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A randomised, controlled, double blind, non-inferiority trial of ultrasound guided fascia iliaca block versus spinal morphine for analgesia after primary hip arthroplasty

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Short title: ultrasound fascia iliaca versus spinal morphine for hip replacement

Summary

We performed a single centre, double blind, randomised, controlled, non-inferiority study comparing ultrasound guided fascia iliaca block with spinal morphine for the primary outcome of 24 h postoperative morphine consumption in patients undergoing primary total hip arthroplasty under spinal anaesthesia with levobupivacaine. One hundred and eight patients were randomised to receive either ultrasound guided fascia iliaca block (2 mg.kg^{-1} levobupivacaine) (fascia iliaca group) or spinal morphine 100 mcg plus a sham ultrasound guided fascia iliaca block using 0.9% saline (spinal morphine group). The pre-defined non-inferiority margin was a median difference between the groups of 10 mg in cumulative intravenous morphine use in the first 24 h postoperatively. Patients in the fascia iliaca group received 25 mg more intravenous morphine than patients in the spinal morphine group (95% CI 9.0-30.5 mg, p < 0.001). Ultrasound guided fascia iliaca block was significantly worse than spinal morphine in the provision of analgesia after total hip arthroplasty. No increase in side effects was noted in the spinal morphine group but the study was not powered to investigate all secondary outcomes.

Musculoskeletal disease is the second most common cause of disability globally and is an increasing healthcare problem [1,2]. Total hip arthroplasty is an effective surgical procedure performed to relieve pain and improve function in patients with disorders such as degenerative or inflammatory arthritis. The aim of the anaesthetist is to provide adequate anaesthesia and optimal analgesia whilst minimising side effects, and facilitating rapid mobilisation and recovery.

Spinal anaesthesia with opioid is recognised as one of the most effective and widely used techniques for providing analgesia for total hip arthroplasty [3]. As morphine is more hydrophobic than other opioids, it has a greater degree of rostral spread and a longer duration of action [4]. Spinal morphine in combination with systemic morphine is a commonly used postoperative regimen for many surgical procedures including total hip arthroplasty [5-7]. The use of spinal opioids can be associated with side-effects such as nausea, pruritus, urinary retention, sedation, and respiratory depression [8]. Such adverse effects may be uncomfortable for the patient, can delay mobilisation and discharge and may, in extreme cases, be life-threatening [9,10]. Consequently, patients receiving spinal opioids require more intensive monitoring postoperatively.

Peripheral nerve blockade has been shown to improve pain scores and reduce morphine consumption in patients undergoing total hip arthroplasty [11]. Consensus guidelines for postoperative analgesia after total hip arthroplasty confirm that proximal approaches to the lumbar plexus (i.e. lumbar plexus blocks) are more effective analgesic techniques than distal approaches (i.e. femoral nerve blocks) [3]. However, lumbar plexus blocks may be associated with significant complications including spinal and epidural placement, psoas haematoma or abscess, retroperitoneal haematoma, renal trauma and systemic local anaesthetic toxicity [12,13]. The performance of this technique requires considerable expertise and may be time-consuming to perform hence limiting its use. The fascia iliaca block provides an indirect proximal approach to the lumbar plexus and provides sensory blockade to several of the nerves that supply the hip [14,15]. Clinical success rates of this block when performed using traditional landmark techniques are variable and have limited its utility [16]. A meta-analysis has demonstrated that ultrasound-guided nerve blocks are significantly more successful and last around 25% longer than those done using peripheral nerve stimulators [17]. Despite being commonly used, there is a lack of evidence relating to the use of the fascia iliaca block for analgesia after total hip arthroplasty. One small study examined the use of a modified landmark technique and demonstrated reduced morphine consumption when compared with placebo [15].

Using ultrasound to perform fascia iliaca blocks increases success rates compared with the landmark technique [18], but until recently the ultrasound-guided technique had not been evaluated clinically. One small, single centre study has compared an ultrasound guided fascia iliaca block with placebo injection in patients with uncontrolled postoperative pain and showed no benefit [19]. There has been no previous comparison of ultrasound-guided fascia iliaca block with spinal morphine in patients undergoing total hip arthroplasty.

