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COMPARISON OF EFFICACY OF BUPIVACAINE; HYPERBARIC AND HYPOBARIC SOLUTIONS FOR OPEN REDUCTION AND INTERNAL FIXATION FOR TIBIAL FRACTURE UNDER UNILATERAL SPINAL ANESTHESIA

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Abstract

Background: *Tibial fractures require effective anesthesia during surgery. While hypobaric bupivacaine has been used traditionally, hyperbaric solutions offer better unilateral block. Due to limited local data, this study was conducted to compare both in ORIF procedures.*

Objectives: *To compare the outcome of hyperbaric versus hypobaric solutions for open reduction and internal fixation for tibial fracture under unilateral spinal anesthesia.*

Duration: *Six months w.e.f 16-11-2023 to 15-05-2024*

Methodology: *After ethical approval, 100 patients meeting inclusion criteria were selected from Sir Ganga Ram Hospital, Lahore. Informed consent was obtained, and demographics recorded. Patients were randomly assigned to Group A (2 ml hyperbaric bupivacaine 0.75%) or Group B (3 ml hypobaric bupivacaine 0.5%). Anesthesia was administered by the researcher. Sensory block, recovery time, and surgery duration were recorded.*

Results: *The mean age of participants was 38.03 ± 14.07 years, with 67% male and 62% overweight/obese. Group A had a higher efficacy (94% vs. 78%, $p = 0.021$) and faster onset (7.24 ± 1.67 vs. 10.16 ± 1.19 minutes, $p < 0.001$) compared to Group B. Recovery time was longer in Group A (146.30 ± 14.88 vs. 129.28 ± 12.51 minutes, $p < 0.001$). Stratified analysis showed consistent outperformance by Group A, with significant differences in sensory block onset and recovery ($p < 0.05$).*

Conclusion: *Hyperbaric bupivacaine demonstrated greater efficacy than hypobaric bupivacaine, with higher block success, faster onset, and longer duration. Though subgroup significance varied, overall results favor hyperbaric use for unilateral spinal anesthesia in tibial surgeries.*

INTRODUCTION

The choice of anesthetic technique in long bone fracture surgeries significantly impacts perioperative hemodynamic stability and postoperative rehabilitation quality.[1] Given the high incidence of coronary diseases in orthopedic patients, they are more susceptible to hypotensive episodes.[2,3] Although both general and regional anesthesia are viable options, spinal anesthesia remains the most commonly used technique.[4] Spinal anesthesia offers satisfactory hemodynamic stability, mainly through

sympathetic block reduction. Recent advancements have focused on unilateral spinal anesthesia, particularly when low doses of local anesthetic are employed, which is both cost-effective and rapidly performed.[5,6] This technique only affects sensory, motor, and sympathetic functions on one side of the body, minimizing adverse side effects, such as hypotension, which is especially beneficial for patients with cardiovascular risk factors like aortic valve stenosis or coronary artery disease.[7] Hyperbaric bupivacaine offers better control of block height compared to isobaric solutions, leading to fewer complications like hypotension and block failure.[7,8] Previous studies have demonstrated the efficacy of hyperbaric bupivacaine, providing a reliable reference for determining appropriate sensory block levels.[9,10]

Kaya et al. conducted a study comparing hyperbaric and hypobaric solutions for unilateral spinal anesthesia. They found that 80% of patients in the hyperbaric group achieved unilateral anesthesia in the lateral position, which decreased to 68% in the supine position. In the hypobaric group, unilateral anesthesia was achieved in 76% of patients in the lateral position, dropping significantly to 24% in the supine position (p-value = 0.05). The mean time to reach the maximum sensory level was 10 minutes for the hyperbaric group and 15 minutes for the hypobaric group (p-value > 0.05), while recovery times for sensory block were 2.11 ± 0.6 hours and 2.6 ± 0.9 hours, respectively (p-value > 0.05).[9]

