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Original Contribution

Erector spinae plane block combined with local infiltration analgesia for total hip arthroplasty: A randomized, placebo controlled, clinical trial

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ABSTRACT

The erector spinae plane block is an emerging analgesic technique, which is gaining popularity for a large number of procedures. The majority of publications are at the thoracic level and almost all indicate some benefit to patients. However, there have been relatively few randomized controlled trials and even fewer studies at the lumbar level. The aim of this study was to assess whether the erector spinae plane block at the lumbar level would confer early analgesic benefits and improve the quality of recovery in patients undergoing elective unilateral primary hip arthroplasty. Sixty-four patients were randomized to receive an erector spinae plane block at the third lumbar vertebra with either 30milliliters (ml) of 0.2% ropivacaine or 30 ml of 0.9% saline. The patient, anesthetist and assessor were blinded to allocation. The primary outcome was pain on movement at 6 h (numeric rating scale 0–10) with a reduction of 2 points considered clinically significant. Secondary outcomes included quality of recovery (QoR-15 score), mobilization and length of stay. In this study there was no appreciable analgesic benefit to adding an erector spinae plane block to patients who already receive neuraxial blocks, local anesthetic infiltration and oral multimodal analgesia for elective primary total hip arthroplasty. Both groups were found to have relatively low pain scores and a high quality of recovery with no significant difference in mobilization or length of stay.

1. Introduction

Total hip arthroplasty is a common operation with almost 250,000 primary hip replaments performed in Australia in the 5 years prior to 2018, a 15% increase on the previous 5 years [1]. The demand for hip arthroplasty is expected to increase in the future and this will create ongoing economic and organizational pressures on healthcare systems [2]. Enhanced recovery programs have been shown to be safe and effective in reducing length of stay, without an increase in morbidity or surgical complications [3–6]. It has become the new norm for surgical pathways. To facilitate improvements in recovery profiles, anesthetic and analgesic techniques will need further refinements. A proportion of patients will experience significant pain after hip arthroplasty, and this will inevitably delay their progress [7]. High quality analgesia is an essential component of "fast-track" recovery and a prerequisite to improving mobility and reducing length of stay.

The ideal anesthetic and analgesic regimen for hip arthroplasty has yet to be described. Neuraxial techniques have been recommended over general anesthesia alone but the evidence is inconclusive [8,9]. There are limits to oral multimodal analgesia. The benefits of pregabalin have recently been questioned and is no longer recommended for routine use due to limited analgesic benefits and excessive side effects [10]. Opioids remain the mainstay of potent analgesia but pose the risk of opioid related side effects and persistent opioid use longer term [11]. Regional anesthetic techniques offer the potential of excellent analgesia but there is no single technique recommended over others and none are ideal. The ideal regional anesthetic technique should be safe, effective, reliable, easy to perform and not result in significant motor dysfunction.

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Techniques include high volume local anesthetic infiltration, femoral nerve block, fascia iliaca block, and lumbar plexus block [12]. Local anesthetic infiltration while safe and easy to perform may lack efficacy [13]. The femoral nerve block and fascia iliaca block may be effective in reducing pain but are likely to produce quadriceps weakness which may increase the risk of falls and delay mobilization [14]. The lumbar plexus block is an effective analgesic technique but is technically demanding and time consuming [15,16].

The usual practice in our institution which performs approximately 1000 hip arthroplasty cases annually was to provide spinal anesthesia combined with local anesthetic wound infiltration and oral multimodal analgesia. A pre-trial audit using this technique predicted median pain scores of 4.6. This is consistent with data from similar cohorts in other Australian institutions [3,4]. We aimed to improve on this.

With a multitude of nerve blocks to choose from for this surgery, it appears that no single technique is clearly better than others. The erector spinae plane block (ESPB) is an emerging analgesic technique which is gaining popularity for a large number of procedures [17]. It has also been described in hip arthroplasty [18]. The rationale for choosing ESPB for hip arthroplasty is that the spread of local anesthetic from a single injection can cover multiple dermatomal levels which is required for this surgery. Furthermore, it has been shown to be a safe technique which can be adopted relatively easily with low risk of intraneural puncture and may be less likely to produce significant motor dysfunction. Prior studies have been largely case reports or case series and observational in nature [19–25]. Outcomes of these studies have been limited without adequate control groups and it is unclear what the role of ESPB in major hip surgery is. The aim of this study was to assess whether the ESPB would confer early analgesic benefits and improve the quality of recovery of patients undergoing elective unilateral primary hip arthroplasty.

