International Journal of Orthopaedic and Trauma Nursing 33 (2019) 35–43

Contents lists available at ScienceDirect

International Journal of Orthopaedic and Trauma Nursing

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

Pre-operative pain management with nerve block in patients with hip fractures: a randomized, controlled trial

Pär Wennberg[a,b,*], Rolf Norlin[c,d], Johan Herlitz[e,f], Elisabeth Kenne Sarenmalm[a], Margareta Möller[b]

[a] Research and Development Centre, Skaraborg Hospital, Skövde, Sweden
[b] University Health Care Research Centre, Region Örebro, and School of Health Sciences, Örebro University, Sweden
[c] Capio Movement, Halmstad, Sweden
[d] Department of Orthopedics, Örebro University Hospital, and Örebro University, Sweden
[e] The Centre of Prehospital Research in Western Sweden, University College of Borås, Sweden
[f] The Centre of Prehospital Research in Western Sweden, Sahlgrenska University Hospital, Gothenburg, Sweden

ARTICLE INFO

Keywords:
Hip fractures
Pain
Nerve block
Pain management
Fascia iliaca compartment block
Analgesia

ABSTRACT

Introduction: Pain management in patients with hip fractures is a major challenge for emergency care. The objective of this study was to evaluate whether the supplementation of pre-operative analgesia with low-dose fascia iliaca compartment block (FICB) compared with placebo would improve pain relief in patients with hip fractures.
Methods: A double-blind, randomized, controlled trial was conducted on 127 patients. At hospital admission, a low-dose FICB was administered to patients with hip fractures as a supplement to regular pre-operative analgesia. Patients with and without cognitive impairment were included. The instruments used were a visual analogue scale (VAS), a numerical rating scale and a tool for behavior related pain assessment. The primary endpoint was the change in reported pain on movement from hospital admission to two hours after FICB.
Results: The intervention group showed improved pain management by mean VAS score for pain on movement compared with the control group ($p = 0.002$).
Conclusions: Our results support the use of low-dose FICB as a pain-relieving adjuvant to other analgesics when administered to patients with a hip fracture.

Introduction

Hip fractures are an international challenge, and projections indicate a threefold global rise to over six million per year by 2050 (Dhanwal et al. 2011). In Sweden, the annual number of patients with hip fractures is approximately 18,000 per year with a predicted twofold increase by 2050 (Rosengren and Karlsson, 2014). The average age of patients with hip fractures is 83 years; they are frail and often receive insufficient pain relief, which increases the incidence of delirium and leads to longer hospital stays (Kuske et al. 2016; NHFD, 2016; Johansen et al. 2017). Cognitive impairment is found in at least one third of this group of patients. Randomized clinical trials (RCTs) are scarce involving patients with hip fractures and rarely include cognitively impaired patients (Mundi et al. 2014). This paper, reports a study that aimed to consider the effectiveness of Fascia Iliaca Compartment Block (FICB) for pain relief following hip fracture.

Background

Pain management during emergency care is a major problem for patients suffering from hip fracture and is especially problematic in persons with cognitive impairment. The objective for nurses and other healthcare professionals when caring for patients with hip fractures is to assess pain, use pain scales and listen to the patient's story, as well as to ensure adequate and effective pain relief which may include the initiation of nerve blocks (Wennberg et al. 2018).

During the acute phase of hip fracture, providing patients with sufficient pain relief for them to easily move about in bed, use a bedpan or undergo pre-operative preparation is a major challenge (Foss et al. 2007). Another challenge is assessing pain using self-report scales for patients with cognitive impairment, so focusing on behavioural pain assessment is essential (Herr and Titler, 2009; Maher et al. 2012).

Research shows that nerve blocks can provide effective analgesia

* Corresponding author. School of Health Sciences, Örebro University, SE-701 82 Örebro, Sweden.
E-mail addresses: par.wennberg@vgregion.se (P. Wennberg), rolf.norlin@gmail.com (R. Norlin), johan.herlitz@hb.se (J. Herlitz), elisabeth.kenne.sarenmalm@vgregion.se (E.K. Sarenmalm).

https://doi.org/10.1016/j.ijotn.2018.11.003
Received 10 January 2018; Received in revised form 17 November 2018; Accepted 27 November 2018

and reduce the incidence of delirium (Foss et al. 2007; Godoy Monzon et al. 2007; Mouzopoulos et al. 2009; McRae et al. 2015). The Fascia Iliaca Compartment Block (FICB) has been used and tested in several settings and has proved to be a simple method for managing acute pain following hip fracture (Candal-Couto et al. 2005; Hauritz et al. 2009; Elkhodair et al. 2011; Fujihara et al. 2013; Haslam et al. 2013; Rashid et al. 2014). FICB can provide analgesia that is as good as, or even better than, morphine (Foss et al. 2007) and, when compared with injections of non-steroidal anti-inflammatory drugs, provides equal analgesia (Godoy Monzon et al., 2010). However, investigation of the potential for improved pain relief accomplished by adding a FICB to pre-operative analgesia with intravenous opioid analgesia is called for (Williams et al. 2016). There is previous research in the field of regional nerve blocks for patients with hip fractures, but more RCTs are needed due to a lack of high quality studies (Ritcey et al. 2016).

The objective of this study was, therefore, to evaluate whether supplementation with low-dose FICB, in addition to pre-operative analgesia, compared with a placebo, would improve pain relief in patients with hip fractures. The primary endpoint was change in reported pain on movement following FICB administration and up to 2 h afterwards.

Secondary endpoints were:

- the change in pain scores on movement 15 min and 6 h after the FICB
- the change in pain scores at rest, 15 min, 2 h and 6 h after the FICB
- pain relief among patients with cognitive impairment
- analgesic consumption
- length of hospital stay

Materials and methods

A prospective, double-blind, randomized, controlled trial was carried out at a university hospital in Sweden. The inclusion criteria were: 1) a radiographically confirmed hip fracture; 2) age > 64 years; 3) Fascia Iliaca Compartment Block administered within 1 h of admission to hospital.

The exclusion criteria were: 1) refusal to participate; 2) more than one fracture; 3) trauma more than 12 h before inclusion; 4) hypersensitivity to local anaesthetics; 5) infection in the injection area; 6) neuro-vascular problems in the affected leg; 7) unable to receive FICB within the inclusion time frame and 8) patients assessed as at risk of complications from the FICB due to health status.

Sample size

Sample size calculation was performed using data from Candal-Couto (Candal-Couto et al. 2005). It was proposed that, using a Visual Analogue Scale (VAS), the pain score on movement would be reduced from 7.2 (SD 1.8) prior to injection to 3.6 (SD 2.4) 1 h after the injection (Candal-Couto et al. 2005). In the control group, we expected a reduction in pain score on movement from 7.2 (SD1.8) to 5.5 (SD2.4) using a VAS. This would give a power of 90% at a significance level of 0.05 using a two-sided Mann-Whitney *U* test if 70 patients, 35 in each arm, were included.