We hypothesised that there would be no clinically meaningful difference between ultrasound-guided fascia iliaca block and spinal morphine for a primary outcome measure of 24 h morphine consumption in patients undergoing primary elective total hip arthroplasty under spinal anaesthesia. If this were the case, then the potential advantages of the ultrasound guided fascia iliaca block would be: decreased opioid-related side effects; reduced nursing workload; and improved safety profile. A non-inferiority design was used in order to test this hypothesis.

Methods

We performed a single centre, randomised, controlled, double blind, non-inferiority study. This study received approval from the West of Scotland Research Ethics Committee and NHS Greater Glasgow and Clyde Research and Development Committee. Written consent was obtained from all patients in keeping with the principles of the Declaration of Helsinki. Study methodology including power calculations and *a priori* statistical analysis was published in a peer-reviewed journal [20].

Patients scheduled to undergo primary total hip arthroplasty in a tertiary referral centre for orthopaedic and trauma surgery were identified and given a study information sheet. Inclusion criteria were: ASA physical status 1-3, 18-85 years of age, weight 50-110 kg, and competence to consent. We did not study patients with any of the following conditions: contraindication to regional anaesthesia; preference for general anaesthesia; allergy to opioids; neurological disorder affecting the lower extremity; significant psychiatric conditions; pregnancy; alcohol or drug dependency; or long term intake of World Health Organisation (WHO) step three analgesics

Randomisation was achieved using a computer-generated randomisation sequence in permuted blocks of four or six patients. The staff member generating the randomisation sequence had no

clinical knowledge of the study and was not involved with patient recruitment or data collection. Allocation concealment was achieved using opaque, sealed, numbered envelopes.

Patients were randomised to one of two groups. Patients in the fascia iliaca group received spinal anaesthesia with 10-15 mg hyperbaric bupivacaine (Marcain Heavy® 0.5%, AstraZeneca, London, UK) plus ultrasound-guided fascia iliaca block 2 mg.kg^{-1} levobupivacaine (Chirocaine®, Abbott Laboratories, Chicago, IL, USA) diluted to a total of 40 ml with 0.9% saline. Patients in the spinal morphine group received spinal anaesthesia as above with the addition of 100 mcg preservative-free spinal morphine (Tayside Pharmaceuticals, Dundee, UK) plus a sham ultrasound-guided fascia iliaca block using 0.9% saline. One hundred micrograms of spinal morphine has been shown to be an optimal dose in terms of maximising analgesic efficacy whilst minimising side-effects [6,7].

An independent anaesthetist, who had no involvement with study design, data collection or analysis, prepared the injectates for the fascia iliaca blocks. This same independent anaesthetist prepared and performed the spinal injections and looked after the patient in theatre. All spinal injections were performed in a standard manner. The use of sedation with a target controlled infusion of propofol and administration of intra-operative fluid was to the discretion of the independent anaesthetist. Anti-emetic drugs were not given in theatre unless felt to be necessary by this anaesthetist. This anaesthetist was the only person who was aware of the group allocation.

A separate study anaesthetist performed the ultrasound-guided fascia iliaca block in a blinded fashion using the pre-prepared injectate. The skin was prepared with 2% chlorhexidine gluconate in 70% isopropyl alcohol. A 6-14MHz linear ultrasound transducer probe (Sonosite S-nerve, Bothell, WA, USA) covered in a sterile sheath was placed transversely on the anterior thigh below the inguinal ligament. The femoral artery and iliacus muscle were identified and the probe moved cranially towards the inguinal crease, proximal to any branching of the femoral artery. A 50 mm block needle (Stimuplex, B.Braun Medical Ltd., Sheffield, UK) was visualised to penetrate the fascia iliaca lateral to the femoral nerve using an out-of-plane technique, and the injection administered incrementally and in a cranial direction after negative aspiration for blood. Block efficacy was not assessed prior to the performance of spinal anaesthesia as this would have unblinded both patient and operator. The study anaesthetist performing the ultrasound-

guided fascia iliaca block, as well as the patient, surgeon, ward staff, and research nursing staff who collected and recorded the outcome data were all blinded to the study intervention.