2. Materials and methods

The study was an investigator initiated, triple blinded, randomized controlled trial using parallel groups with a 1:1 allocation ratio. There were no changes to the trial design after trial commencement. After obtaining approval from the Hollywood Private Hospital Human Research Ethics Committee (HPH 453) and registration with the Australian New Zealand Clinical Trials Registry (Registry No: ACTRN12619000071123, Universal trial number U1111–1226-7064), we screened all sequential hip arthroplasty cases booked with two senior surgeons at Hollywood Private Hospital from January until November 2019. Patients who were scheduled for elective primary unilateral hip arthroplasty using a posterolateral surgical approach were selected. No patients underwent anterior hip replacement. Exclusion criteria included patients unable or unwilling to provide consent in English, revision arthroplasty, bilateral arthroplasty, significant pre-existing neuromuscular disease limiting mobility, chronic opioid use (≥40 mg oral morphine equivalent) or allergy to local anesthetics.

After written informed consent was obtained by the primary investigator, patients were randomly allocated, by computerized sequence generation, to receive an ESPB with 0.2% ropivacaine or 0.9% saline. Allocations were concealed in opaque numbered envelopes stored in a secure location in the anesthetic room adjacent to the operating theatre. The patient, anesthetist and assessor were blinded to the allocation. This was achieved by the anesthesia technician opening the randomization envelope and then dispensing 30 ml of the relevant clear colorless solution into a container on the sterile anesthetic procedural trolley in a separate anesthetic room. Patients were provided data sheets to complete which were cross checked and collected by a research nurse 24 h later and subsequently analyzed by an assessor with all groups unaware of allocation.

All patients received a standardized anesthetic and all ESPBs were performed by a single anesthesiologist. Oral premedication included 1 g acetaminophen, 1 g tranexamic acid and 75 mg of pregabalin. Patients received standard monitoring in accordance with Australian and New Zealand College of Anaesthetists guidelines. Large bore intravenous (IV) access was secured and patients received anxiolysis with midazolam 1 to 2 mg IV then self-positioned with assistance to the lateral position as for the surgery. Further sedation was administered with a propofol infusion (plasma concentration 0.5 to 1.5 μg/ml) prior to intrathecal administration of isobaric 0.5% bupivacaine 1.5 ml via a 24G spinal needle with full aseptic precautions. No other intrathecal medications were administered. Following a check of the patient identity, the surgical consent and surgical site marking, a covered sterile ultrasound probe (C35xp 8-3MHx, Sonosite X-Porte®, FUJIFILM SonoSite, Inc., Bothell, WA, USA) was used to identify the transverse process at the third lumbar vertebra on the operative side in the sagittal plane. The skin was then infiltrated with 1% lignocaine and an 18G echogenic SonoPlex cannula needle (Pajunk® 18G needle, Pajunk Medizintechnologie, Geisingen, Germany) was directed onto the lateral margin of the transverse process using real-time in-plane visualization from a cephalad approach. Thirty ml of the study solution was then administered visualizing superior and inferior spread of the solution along the erector spinae plane (Fig. 1). A light general anesthetic was then administered with a continuous propofol infusion [plasma concentration 2.0 to 3.5 micrograms per ml (μg/ml)] and fentanyl 1.0 to 1.5 μg/kg was administered to facilitate laryngeal mask insertion. The addition of the general anesthetic was the anesthesiologist preference to meet the expectations of the patients to be unaware of all surgical activity and to provide a stable unobstructed airway intraoperatively.

