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Randomised trial of the fascia-iliaca block versus the "three-in-one" block for femoral neck fractures in the Emergency Department.

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ABSTRACT

Introduction
Femoral neck fractures are a common and painful injury. Femoral nerve blocks, and a variant of this technique termed the '3-in-1' block, are often used in this patient group, but their effect is variable. The fascia iliaca compartment block (FIB) has been proposed as an alternative, but the relative effectiveness of the two techniques in the early stages of care is unknown. We therefore compared the FIB versus the 3-in-1 block in a randomised trial conducted in two UK emergency departments.

Methods
Parallel, two group randomised equivalence trial. Consenting patients older than 18 years with a femoral neck fracture were randomly allocated to receive either a fascia iliaca compartment block or a 3-in-1 block. The primary outcome was pain measured on a 100mm visual analogue scale at 60 minutes. The between group difference was adjusted for centre, age, sex, fracture type, pre-block analgesia and pre-block pain score

Results
178 patients were randomised and 162 included in the primary analysis. The mean 100mm visual analogue pain scale score at 60 minutes was 38mm in the FIB arm and 35mm in the 3-in-1 arm. The adjusted difference between the arms was 3mm, with a 95% confidence interval (-4.7 to 10.8) that excluded a clinically important difference between the two interventions.

Conclusions
The fascia iliaca compartment block is equivalent to the 3-in-1 block for immediate pain relief in adult neck of femur fractures.

INTRODUCTION

Around 75,000 people suffer a hip fracture each year in the UK[1]. These injuries are associated with considerable mortality and morbidity in a predominantly elderly patient population.[1]

Integral to the Emergency Department (ED) management of hip fracture is the rapid provision of effective analgesia. The UK College of Emergency Medicine standard is that 100% of patients in moderate or severe pain should be offered or receive analgesia within 60 minutes of arrival at the ED.[2] Peripheral nerve block techniques are considered in patients for whom paracetamol and opiates do not provide adequate analgesia, or to limit opioid dosage.[1]

There are two principal techniques described; the fascia iliaca compartment block (FIB) and the 3-in-1 block. The FIB was first described by Sharrock[3] in 1989. The 3-in-1 block was first described in 1973 by Winnie et al.[4] Both are single injection anterior thigh approach techniques which aim to block the femoral, obturator and lateral femoral cutaneous nerves.

Whilst each has been studied individually there is very little evidence comparing the two techniques in the early stages of care, although one study showed superiority of a standard femoral nerve block over FIB in a nurse-delivered acute pain service.[5]

With the majority of evidence suggesting similar effect, this study was designed to establish whether the fascia-iliaca compartment block is equivalent to the 3-in-1 femoral nerve block for immediate pain relief in adult neck of femur fractures.

METHODS

Design, setting, participants

We completed a two group parallel randomised equivalence trial at University Hospitals Bristol NHS Foundation Trust and Plymouth Hospitals NHS Trust. Consenting adult patients (18 years and older) with a radiographically confirmed femoral neck fracture were invited to participate and offered a patient information leaflet by either an emergency medicine consultant or senior trainee. Following written consent they were randomly allocated to receive either a FIB or 3-in-1 block. The exclusion criteria were; patient refusal, an abbreviated mini mental state examination of 7/10 or less, other distracting painful pathology, contraindication to local anaesthetic agents, an inability to speak or understand spoken English and injury more than 24 hours previously.

Interventions

Fascia iliaca compartment blocks were performed using anatomical landmarks. Bupivicaine 0.5% solution was injected at a point 1cm perpendicular and distal to the junction of the middle and outer thirds of a line drawn between the anterior superior iliac crest and the pubic tubercle. The dose used was 2mg per kilogram up to a maximum of 150mg (30ml of 0.5% bupivicaine). Where the dose was less than 150mg, the total volume of solution was diluted to 30ml with 0.9% sodium chloride. To identify the correct compartment, an 18g Tuohy needle was inserted at 90 degrees and advanced until two distinct 'pops' or loss of resistance were felt as firstly the fascia lata and then fascia iliaca were penetrated.

