

Fascia Iliaca Compartment Blockade for Acute Pain Control in Hip Fracture Patients

A Randomized, Placebo-controlled Trial

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Background: Hip fracture patients are in severe pain upon arrival at the emergency department. Pain treatment is traditionally based on systemic opioids. No study has examined the effect of fascia iliaca compartment blockade (FICB) in acute hip fracture pain management within a double-blind, randomized setup.

Methods: Forty-eight patients with suspected hip fracture were included immediately after arrival in the emergency department, before x-ray confirmation of their fracture. Included patients were randomly assigned to two groups of 24. In the FICB group, the patients received an FICB with 1.0% mepivacaine and a placebo intramuscular injection of isotonic saline. In the morphine group, the patients received a placebo FICB with 0.9% saline and an intramuscular injection of 0.1 mg/kg morphine. Patients received intravenous rescue morphine when necessary.

Results: Maximum pain relief was superior in the FICB group both at rest ($P < 0.01$) and on movement ($P = 0.02$). The median total morphine consumption was 0 mg (interquartile range, 0–0 mg) in the FICB group and 6 mg (interquartile range, 5–7 mg) in the morphine group ($P < 0.01$). More patients ($P = 0.05$) were sedated in the morphine group at 180 min after block placement as compared with the FICB group.

Conclusion: Pain relief was superior at all times and at all measurements in the FICB group. The study supports the use of FICB in acute management of hip fracture pain because it is an effective, easily learned procedure that also may reduce opioid side effects in this fragile, elderly group of patients.

HIP fracture patients are in severe pain upon arrival at the emergency department (ED).¹ Pain treatment is traditionally based on systemic opioids,² which have a large potential for side effects in these frail and elderly patients.³ Blockade of the lumbar plexus has been proposed as an alternative method of acute pain control, and femoral nerve block has been evaluated in some

descriptive series and a few randomized studies.⁴⁻⁷ None of the studies have compared regional blockade of the plexus with a standardized systemic analgesic regimen where other analgesics have not yet been administered. Furthermore, no studies have used a double-blind setup. Also, no study has examined the effect of fascia iliaca compartment blockade (FICB) in acute hip fracture pain management.

Therefore, the current study was performed to evaluate the effect of the FICB method compared with standardized systemic morphine analgesia in acute hip fracture patients after arrival in the ED in a double-blind controlled setup with placebo blockade.

Materials and Methods

Patients and Design

From May 2003 till January 2006, patients arriving at the ED at Hvidovre University Hospital (Copenhagen, Denmark) with clinical signs of a primary hip fracture were screened for inclusion in the study. Patients were only screened if one of the nine investigators was on call at the time of arrival of the patient. Inclusion criteria were clinical signs of hip fracture as assessed by the ED staff, intact cognitive status on admission, and the ability to provide written informed consent. Exclusion criteria were refusal to participate in the study, previous surgery in the affected hip, regular prefracture opioid or glucocorticoid therapy, alcohol or substance abuse, infection at the injection site, morphine intolerance, or any previous opioid administration for the acute pain and nonconfirmation of the hip fracture suspicion on x-ray.

The study was approved by the local ethics committee (Copenhagen and Frederiksberg, Denmark) and the Danish data protection agency (Copenhagen, Denmark) and was registered with ClinicalTrials.gov under the US National Library of Medicine (code NCT00162630).

Forty-eight included patients were randomly assigned to two groups of 24. In the FICB group, the patients received an FICB with 1.0% mepivacaine with 1:200,000 epinephrine on the side of the fracture and a placebo intramuscular injection of isotonic saline in the contralateral gluteal region. In the morphine group, the patients received a placebo FICB with 0.9% saline on the fractured side and an intramuscular injection of 5.0 mg/ml, 0.1 mg/kg morphine in the contralateral gluteal region.

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The study was double blind. The randomization was done *via* a computer-generated list, and the medicine used for each individual patient was prepared by a nurse not otherwise involved with the collection of patient data.

All inclusion and patient procedures were performed by one of nine investigators. All investigators were junior anesthesiologists with less than 2 yr of training (median, 1 yr). All had been instructed in block procedures as part of their standard training at the department, but none had any extensive training or experience with the FICB procedure.