In addition, patients received cephazolin 2 g, dexamethasone 8 mg, granisetron 1 mg and parecoxib 40 mg (unless a contraindication: estimate glomerular filtration rate (eGFR) < 60 ml/min, active peptic ulcer disease). One liter of IV fluid was delivered over two hours (compound sodium lactate) with two further boluses of 500 ml of fluid as required if the systolic blood pressure was below 100 mm Hg. One hundred ml of 0.2% ropivacaine with 2 g of tranexamic acid was widely infiltrated into the periarticular tissues by the surgeon. In the post-anesthesia care unit all patients received 50 mg of tapentadol slow release orally. Postoperatively, patients in both groups were prescribed a standardized multimodal oral analgesia regimen. This consisted of acetaminophen 1 g four times daily, celecoxib 200 mg twice daily, pregabalin 25 mg at night and slow release tapentadol 50 mg, twice daily. Immediate release tapentadol 50 - 100 mg or hydromorphone 2 - 4 mg was available two hourly as required for breakthrough pain.

The primary outcome was dynamic pain on flexing the operative hip to 45 degrees, 6 h after administration of the spinal anesthetic (numeric

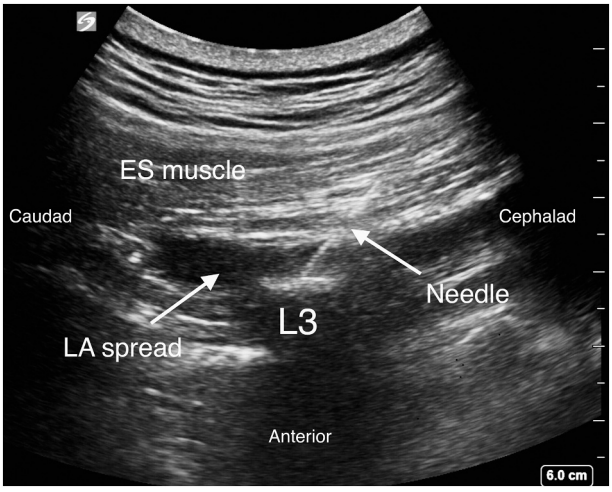

Fig. 1. Ultrasound image of erector spinae plane block at transverse process of L3.
ES: Erector spinae muscle, LA: Local anesthetic, L3: Transverse process L3.

rating scale, NRS from 0 to 10). A difference of 2 points on the NRS pain scale was considered an appreciable analgesic benefit [26]. Secondary outcomes included pain at rest at 6 h, pain at rest and with movement at 24 h, and quality of recovery score (QoR-15) at 24 h. The QoR-15 score is a composite score derived from a patient reported questionnaire detailing 15 questions over various clinically relevant domains of recovery which includes pain, sleep quality, mood, nausea and vomiting, and general well being [27]. Each question is scored out of 10 with a maximum score of 150. A difference of 8 points between the groups is considered clinically important [28]. Mobilization was assessed twice daily during physiotherapy sessions. The first physiotherapy session occurred on the day of surgery between 4 and 6 h post-operatively - after offset of the spinal anesthetic but during the expected duration of the ESPB. The day after surgery (day 1 postoperatively), physiotherapy commenced at 8 am with a second session at 2 pm. The minimum threshold for mobilization as determined by the physiotherapy pathway was ability to stand on the day of surgery, mobilize 5 m on the morning after surgery, 20 m in the afternoon and on the second day after surgery a threshold of 40 m was set. Length of stay was also recorded.

Sample size was calculated to achieve power (1-β) of 0.8 to detect a 2-point difference in pain NRS, with a two-tailed significance level of 0.05. For the primary endpoint, a mean (standard deviation, SD) for NRS pain score of 4.6 (2.8) was derived from a large series of ambulatory pain scores for hip arthroplasty from our own institution. Twenty-eight patients in each group were required, and allowing for 15% attrition, 32 patients in each group were recruited for a total of 64 patients. SPSS version 25 (IBM) was used for the statistical analyses. Primary and secondary outcomes were analyzed using a Wilcoxan Rank Sum test for ordinal data sets, or a X^2 test with Yates correction for categorical data. Results will be reported as mean (SD), median [interquartile range (IQR)], and percentages as appropriate.

3. Results

A participant flow diagram is shown in Fig. 2. Eighty-three patients were screened with 13 not meeting inclusion criteria, and 6 patients either unwilling or unable to provide consent. The remaining 64 were successfully allocated with 32 in each group. One patient in the treatment group had an unanticipated femoral fracture intraoperatively resulting in longer more complex surgery and was excluded from further analysis. One patient in the control group developed early postoperative confusion and was unable to complete the questionnaire or report pain scores. Thirty-one patients in each group were analyzed.