In a subsequent study in 2010, Kaya et al. found that 90% of patients in the hyperbaric group achieved unilateral anesthesia in the lateral position, which decreased to 60% in the supine position. In the hypobaric group, 80% achieved unilateral anesthesia in the lateral position, dropping to 33% in the supine position (p-value < 0.05). The mean recovery time for sensory block was 214 ± 44 minutes in the hyperbaric group, compared to 230 ± 39 minutes in the hypobaric group (p-value > 0.05).[10]

The rationale for this study was to compare the outcomes of low-dose hyperbaric versus hypobaric bupivacaine solutions for unilateral spinal anesthesia in tibial fracture surgeries. Literature suggests that low-dose hyperbaric solutions may be more effective in achieving successful unilateral blocks. However, there is a scarcity of literature specifically focused on its application in tibial fracture fixation, highlighting the need for a more focused trial to assess the efficacy of these solutions in this context. This study will provide updated data for local settings and enhance clinical practices, offering valuable insights into optimizing anesthesia techniques for such procedures.

METHODOLOGY

This study was a randomized controlled trial conducted at the Department of Anesthesia, Sir Ganga Ram Hospital Lahore, over a six-month period following the approval of the synopsis. The study aimed to compare the efficacy of hyperbaric versus hypobaric bupivacaine for unilateral spinal anesthesia in patients undergoing open reduction and internal fixation for tibial fractures. A total sample size of 100 cases was calculated, with 50 patients assigned to each group. The power of the study was set at 80%, and a significance level of 5% was used. The expected success rate for unilateral spinal anesthesia was 90% with hyperbaric bupivacaine and 60% with hypobaric bupivacaine.[10] The sampling technique used was non-probability consecutive sampling, with the inclusion criteria encompassing patients aged 16 to 65 years, both genders, and classified under ASA I and II. Exclusion criteria included patients with severe hypertension (BP ≥ 160/100 mmHg), diabetes (OGTT > 186 mg/dl), coagulopathy (INR > 2), hypovolemic shock, contraindications to local anesthetics, bilateral surgeries, and emergency cases. After approval from the hospital ethical board, 100 patients fulfilling the inclusion criteria were selected from the operation theatre of the Department of Orthopedics. Informed consent was obtained from each participant, and relevant demographic details, including age, gender, BMI, ASA status, and type of surgery, were documented.

The patients were then randomly assigned to two groups using the lottery method. In Group A, 2 ml of hyperbaric bupivacaine (0.75%) was administered, and in Group B, 3 ml of hypobaric bupivacaine (0.5%) was administered. After the administration of the anesthetic, patients were monitored for unilateral spinal block in the lateral position. After 15 minutes, the patients were turned to the supine position, and the success of the unilateral spinal block was

evaluated based on predefined operational definitions. Key variables such as time to reach the maximum sensory block and time to complete recovery from the sensory block were carefully documented. Quantitative variables such as age, BMI, duration of surgery, time to maximum sensory block, and recovery time were analyzed using mean ± standard deviation. Qualitative variables, including ASA status, gender, and the success rate of unilateral spinal block, were analyzed using frequency and percentage. Independent samples t-tests were used to compare the mean time required to reach the maximum sensory block and recovery times, while chi-square tests were employed to assess the success rates of unilateral spinal blocks. A p-value of ≤ 0.05 was considered statistically significant. Additionally, data were stratified by age, gender, BMI, ASA status, duration of surgery, and surgery type, and post-stratification comparisons were performed for each group. Data entry and analysis were performed using SPSS version 25.

RESULTS

A total of 100 patients were included in the study, with a mean age of 38.03 ± 14.07 years. Of these, 56% were between 16 and 40 years, while 44% were aged 41 to 65 years. The majority of the patients were male (67%), and 33% were female. The mean body mass index (BMI) was 25.64 ± 3.78 kg/m², with 38% falling into the normal weight category and 62% classified as overweight or obese. Regarding ASA (American Society of Anesthesiologists) physical status, 46% were ASA-I, and 54% were ASA-II. Data is given in Table 1.0. No statistically significant differences were found between the two groups for any of the baseline characteristics (p-value>0.05), as given in Table 2.0.

