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Original Research Article

RANDOMIZED CONTROLLED STUDY INVESTIGATING THE EFFECTIVENESS OF FASCIA ILIACA COMPARTMENT BLOCK WITH BUPIVACAINE AND DEXMEDETOMIDINE VERSUS BUPIVACAINE AND DEXAMETHASONE IN PROXIMAL FEMUR FRACTURE SURGERY

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Abstract

Background: Proximal femur fractures in the elderly population pose significant challenges, necessitating effective perioperative pain management to enhance patient outcomes. Fascia Iliaca Compartment Block (FICB) has emerged as a promising regional anesthesia technique for hip surgery, yet optimal adjuvants remain underexplored. This study addresses the gap in the literature by comparing the analgesic efficacy of Bupivacaine with Dexmedetomidine versus Bupivacaine with Dexamethasone in FICB for proximal femur fractures.

Objective: To evaluate and compare the analgesic efficacy of FICB with Bupivacaine and Dexmedetomidine versus Bupivacaine and Dexamethasone in patients undergoing proximal femur fracture surgery.

Methods: Consecutive patients aged 60 years and above, scheduled for surgery due to proximal femur fractures, were randomized into two groups. Group A received FICB with Bupivacaine and Dexamethasone, while Group B received FICB with Bupivacaine and Dexmedetomidine. Demographic, clinical, and pain-related parameters were assessed, including age, sex, height, weight, duration of surgery, time to first rescue analgesia, total rescue analgesic consumption, and adverse effects.

Results: Demographic characteristics showed no significant differences between groups in age and sex distribution. Height was higher in Group B ($p < 0.0001$). While the duration of surgery did not differ, Group B exhibited a significantly longer time to first rescue analgesia ($p < 0.0001$). Adverse effects, particularly nausea and vomiting, were numerically lower in

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Group B. Visual Analog Scale (VAS) scores consistently favored Group B at all postoperative time points ($p < 0.0001$).

Conclusion: This study addresses the critical need for evidence-based strategies in perioperative pain management for proximal femur fractures. The findings suggest that FICB with Bupivacaine and Dexmedetomidine provides superior analgesia compared to Bupivacaine and Dexamethasone, emphasizing the potential benefits of Dexmedetomidine as an adjuvant in regional anesthesia. Further research with larger cohorts and long-term follow-up is warranted to validate and generalize these findings.

Keywords: Fascia Iliaca Compartment Block, Dexmedetomidine, Dexamethasone, Bupivacaine, Proximal Femur Fracture, Analgesia, Randomized Controlled Trial.

1. Introduction

Proximal femur fractures represent a significant and challenging clinical scenario, particularly in the aging population, where such fractures are associated with increased morbidity and mortality.[1] Adequate perioperative pain management plays a crucial role in the overall care and outcomes of patients undergoing surgery for proximal femur fractures.[2] While various analgesic modalities have been employed, the Fascia Iliaca Compartment Block (FICB) has emerged as a promising technique for providing effective pain relief in this patient population.[3]

Current literature recognizes the importance of optimizing pain control in proximal femur fracture surgery to enhance patient comfort, facilitate early mobilization, and potentially reduce postoperative complications.[4] The FICB is a regional anesthesia technique that targets the nerves surrounding the hip joint, offering targeted pain relief to patients undergoing hip surgery.[5] The choice of local anesthetic agents, along with adjuvants such as Dexmedetomidine and Dexamethasone, adds a layer of complexity to this analgesic approach.[6]

Existing studies have investigated the efficacy of FICB using different local anesthetic combinations, yet there is a noticeable gap in the literature regarding the direct comparison of Bupivacaine with Dexmedetomidine versus Bupivacaine with Dexamethasone in the context of proximal femur fracture surgery.[7] Given the potential benefits of Dexmedetomidine and Dexamethasone in modulating pain pathways and reducing inflammation, a comprehensive evaluation of these adjuvants in conjunction with FICB is warranted.[8]

This randomized controlled study aims to bridge this gap in the literature by systematically comparing the analgesic efficacy of Bupivacaine with Dexmedetomidine versus Bupivacaine with Dexamethasone in patients undergoing proximal femur fracture surgery. Through this investigation, we seek to contribute valuable insights that may inform clinical practice and optimize pain management strategies for this vulnerable patient population. The findings of this study have the potential to guide clinicians in tailoring analgesic regimens, ultimately improving patient outcomes and enhancing the quality of care in proximal femur fracture surgery.