Randomization was carried out using Statistical Package for the Social Sciences for Windows, Version 14.0.1, and information about the study intervention was sealed in envelopes. The envelopes were numbered and stacked in numerical order; the code number matched the consecutive inclusion of patients. Randomization and preparation were carried out by a statistics expert not involved in the evaluation of the study. A flowchart presenting the inclusion and randomization process can be found in Fig. 1.

Baseline characteristics

Demographic data was retrieved from the patients' medical records. Classification of comorbidity was made using the American Society of Anesthesiologists (ASA) Physical Status Classification System. The fracture was defined according to the classification of hip fractures used by the Swedish National Registry of Hip Fracture Patient Care, i.e. cervical, trochanteric and sub-trochanteric fracture.

Pre-operative analgesia

In this study, pre-operative analgesia was defined as pre-hospital and in-hospital analgesia administered before surgery. Morphine was administered on demand. In Sweden, ambulances are staffed by a prehospital emergency nurse (PEN) for whom it is standard procedure to titrate morphine for intravenous pain relief at the site of injury, during transport, and until admission to hospital. The titration of morphine on demand is continued by nurses on the ward. Before surgery, paracetamol is often prescribed on demand and has been found to be effective. There was no standard prescribed pre-operative dosage of either morphine or paracetamol. The average dosage is presented in the results.

The procedure

The hospital where this study took place had adopted a fast-track protocol. This means that the prehospital emergency nurse (PEN) made an assessment at the site of the injury and diagnosed suspected hip fracture. Typical symptoms were assessed, including classical clinical signs such as: an externally rotated, shortened leg; severe hip pain; inability to lift the leg; and a history of falling prior to the hip pain. Pain medication was provided, and the patient was transported to the X-ray department (the PEN routinely made a call to prepare the X-ray department). The X-ray confirmed or rejected the suspicion of fracture. If there was no fracture, the patient was transported to the emergency department.

Following the verification of hip fracture, potential participants were transferred directly to the orthopaedic ward. The nurse in charge informed the patient of the opportunity to participate in the study. Inclusion was commenced less than 1 h after hospital admission as FICB had to be performed within 1 h of hospital admission in order to fulfil the inclusion criteria. After inclusion, a sealed opaque envelope with instructions was opened by a nurse not connected to the study, who prepared a syringe with 30 ml of 2 mg/ml ropivacaine or 30 ml of placebo (saline) depending on allocation to the intervention or control group. The FICB was administered to the affected hip by the orthopaedic surgeon who examined the patient by perpendicular injection with a two-pop technique as a complement to pre-operative analgesia. The insertion point was identified by drawing a line between the *spina iliaca anterior superior* and *os pubis*, 1 cm lateral to the conjunction of the two thirds closest to the *spina iliaca anterior superior*. The insertion was made by loss of resistance; when passing first the *fascia lata* and then the *fascia iliaca* (2 pops), the investigation fluid was then injected (Fig. 2). The needle used was a regular needle for intramuscular injections; a choice made depending on what was available on the ward.

The case report form was filled out by the ward staff, who also conducted the assessment of the study patients. The patient, the doctor performing the FICB and the nursing staff performing tests and filling out case report forms were blinded to the substance administered.

Thirty-four physicians performing the FICB underwent training for involvement in the study, consisting of theory and practice under supervision. All staff members were educated in pain assessment (using the Stockholm South General Hospital Pain Instrument), filling out case report forms, randomization and blinding, according to the study protocol. The study was conducted under the surveillance of an external monitor between October 2010 and February 2012.

Measurements

The instrument used to assess pain was the Stockholm South General Hospital Pain Instrument (SSGHPI) (Fig. 3). The SSGHPI is a combination of self-rating scales: a visual analogue scale (VAS), a numerical rating scale (NRS) from 0 to 10, a verbal rating scale (VRS) and a behavioural rating scale (BRS) (Edberg and Soderqvist, 2012). The

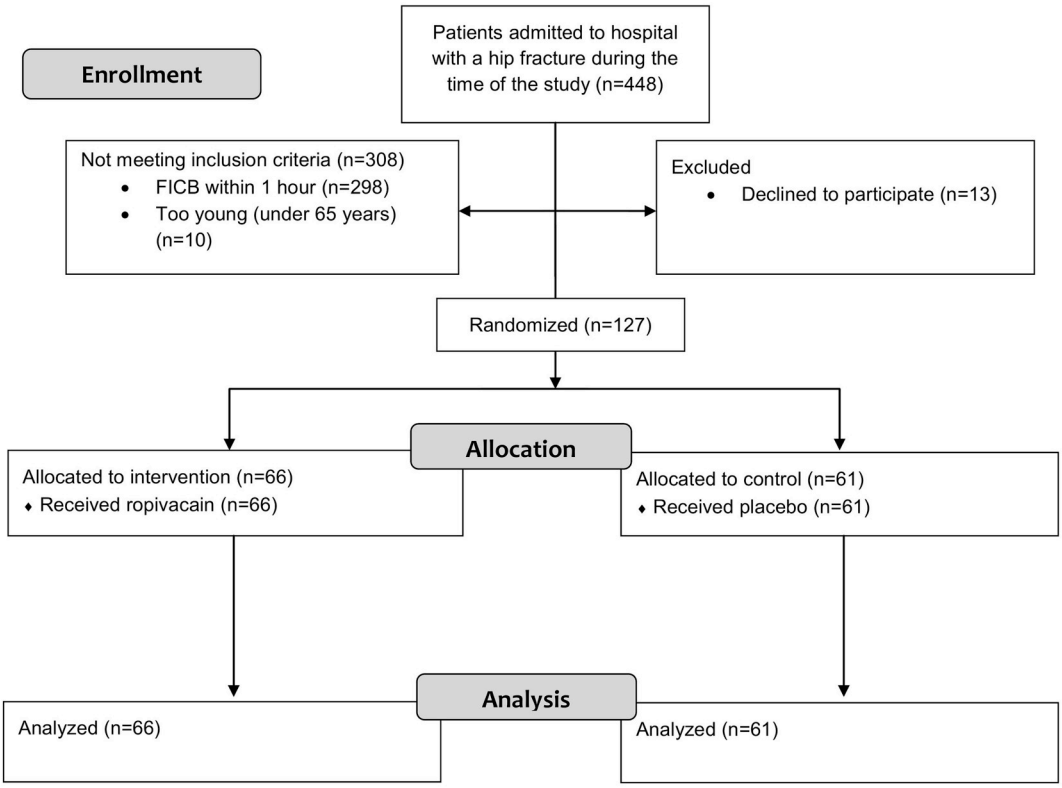

Fig. 1. Flow diagram (CONSORT 2010) showing the inclusion and analysis process of the RCT.

patient used the scale that he or she found most appropriate. The fourth scale, the BRS, was used by the staff only when the patients were not able to assess and describe their own pain. The BRS is a three-category scale categorizing pain from the patients' behaviour used when cognitive impairment makes self-assessment difficult. The three categories are: 1 - no pain or mild pain; 2 - moderate pain; and 3 - severe pain. The BRS has been agreement-tested with acceptable agreement with the VAS when used with patients suffering from hip fractures (Edberg and Soderqvist, 2012). Similar categorizations of numerical pain scales into three categories have previously been carried out (Hansson et al. 2005; Dale and Bjornsen, 2015).