Patient characteristics were similar in both groups and typical for this type of surgery (Table 1).

Spinal anesthesia was clinically successful in all patients. No patients in either group required additional analgesia intraoperatively and none reported any pain in the post-anesthesia care unit. Surgical duration and technique were similar in both groups. Patients in the ropivacaine group reported median (IQR) pain scores with movement at 6 h of 3 (1–5.5) compared to 2 (1–4.5) in the saline group ($p = 0.657$). There was no clinically significant difference in pain either at rest or with movement at any other time point (Table 2). Both groups had very similar quality of recovery scores at 24 h with median scores of 123 and 125 in the

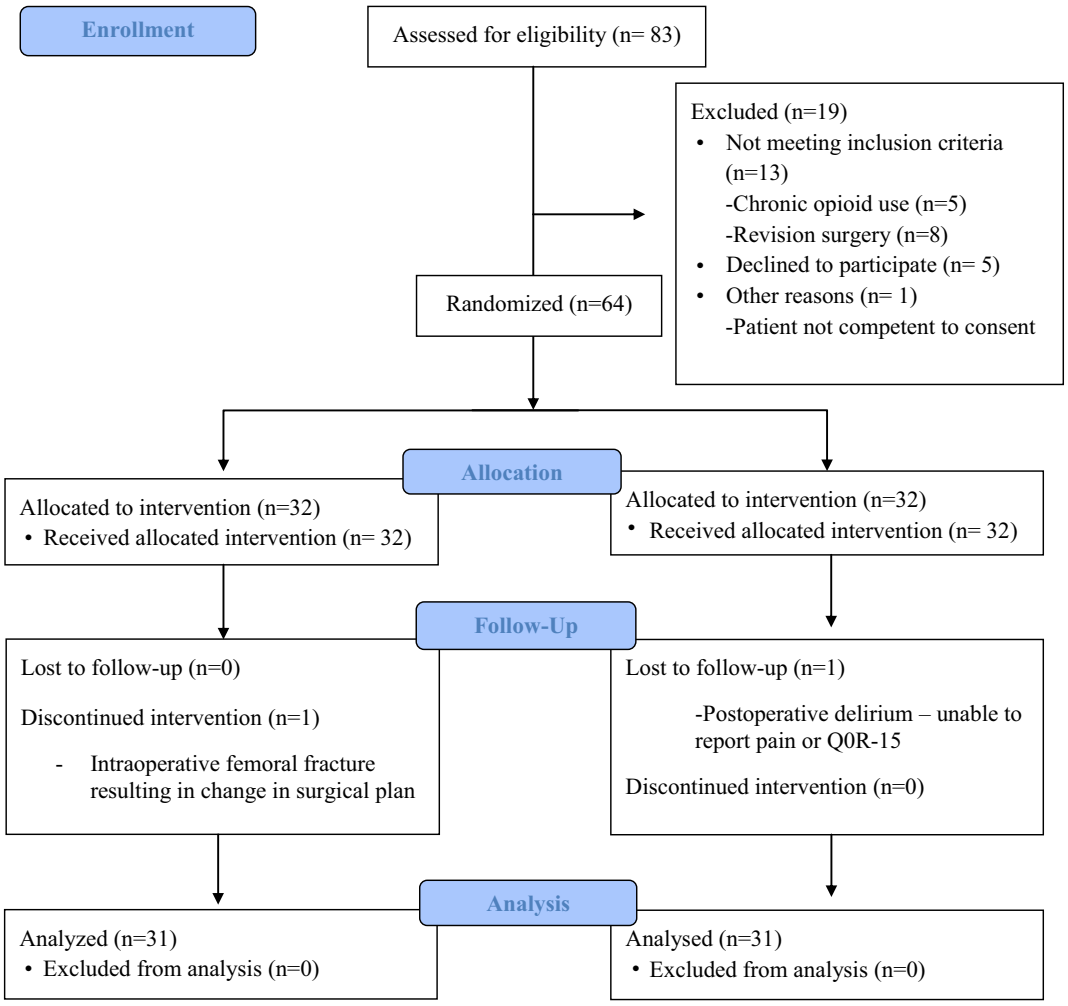

Fig. 2. Study participant flow diagram.