To deliver the 3-in-1 block, the femoral nerve was identified either anatomically, by ultrasound or by nerve stimulation. This was a deviation from the original protocol of using only nerve stimulator guidance. Because of a the prevalence and preference for ultrasound guidance and user reported difficulties with nerve stimulator guidance, a pragmatic modification to the protocol allowing the 3-in-1 block to be delivered by the technique that the operator was trained and current in was approved and initiated. The femoral nerve was identified anatomically using an injection point just lateral to the femoral arterial pulse at the femoral crease. If using a nerve stimulator proximity was confirmed with a linear patella jerk at 30mV. If using ultrasound the block was delivered under continuous visualisation. Once located 2mg per kilogram of 0.5% bupivicaine was injected with distal pressure over the femoral nerve during and for 30 seconds after the injection. No head down tilt was applied to the patient. Again, where the dose was less than 150mg (30ml 0.5% bupivicaine) the volume injected was diluted to 30mls with 0.9% sodium chloride.

Randomisation

Participants were allocated on a 1:1 ratio using a secure online computer generated randomisation service provided by the Bristol Randomised Trials Collaboration, a UKCRC-registered clinical trials unit. This concealed allocation from recruiting staff. Allocation was stratified by centre, and minimised, retaining a random element, by age, sex, fracture type, pre-block analgesia, and pre-block pain score.[6]

Outcomes and blinding

The primary outcome was pain measured using a 100mm Visual Analogue Scale (VAS) at 60 minutes after the block was delivered. Secondary outcome measures were pain at 30 minutes after block delivery, analgesia consumption in the pre-operative period up to 24 hours post admission, analysed separately by drug type; and length of hospital stay. The VAS scores were recorded by the patient and collected by a member of the ED nursing staff. Patients were asked to record their pain by placing a mark on a 100mm non-graduated line, representing no pain at all to the worst pain ever at 100mm. Patients were unlikely to recognise the type of block allocated and were therefore blinded to treatment allocation. The member of ED staff collecting data booklet was not blinded. Analgesia consumption was recorded from the patient's drug prescription chart by a research nurse and research assistant who were not blinded.

Sample size

The study was powered to investigate equivalence between the FIB and 3-in-1 blocks in terms of patient-reported 0-100mm VAS pain score. Previous studies report a standard deviation of 21 points on a 0-100mm VAS and a difference of 13 points as the minimum clinically important difference.[7] With a conservative difference beyond which the groups would not be regarded as equivalent of 10mm, 80% power and 2.5% two-sided alpha, the study required 86 patients per arm. Allowing for up to 10% non-collection of the primary outcome, we aimed to recruit 190 participants.

Statistical methods

We used appropriate descriptive statistics to examine balance between the trial arms in baseline characteristics. Analyses of primary and secondary outcomes were conducted on an intention to treat basis without imputation – that is, all patients were analysed according to their randomised groups, except for those who did not provide follow-up data. We used multivariable linear regression models to investigate between group differences, adjusted for centre, age, sex, fracture type, pre-block analgesia and pre-block pain score as stratification and minimisation variables.

In pre-specified subgroup analyses using interaction terms in the primary regression model, we explored whether any differences between the trial arms differed according to fracture type and pre-block analgesia type. Additional subgroup analyses for the primary outcome were conducted by gender and baseline pain score. These analyses were not pre-specified in the protocol. However, in discussions prior to conducting the data analysis, we defined these to be of interest but are to be considered exploratory.

Following the protocol change we explored the primary outcome for participants who had the 3-in-1 block delivery guided by ultrasound, nerve stimulator, and anatomically. We conducted a sensitivity analysis by excluding all participants with nerve stimulator guidance in the 3-in-1 arm, and all participants in the FIB arm randomised up to and including the same date as the final nerve stimulator guided 3-in-1 block.

Statistical analyses were conducted using Stata version 11.

Ethics and Trial Registration

Ethical approval was given by the Frenchay Research Ethics Committee. The trial was registered with Current Controlled Trials (ISRCTN16152419) before patient recruitment commenced.

RESULTS

Participant flow

We recruited and randomised patients between December 2008 and December 2012. A total of 178 participants were randomised, with 162 included in the primary analysis. Figure 1 illustrates the flow of patients during the trial, including reasons why primary outcome data were not available for 16 participants. The trial arms were well balanced at baseline (Table 1). Primary outcome data were obtained from 91% of participants. At the Plymouth site, the routine technique for the 3-in-1 block was anatomical, and at Bristol it was ultrasound.