Postoperatively, patients were transferred to the recovery area where they were familiarised with a patient controlled analgesia (PCA) device (morphine sulphate 1 mg bolus with 5 min lockout). Regular analgesia with paracetamol 1g every 6 h was prescribed and the patients' usual medications (including non-steroidal anti-inflammatory drugs) were continued. After 24 h, the PCA was discontinued and oral morphine used as required.

The primary outcome measure was 24 h postoperative morphine consumption as self-administered using a PCA. Secondary outcomes included: time to first morphine administration; morphine consumption at 3 h, 6 h, 12 h, 36 h and 48 h; pain scores at 3 h, 6 h, 12 h, 24 h, 36 h and 48 h at rest and on movement (as measured by an 11-point numeric rating score pain score where 0 is no pain and 10 the worse pain imaginable); episodes of respiratory depression; hypotension; postoperative nausea and vomiting (nausea score of ≥2 where 0 = none, 1 = mild, 2 = moderate, 3 = severe nausea and 4 = patient vomiting); pruritus; sedation (sedation score of ≥ 2 where 0 = awake, S = normal sleep, 1 = drowsy but easy to rouse, 2 = sedated and difficult to rouse, and 3 = unconscious); administration of naloxone; urinary retention requiring catheterisation; quadriceps strength pre-mobilisation (Medical Research Council power grade 0-4); time to first mobilisation (as defined by patient able to mobilise from bed to chair); and patient satisfaction at 48 h using a visual analogue scale (0–100 mm, where 0 is absolutely not satisfied and 100 is completely satisfied). These data were recorded by ward staff and collated by research nursing staff who were blinded to group assignment. Data relating to demographics, performance of fascia iliaca block and spinal injections, use of paracetamol pre-operatively, length of surgery, and surgical blood loss were also collected.

In order to calculate sample size, we used a method suggested for non-inferiority trials [21,22]. Type 1 error (α) was set at 0·05 and type 2 error (β) at 0·8. We considered a difference between groups (δ) of greater than 10 mg of morphine to be clinically significant as this equates to one subcutaneous dose of morphine, which is commonly used in postoperative analgesia pain protocols [23]. Including allowance for an attrition rate of 10%, we planned to recruit 108 patients.

Statistical analyses were performed using RStudio (version 0·98·953, RStudio Inc., Boston MA, USA). Both intention to treat and 'as treated' analyses were performed. Data were assessed for normality using the Shapiro test. The primary outcome measure was assessed using the difference in median values and confidence intervals between the two groups as is recommended for non-inferiority studies [21]. We planned to declare non-inferiority of the fascia iliaca group with respect to the spinal morphine group if the upper boundary of the two-sided 95% confidence interval of the difference in median 24 h morphine consumption between groups was <10 mg. Because of the right-skewed distribution of median 24 h morphine consumption, confidence interval construction was done without distribution assumptions by using a bias-corrected bootstrapping technique with 10,000 replications [24,25]. Descriptive statistics were calculated for demographic variables. Z tests of two proportions were used for simple count data, Student's t tests for normally distributed demographic variables and Wilcoxon rank sum tests for non-parametric data. Statistical tests were two sided and a p value of <0·05 was considered statistically significant. There was no data monitoring committee appointed to oversee this study but any serious adverse events were reported to the West of Scotland Research Ethics Committee and NHS Greater Glasgow and Clyde Research and Development Committee for review.

Results

From 23rd May 2011 to 7th April 2014, 108 patients were recruited and randomised to either of the two study groups (Fig. 1). Two patients did not undergo study intervention and subsequent surgery. The first had cellulitis near the operative site and was postponed by the operating surgeon, and the second was postponed due to lack of time on the operating list. Both of these patients were withdrawn from the 'as treated' analysis. Two patients required general anaesthesia due to failure of spinal insertion (fascia iliaca group) and failure of spinal block (spinal morphine group). One patient required general anaesthesia due to the development of jerking movements, for which no sinister cause could be found, whilst being sedated with propofol (fascia iliaca group). These patients were withdrawn from the study as directed by the study protocol [20]. One-hundred and eight patients were analysed in the intention to treat analysis and 103 in the 'as treated' analysis.