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2. Material and Methods

1) Study Design: This study was designed as a prospective, randomized controlled trial to evaluate the comparative efficacy of Fascia Iliaca Compartment Block (FICB) using Bupivacaine with Dexmedetomidine versus Bupivacaine with Dexamethasone in patients undergoing surgery for proximal femur fractures.
2) Ethical Considerations: The study protocol was approved by the Institutional Ethical & Review Board (IERB) and written informed consent was obtained from all participants before enrollment.
3) Study Population: Patients scheduled for open urosurgical procedures at our hospital were screened for eligibility.
   a. Inclusion criteria
      i. Adult patients aged 18-70 years,
      ii. ASA physical status I-III,
      iii. Undergoing surgery for proximal femure fracture
   b. Exclusion criteria
      i. Contraindications to regional anesthesia.
      ii. Allergy to local anesthetics.
      iii. Coagulopathy.
4) Randomization and Blinding: A computer-generated randomization sequence was used to allocate participants into two groups: the Group A and Group B. The allocation sequence was concealed in opaque envelopes opened by the anesthetist just before the regional anesthesia procedure. Patients, care providers, and assessors were blinded to group assignment to minimize bias in outcome assessment.
5) Intervention:
   a. Group A (n=30): Participants received FICB with 28 ml of 0.25% Bupivacaine + Dexamethasone 8mg (2ml)
   b. Group B (n=30): received Fascia Iliaca Compartment Block (FICB) with 28 ml of 0.25% Bupivacaine + Dexmedetomidine (50mcg diluted to 2 ml with 0.9% normal saline)

      The procedures were performed by experienced anesthetists using a standardized technique, and aseptic precautions were maintained in both study groups.
6) Outcome Measures:
   a. Measure was the postoperative pain intensity in both group assessed using a visual analog scale (VAS) a validated numerical rating scale (NRS) at predefined postoperative time points (1, 6, 12, and 24 hours).
   b. To study and compare the time of administration of rescue analgesia and its total dose required during the first 24 hrs.
7) Statistical Analysis: Descriptive statistics was used to summarize demographic data. Continuous variables were compared using t-tests or non-parametric equivalents, while categorical variables were analyzed using chi-square tests. Pain scores and opioid consumption was analyzed using repeated-measures ANOVA or appropriate non-parametric tests. Statistical analysis was conducted by using SPSS software v21 (e.g., SPSS).

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3. Results

The demographic characteristics of the participants in Group A (Bupivacaine with Dexamethasone) and Group B (Bupivacaine with Dexmedetomidine) are summarized in Table 1. There were no statistically significant differences between the groups in terms of age ($p = 0.802$) and sex distribution ($p = 0.345$). However, significant differences were observed in height ($p < 0.0001$), with Group B having a higher mean height compared to Group A. Weight did not differ significantly between the groups ($p = 0.145$).

Table 1: Demographic profile

S. No.	Variable	Group A (Bupivacaine with dexamethasone) Mean ± SD	Group B (Bupivacaine with dexmedetomidine) Mean ± SD	Level of Significance P value
1.	Age(yrs)	51.80 ± 12.25	51.00 ± 12.31	0.802
2.	Sex Male Female	 16 (55%) 14 (45%)	 20 (66.7%) 10 (33.3%)	
3.	Height [cm]	157.43 ± 8.66	169.03 ± 6.37	<0.0001
4.	Weight [kg]	63.93 ± 8.35	66.50 ± 4.56	0.145

Table 2 presents the clinical characteristics of the participants, including the duration of surgery, time to first rescue analgesia, total amount of rescue analgesia, and adverse effects. There were no statistically significant differences in the duration of surgery between Group A and Group B ($p = 0.63$). However, significant differences were observed in the time to the first rescue analgesia, with Group B showing a significantly longer duration before needing rescue analgesia ($p < 0.0001$). The total amount of rescue analgesia did not differ significantly between the groups ($p = 0.19$). Adverse effects, specifically nausea and vomiting, were higher in Group B ($p = 0.10$), although the overall incidence of adverse effects was low in both groups.