Table 1
Baseline Characteristics.

	Saline	Ropivacaine
Age, years	67.5 (8.5%)	65.3 (12.9%)
Sex, Female	23 (74%)	22 (71%)
Body mass index, kg/m^2	29.3 (4.6)	27.3 (4.6)
ASA physical status		
2	28 (90%)	26 (84%)
3	3 (10%)	5 (16%)
Operation times, mins	62.2 (11.0)	63.8 (9.8)

Values are mean (standard deviation) or number (percentage)

Table 2
Pain scores (NRS 0–10), Quality of Recovery Scores (0–150).

	Saline	Ropivacaine	*P*
Pain at 6 h (rest)	2 (0.5–3)	2 (0–3)	0.994
Pain at 6 h (mvt)	2 (1–4.5)	3 (1–5.5)	0.657
Pain at 24 h (rest)	1 (0–2)	2 (1–3.5)	0.068
Pain at 24 h (mvt)	4 (2–5)	4 (3–6)	0.508
QoR-15 Score	125 (115–135)	123 (112.5–133.5)	0.699

Data presented as median (IQR).
P – value calculated from Wilcoxan Rank – Sum test.
Mvt = movement, QoR = Quality of recovery score (0–150).

ropivacaine and saline groups respectively.

While not pre-specified we were also unable to find any clinically significant difference in the reported incidence of severe pain (NRS $\geq$ 7) at any time point either at rest or with movement (Table 3).

There was no difference in the number of patients who successfully mobilized in each group at any of the time points measured (Table 4). A significant but similar proportion of patients in each group failed to mobilize on the day of surgery. This was largely due to orthostatic intolerance or a lack of physiotherapy resources with patients returning to the ward in the evening. Of note, neither pain nor motor block was a significant cause of delayed mobilization in either group. On the first morning after surgery, 55% of the Ropivacaine group and 58% in the Saline group successfully mobilized. The main reason for failure in both groups was orthostatic intolerance. In the afternoon of Day 1, 84% and 77% mobilized the required 20 m in the Ropivacaine and Saline groups respectively. Orthostatic intolerance remained the main limiting factor (Table 5). By Day 2 all patients in the treatment group and 94% in the control group were successfully mobilized at least 40 m.

There was no difference in length of stay (mean, SD) - Ropivacaine group 3.4 (0.97) days, Saline group 3.6 (1.05) days. One patient in the saline group developed a transient severe bradycardia associated with chest pain and syncope in the early postoperative period and was admitted to the coronary care unit. Subsequent coronary angiogram the following day was negative, and the complication was deemed unrelated to the study.

4. Discussion

In this study there were no appreciable analgesic benefits to adding an ESPB to patients who already receive neuraxial block, local anesthetic infiltration and oral multimodal analgesia for elective primary total hip arthroplasty. Both groups were found to have relatively low pain scores and a high quality of recovery with no significant difference in successful mobilization or length of stay.

Table 3
Reported incidence of severe pain (NRS $\geq$ 7).

	Saline	Ropivacaine	*P*
Pain $\geq$7 at 6 h (rest)	1 (3.2%)	1 (3.2%)	1
Pain $\geq$7 at 6 h (mvt)	4 (12.9%)	3 (9.7%)	0.688
Pain $\geq$7 at 24 h (rest)	2 (6.5%)	1 (3.2%)	0.554
Pain $\geq$7 at 24 h (mvt)	6 (19.4%)	7 (22.6%)	0.755

Data presented as n (%).
P – value calculated from X^2 test with Yates correction, mvt = movement.

Table 4
Mobilization data.