Figure 1. CONSORT flow diagram of patients undergoing total hip arthroplasty and randomised to fascia iliaca or spinal morphine groups.
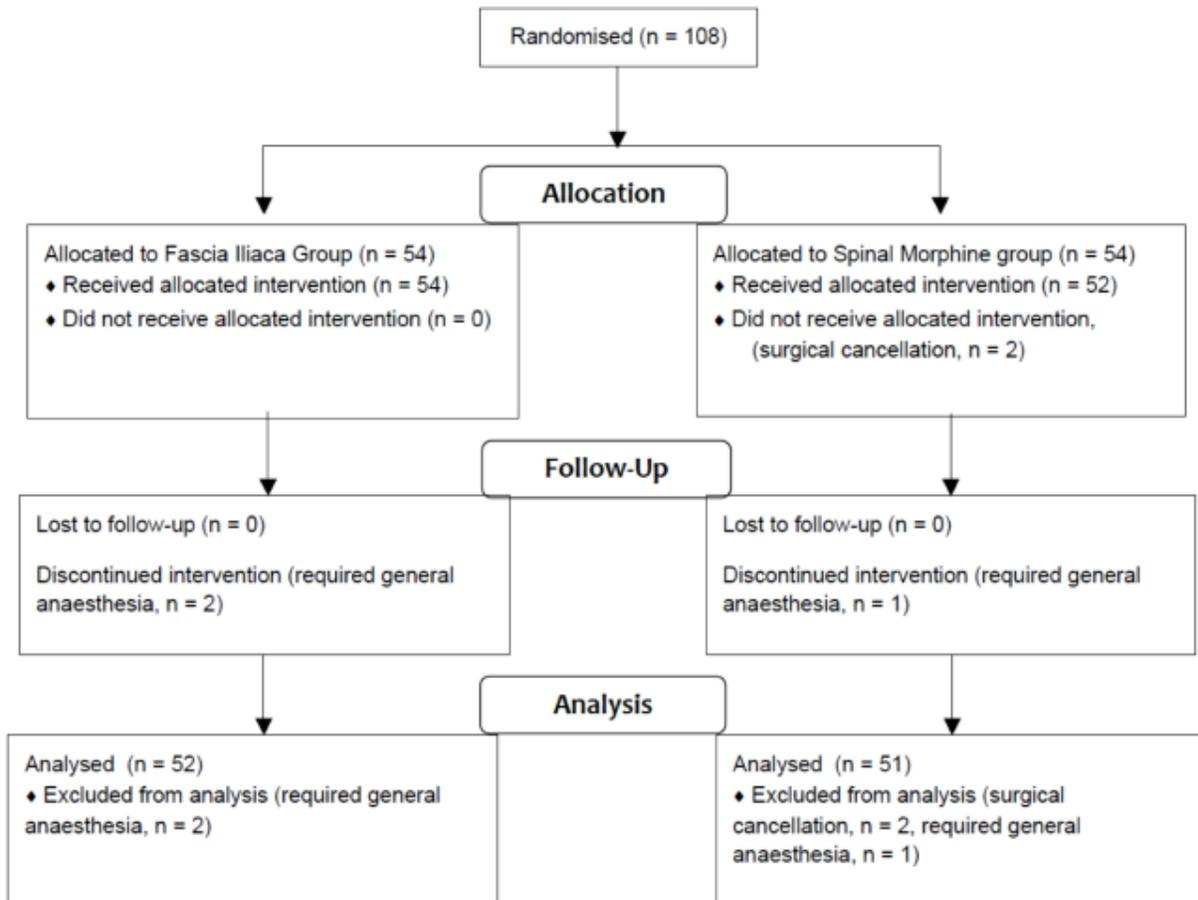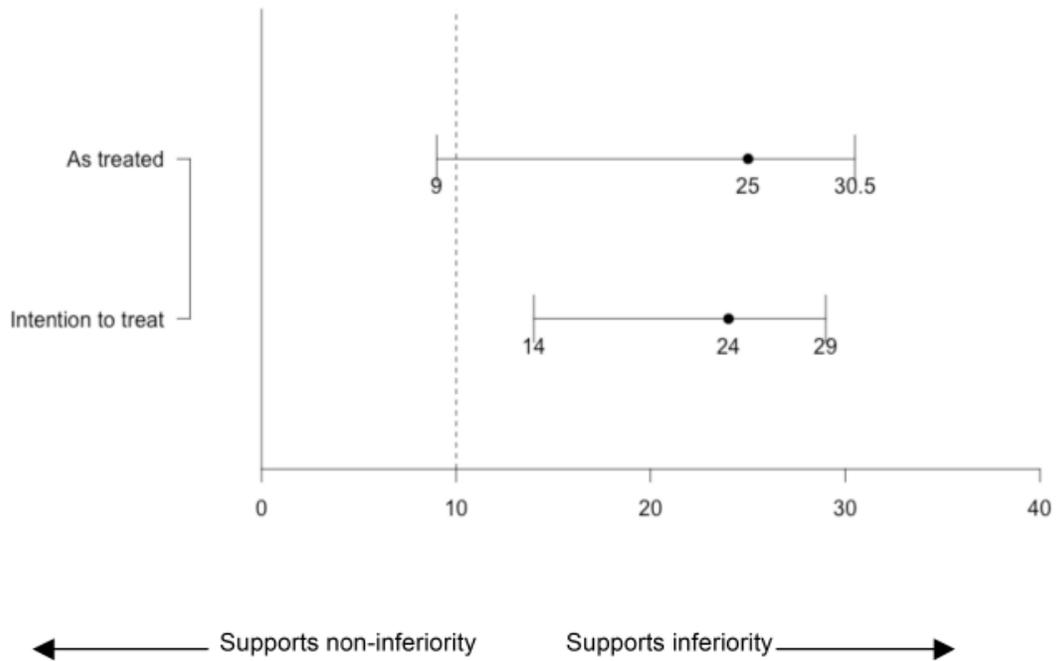