Procedures

Immediately upon arrival in the ED of a patient with a suspected hip fracture, the ED staff started oxygen therapy by nasal cannulae at 2 l/min, inserted an intravenous line, started fluid resuscitation, gave 1 g oral paracetamol, and summoned the investigators who, after informed consent, included the patient in the study. The investigator then performed an FICB as originally described by Dalens *et al.*^{8,9} A line was drawn from the pubic tubercle to the anterior superior iliac spine, and after dividing this line in three equal sections, the puncture site was marked 1 cm caudal to the point dividing the lateral third and medial two thirds of this line. After skin disinfection, the skin was pierced with a sharp needle, and a short blunt needle (Plexufix[®] 50-mm, 24-gauge needle; B. Braun Medical A/S, Frederiksberg, Denmark) was inserted perpendicular to the skin. Loss of resistance was noted first on passing the fascia lata and second on passing the fascia iliaca. After the second loss of resistance had been felt, aspiration was performed, and when no blood could be drawn, 40 ml of study drug was injected slowly, consisting of 1.0% mepivacaine with 1:200,000 epinephrine in the FICB group and 0.9% saline in the morphine group. After completion of the block, an intramuscular injection was performed in the contralateral gluteal region, where 0.02 ml/kg of study drug was injected, consisting of 0.9% saline in the FICB group and 5.0 mg/ml morphine in the morphine group.

Thirty minutes after performing the "block," the patients were taken to the x-ray department, and after x-ray confirmation of the fracture, patients were transferred to the postanesthesia care unit. The investigators assessed the patients at 30, 60, and 180 min after the block procedure. From 30 min and beyond, the patients received 2.5 mg morphine intravenously if they had a pain score of 5 or greater at rest, as indicated on a 10-point verbal ranking scale (VRS). The study was terminated 3 h after the "block." At the conclusion of the study, an epidural catheter was inserted in the L2-L3 or L3-L4 interspace and tested with 60 mg lidocaine, 2%, with 1:200,000 epinephrine. Epidural analgesia was provided with a bolus of 25 mg bupivacaine, 0.25%, followed by a continuous epidural infusion of 0.125% bupivacaine and

50 μ g/ml morphine at a rate of 4 ml/h. The patients were advised to eat and drink freely until 6 h before surgery and to drink clear fluids and protein drinks until 2 h before. Postoperatively, patients were admitted to a specialized hip fracture unit and treated according to a well-defined multimodal fast-track rehabilitation regimen.³

Study Parameters

Upon inclusion, all patients had vital parameters measured in the form of blood pressure, heart rate, and oxygen saturation. Pain at rest and on movement was assessed on a 10-point VRS, with 0 indicating no pain and 10 indicating the worst imaginable pain; movement pain was elicited by passively elevating the fractured leg to 15°.

The time to perform the FICB procedure was measured as the time used from beginning marking the anatomical landmarks until the end of the injection. After the procedure, patients were asked to describe the discomfort associated with the procedure on a 5-point VRS: 0 = no discomfort, 1 = slight discomfort, 2 = moderate discomfort, 3 = severe discomfort, and 4 = very severe discomfort.

At 30, 60, and 180 min after the block procedure, the investigators measured vital parameters, pain at rest and on movement, sedation, and nausea on 4-point scales, with 0 = none, 1 = slight, 2 = moderate, and 3 = severe. At 30 min after the procedure, the patients were asked to evaluate overall pain relief on a 4-point VRS, with 0 = no relief, 1 = slight relief, 2 = moderate relief, 3 = good pain relief, and 4 = complete pain relief. In addition, sensory perception in the anterior and lateral aspects of the fractured thigh was assessed by cold perception by the investigator. A successful block was defined as absence of cold perception in any part of the thigh.

At any point at least 60 min after the block procedure, the investigator assessed pain on repositioning of the patient on a 10-point VRS, either when the patient was taken from the trolley to the bed or when the patient was replaced in the lateral position in the bed.