In order to compare pain measurements with the different scales, a synthesis of the scales was made; NRS and VRS scores were converted to the VAS. We will now refer to this synthesis of as “generalized VAS”; this is presented as VAS in our results with a scoring range from 0 to 10.

For a comparison of all patients, regardless of cognitive function, our “generalized VAS” was then converted into the three BRS categories (primarily used in cases of cognitive impairment) in the following way: 0–3.0 = 1; 3.1–7.9 = 2 and 8.0–10 = 3 (Edberg and Soderqvist, 2012).

Baseline assessments for pain scores were made before the FICB was administered. The consumption of opioids was recorded at baseline, since patients had already received analgesics from the PENs.

Pain was scored on movement and at rest. Intervals for pain scores, apart from baseline and 2 h after the FICB, were 15 min and 6 h after the FICB. Movement was assessed by ability to perform foot rotation. In this setting, foot rotation was defined thus: the injured leg was rotated with the knee extended to evaluate whether or not, due to pain, it could be rotated past its neutral position. Rest was defined as the patient

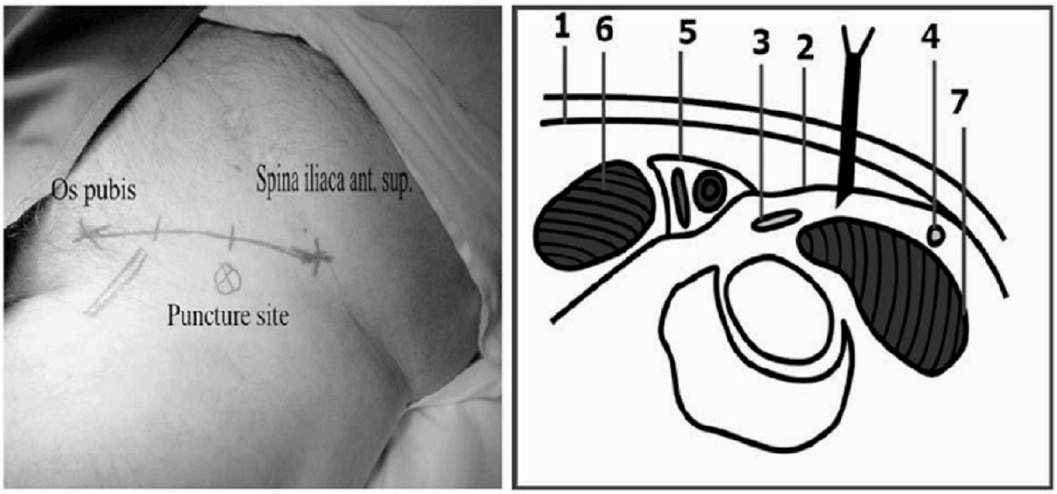

Fig. 2. (a). Puncture site, (b). Anatomy of the fascia iliaca compartment: 1 fascia lata, 2 fascia iliaca, 3 N. femoralis, 4 N. cutaneous femoris lateralis, 5 V and A. femoralis, 6 M. pectinale, 7 M. psoas (figures with permission from Hoeg A., Strat Traum Limb Recon (2008) 3:65–70).

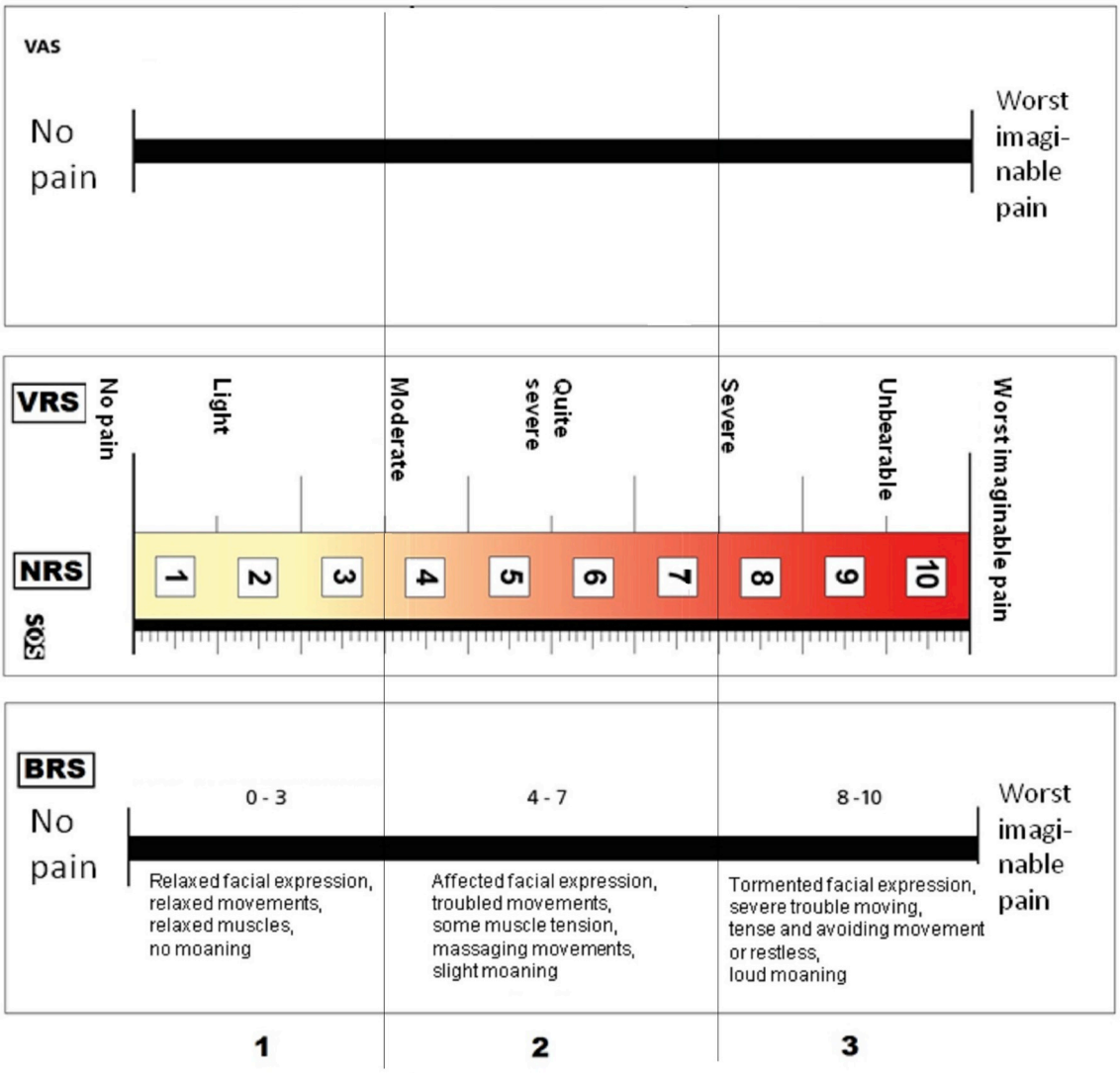

Fig. 3. Stockholm South General Hospital Pain Instrument: visual explanation of the translation of the four scales. The three categories are separated by the lines in the figure, categories represented by the numbers. All four possible versions of pain assessment using the Stockholm South General Hospital Pain Instrument: visual analogue scale (VAS), verbal rating scale (VRS), numerical rating scale (NRS) and behavioural rating scale (BRS). The latter is used by staff to assess pain in patients who are unable to use any of the other scales.

choosing a position for the best comfort (Candal-Couto et al. 2005).