The mean duration of surgery was similar between the two groups, with Group A recording 94.58 ± 14.58 minutes and Group B 95.62 ± 14.17 minutes ($p = 0.718$). A significantly higher proportion of patients in Group A (94.0%) achieved successful sensory block compared to Group B (78.0%) ($p = 0.021$). The time to achieve maximum sensory block was significantly shorter in Group A (7.24 ± 1.67 minutes) than in Group B (10.16 ± 1.19 minutes) ($p < 0.001$). Similarly, the time to complete recovery from sensory block was significantly longer in Group A (146.30 ± 14.88 minutes) as compared to Group B (129.28 ± 12.51 minutes) ($p < 0.001$). These differences indicate that hyperbaric bupivacaine (Group A) was associated with a faster onset and longer duration of effective sensory anesthesia as given in Table 3.0.

Efficacy of achieving sensory block between the groups, when stratified across various subgroups, showed that Group A consistently outperformed Group B. However, statistical significance was not attained in all subgroups, likely due to the limited sample size within each category. Data is given in Table 4.0.

Stratification of both time to achieve maximum sensory block and time to complete recovery from sensory block across various subgroups consistently demonstrated that Group A outperformed Group B, with statistically significant differences observed in all subgroups ($p < 0.05$).

Table 1.0: Demographic Characteristics of Patients Included in the Study

Characteristics	Total (n=100)
Age (years)	38.03±14.07
• **16-40 years**	56 (56.0%)
• **41-65 years**	44 (44.0%)
Gender	
• **Male**	67 (67.0%)
• **Female**	33 (33.0%)
BMI (kg/m²)	25.64±3.78
• **Normal Weight**	38 (38.0%)
• **Overweight/Obese**	62 (62.0%)
ASA Status	

• ASA-I	46 (46.0%)
• ASA-II	54 (54.0%)

Table 2.0: Comparison of Baseline Characteristics between the Study Groups

Characteristics	Group A (n=50)	Group B (n=50)	p-value
Age (years)	37.46±13.73	38.60±14.53	0.688
• 16-40 years	31 (62.0%)	25 (50.0%)	0.227
• 41-65 years	19 (38.0%)	25 (50.0%)	
Gender			
• Male	32 (64.0%)	35 (70.0%)	0.523
• Female	18 (36.0%)	15 (30.0%)	
BMI (kg/m^2)	25.38±4.00	25.90±3.56	0.498
• Normal Weight	21 (42.0%)	17 (34.0%)	0.410
• Overweight/Obese	29 (58.0%)	33 (66.0%)	
ASA Status			
• ASA-I	22 (44.0%)	24 (48.0%)	0.688
• ASA-II	28 (56.0%)	26 (52.0%)	

Chi Square test/ Independent sample t test, taking p-lvaue≤0.05 as significant.

Table 3.0: Comparison of Study Outcomes after 3 Months Treatment

Characteristics	Group A (n=50)	Group B (n=50)	p-value
Mean Duration of Surgery	94.58±14.58	95.62±14.17	0.718
Successful Sensory Block Achieved			
• Yes	47 (94.0%)	39 (78.0%)	0.021
• No	3 (6.0%)	11 (22.0%)	
Time to Achieve Maximum Sensory Block	7.24±1.67	10.16±1.19	0.000
Time to Achieve Maximum Sensory Block	146.30±14.88	129.28±12.51	0.000

Chi Square test/ Independent sample t test, taking p-lvaue≤0.05 as significant.