Statistics

Data from previous studies of acute hip fracture pain management¹⁰ indicated that 21 patients were needed in each group to demonstrate a 30% difference in pain score on movement with a significance of 0.05 and a power of 0.80, and 24 patients were included in each group to compensate for inaccuracies. Tests for significant differences between groups were done with the chi-square test for categorical data, the Mann-Whitney test was used for continuous numeric data that were not normally distributed, and the Student *t* test was used for normally distributed categorical data. *Post hoc* correction for repeated measures was done with the Bonfer-

Table 1. Demographic Data in Hip Fracture Patients Randomized to Fascia Iliaca Compartment Blockade (A) versus Placebo (B)

	Group A (n = 24)	Group B (n = 24)	P Value
Age, yr	83 (75–88)	77 (69–88)	0.10
Sex, M/F	10/14	3/21	0.02
ASA, I/II/III	0/13/11	3/15/6	0.10
Weight, kg	60 (50–80)	60 (50–65)	0.13
BMI, kg/m ²	22.8 (20.8–28.4)	21.3 (19.5–21.2)	0.13
Fracture type, I/T/S	10/12/2	8/11/5	0.46

Values are given as median (interquartile range) where relevant. ASA = American Society of Anesthesiologists physical status; BMI = body mass index; I = intracapsular; S = subtrochanteric; T = trochanteric.

roni correction. All data analysis was conducted with SPSS for Windows version 10.1 (SPSS Inc., Chicago, IL).

Results

Forty-eight patients were included in the project between May 2003 and February 2006. One patient did not have a fracture but only a severe contusion and was excluded after x-ray; an extra patient was therefore included on a new number. Patient demographics are shown in table 1. There was no significant difference in age, level of comorbidities, or fracture type between the two groups, but there was a significantly higher proportion of men in the FICB group.

Before block placement, pain at rest was significantly lower ($P = 0.05$) in patients with intracapsular fractures (median, 2 [interquartile range (IQR), 0–5]) compared with those who had trochanteric (median, 4 [IQR, 2–5]) or subtrochanteric fractures (median, 5 [IQR 4–7]), but there was no significant difference in movement-associated pain between fracture types, which was median 8 (IQR, 6.5–10), 9 (IQR, 8–10), and 10 (IQR, 8–10) for intracapsular, trochanteric, and subtrochanteric fractures, respectively.

Block of all or part of the lumbar plexus was registered in 16 of 24 patients (67%) in the FICB group and in 1 of the patients in the morphine group in whom sensitivity to cold was absent on the anterior part of the femur at all assessments. Three patients in each group received supplementary opioids; these constituted 1, 2, and 4 supplementations in the FICB group and 1, 1, and 2 in the morphine group. In the 16 patients with a successful block, only one supplementation was given to one patient. Two patients (one from each group) had protocol violations because they received sufentanil as supplementation instead of morphine; both of these supplementations occurred in the postanesthesia care unit more than 60 min after block placement. Total morphine consumption was median 0 mg (IQR, 0–0 mg) in the FICB group and 6 mg (IQR, 5–7 mg) in the morphine group ($P < 0.01$).

