Hypotension (defined as a decrease in mean arterial pressure more than 20% of the baseline value) was treated with intravenous fluids and intravenous ephedrine 10 mg boluses as needed. Bradycardia (defined as a heart rate less than 50 beat/min) was treated with atropine 0.01 mg/kg IV. Depression of respiration (defined as respiratory rate less than 10 breath/min or O_2 saturation less than 92% on room air) was treated by oxygenation, a trial for arousal and naloxone 0.1 mg if needed.

Ramsay score was used to assess postoperative sedation [14]. Patient satisfaction was also recorded.

2.1. Statistical analysis

Calculation of the sample size was based on the reduction of postoperative VAS score. Based on the results of our pilot study carried on 10 patients divided into two groups, at least 27 patients were needed to detect a 20% difference at an α error of 0.05 and 80% power of the study. We used SPSS 16 software (SPSS Inc., Chicago, IL, USA) for statistical analysis. Kolmogorov–Smirnov test was performed for verification of the assumption of normality. Quantitative data were described as mean ± SD and independent sample *t*-test was used for comparison between both groups. Categorical data were described as number or frequencies (%) and Chi-square test or Fisher's exact test were used as appropriate for comparison between both groups. Mann-Whitney test was used for analysis of sedation score. P-value < .05 was considered significant.

3. Results

68 patients were evaluated for enrollment in the study, 5 patients didn't meet the inclusion criteria and 3 patients refused to be involved in the study. 60 patients were enrolled and randomly divided into two groups (Fig. 1).

Demographic data including age, weight, gender and surgical duration were comparable among the two studied groups (P > .05) (Table 1).

VAS score was comparable in both groups on admission to PACU (P value > .05). VAS score significantly decreased in PC-FICA group compared to PC-IVF group at 1 h, 3 h and 6 h postoperative (P < .05) with confidence interval (CI) of (−1.340 to −0.460), (−1.489 to −0.577) and (−1.607 to −0.860) respectively. VAS scores were comparable between groups at 12 h and 24 h (P > .05) (Fig. 2).

Intraoperative fentanyl consumption was comparable in the studied