Figure 1: Participant flow diagram

Table 1: Baseline characteristics of randomised participants

	3 in 1 (n=90)	**FIB (n=88)**
Age in years, mean (SD)	78 (11)	80(10)
Female, n (%)	65 (72)	66(75)
Fracture type, n (%)		
Subcapital	43 (48)	42(48)
Intertrochanteric	37(41)	34(38)
Basicervical	10 (11)	12(14)
Centre, n (%)		
Bristol	57(51)	55(49)
Plymouth	33(50)	33(50)
Pre-block analgesia n (%)		
None	5(6)	10(11)
Oral only	11(12)	8(9)
IV Paracetamol	8(9)	8(9)
IV Morphine	66(73)	62(71)
Pre-block pain score, mean (SD)	64(26)	65(26)

Primary and secondary outcomes

The adjusted difference in mean pain scores at 60 minutes comparing 3 in 1 with FIB was 3.0mm, with 95% confidence interval -4.7mm to 10.8mm (Table 2).

Pain scores after 30 minutes were equivalent between the arms (Table 2). There was evidence that length of stay was longer in the FIB group compared with the 3 in 1 group (95% confidence interval for ratio of geometric mean 1.07 to 1.57) (Table 2).

Table 2: Pain score and length of stay

	FIB		3 in 1				
Primary outcome	Mean (SD)	N	Mean (SD)	N	Difference	95% CI	p-value
Pain score at 60 minutes in mm	38 (25)	79	35 (25)	83	3.0	-4.7 to 10.8	0.44
Secondary outcomes							
Pain score at 30 minutes in mm	44 (26)	80	45 (24)	85	-0.7	-8.1 to 6.6	0.85
Length of	[a] 13.5	84	[a] 10 (7,	87	0.26[b]	0.07 to	0.006

stay in days	(9.5, 28.5)		16),			0.45	

[a] Median (Q1, Q3), sample size

[b] Length of stay data were positively skewed, therefore data were transformed using natural logarithms. The exponentials of the between-group difference and 95% confidence interval represents the ratio of the geometric means.

Table 3 shows that the use of analgesia after randomisation and prior to operation was very similar between the two groups. Oral paracetamol and oral codeine were the most commonly used analgesics. Comparing means for FIB versus 3 in 1 yielded 95% confidence intervals of -305 to 275mg for oral paracetamol and -17 to 52mg for oral codeine respectively. Between-group comparisons for the other drugs were not performed due to small numbers.

Table 3 Analgesia consumption post block in pre-operative phase up to 24 hours

		, sample size[a]		
	FIB		3 in 1	
	Median (10^{th}-90^{th} centiles)	N	Median (10^{th}-90^{th} centiles)	N
IV paracetamol (mg)	1000 (1000-4000)	5	1000 (1000-1000)	12
Oral paracetamol (mg)	3000 (2000-4000)	75	3000 (2000-4000)	74
Oral codeine (mg)	180 (32-240)	31	120 (60-240)	35
IV morphine (mg)	5 (3-20)	7	8 (5-36)	6
Oral ibuprofen (mg)	600 (400-800)	2	800 (na)	1

[a] Numbers in each group sum to greater than number randomised due to some participants receiving more than one analgesic.

There was no evidence of any interaction between treatment arm and fracture type (p=0.82), pre-block analgesia (p=0.11), gender (p=0.93) and baseline pain score (p=0.16) for the primary outcome (data not shown).

Mean (95% CI) VAS pain scores at 60 minutes for patients in the 3 in 1 arm who had block delivery guided by nerve stimulator, anatomical and ultrasound were 32mm (22 to 43), 35mm (26 to 43), and 37mm (28 to 47) respectively. Excluding primary outcome data for those with nerve stimulator guided 3-in-1 blocks (n=18) and fascia iliaca blocks delivered up to the date of protocol change (n=14), the difference in mean VAS score at 60 minutes was 5mm (95% CI -4 to 13).

DISCUSSION

This trial has shown that the FIB and 3-in-1 block are equivalent in reducing pain scores at 60 minutes using a 0-100mm VAS. Whilst the upper 95% confidence limit

of the difference measured marginally exceeded the conservative 10mm equivalence limit proposed at trial design, it is still well within the 13mm difference considered previously as minimally clinically important.[7] Sub-group analysis according to fracture type suggested that the blocks are equally effective in intracapsular and extracapsular fracture types. Similarly, there was no evidence that the blocks were differentially effective according to gender, age or pre-block analgesia. There was an increase in length of stay in the FIB arm. This is difficult to explain, though we think is unlikely to be due to the block itself, but related to patient and service factors not considered in this study.