Statistics

Continuous variables are presented as the mean, standard deviation, median and range. Categorical variables are presented as percentages. For comparisons between the intervention group and the control group, the Mann-Whitney *U* test was used for continuous variables, the Mantel-Haenszel chi-square test was used for ordinal categorical variables, Fisher's exact test was used for dichotomous variables and the Pearson chi-square test was used for non-ordinal categorical variables. Changes in pain score from baseline to 15 min, 2 h, and 6 h were compared between the intervention and the control group. Mean differences in changes between intervention and control group are given, together with a bootstrapped 95% confidence interval for the VAS in the tables.

Adjustments for differences in baseline variables were made using covariance analysis (ANCOVA) for continuous variables. An adjusted mean difference with 95% confidence intervals was calculated in the ANCOVA analyses. Changes within groups were analyzed with Wilcoxon's signed rank test for continuous variables and with the sign test for ordered categorical variables. All significance tests were two-sided and conducted at the 5% significance level. All statistical analyses and tests were carried out using IBM SPSS Statistics Version 22.

Ethical considerations

Ethical approval was received from the Regional Ethics Board in Uppsala, Dnr. 2008/172. The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration. Approval was also given by the Swedish Medical Products Agency, Dnr. 151:2008/60682. Trial registry: EudraCT number 2008-004303-59.

Written consent was obtained from participants. Patients who were unable to give their consent were included following presumed consent; they were assessed as not having the capacity for consent at the time of inclusion. This assessment was made by the including physician, together with the nurse responsible for the patient. The Short Portable Mental Status Questionnaire was used to support the decision of inclusion on presumed consent (Pfeiffer, 1975).

Presumed consent was given with the support of the Regional Ethics Board in Uppsala, as directed by Swedish law.

The FICB was given in addition to the regular analgesia that all

Table 1
Baseline characteristic data.

Description	Intervention group (n = 66)	Control group(n = 61)	p-value
Age, years			0.84
Mean (SD)	84.6 (6.7)	84.9 (7.7)	
Median (min; max)	85 (68; 99)	86 (65; 97)	
Gender, *n (%)*			0.78
Female	45 (68.2%)	43 (70.5%)	
Male	21 (31.8%)	18 (29.5%)	
ASA score, *n (%)*			0.55
1	1 (1.5%)	3 (4.9%)	
2	30 (45.5%)	27 (44.3%)	
3 & 4	35 (53.0%)	31 (50.8%)	
Type of fracture, *n (%)*			0.88
Cervical	33 (50.0%)	29 (47.5%)	
Trochanteric	29 (43.9%)	29 (47.5%)	
Subtrochanteric	4 (6.1%)	3 (4.9%)	
Pre-hospital analgesia, *n (%)*	56 (84.8%)	51 (83.6%)	0.66
Pre-hospital morphine in mg			0.99
Mean (SD)	6.2 (4.7)	5.7 (3.5)	
Median (min; max)	5 (0; 25)	5 (0; 15)	
Waiting time in hours from hospital admission to operation			0.95
Mean (SD)	19.8 (13.4)	20.3 (13.7)	
Median (min; max)	20 (3; 94)	19 (1; 73)	
Inclusion on presumed consent, *n (%)*	25 (37.9%)	22 (36.1%)	0.83

patients received. In order to find evidence for whether FICB is of real benefit to patients with hip fractures or not, blinding was necessary. The fact that half of the patients were exposed to an invasive placebo procedure without pain-relieving substance may be regarded as questionable from an ethical perspective. The control group received "regular" analgesia in order to minimize inequalities in pain treatment.

Results

Baseline characteristic data

One-hundred and twenty-seven patients were included in this study, sixty-six in the intervention group and sixty-one the control group. As seen in Table 1, there was no significant difference in individual characteristics between the two groups. The mean age of the participants was 84 years and 69% were women.

Assessment of pain

Pain at all time points of measurement is presented in Table 2. The mean VAS score for pain on movement was higher at baseline (0 min) in the intervention group compared to the control group (p = 0.03). Otherwise, no significant differences were found at baseline. For logistical reasons, there was some loss of pain measurement data in both groups; the missing data had an even distribution between the two groups.

Primary endpoint

With respect to change in pain on movement from admission to 2 h (Table 3), the mean VAS score for pain on movement decreased by 1.0 (SD 1.9) in the intervention group from admission until 2 h, compared with an increase of 0.5 (SD 2.8) in the control group, (p = 0.002; adjusted for difference at baseline p = 0.09). The table also shows that, within the groups, the decrease in the VAS (mean = 1.0) in the intervention group was significant (p = 0.002), whereas the increase in the VAS (mean = 0.5) in the control group was not significant. The change in the BRS from admission to 2 h (improvement, no change or deterioration) differed significantly between the two groups in favour of the intervention (p = 0.01).

Secondary endpoints

With respect to change in pain from admission to 2 h at rest (Table 3), there was no significant improvement in the VAS score for pain at rest. The change in the BRS differed significantly in favour of the intervention (p = 0.02).

With respect to change in pain from admission to 15 min (Table 3), the mean VAS score for pain on movement improved significantly in the intervention group compared with the control group during the first 15 min (p < 0.001; adjusted p-value < 0.001). The change in the BRS differed significantly in favour of the intervention (p < 0.001).

The mean VAS score for pain at rest improved significantly in the intervention group compared with the control group (p = 0.002). The change in the BRS differed significantly in favour of the intervention (p < 0.001).

With respect to change in pain from admission to 6 h (Table 3), the mean VAS score for pain on movement improved significantly in the intervention group compared with the control group (p = 0.02). However, the change in the BRS did not differ significantly between the two groups. The change in pain at rest did not differ between the two groups either with regard to the VAS or the BRS.

With respect to patients with cognitive impairments (Table 4) the mean VAS score for pain on movement improved significantly during the first 15 min in the intervention group compared with the control group (p = 0.03). However, in the remaining comparisons, the changes did not differ significantly between the two groups.

Other effects

The analgesic drugs used during the first 6 h after the FICB mainly comprised intravenous morphine, which was given on demand. There were no significant differences in the use of morphine between the intervention group (n = 66) and the control group (n = 61) between arrival at hospital and 2 h after the FICB, mean 2.2 mg (SD 2.7) vs. 2.3 mg (SD 2.0) (p = 0.36), or between arrival at hospital and 6 h after the FICB, mean 3.1 mg (SD 3.6) vs. 3.4 mg (SD 2.9) (p = 0.37).