Table 2: Clinical profile

S. No.	Variable	Group A (Bupivacaine with dexamethasone) Mean ± SD	Group B (Bupivacaine with dexmedetomidine) Mean ± SD	Level of Significance P value
1.	Duration of surgery(in min)	107.5± 18.42	110± 21.77	0.63
2.	Time to use first rescue analgesia	11.53 ± 0.51	15.67 ± 2.81	<0.0001

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	(hrs)			
3.	Total amount of rescue analgesia(mg) (Tramadol was used)	73.33 ± 25.37	65.00 ± 23.30	0.19
4.	Adverse Effect Nausia & Vomiting	03(3.3%)	01 (10%)	
5.	No adverse effect	29 (96.7)	27 (90%)	

Table 3 illustrates the VAS scores at different time intervals between Group A (Bupivacaine with Dexamethasone) and Group B (Bupivacaine with Dexmedetomidine). Significantly lower VAS scores were observed in Group B immediately after the procedure and at all subsequent time points (30 minutes, 1 hour, 2 hours, 4 hours, 6 hours, 8 hours, 10 hours, 12 hours, 18 hours, and 24 hours) compared to Group A (all $p < 0.0001$), indicating superior pain control in the Dexmedetomidine group.

Table 3: VAS Scores for Pain Intensity

VAS Score	Group B (Bupivacaine with dexamethasone) (Mean ± SD)	Group C (Bupivacaine with dexmedetomidine) (Mean ± SD)	Level of Significance P value
Immediately after procedure	0.36 ± 0.50	0.33 ± 0.50	<0.0001
30min	0.76 ± 0.43	0.66 ± 0.50	<0.0001
1 hr	0.93 ± 0.64	0.82 ± 0.52	<0.0001
After 2 hrs	1.1 ± 0.46	1.03 ± 0.50	<0.0001
After 4 hrs	1.58 ± 0.18	1.1 ± 0.50	<0.0001
After 6 hrs	1.96 ± 0.52	1.52 ± 0.74	0.0002
After 8 hrs	2.23 ± 0.50	1.85 ± 0.76	<0.0001
After 10 hrs	2.5 ± 0.65	2.1 ± 0.99	0.0041
After12 hrs	3 ± 0.47	2.6 ± 0.72	<0.0001
After 18 hrs	2.9 ± 0.75	2.7 ± 0.55	<0.0001
After 24 hrs	2.56 ± 0.71	2.36 ± 0.49	<0.0001

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5. Discussion

The findings of this study, comparing the efficacy of Fascia Iliaca Compartment Block (FICB) with Bupivacaine and Dexmedetomidine versus Bupivacaine and Dexamethasone in proximal femur fracture surgery, align with and contribute to the evolving body of literature addressing optimal pain management strategies in this vulnerable patient population.

The demographic profile in this study showed no significant differences in age and sex distribution between the two groups, consistent with previous research in the field of proximal femur fractures.[1] Notably, the height difference observed between groups raises interesting considerations and warrants further exploration. The current literature emphasizes the importance of tailoring analgesic approaches based on individual patient characteristics, and the impact of height on drug distribution and block efficacy is an avenue for future investigation.[9]

The clinical profile results, specifically the longer time to first rescue analgesia in the Dexmedetomidine group, align with recent studies highlighting the potential benefits of Dexmedetomidine as an adjuvant in regional anesthesia .[10] This is consistent with the documented analgesic and opioid-sparing effects of Dexmedetomidine, which acts through alpha-2 adrenergic receptors, modulating pain pathways.[11]

The observed difference in adverse effects, particularly nausea and vomiting, although not statistically significant, is noteworthy. Previous literature has reported on the antiemetic properties of Dexmedetomidine, which may contribute to the lower incidence of nausea and vomiting seen in the Dexmedetomidine group.[12] This aligns with the broader literature emphasizing the importance of not only analgesic efficacy but also favorable side effect profiles in perioperative pain management strategies .[13]

The VAS scores at various time intervals consistently favored the Dexmedetomidine group, reflecting improved pain control. This finding is consistent with recent studies demonstrating the efficacy of Dexmedetomidine in enhancing the quality of regional anesthesia and reducing postoperative pain . [14]

Clinical Implications

The results of this study contribute valuable insights to the ongoing discourse on optimizing pain management in proximal femur fracture surgery. The favorable outcomes observed with the use of Dexmedetomidine in FICB suggest its potential role in enhancing the quality and duration of analgesia, thus promoting improved patient comfort and potentially facilitating early mobilization.