	Saline	Ropivacaine	*P*
DOS - Stand	21 (68%)	16 (52%)	0.300
Day 1 - AM (5 m)	18 (58%)	17 (55%)	0.798
Day 1 - PM (20 m)	24 (77%)	26 (84%)	0.748
Day 2 - AM (40 m)	29 (94%)	31 (100%)	NA

Data presented as n (%)
DOS: Day of surgery. Day 1: First day after surgery
P-Value calculated from X^2 test with Yates correction

The results of this study suggest that in the context of the listed analgesic adjuncts in our control group, the ESPB does not add clinically significant benefit. There was no reduction in pain scores at any time point, no reduction in the incidence of severe pain reported and no improvement in the overall quality of recovery. Although our control group had lower than anticipated pain scores, had a significant difference existed between the groups, it should still have been detected.

Since the first description by Forero in 2016, there have been at least 242 published cases in 85 publications suggesting that it is a safe and effective block for a wide number of operations [17,29]. Most of the published data relate to thoracic and abdominal procedures. There are fewer publications relevant to major hip surgery [19–25]. These have largely been case reports or observational series, all indicating potential benefit. However, these studies did not have adequate controls and often listed opioid use as an endpoint. There have been relatively few high quality clinical trials as highlighted in recent publications questioning the “magic bullet” promise of the ESPB [30,31].

One interpretation from this study was that the analgesic regimen in the control group was over-zealous thus masking any potential benefit from the ESPB. This is possible, and had wound infiltration been omitted from both groups and more a limited multimodal analgesic regimen used, a benefit may have been identified, but this is not clear. Despite its variable efficacy, local anesthetic wound infiltration was an established technique in our institution which was known to be safe and simple to do. A decision was made to retain the technique on the grounds that we did not want our control group to have potentially less analgesia than previously offered.

The oral multimodal component contained several medications. The use of acetaminophen and anti-inflammatory medication is recommended in most multimodal regimens. However, pregabalin could have been omitted. Since performing this study, we no longer use this medication routinely due to recommendations from the large meta-analysis by published recently by Verret, highlighting the analgesic limitations and excessive side effects of pregabalin [10]. Future studies may benefit from a simpler approach with the omission of field infiltration and use of pregabalin.

Our understanding of the spread of local anesthetic following ESPB both at the thoracic and lumbar level is limited [32–34]. The sensory supply of the hip joint is complex with multiple nerve roots involved from L1 to the upper sacral plexus. There are some reports of modifications to the ESP technique to cover additional nerve roots such as the superior cluneal nerve (the dorsal roots of L1-L2-L3) and the upper part of the sacral plexus [22,35]. It is possible that a single lumbar ESPB injection may not sufficiently cover all the necessary nerve roots for hip surgery.

Furthermore, we used a relatively low concentration of ropivacaine for the ESPB. This has been our established practice for many years on the clinical grounds that 0.2% can produce effective analgesia with relative sparing of motor block and a wider margin of safety [36]. It is possible that higher concentrations or greater volumes of ropivacaine could have produced different results.

Table 5
Reasons for failure to mobilize.

	DOS		Day 1 AM		Day 1 PM	
	Saline	RP	Saline	RP	Saline	RP
Orthostatic intolerance	3 (9.7%)	6 (19.3%)	12 (38.7%)	10 (32.2%)	4 (13%)	2 (6.4%)
Not attempted*	8 (25.8%)	3 (9.7%)	1 (3.2%)	1 (3.2%)	0 (0%)	0 (0%)
Motor block	1 (3.2%)	1 (3.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pain	1 (3.2%)	0 (0%)	0 (0%)	1 (3.2%)	0 (0%)	0 (0%)
Other	2 (6.4%)	1 (3.2%)	1 (3.2%)	2 (6.4%)	2 (6.4%)	3 (10%)

Data presented as n (%).
DOS: Day of surgery, RP: Ropivacaine.
* Physiotherapist unavailable (after hours)

Another consideration was that there may have been significant differences in opioid use between the groups such that the control group may have consumed more opioid to achieve the same analgesic endpoint as the ESPB group thus masking the benefit of the block. This is an important consideration. Reductions in opioid use have been routinely used as a valid endpoint to justify regional anesthesia interventions. In the large review of ESPB publications by Tsui, opioid use was the primary outcome reported in 76% of cases [17]. Whether opioid reductions alone are a sufficient reason to adopt a novel nerve block is debatable. An international collaboration has specifically recommended against the recording and reporting of opioid use in an effort to standardize endpoints in peri-operative medicine research (StEP initiative) [37]. We adopted these recommendations when choosing our outcome criteria. The rationale is that opioid use alone is not a sufficiently important metric when better patient centered outcome measures are available, such as the QoR-15, which reflect overall quality of recovery. A significant difference in opioid use may have some relevance if reductions in opioid related side effects are also observed. In this study the incidence of nausea and vomiting was negligible in both groups (mean score of 9.5 and 9.6 out of 10 respectively, where 10 indicates no nausea or vomiting at any time during the first 24 h).