There was no significant difference in the consumption of paracetamol between the two groups. The following doses of paracetamol were given on the day of admission: mean 0.9 g (SD 0.9) in the intervention group (n = 65) and mean 1.1 g (SD 1.0) in the control group (n = 61) (p = 0.29).

The mean length of stay in hospital (LOS) was 10.9 days (SD 5.8) in the intervention group and 10.6 days (SD 5.6) in the control group (p = 0.79).

No serious adverse events due to the FICB were reported in this study.

Discussion

In this study, which evaluated the pain-relieving effect of nerve block when added to routine analgesia for patients with hip fractures in the preoperative setting, it was found that pain was further relieved after the nerve block was given in 27% of the patients during the subsequent 2 h.

The two groups were relatively well balanced at baseline with the exception of pain on movement according to the VAS, where patients in the intervention group scored higher than the control group.

The change in the BRS, (according to whether the pain on movement 2 h after the nerve block (primary endpoint) was further relieved, remained unchanged or deteriorated), differed significantly between the two groups. Our results, thus, suggest that superior pain relief is demonstrated by the difference between the two groups by either: 1) reducing pain scores, or 2) not increasing pain scores.

As the majority of patients were given pain medication (intravenous morphine) before the start of study treatment, a "washout effect" in the first 2 h was possible. This is one of the reasons why it is important to

Table 2
Pain assessment according to the VAS and BRS and use of morphine. at admission, 2 h and 6 h (all patients).

Pain scale	0 min		2 h		6 h	
	Intervention group (n = 64)	Control group(n = 61)	Intervention group(n = 63)	Control group(n = 59)	Intervention group(n = 37)	Control group(n = 37)
VAS Movement	7.61 (2.36)* 8 (1; 10) n = 44	6.22 (3.08) 7 (0; 10) n = 44	6.83 (2.41) 7 (3; 10) n = 40	6.79 (3.00) 7 (0; 10) n = 34	6.68 (1.93) 7 (2; 10) n = 28	6.61 (3.06) 7 (0; 10) n = 23
VAS Rest	4.16 (3.28) 4 (0; 10) n = 44	3.37 (3.10) 3 (0; 10) n = 47	3.39 (2.84) 3 (0; 10) n = 41	3.64 (3.12) 3 (0; 10) n = 37	3.16 (2.84) 3 (0; 10) n = 31	3.25 (3.14) 3 (0; 10) n = 24
BRS Movement						
1	7 (10.9%)	15 (25.9%)	8 (12.9%)	9 (16.1%)	1 (3.1%)	10 (27.8%)
2	25 (39.1%)	20 (34.5%)	31 (50.0%)	22 (39.3%)	21 (65.6%)	13 (36.1%)
3	32 (50.0%)	23 (39.7%)	23 (37.1%)	25 (44.6%)	10 (31.3%)	13 (36.1%)
BRS Rest						
1	28 (43.8%)	39 (63.9%)	41 (65.1%)	36 (62.1%)	24 (64.9%)	27 (73.0%)
2	27 (42.2%)	15 (24.6%)	18 (28.6%)	17 (29.3%)	10 (27.0%)	5 (13.5%)
3	9 (14.1%)	7 (11.5%)	4 (6.3%)	5 (8.6%)	3 (8.1%)	5 (13.5%)
Morphine in mg	6.2 (4.7)5 (0; 25)n = 66	5.7 (3.5)5 (0; 15)n = 61	2.2 (2.7)2 (0; 18)n = 66	2.3 (2.0)2 (0; 7)n = 61	3.1 (3.6)2 (0; 23)n = 66	3.4 (2.9)3 (0; 14)n = 61

For continuous variables, the mean and SD are presented at the top and the median, min; max and n are presented below.
For categorical variables, n (%) is presented.
*$p < 0.05$ for comparisons between the intervention group and the control group regarding the VAS on movement at time 0.
For explanation on pain scale scores please advice Fig. 3 and Measurement section.

include the absence of an increase in pain scores in the evaluation.

There was a significant improvement in pain score, according to the VAS, in the intervention group compared to the control group during the first 2 h after randomization. However, when adjusting for the imbalance between groups at baseline, no significant difference was retained.

The improvement in pain after the FICB was less marked than calculated in our power analysis. The mechanisms behind this finding are unclear.

Two randomized clinical trials have previously been carried out to evaluate the effect of an FICB on pain in hip fractures. One of them compared nerve block with intramuscular morphine (Foss et al. 2007), while the other compared nerve block with non-steroidal anti-inflammatory drugs (Godoy Monzon et al., 2010). Both studies showed that the nerve block was as good as, or superior to, the alternative treatment. However, the design of these trials differed from ours as, in the present study, we evaluated the effect of a FICB when added to the routinely administered pre-operative analgesia.

Our study shows that there are now three RCTs which, in various ways, suggest that a nerve block appears to play a positive role in the treatment of pre-operative pain in hip fracture care.

Fifteen minutes after the FICB, pain scores improved in the intervention group when compared with the control group. This reflects the rapid onset of the block, which confirms the results of previous RCTs (Foss et al. 2007, Godoy Monzon et al., 2010).

Our results suggest that a FICB may have an effect on pain for a longer time period, even in lower doses. It is likely that the choice of dose had an impact on the duration of the FICB, although the difference in pain between the two groups measured on movement was significant also after 6 h. Our results are in line with those of Godoy Monzon (Godoy Monzon et al., 2010), who also used a reduced dose and also showed that the effect had started to wear off 8 h after the block.

Some patients required physiological stabilization, but the majority were in a physical condition that allowed immediate surgery. The median waiting time for surgery in this study was 19 h, which is comparable with other hospitals in Sweden (Rikshoft, 2013). Other studies suggest that waiting times for patients with a hip fracture should not exceed 12 h (Bjorkelund et al. 2011). Shorter waiting times mean less movement at the fracture site and it is reasonable to suppose that this would improve the overall pain relief. Repeated FICB administration, or the insertion of a catheter, might be an alternative approach.

The most appropriate timing for an eventual administration of a FICB in the emergency chain of care for hip fractures should be considered in future investigations. Administration of pre-hospital FICB to patients with hip fractures has been identified as a possibility (Chesters and Atkinson, 2014; Dochez et al. 2014; McRae et al. 2015).

Cognitively impaired patients are an important group of patients with hip fractures that have previously mostly been excluded from participation in clinical trials. The reason for this is most likely that the methods used to evaluate pain among these patients are insufficient. Since the sample size in this study was small and since the analysis of these patients was a secondary endpoint, no definitive conclusions were drawn.