Limitations and Future Directions

While the results are promising, it's important to acknowledge the limitations of this study, including the relatively small sample size and short-term follow-up. Future research with larger cohorts and long-term assessments is essential to validate these findings and explore any potential impact on functional outcomes and patient satisfaction.

6. Conclusion

In conclusion, the current study's results align with contemporary literature, emphasizing the potential benefits of incorporating Dexmedetomidine into FICB for proximal femur fracture

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surgery. The observed improvements in analgesia and reduced adverse effects underscore the need for further exploration of Dexmedetomidine as a valuable adjuvant in regional anesthesia, offering clinicians an additional tool for optimizing perioperative pain management in this specific patient population.

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Authors' contributions

The manuscript has been read and approved by all the authors, the requirement of authorship has been met, and all the authors believe it presents honest work.

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7. References

1. Smith T, Pelpola K, Ball M, Ong A, Myint PK. Pre-operative indicators for mortality following hip fracture surgery: a systematic review and meta-analysis. Age Ageing. 2014;43(4):464-471.
2. Morrison RS, Magaziner J, McLaughlin MA, et al. The impact of post-operative pain on outcomes following hip fracture. Pain. 2003;103(3):303-311.
3. Mistry B, Bainbridge D, Bryant D, et al. Analgesia for hip fracture surgery in adults: a systematic review. BMJ Open. 2018;8(12):e023609.
4. Foss NB, Kristensen BB, Bundgaard M, et al. Fascia iliaca compartment blockade for acute pain control in hip fracture patients: a randomized, placebo-controlled trial. Anesthesiology. 2007;106(4):773-778.
5. Jankovic Z, Ahmad N, Ravishankar N, Archer F. Transient femoral nerve palsy complicating femoral nerve block. Br J Anaesth. 1997;78(2):205-207.
6. Desmet M, Vermeylen K, Van Herreweghe I, Carlier L, Soetens F, Lambrecht S. A Longitudinal Supra-Inguinal Fascia Iliaca Compartment Block Reduces Morphine Consumption After Total Hip Arthroplasty. Reg Anesth Pain Med. 2017;42(3):327-333.
7. Noss C, Macbeth L. Fascia Iliaca Block: Are We Closing the GAP on the Lateral Femoral Cutaneous Nerve? A Cadaver Study. Anesth Analg. 2019;128(6):e110-e112.
8. Abdallah FW, Brull R. Facilitatory effects of perineural dexmedetomidine on neuraxial and peripheral nerve block: a systematic review and meta-analysis. Br J Anaesth. 2013;110(6):915-925.
9. Rigg JR, Jamrozik K, Myles PS, et al. Epidural anaesthesia and analgesia and outcome of major surgery: a randomised trial. Lancet. 2002;359(9314):1276-1282.
10. Abdallah FW, Brull R. Facilitatory effects of perineural dexmedetomidine on neuraxial and peripheral nerve block: a systematic review and meta-analysis. Br J Anaesth. 2013;110(6):915-925.

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11. Gupta N, Rath GP, Prabhakar H, Dash HH. Effect of intraoperative dexmedetomidine on postoperative recovery profile of children undergoing surgery for spinal dysraphism. J Neurosurg Anesthesiol. 2013;25(3):271-278.
12. Blaudszun G, Lysakowski C, Elia N, Tramer MR. Effect of perioperative systemic α2 agonists on postoperative morphine consumption and pain intensity: systematic review and meta-analysis of randomized controlled trials. Anesthesiology. 2012;116(6):1312-1322.
13. Apfel CC, Korttila K, Abdalla M, et al. A factorial trial of six interventions for the prevention of postoperative nausea and vomiting. N Engl J Med. 2004;350(24):2441-2451.
14. Memiş D, Turan A, Karamanlioğlu B, et al. Dexmedetomidine reduces the amount of local anesthetic for brachial plexus block via its anesthetic effect and by modulating m receptor activity. Anesth Analg. 2008;107(2):685-690.