Pain at rest and on 15° leg lift of the fractured leg is

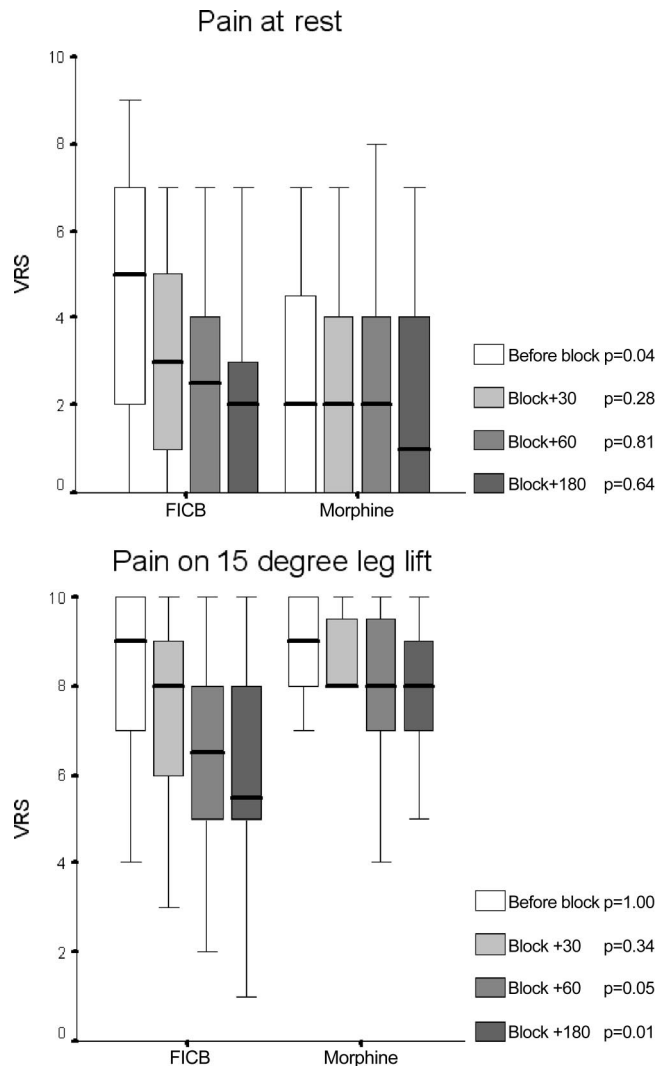


Fig. 1. Pain at rest and on movement in hip fracture patients randomized to fascia iliaca compartment blockade (group FICB) or systemic morphine (group morphine) preblock and at 30, 60, and 180 min after block. VRS = 10-point verbal ranking scale.

shown in figure 1. After correction for repeated measures, pain at rest showed no significant difference between groups. Pain on 15° leg lift was 9 (median) in both groups ($P = 1.00$) before block placement; movement-elicited pain was significantly lower in the FICB group at 180 min ($P = 0.04$) after block placement.

Block placement took a median of 4 min (IQR, 3–5 min). Patients assessed the block placement discomfort at median 0.5 (IQR, 0–2) on a 5-point VRS score; there was no difference in discomfort ($P = 0.37$) between those patients who received mepivacaine and those who received saline in the block.

Overall pain relief assessed 30 min after block placement with a 5-point VRS scale was median 1 (IQR, 0–2.75) in the FICB group and 0 (IQR, 0–1) in the morphine group ($P = 0.09$). Maximum pain relief in measured resting pain (10-point VRS) was median 2 (IQR, 0–4) in the FICB group versus 0 (IQR, 0–2) in the

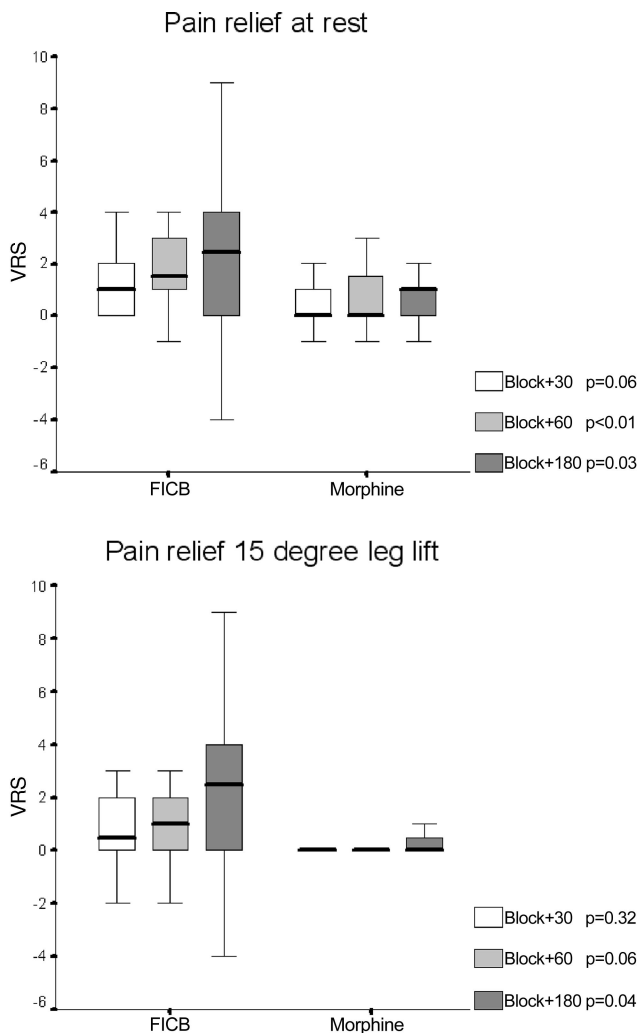


Fig. 2. Pain relief at rest and on movement in hip fracture patients randomized to fascia iliaca compartment blockade (group FICB) or systemic morphine (group morphine) preblock and at 30, 60, and 180 min after block. VRS = 10-point verbal ranking scale.