Limitations

This trial was a pragmatic and realistic representation of nerve block practice for femoral neck fractures in emergency departments today where 66% of nerve blocks are delivered anatomically, and the rest nerve stimulator or ultrasound guided.[8] The protocol change to allow the 3-in-1 blocks to be given using the technique in which the operator was trained may be considered a limitation. Newman et al showed that a nerve stimulator guided 3-in-1 block was superior to the FIB.[5] In their study, 93% of the blocks were delivered by two operators and the difference between the mean VAS score reduction was 0.9cm (95% CI 0-1.8cm p= 0.047), which would not be considered as clinically important.[7] There were no restrictions on use of pre-block analgesia in our study, which could also be viewed as a limitation. However allocation was minimised by pre-block analgesia, resulting in no important difference in pre-block analgesia between the two groups. The number of participants included in the primary analysis was 162 compared with the target of 172, which may have resulted in reduced precision of between-group estimated differences in outcome. The primary outcome was self-reported by participants. It is unlikely that they would have been aware of which block they had received, therefore this outcome is at low risk of bias due to unblinding. However, staff collecting the self-completed data booklets from the patients were not blinded, and this could have introduced a source of bias. Analgesia consumption and length of stay were extracted from patient medical records by unblinded research staff. However as these are objective outcomes, we again consider the risk of bias to be low.

Aside from diagnosis, management of acute co-morbidities and preparation for surgery, pain relief is vital for patients with a fractured neck of femur and is a nationally audited quality benchmark for emergency departments. Patients are often frail and elderly, and injury is often a result of multiple physical and cognitive factors. Safe but effective analgesia can be a challenge, and usually involves the administration of parenteral opiates. Whilst opiates can exacerbate or cause delirium, evidence also shows that cognitively intact patients with inadequately treated pain from hip fracture are nine times more likely to develop delirium.[9] A careful balance is therefore required as delirium is independently associated with poor functional recovery after hip fracture.[10] Other agents such as non-steroidal anti-inflammatory drugs are effective, but are associated with gastrointestinal and renal side effects, particularly in repeated doses. Intravenous paracetamol is a commonly used analgesic with a very good safety profile, and there is also some evidence to suggest that it is comparable to intravenous morphine in acute traumatic limb pain.[11] However ongoing pain relief with parenteral or enteral medication requires repeat administration and in busy departments and wards it can be a challenge to provide timely and adequate pain relief.

In this study, there was no difference between the two groups in the use of intravenous morphine, intravenous or oral paracetamol, oral codeine and oral ibuprofen. There was, however, a wide range of analgesic strategies employed on the wards to treat hip fracture pain suggesting there is scope to implement a structured approach to analgesia for these patients.

Given our finding of equivalent pain relief, we can consider other factors when choosing a nerve block for this patient group. The FIB is quick to deliver; less than five minutes in one study,[12] and half the time compared with 3-in-1 by another.[5] It suits the requirements of a modern ED with trainees who have not yet received ultrasound training. It is simple to anatomically define the correct landmarks and thus injection point, which is distant from the femoral neurovascular bundle. A correctly placed injection should have very little chance of intravascular injection or neural injury. The FIB has a good safety profile, with only a clinically insignificant pneumoretroperitoneum[13], a temporary neuropathy[14] and an accidental bladder[15] puncture reported in literature. In a review of literature in 2007, Brull[16] et al reported the risk of neurological injury in femoral nerve blockade to be as low as 0.03 in one study.[17]
The least expensive way to deliver an effective block would be an anatomically guided 3-in-1 block as it requires no additional equipment beyond a standard syringe and needle. The major expenditure associated with ultrasound is the machine itself. Although its usefulness would not be limited to nerve block delivery this is a real consideration for emergency departments. The cost of a nerve-stimulator needle is in the region of £3-5, whilst a Tuohy needle costs around 50 pence. The drug costs between the two groups are similar with identical dosing. Rashid et al surveyed UK emergency department regional anaesthetic practice in hip fractures and reported that only 44% were routinely using nerve blocks for hip fractures.[8] The most frequently cited reasons for not providing a nerve block were insufficient trained staff (36%) and a lack of equipment (22%). It was felt to be too time consuming by 10% of departments. Of those who did perform nerve blocks for hip fractures 60% used a femoral nerve block and 22% the FIB. Looking at all femoral fractures, a survey of 91% of UK departments reported that only 55% regularly used femoral nerve blocks by any technique and only 10% regularly used ultrasound despite 74% having access to a machine.[18] Clearly there is room to improve the uptake of regional techniques in managing hip fracture pain, and the fascia iliaca block would appear well suited to address this in the ED.