There were no significant differences in demographics, duration of surgery or blood loss between study groups (Table 1).

Table 1. Baseline and procedural characteristics of patients undergoing total hip replacement and randomised to fascia iliaca and spinal morphine groups. Values are mean (SD), number, or median (IQR [range]).

	Fascia iliaca group (n = 54)	Spinal morphine group (n = 54)
Age; years	67 (56-78 [40-83])	64 (55-73 [41-84])
Male sex	31	22
Weight; kg	79·9 (14·29)	80·2 (13·46)
Height; cm	166 (8·22)	164 (8·80)
BMI	29 (26-32.75 [21-41])	29·5 (27.25-32 [23-40])
Pre-operative systolic blood pressure; mmHg	134 (16)	135 (14)
Surgical time; min	79 (60-91.25 [45-130])	88 (73.5-97 [47-155])
Surgical blood loss; ml	300 (200-400 [100-1000])	300 (200-400 [150-1000])
Pre-operative paracetamol	41	33
Intra-operative anti-emetic	1	3

In the 'as treated' analysis, the difference between median (95% CI) 24 h morphine consumption of the two groups was 25 (9.0-30.5) mg. The intention to treat analysis yielded a similar difference between median (95% CI) morphine consumption of 24 (14-29) mg (Fig. 2). The intention to treat analysis therefore shows inferiority of ultrasound guided fascia iliaca block with respect to spinal morphine as the 95% CI lies completely outside the non-inferiority bounds. The 'as treated' analysis includes fewer subjects and therefore has less power to show inferiority. However, it still shows that ultrasound guided fascia iliaca block is significantly worse than spinal morphine.

Figure 2. Cumulative postoperative 24 h morphine consumption in fascia iliaca and spinal morphine groups, shown as intention to treat and 'as treated' analyses. Values are median with error bars indicating two-sided 95% confidence intervals. The zone of non-inferiority is represented by the dashed line and was set a priori at < 10 mg of morphine.