morphine group. Maximum pain relief on movement elicited pain was median 3 (IQR, 1–4) in the FICB group *versus* 1 (IQR, 0–2) in the morphine group. Both differences were significant at $P < 0.01$ and $P = 0.02$, respectively. Pain relief presented as Δ VRS (0–10) between preblock pain scores and pain at 30, 60, and 180 min after block placement are shown in figure 2. There was significantly higher Δ pain at rest in the FICB group at 60 and 180 min ($P = 0.01$ and 0.03 respectively) and Δ pain on 15° leg lift at 180 min ($P = 0.04$).

Pain on repositioning of the patient in the bed as assessed on 10-point VRS was median 6 (IQR, 2–7.75) in the FICB group and 7.5 (4.75–9) in the morphine group ($P = 0.18$).

Post hoc analysis of pain relief in the FICB group, according to whether the block was considered successful on the cold test, showed that patients with an unsuccessful block had a higher maximum pain relief of median 3 (IQR, 2–5) on 15° leg movement compared with

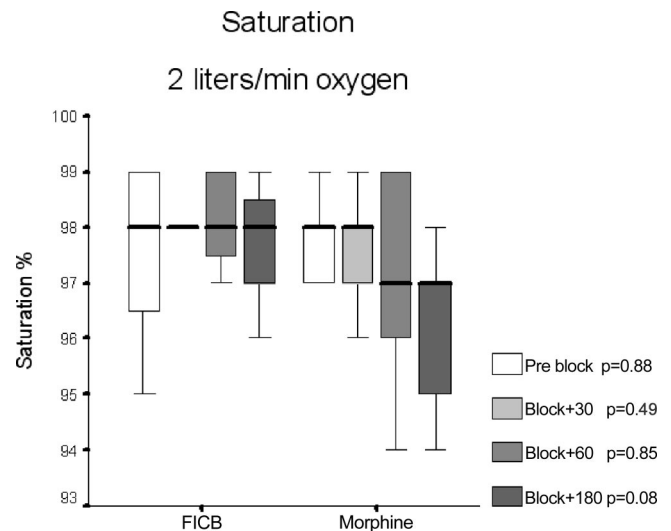


Fig. 3. Oxygen saturation in hip fracture patients randomized to fascia iliaca compartment blockade (group FICB) or systemic morphine (group morphine) preblock and at 30, 60, and 180 min after block.

those with an unsuccessful block—median 1 (IQR, 0–3) ($P = 0.02$). Pain relief at rest was not significantly different ($P = 0.7$), with a maximum relief of median 2.5 (IQR, 0–4) in those with a successful block, compared with 1.5 (IQR, 0–5) in those with an unsuccessful block.

At 180 min after block placement, one patient in the FICB group *versus* six patients in the morphine group was sedated ($P = 0.05$). There was no difference between groups in nausea and vomiting, with three patients in each group having these side effects. One patient in the FICB group was nauseated from the 30-min postblock test and developed hematemesis 2 h after block placement. Oxygen saturation is presented in figure 3. There was a tendency toward a lower saturation in the opioid group at 60 and 180 min after the block despite oxygen supplementation ($P = 0.08$). There were no significant differences in mean arterial pressure or heart rate between groups at any time point during the investigation; no side effects attributable to the FICB were noted in any patients during their hospital stay.

Discussion

Fascia iliaca compartment blockade has not previously been assessed as acute analgesic procedure in hip fracture or other surgical patients in a randomized blinded study. This study shows that FICB provides superior pain relief to 0.1 mg/kg intramuscular morphine both at rest and on 15° leg lift in hip fracture patients. At all measurements after the placement of the block, pain relief was superior in the FICB group. No side effects of the FICB were recorded, and patients in the morphine group were significantly more sedated and had a tendency toward lower oxygen saturation.

Pain treatment in hip fracture patients is often based on local tradition and ED staffing rather than evidence. A recent study showed that 36% of hip fracture patients reporting pain in the ED received no analgesia, 7% received only nonopioids, and 57% received opioids.¹¹ Another study reported a mean hourly morphine equivalent administration of 0.79 mg for the first 24 h of hospitalization, with 50% of patients receiving an intramuscular analgesic injection.²

Several studies⁴⁻⁷ have assessed blockade of the femoral nerve on patients with a radiologically confirmed hip fracture, but none have been blinded, none have compared regional blocks with a standardized systemic analgesia, and only one⁶ describes the analgesia that had been provided during initial admission and x-ray confirmation of the fracture.