CONCLUSION

The fascia iliaca block and 3-in-1 block are equivalent in reducing VAS pain scores in patients with a fractured neck of femur. Emergency physicians can have confidence in either technique when relieving pain in patients who present with a neck of femur fracture.

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Competing interests

None

Ethics approval

This study was approved by the Regional Ethics Committee, Frenchay Hospital, Bristol.

REFERENCES

1. National Institute for Health and Care Excellence. Clinical Guideline 124 Hip Fracture: The management of hip fracture in adults. NICE (London) 2011. Available at: http://guidance.nice.org.uk/CG124 (accessed 11/10/13).

2. College of Emergency Medicine. Clinical Standards for Emergency Departments. CEM (London), 2013. Available at: http://www.collemergencymed.ac.uk/Shop-Floor/Clinical%20Standards/default.asp (accessed 11-10-13).

3. Sharrock NE. Inadvertent '3 in 1' block following injection of the lateral cutaneous nerve of the thigh. Anesth Analg 1989;59:887-8.

4. Winnie AP, Ramamurthy S, Durrani Z: The inguinal paravascular technique of lumbar plexus anaesthesia: The "3-in-1" block. Anesth Analg 1973;52:989-996.

5. Newman B, McCarthy L, Thomas PW, et al: A comparison of pre-operative nerve stimulator guided femoral nerve block and fascia iliaca compartment block in patients with a femoral neck fracture. Anaesthesia 2013;69:899-903

6. Taves DR. Minimization: a new method of assigning subjects to treatment and control groups. *Clin Pharmacol Therapeut.* 1974;15:443-453.]

7. Todd KH, Funk KG, Funk JP, et al. Clinical significance of reported changes in pain severity. Ann Emerg Med 1996;27:485e9.

8. Rashid A, Beswick E, Galitzine S: 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 2013 Jul 22 (Epub ahead of print)

9. Morrison R, Magaziner J, Gilbert M, et al: Relationship between pain and opiate analgesics on the development of delirium following hip fracture. J Gerontol A Biol Sci Med Sci 2003;58:76-81

10. Marcantonio E, Flacker J, Michaels M et al: Delirium is independently associated with poor functional recovery after hip fracture. J Am Geriatr Soc 2000;48:618-24

11. Craig M, Jeavons R, Probert J, Benger J. Randomised comparison of intravenous paracetamol and intravenous morphine for acute traumatic limb pain in the emergency department. Emerg Med J 2012;29:37-9

12. Monzon D, Iserson K, Vasquez J: Single fascia iliaca compartment block for post hip fracture pain relief. J Emerg Med 2007;32:257-62

13. Shelley B, Haldane G: Pneumoretroperitoneum as a consequence of fascia iliaca block. Reg Anesth Pain Med 2006;31:582-3

14. Atchabahian A, Brown A: Postoperative Neuropathy following Fascia Iliaca Compartment Blockade. Anesthesiology 2001;94:534-6

15. Blackford D, Westhoffen P: Accidental badder puncture: a complication of modified fascia iliaca block. Anaesth Intensive Care 2009;37:140-1

16. Brull B, McCartney C, Chan V, et al: Neurological Complications After Regional Anaesthesia: Contemporary Estimates of Risk. Anesth Analg 2007;104:965-74

17. Auroy Y,Benhamou D, Bargues L, et al Major complications related to regional anaesthesia: the SOS regional anesthesia hotline service. Anesthesiology 2002;97:1274-80

18. Mittal R, Vermani E: Femoral nerve blocks in fractures of femur: variation in the current UK practice and a review of the literature. Emerg Med J 2014;31:143-7