All predefined secondary outcomes which reached statistical significance (p < 0.05) favoured spinal morphine (Tables 2-4). There were no statistically significant differences between the groups for the remaining secondary outcomes; however, the study was not powered for these outcomes.

Table 2. Cumulative morphine consumption at different time points in patients undergoing total hip arthroplasty and randomised to fascia iliaca and spinal morphine Groups. Values are median (IQR [range]). * includes intravenous equivalent of oral morphine administered.

	Fascia iliaca group (n = 52)	Spinal morphine group (n = 51)	p value
Time to first morphine requirement; min	130·5 (60-240 [5-1170])	129 (55-228 [5-1830])	0.930
Cumulative i.v. morphine consumption at 3 h; mg	3 (0-11 [0-25])	1 (0-3 [0-12])	0.007
Cumulative i.v. morphine consumption at 6 h; mg	13.5 (5.75-20.75 [0-44])	4 (2-9 [0-38])	< 0.001
Cumulative i.v. morphine consumption at 12 h; mg	24 (14-35·5 [0-75])	10 (2.5-22·5 [0-65])	< 0.001
Cumulative i.v. morphine consumption at 24 h; mg	39 (18-49·5 [0-138])	14 (4.5-32·5 [0-105])	< 0.001
Cumulative i.v. morphine consumption at 36 h; mg	39.5 (18-55 [0-143])	15 (5-32.5 [0-105])	< 0.001
Cumulative morphine consumption at 48 h*; mg	42.3 (20.25-55.08 [0-163]	19 (11-38.67 [0-105])	0.003

Table 3. Postoperative pain scores at rest and on movement as measured by Numeric Rating Score (NRS) in patients undergoing total hip arthroplasty and randomised to fascia iliaca and spinal morphine Groups. Values are median (IQR [range]).

	Fascia iliaca group (n = 52)	Spinal morphine group (n = 51)	p value
NRS 3 h at rest	0 (0-4 [0-9])	0 (0-1 [0-7])	0.151
NRS 6 h at rest	3 (0-5 [0-10])	0 (0-2 [0-7])	<0.001
NRS 12 h at rest	2 (0-3 [0-9])	0 (0-2 [0-7])	0.004
NRS 24 h at rest	0.5 (0-3.75 [0-8])	0 (0-4 [0-10])	0.828
NRS 36 h at rest	0 (0-4.75 [0-10])	0 (0-1 [0-7])	0.519
NRS 48 h at rest	1 (0-2 [0-7])	1 (0-4 [0-7])	0.265
NRS 3 h on movement	0 (0-4 [0-10])	0 (0-2 [0-10])	0.950
NRS 6 h on movement	3 (0-5.25 [0-10])	0 (0-3.5 [0-10])	0.026
NRS 12 h on movement	2 (0-4 [0-10])	0 (0-2 [0-10])	0.032
NRS 24 h on movement	2 (0-4 [0-10])	2 (0-6 [0-10])	0·511
NRS 36 h on movement	0 (0-4 [0-10])	0 (0-2.5 [0-10])	0.674
NRS 48 h on movement	4 (2-6 [0-10])	4 (3-7 [0-10])	0.579

Table 4 – Secondary outcomes measures for patients undergoing total hip arthroplasty and randomised to fascia iliaca and spinal morphine groups. Values are number or median (IQR [range]).

	Fascia iliaca group (n = 52)	Spinal morphine group (n = 51)	p value
Respiratory depression < 8 breaths min^{-1}	0	0	-
Systolic blood pressure < 80 mmHg	6	1	0.124
Systolic blood pressure decrease > 25% from baseline	29	25	0.625
Urinary catheterisation	15	20	0.367
PONV score >2	9	7	0.818
Anti-emetic administration	24	25	0.925
Pruritus requiring treatment	1	2	0.986
Pruritus considered to be distressing	3	6	0.466
Sedation score > 2	1	0	1.000
Time to mobilisation; h	25 (20-42 [3-66])	23 (19-25.5 [4-48])	0.039
Mobile at first attempt	38	44	0.156
Quadriceps strength prior to mobilisation; MRC grade	4 (4-5 [0-5])	4 (4-5 [3-5])	0.063
Patient satisfaction at 48 h measured by VAS; mm	80 (50-89 [21-100])	76 (59-89 [0-100])	0.57

PONV, postoperative nausea and vomiting; MRC, Medical Research Council; VAS, visual analogue scale.