Our study had several limitations. Firstly, we did not perform dermatomal assessment to determine block efficacy and extent of local anesthetic spread. This may have been useful to determine if the block was 'successful'. However, the trial was designed to minimize bias with the use of placebo and comprehensive blinding. Neither the patient nor proceduralist were aware of the allocation and dermatomal testing could potentially have had a negative impact on the blinding procedure. In a recent editorial, Chin and Barrington specifically argue the importance of adequate blinding in the conduct of ESPB trials in an effort to improve the quality of emerging publications [30]. All ESPBs were performed by a single anesthetist experienced with the technique, with spread of local anesthetic (or placebo) directly and consistently observed along the erector spinae plane.

A second limitation was the potential for either the spinal anesthesia to have lasted longer than 6 h or for the offset of the ESPB prior to the 6-h mark thus masking any potential analgesic benefit. However, the dose of the spinal anesthetic was at the lower end of the therapeutic range and would not have been expected to last more than 4 h [38]. The duration of the ESPB is variable but a minimum duration of 6 h is consistent with published literature and our own experience [36,39,40]. There were no differences in the operative times. The 6-h time point itself is not critical, other than potentially reducing spinal offset hyperalgesia, but had the trial proved positive we could have subsequently explored other methods to prolong block duration such as the addition of dexmedetomidine or insertion of a catheter for continuous infusion of local anesthetic.

Mobilization data was not a standardized test such as the 'timed up and go' test [41]. This was a pragmatic decision. Of note, delays in mobilization were not due to pain in either group and was largely attributed to orthostatic intolerance. The length of stay was longer than may be expected in other health jurisdictions such as the United States. No patients were planned to have same day or next day discharge. This is a reflection of local health policy, patient and surgeon expectations. There are few community supports in the early discharge period and funding models currently support longer in-hospital stays. "Readiness for discharge" would have been a preferable outcome metric to capture.

This was a small single centre study and thus has limitations in terms of generalizability. However, this allowed for consistent application of the trial protocol for the surgical, anesthetic and analgesic methods.

Our study is the first blinded, placebo controlled, randomized trial of ESPB for total hip arthroplasty. The strengths of the trial include sound methodology, and validated outcome measurements specifically aligned with international recommendations for standardized outcomes in perioperative medicine [36].

The results from this trial indicate that in the context of local anesthetic infiltration and oral multimodal analgesia, the addition of an ESPB for hip arthroplasty is not warranted. Our cohort of patients experienced an acceptable quality of recovery with high QoR scores, irrespective of the ESPB. Further refinements in our technique suggests that a focus on reducing orthostatic intolerance rather than improving analgesia may prove more beneficial. Despite the lack of benefit observed in our patient group, it is possible that other patient groups may benefit, such as those who are opioid tolerant or in those undergoing more complex hip surgery. Further studies are warranted.

5. Conclusion

In this study there were no appreciable early analgesic benefits detected when adding a single pre-operative erector spinae plane block to patients who already receive spinal anesthesia, local anesthetic infiltration and oral multimodal analgesia for elective primary total hip arthroplasty.

Funding

Nil.

Declaration of Competing Interest

The manuscript entitled Erector spinae plane block combined with local infiltration analgesia for total hip arthroplasty: a randomized, placebo controlled, clinical trial is an honest and transparent account of the trial that was completed. No important aspects have been omitted. There were no changes to the trial design after trial commencement. The trial was approved by the Hollywood Private Hospital Human Research Ethics Committee (HPH 453) and registered with the Australian New Zealand Clinical Trials Registry (Registry No: ACTRN12619000071123, Universal trial number U1111–1226-7064).

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