We found significantly improved maximum pain relief both at rest and on movement. The interpretation of the data on pain relief at rest is rendered somewhat difficult by the higher initial resting pain score in the FICB group. As such, it is not possible to conclude with certainty whether the FICB provides superior pain relief at rest or whether the demonstrated effect is caused by the initial discrepancy in pain scores at rest between the two study groups.

Regional analgesia with local anesthetics has previously been associated with improved dynamic pain relief compared with systemic opioid therapy,^{3,12} a superiority that has not been demonstrated to the same degree with pain at rest. The current data would also suggest that systemic opioid therapy fails to provide dynamic pain relief in acute hip fracture patients.

Compared with other studies, we had a relatively low percentage of successful blocks (67%). Previous studies with higher reported success rates (81-96%) had all blocks performed by a limited number of experts,^{4,6,13} whereas the study by Fletcher *et al.*,⁶ where blocks were performed by all ED physicians on duty, did not report the success rates for their blocks. Our low success rate could have several explanations. First, although the block is relatively easy to learn, there probably is a learning curve, and the blocks in the current study were all performed by anesthesiologists in training. Second, no previous studies examined block success rate within a double-blinded setup; potentially unblinded studies of analgesic blocks have an inherent tendency to overestimate the success rate. However, even the patients with "unsuccessful" blocks actually had some degree of pain relief by the FICB compared with the opioid group. Opioid side effects were demonstrable in the morphine group despite the low dosages used. Significantly more patients were sedated, and there was a tendency toward a lower saturation in the morphine group.

The main disadvantage of the current study is the bolus intramuscular morphine technique used for comparison with the FICB. The gold standard for opioid analgesia

deliverance is patient-controlled intravenous opioids, but this technique is not logistically possible in this acute setting with elderly patients requiring pain treatment immediately after arrival in the ED, where patient education in the use of this analgesic technique is impossible. Intramuscular injection route was already used as a standard by our ED before the study and has also been used in previous randomized studies of acute pain management in hip fracture patients.^{10,14} Intramuscular injection of morphine has a peak plasma concentration within 30 min of injection¹⁵ and as such should provide analgesia within the time frame of the study. In addition, the patients had subsequent titration with small boluses of intravenous morphine where necessary.

Our randomization did not fully succeed in making two comparable groups because there was a significant higher proportion of male patients in the FICB group, which, however, should not influence the results because analgesia requirements are independent of sex in this age group.¹⁶

The FICB technique has some potential advantages compared with the femoral nerve block technique, in the acute setting. The site of injection with the FICB is distant from any nerves or blood vessels, which theoretically should eliminate the possibility of intravascular or intraneural injection. We chose a short-acting local anesthetic (mepivacaine) over longer-acting drugs for three reasons: First, we wanted a fast onset of the block; second, patients were scheduled to receive preoperative epidural analgesia as soon as the study was finished; and third, we did not want any neural blockade to intervene with postoperative mobilization in those patients who had surgery shortly after admission. However, longer-acting local anesthetics could equally well be used, although the duration of analgesia remains to be studied in detail.

We did not observe any side effects of the FICB technique, comparable with only one incidence of transient femoral paresthesia reported in the literature.¹⁷

Although pain relief was improved by FICB, there is still room for further improvement *via* a multimodal approach possibly including intravenous paracetamol, cyclooxygenase-2 inhibitors (in patients without contraindications such as coronary artery disease or renal failure), or a combination. Treatment with nonsteroidal antiinflammatory drugs is probably not an option because they have been associated with increased blood loss in these patients, which is not the case with cyclooxygenase-2 inhibitors.¹⁸

Epidural blockade has been shown to decrease morbidity when instituted in the preoperative phase,¹⁰ but it is not a procedure that is feasible for hyperacute analgesia in the first hours before the confirmation of fracture. The current data support the use of FICB in acute management of hip fracture pain because it is an effective, low-tech, low-risk, easily learned procedure that has the

potential to reduce opioid side effects in this fragile group of patients.

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