There were six serious adverse events which are shown in Table 5. There were no statistically significant differences in the number of adverse or serious adverse events between the groups. Each of these incidents was reported according to local research governance protocols. Only serious adverse event number five is potentially related to the study intervention and was not permanent. All patients were followed up by the surgical team.

Table 5. Serious adverse events occurring in patients undergoing total hip arthroplasty and randomised to fascia iliaca and spinal morphine groups.

Nature of serious adverse event	Study Group
Pulmonary embolism	Spinal morphine
Pulmonary embolism	Fascia iliaca
Multiple pulmonary emboli	Fascia iliaca
Wound infection resulting in multi-organ failure	Spinal morphine
Femoral nerve palsy (resolved completely within 3 months)	Fascia iliaca
Late wound infection, hyponatraemia and confusion	Fascia iliaca

Discussion

This randomised, controlled, double blind, non-inferiority study, showed that ultrasound-guided fascia iliaca block is inferior to spinal morphine in the provision of analgesia after total hip arthroplasty and does not confer any advantage in terms of side-effect profile. This is the first study to compare spinal morphine with ultrasound-guided fascia iliaca block for total hip arthroplasty. This study adds useful information to what is already known about the provision of anaesthesia for total hip arthroplasty and is consistent with other evidence that confirms lumbar plexus block as being inferior to spinal morphine for these patients [5,26].

A non-inferiority study has a number of advantages over a traditional superiority study [21]. In

particular, a non-inferiority design is useful to compare two interventions whereas a superiority study is useful in comparing an intervention with placebo. The most important consideration in a non-inferiority study is the magnitude of the non-inferiority margin (δ). This should be the smallest difference that would be clinically important and the magnitude of the non-inferiority margin should therefore be smaller than differences between groups that are used in superiority study design. As the non-inferiority margin is so important it should be specified prior to commencement of the study, otherwise non-inferiority may be demonstrated by increasing the non-inferiority margin. In this trial we used a non-inferiority margin of 10mg morphine, the equivalent to a single subcutaneous dose. A further advantage of an adequately powered non-inferiority study is that there is no possibility of a "negative" trial; the possible outcomes are non-inferior, inferior, superior or uncertain. This means that if a new treatment is shown to be non-inferior, this allows the newer intervention to be evaluated on the basis of other considerations such as side effects or cost. In the reporting of a non-inferiority study, it is recommended that both intention to treat and 'as treated' analyses are reported. There is greater confidence in the validity of the results when both analyses give consistent results [21]. Both intention to treat and 'as treated' analyses are consistent, in that the value for the median difference in morphine consumption is to the right of the non-inferiority margin. From these data, we do not recommend replacing spinal morphine with ultrasound-guided fascia iliaca block.

These findings can be explained by the innervation of the hip joint. Even if a fascia iliaca block was entirely successful in anaesthetising the lateral cutaneous nerve of thigh, femoral and obturator nerves, it would not provide complete anaesthesia and hence analgesia of the hip, due to the innervation received from the sacral plexus as well as a variable supply from the ilioinguinal, iliohypogastric and genitofemoral nerves. A limitation of our study relates to the fact that fascia iliaca block efficacy was not assessed prior to administering the spinal anaesthetic. This could have resulted in patients in the fascia iliaca group having higher analgesic requirements due to inadequacy of the block. There were several reasons for not checking block efficacy. The routine method for checking block efficacy is assessing sensation in the distribution of the lateral cutaneous nerve of thigh and the femoral nerve, and motor power in the distribution of the obturator nerve. This, however, is time consuming and not representative of usual clinical practice. Furthermore, any assessment of the efficacy of the block could have unblinded both the patient and the anaesthetist performing the block.