There was no significant difference between the two groups in terms of morphine administered pre-hospital or morphine administered up to 2 h after the block. Other studies have implied that the use of nerve blocks may reduce the requirement for morphine (Fletcher et al. 2003; Foss et al. 2007; Beaudoin et al. 2013; Diakomi et al. 2014). Eighty-five percent of the patients in this study received pre-hospital analgesia. This is in contrast to most previous studies where no analgesia had been administered before the FICB (Capdevila et al. 1998; Candal-Couto et al. 2005; Foss et al. 2007; Hauritz et al. 2009; Elkhodair et al. 2011; Fujihara et al. 2013; Haslam et al. 2013; Rashid et al. 2014).

Since limited patient monitoring was available (oxygen saturation and heart rate), a dose reduction was recommended by the Swedish Medical Products Agency for safety reasons. The dose of ropivacaine in our study proved to be safe – no serious adverse events were reported.

Strengths and limitations

This study was a double blind randomized clinical trial incorporated in the everyday clinical work at a university orthopaedic departemnt. This is regarded as the highest ranked methodology when clinical trials are performed. The reduction of reported pain, by 1.5 on a 10-point

Table 3
Change in the VAS and BRS from admission to 15 min, 2 h and 6 h, test between and within groups. and bootstrapped 95%CI (all patients).

	0–15 min			0–2 h			0–6 h		
	Intervention group (n = 58)	Control group (n = 56)	p-value[b] (adj p-value[c]) *Mean change (95% CI)*[d]	Intervention group (n = 63)	Control group (n = 59)	p-value[b] (adj p-value[c]) *Mean change (95% CI)*[d]	Intervention group (n = 37)	Control group (n = 37)	p-value[b] (adj p-value[c]) *Mean change (95% CI)*[d]
Change VAS Movement	−1.5 (2.3) 0 (−7; 2) n = 33 p < 0.001[a]	0.8 (1.8) 0 (−2; 7) n = 38 p = 0.006[a]	< 0.001 (< 0.001) *−2.3 (-3.3; -1.4)*	**−1.0 (1.9)** **0 (-6; 2) n = 39** **p = 0.002**[a]	**0.5 (2.8)** **0 (-10; 7) n = 34** **p = 0.13**[a]	**0.002 (0.09)** ***−1.4 (-2.5; -0.4)***	−1.1 (2.4) 0 (−7; 4) n = 26 p = 0.02[a]	1.0 (3.2) 0 (−5; 8) n = 22 p = 0.18[a]	0.02 (0.31) *−2.1 (-3.7; -0.5)*
Change VAS Rest	−1.0 (2.8) 0 (−10; 8) n = 37 p = 0.008[a]	0.6 (2.0) 0 (−3; 6) n = 41 p = 0.05[a]	0.002 *−1.6 (-2.7; -0.5)*	−0.6 (2.6) 0 (−7; 6) n = 40 p = 0.16[a]	0.4 (2.0) 0 (−4; 5) n = 37 p = 0.25[a]	0.07 *−1.0 (-2.1; 0.0)*	−1.3 (3.4) −1 (−8; 6) n = 29 p = 0.02[a]	0.3 (3.0) 0 (−4; 8) n = 24 p = 0.94[a]	0.09 *−1.7 (-3.4; -0.0)*
Change BRS Movement Decrease Equal Increase	 14 (26.9%) 35 (67.3%) 3 (5.8%)	 1 (1.9%) 41 (77.4%) 11 (20.8%)	 < 0.001	 **13 (21.0%)** **44 (71.0%)** **5 (8.1%)**	 **6 (10.7%)** **36 (64.3%)** **14 (25.0%)**	 **0.01**	 10 (31.3%) 17 (53.1%) 5 (15.6%)	 8 (22.9%) 17 (48.6%) 10 (28.6%)	 0.23
Change BRS Rest Decrease Equal Increase	 14 (24.1%) 42 (72.4%) 2 (3.4%)	 3 (5.4%) 43 (76.8%) 10 (17.9%)	 < 0.001	 20 (31.7%) 39 (61.9%) 4 (6.3%)	 7 (12.1%) 46 (79.3%) 5 (8.6%)	 0.03	 14 (37.8%) 19 (51.4%) 4 (10.8%)	 6 (16.2%) 25 (67.6%) 6 (16.2%)	 0.09

For continuous variables, the mean and SD are presented at the top and the median, min; max and n are presented below.
For categorical variables, n (%) is presented.

[a] p-value within group.

[b] Test between groups, intervention change vs. control change.

[c] Adjusted p-values are given for variables that differ significantly (p < 0.05) at baseline between the Intervention and control group.

[d] Difference between groups. Calculation of confidence interval for continuous variables is based on bootstrapping of 10000 replicates picking the 2.5 and 97.5 percentiles of the 10000 mean differences as confidence interval. Outlined values present the primary endpoint.

Table 4
Change in the VAS and BRS from admission to 15 min, 2 h and 6 h; test within and between groups and bootstrapped 95%CI (patients with presumed consent).

Variable	Change 0–15 min			Change 0–2 h			Change 0–6 h		
	Intervention group (n = 21)	Control group (n = 21)	p-value[b] *Mean change (95% CI)*[c]	Intervention group (n = 23)	Control group (n = 22)	p-value[b] *Mean change (95% CI)*[c]	Intervention group (n = 12)	Control group (n = 14)	p-value[b] *Mean change (95% CI)*[c]
Change VAS Movement	−1.83 (2.64) −1 (−7; 0) n = 6 p = 0.13[a]	0.63 (1.85) 0 (−1; 5) n = 8 p = 0.75[a]	0.032 *−2.5* *(-5.2; -0.5)*	−0.50 (2.35) −1 (−4; 2) n = 6 p = 0.002[a]	−0.11 (0.60) 0 (−1; 1) n = 9 p = 1.00[a]	0.75 *−0.4* *(-2.4;1.5)*	−0.75 (0.96) −1 (−2; 0) n = 4 p = 0.50[a]	2.00 (2.83) 2 (0; 4) n = 2 p = 1.00[a]	0.22 *−2.8* *(-5.3;0.0)*
Change VAS Rest	−0.29 (0.95) 0 (−2; 1) n = 7 p = 0.75[a]	0.75 (2.70) 0 (−3; 6) n = 10 p = 0.63[a]	0.53 *−1.0* *(-2.9; 0.7)*	1.67 (2.34) 1 (0; 6) n = 6 p = 0.25[a]	0.33 (2.60) 0 (−4; 5) n = 9 p = 0.81[a]	0.35 *1.3 (-1.0; 3.9)*	−1.20 (3.83) 0 (−8; 1) n = 5 p = 1.00[a]	1.83 (4.07) 0.00 (−1; 6) n = 3 p = 1.00[a]	1.00 *−3.0* *(-8.8;1.4)*
Change BRS Movement									
Decrease	3 (16.7%)	1 (5.3%)		5 (21.7%)	1 (4.5%)		3 (33.3%)	3 (23.1%)	
Equal	15 (83.3%)	14 (73.7%)		15 (65.2%)	18 (81.8%)		4 (44.4%)	6 (46.2%)	
Increase	0 (0.0%)	4 (21.1%)	0.075	3 (13.0%)	3 (13.6%)	0.39	2 (22.2%)	4 (30.8%)	0.78
Change BRS Rest									
Decrease	5 (23.8%)	1 (4.8%)		8 (34.8%)	2 (9.1%)		3 (25.0%)	2 (14.3%)	
Equal	15 (71.4%)	18 (85.7%)		14 (60.9%)	19 (86.4%)		9 (75.0%)	11 (78.6%)	
Increase	1 (4.8%)	2 (9.5%)	0.18	1 (4.3%)	1 (4.5%)	0.12	0 (0.0%)	1 (7.1%)	0.42

For continuous variables, the mean and SD are presented at the top and the median, min; max and n are presented below.
For categorical variables, n (%) is presented.
[a] p-value within group.
[b] Test between groups, intervention change vs. control change.
[c] Difference between groups. Calculation of confidence interval for continuous variables is based on bootstrapping of 10000 replicates picking the 2.5 and 97.5 percentiles of the 10000 mean differences as confidence interval.

VAS scale in favour of the intervention group, can be considered clinically meaningful.

The endpoints with dynamic pain were chosen because it is challenging to provide good pain relief for patients when they move about in bed, use a bedpan or undergo pre-operative preparation. The static pain endpoints reflect pain during the larger part of the waiting time for surgery. The different time intervals were chosen with the purpose to measure the onset and the duration of the fascia iliaca compartment block.

At least two pain observations in each patient were required to be included in the analyses. Logistical reasons were given for missing information on pain assessment, for example that the patient was asleep, was undergoing investigations elsewhere or was already at surgery. The loss of data was evenly distributed between the two groups and had a random occurrence without any connection to the patient's condition. Due to the internal loss of data, our results must be interpreted with some caution.

The BRS has only been validated once with acceptable agreement between the VAS and the BRS. This validation has been published in Swedish, which can be regarded as a limitation.

There was an imbalance between the two groups at baseline regarding pain according to the VAS for pain on movement, which might have affected our results. We used computerized randomization and even after a correct randomization procedure, there is still a risk of imbalance at baseline between the two study groups.

Four important factors may have influenced our results: 1) a large number of health-care providers with a varying degree of clinical experience in using the method may have affected the results in a negative fashion; 2) low doses of ropivacaine were used and it is not unlikely that increased doses may have improved pain relief even further. However, these patients had received pharmacological pain relief before the FICB. As a result, a lack of further pain relief should not always be regarded as a failure of the nerve block; 3) morphine administered on demand (as is the routine at this hospital) can relieve pain effectively; and 4) if a blunt needle for FICB insertion had been chosen, instead of the sharp one that was used, the results might have been different (Foss et al. 2007; Høgh et al. 2008).

Although information on concomitant pain-relieving medication both before and after the intervention was at hand, this information could have been even more detailed in terms of treatment protocols. Furthermore, the definition of cognitive impairment could have been even more detailed, although an instrument was used. However, such deficits must be viewed from the perspective of a clinical trial incorporating routine clinical work with all its advantages and disadvantages.

Part of our presentation is based on the principle that since ordinal data was available, a statistical analysis of individual changes in pain was considered the most appropriate. Making a synthesis of several pain scales can be regarded as unconventional. Dividing the VAS into three groups makes the scales less sensitive. To compensate for this discrepancy, we included more patients than the power calculation recommended.

In most countries, nerve blocks are interventions mainly led by surgeons, although nurses have an important role to play in the implementation of interventions. Nurses can facilitate this implementation as they are closest to the patient and are often the patient's voice in the healthcare system. The implementation can also be facilitated by setting up routines and making nerve blocks a part of the standard routine for the pre-operative care received by patients with hip fractures. Even though nurses themselves may not execute the intervention, suggestions for setting up this service can be initiated and facilitated by nurses. Nerve block interventions have been led by trained nurses in the United Kingdom, the Netherlands and Australia (Layzell, 2007; Dochez et al. 2014; McRae et al. 2015). In the United Kingdom this is encouraged where local standards are applicable (AAGBI, 2013).

Conclusion

A FICB, as an adjuvant treatment to routine pre-operative analgesia with morphine and paracetamol, is of benefit in pre-operative pain

management in a significant proportion of patients with hip fractures. One out of four patients with a hip fracture appears to obtain further pain relief with a pre-operative FICB. Further research on the Fascia Iliaca Compartment Block with different dosages is required to give this strategy its optimal position in the preoperative handling of patients with hip fracture.

Ethical statement

Ethical approval was received from the Regional Ethics Board in Uppsala, Dnr. 2008/172. The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration. Approval was also given by the Swedish Medical Products Agency, Dnr. 151:2008/60682. Trial registry: EudraCT number 2008-004303-59.

Role of funding source

The salary to the first author during writing and statistical support was funded by Skaraborg Hospital. External monitoring was funded by Örebro County Council.

Competing interests

The authors declare that they have no competing interests.

Acknowledgements

The authors thank Salmir Nasic, Research and Development Centre, Skaraborg Hospital, Skövde, Sweden. We are grateful for the financial and practical support provided by the research funds at Skaraborg Hospital and Örebro County Council, Sweden.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijotn.2018.11.003.

References

AAGBI, 2013. Association of Anaesthetists of Great Britain and Ireland Position Statement 2013 Fascia Iliaca Blocks and Non-physician Practitioners. Association of Anaesthetists of Great Britain and Ireland. Available at: https://www.aagbi.org/news/fascia-iliaca-blocks-and-non-physician-practitioners-aagbi-position-statement%C2%A0 (accessed Sept 13 2018).

Beaudoin, F.L., Haran, J.P., Liebmann, O., 2013. A comparison of ultrasound-guided three-in-one femoral nerve block versus parenteral opioids alone for analgesia in emergency department patients with hip fractures: a randomized controlled trial. Acad. Emerg. Med. 20, 584–591.

Bjorkelund, K.B., Hommel, A., Thorngren, K.G., Lundberg, D., Larsson, S., 2011. The influence of perioperative care and treatment on the 4-month outcome in elderly patients with hip fracture. AANA Journal 79, 51–61.

Candal-Couto, J.J., McVie, J.L., Haslam, N., Innes, A.R., Rushmer, J., 2005. Pre-operative analgesia for patients with femoral neck fractures using a modified fascia iliaca block technique. Injury 36, 505–510.

Capdevila, X., Biboulet, P., Bouregba, M., Barthelet, Y., Rubenovitch, J., d'Athis, F., 1998. Comparison of the three-in-one and fascia iliaca compartment blocks in adults: clinical and radiographic analysis. Anesth. Analg. 86, 1039–1044.

Chesters, A., Atkinson, P., 2014. Fascia iliaca block for pain relief from proximal femoral fracture in the emergency department: a review of the literature. Emerg. Med. J. 31, e84–87.

Dale, J., Bjornsen, L.P., 2015. Assessment of pain in a Norwegian emergency department. Scand. J. Trauma Resuscitation Emerg. Med. 23, 86.