The morphine consumption seen in both groups was in keeping with that seen in other studies. In a spinal morphine dose finding study, patients undergoing total hip arthroplasty who received spinal anaesthesia with no spinal opioid required around 75 mg of intravenous morphine in the first 24 h postoperatively [27]. This is significantly more than was required by patients receiving the ultrasound-guided fascia iliaca block in our study indicating that these patients did receive some analgesia benefit from the block. In other studies examining femoral and "3 in 1" nerve blocks for total hip arthroplasty, 24 h postoperative consumption of intravenous morphine (or its equivalent when other opioids were used) ranged from 7-60 mg [28-32]. However, these studies were highly heterogeneous making direct comparison difficult. In other studies in which 0·1mg of spinal morphine was administered to patients undergoing total hip arthroplasty, mean intravenous 24 h morphine consumption was reported to be 10-30 mg [6,27]. The median 24 h morphine consumption of 14 mg in the spinal morphine group in our study would, therefore, be in keeping with this range.

The use of the fascia iliaca block for analgesia after total hip arthroplasty has been investigated in two other studies. The first found that a fascia iliaca block performed using a modified landmark technique reduced 24 h morphine consumption when compared with placebo [15]. Direct comparison with our study is complicated, however, by the addition of clonidine to the fascia iliaca block. This could have influenced analgesic requirements as clonidine has analgesic as well as sedating effects even when administered perineurally [33]. A second, more recent study, compared the postoperative performance of ultrasound-guided fascia iliaca block with placebo in patients who had undergone total hip arthroplasty and had a numeric rating pain score of > 3 in the post-anaesthesia care unit. The group of patients receiving fascia iliaca block had neither improved postoperative pain scores nor reduced morphine consumption [19]. This is in keeping with our findings.

Pain scores in our study were generally low, and whilst statistically significantly different at some points, this is arguably unlikely to have resulted in a clinically significant difference. This is likely to be due to the fact that all patients had the ability to titrate their analgesia to effect using the PCA device. The greatest difference in morphine consumption was seen between 6 and 12 h when the analgesic effect of the fascia iliaca blocks may have been wearing off. Whilst the use of ultrasound guidance has been shown to increase the duration of nerve blockade [17], our data suggest that any analgesic effect of the fascia iliaca blocks was diminishing prior to the offset of analgesia from the spinal morphine. Morphine consumption between 24 and 48 h was

comparably low in each group indicating that the first 24 h is the most painful period postoperatively. Reassuringly, there were no episodes of respiratory depression in either group. Side effects commonly attributed to spinal morphine such as urinary retention, pruritus, sedation, nausea, and hypotension were no different between groups. However, it should be noted that this study was not powered for the secondary outcomes.

The use of sham blocks in randomised controlled trials remains controversial [34]. We considered the use of a sham block in this study to have scientific merit as there was no other way of ensuring that the study was truly double blind. The risk to the patient from an ultrasound-guided fascia iliaca block with saline is recognised to be lower than other regional techniques due to the fact that the needle is not directed toward the femoral nerve or artery; indeed national bodies have agreed that due to this lower risk, the fascia iliaca block can be performed by non-physicians [35]. We accept that the fascia iliaca block is not without risk and patients were informed and consent obtained for the possibility that they may receive a sham nerve block.

Total hip arthroplasty is one of the commonest procedures performed in the UK. The patients in this study are similar in terms of weight, and physical status (ASA grade) of the patients reported in the UK National Joint Registry [36]. It is, therefore, reasonable to consider that the results of this study are relevant to UK practice. This single centre, randomised, double blind, non-inferiority study has shown that ultrasound-guided fascia iliaca block is not only significantly worse in the provision of analgesia after total hip arthroplasty but confers no advantage in reducing the side-effect profile. The effects of an ultrasound-guided fascia iliaca block administered in addition to spinal morphine, or the use of a fascia iliaca continuous infusion were not investigated in this study but would be of interest as these may have a morphine-sparing effect in the postoperative period.

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