Dhanwal, D.K., Dennison, E.M., Harvey, N.C., Cooper, C., 2011. Epidemiology of hip fracture: worldwide geographic variation. Indian J. Orthop. 45, 15–22.

Diakomi, M., Papaioannou, M., Mela, A., Kouskouni, E., Makris, A., 2014. Preoperative fascia iliaca compartment block for positioning patients with hip fractures for central nervous blockade: a randomized trial. Reg. Anesth. Pain Med. 39, 394–398.

Dochez, E., van Geffen, G.J., Bruhn, J., Hoogerwerf, N., van de Pas, H., Scheffer, G., 2014. Prehospital administered fascia iliaca compartment block by emergency medical service nurses, a feasibility study. Scand. J. Trauma Resuscitation Emerg. Med. 22, 38.

Edberg, U.-K., Soderqvist, A., 2012. A pain behaviour scale for pain assessment of older individuals with impaired cognitive function in emergency care. Nordic Journal of Nursing Research & Clinical Studies 32, 14–17.

Elkhodair, S., Mortazavi, J., Chester, A., Pereira, M., 2011. Single fascia iliaca compartment block for pain relief in patients with fractured neck of femur in the emergency department: a pilot study. Eur. J. Emerg. Med. 18, 340–343.

Fletcher, A.K., Rigby, A.S., Heyes, F.L., 2003. Three-in-one femoral nerve block as analgesia for fractured neck of femur in the emergency department: a randomized, controlled trial. Ann. Emerg. Med. 41, 227–233.

Foss, N.B., Kristensen, B.B., Bundgaard, M., Bak, M., Heiring, C., Virkelyst, C., Hougaard, S., Kehlet, H., 2007. Fascia iliaca compartment blockade for acute pain control in hip fracture patients: a randomized, placebo-controlled trial. Anesthesiology 106, 773–778.

Fujihara, Y., Fukunishi, S., Nishio, S., Miura, J., Koyanagi, S., Yoshiya, S., 2013. Fascia iliaca compartment block: its efficacy in pain control for patients with proximal femoral fracture. J. Orthop. Sci. 18, 793–797.

Godoy Monzon, D., Iserson, K.V., Vazquez, J.A., 2007. Single fascia iliaca compartment block for post-hip fracture pain relief. J. Emerg. Med. 32, 257–262.

Godoy Monzon, D., Vazquez, J., Jauregui, J.R., Iserson, K.V., 2010. Pain treatment in post-traumatic hip fracture in the elderly: regional block vs. systemic non-steroidal analgesics. Int. J. Emerg. Med. 3, 321–325.

Hansson, E., Fridlund, B., Hallstrom, I., 2005. Developing and testing a questionnaire to assess the quality of pain management in acute care in Sweden. Pain Manag. Nurs. 6, 91–104.

Haslam, L., Lansdown, A., Lee, J., van der Vyver, M., 2013. Survey of current practices: peripheral nerve block utilization by ED physicians for treatment of pain in the hip fracture patient population. Canadian Geriatrics Journal 16, 16–21.

Hauritz, R.W., Gerlif, C., Ronholm, E., 2009. Fascia iliaca block performed by emergency department physician trainees in hip fractures. Ugeskr Laeger 171, 515–518.

Herr, K., Titler, M., 2009. Acute pain assessment and pharmacological management practices for the older adult with a hip fracture: review of ED trends. J. Emerg. Nurs. 35, 312–320.

Høgh, A., Dremstrup, L., Jensen, S.S., Lindholt, J., 2008. Fascia iliaca compartment block performed by junior registrars as a supplement to pre-operative analgesia for patients with hip fracture. Strategies in Trauma and Limb Reconstruction 3, 65–70.

Johansen, A., Golding, D., Brent, L., Close, J., Gjertsen, J.E., Holt, G., Hommel, A., Pedersen, A.B., Rock, N.D., Thorngren, K.G., 2017. Using national hip fracture registries and audit databases to develop an international perspective. Injury 48, 2174–2179.

Kuske, S., Moschinski, K., Andrich, S., Stephan, A., Gnass, I., Sirsch, E., Icks, A., 2016. Drug-based pain management in people with dementia after hip or pelvic fractures: a systematic review protocol. Syst. Rev. 5, 113.

Layzell, M., 2007. Pain management: setting up a nurse-led femoral nerve block service. Br. J. Nurs. 16, 702–705.

Maher, A.B., Meehan, A.J., Hertz, K., Hommel, A., MacDonald, V., O'Sullivan, M.P., Specht, K., Taylor, A., 2012. Acute nursing care of the older adult with fragility hip fracture: an international perspective (Part 1). International Journal of Orthopaedic and Trauma Nursing 16, 177–194 118p.

McRae, P.J., Bendall, J.C., Madigan, V., Middleton, P.M., 2015. Paramedic-performed fascia iliaca compartment block for femoral fractures: a controlled trial. J. Emerg. Med. 48, 581–589.

Mouzopoulos, G., Vasiliadis, G., Lasanianos, N., Nikolaras, G., Morakis, E., Kaminaris, M., 2009. Fascia iliaca block prophylaxis for hip fracture patients at risk for delirium: a randomized placebo-controlled study. J. Orthop. Trauma 10, 127–133.

Mundi, S., Chaudhry, H., Bhandari, M., 2014. Systematic review on the inclusion of patients with cognitive impairment in hip fracture trials: a missed opportunity? Can. J. Surg. 57, E141–E145.

NHFD, 2016. National hip fracture database annual report. Available at: http://web1.crownaudit.org/Report2016/NHFD2016Report.pdf, Accessed date: 13 September 2018.

Pfeiffer, E., 1975. A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. J. Am. Geriatr. Soc. 23, 433–441.

Rashid, A., Beswick, E., Galitzine, S., Fitton, L., 2014. Regional analgesia in the emergency department for hip fractures: survey of current UK practice and its impact on services in a teaching hospital. Emerg. Med. J. 31, 909–913.

Rikshoft, 2013. Year report (Swedish). Swedish National Registry of hip fracture patient care. Available at: http://rikshoft.se/wp-content/uploads/2015/05/Arsrapport-RIKSHOFT-2013-uppdaterad.pdf, Accessed date: 13 September 2018.

Ritcey, B., Pageau, P., Woo, M.Y., Perry, J.J., 2016. Regional nerve blocks for hip and femoral neck fractures in the emergency department: a systematic review. CJEM 18, 37–47.

Rosengren, B.E., Karlsson, M.K., 2014. The annual number of hip fractures in Sweden will double from year 2002 to 2050: projections based on local and nationwide data. Acta Orthop. 85, 234–237.

Wennberg, P., Andersson, H., Wireklint Sundstrom, B., 2018. Patients with suspected hip fracture in the chain of emergency care: an integrative review of the literature. International Journal of Orthopedic and Trauma Nursing 29, 16–31.

Williams, H., Paringe, V., Shenoy, S., Michaels, P., Ramesh, B., 2016. Standard preoperative analgesia with or without fascia iliaca compartment block for femoral neck fractures. J. Orthop. Surg. 24, 31–35.