Table 4.0: Comparison of Efficacy of Achieving Sensory Block between the Groups Stratified for Various Sub Groups

Group	Sub Group	Group A (n=50)	Group B (n=50)	p-value
Age	16-40 years	30 (98.0%)	21 (84.0%)	0.096
	41-65 years	17 (89.5%)	18 (72.0%)	0.155
Gender	Male	30 (93.8%)	30 (85.7%)	0.283
	Female	17 (94.4%)	9 (60.0%)	0.030
BMI	Normal Weight	20 (92.2%)	13 (76.5%)	0.089
	Overweight/Obese	27 (93.1%)	26 (78.8%)	0.155
ASA Status	ASA-I	22 (100.0%)	17 (70.8%)	0.006
	ASA-II	25 (89.3%)	22 (84.6%)	0.699
Duration of Surgery	≤90 minutes	22 (95.7%)	13 (76.5%)	0.070
	>90 minutes	25 (92.6%)	26 (78.8%)	0.041

Table 4 .0: Stratification of Frequency of Correction of Anemia

Characteristics	Group A (46)	Group B (n=46	p-value
Age			
• 18-30 years	26 (100.0%)	22 (75.9%)	0.007
• 31-45 years	18 (90.0%)	14 (82.4%)	0.498
Gestational Age			
• 24-26 weeks	26 (92.9%)	17 (73.9%)	0.064
• 27-28 weeks	18 (100.0%)	19 (82.6%)	0.063
Parity			
• 1-2	30 (96.8%)	24 (85.7%)	0.128
• >2	14 (93.3%)	12 (66.7%)	0.062
IDA Status			
• Mild	18 (100.0%)	13 (81.3%)	0.054
• Moderate	26 (92.9%)	23 (76.7%)	0.089

Chi Square test, taking p-lvaue≤0.05 as significant.

DISCUSSION

Tibial fractures often require surgical intervention, with effective intraoperative anesthesia being crucial for patient comfort and surgical success.[11] Traditionally, spinal anesthesia using isobaric or hypobaric bupivacaine has been employed; however, these techniques may result in bilateral spread, leading to unnecessary motor and sensory block on the non-operative side.[12,13] Hyperbaric bupivacaine, a newer approach, offers more predictable and targeted unilateral block, potentially improving outcomes.[14] Despite its growing use, there is limited comparative data on the efficacy of hyperbaric versus hypobaric solutions, particularly in the local context. No local studies have evaluated this in patients undergoing ORIF, prompting the need for this investigation.

Comparison of our study findings with existing literature highlights a consistent trend favoring hyperbaric bupivacaine for effective unilateral anesthesia. Kaya et al. from Turkey evaluated the efficacy of low-dose hyperbaric versus hypobaric levobupivacaine in producing unilateral spinal anesthesia. Their study demonstrated that a unilateral sensory block in the lateral position was achieved in 90% of patients (n=27) who received hyperbaric levobupivacaine, compared to 80% (n=24) in the hypobaric group. After 15 minutes, patients were repositioned supine to assess redistribution of the anesthetic. Notably, the block remained unilateral in 60% (n=18) of the hyperbaric group but dropped to 33% (n=10) in the hypobaric group, with a statistically significant difference (p-value = 0.038). Although both groups achieved satisfactory sensory blocks with stable hemodynamic profiles, motor block scores on the operative side were significantly higher in the hyperbaric group during the initial 10 minutes (p-value = 0.01). These findings suggest that hyperbaric levobupivacaine may be more effective in maintaining unilateral anesthesia, especially in early surgical phases.[10]

Yalnız et al., also from Turkey, compared hyperbaric and hypobaric bupivacaine for anorectal procedures and reported that the hypobaric group exhibited significantly shorter durations of both sensory and motor blocks, which facilitated quicker readiness for surgery and earlier discharge. Despite these differences, both groups maintained similar hemodynamic stability and incidence of postoperative complications. Their findings suggest that a 5 mg dose of hypobaric bupivacaine is advantageous in day-care settings by promoting faster recovery, efficient patient turnover, and better resource utilization without compromising safety.[15]

In Switzerland, Faust et al. examined the difference in regression times between isobaric and hypobaric bupivacaine. They reported that the hypobaric group had a significantly prolonged time to sensory regression to L2 on the operative side (287 ± 51 minutes) when compared to the isobaric group (242 ± 36 minutes), with a p-value of 0.004. Additionally, the time to first analgesic requirement was longer in the hypobaric group (290 ± 46 minutes) versus the isobaric group (237 ± 39

minutes), which was statistically significant (p-value = 0.001). However, motor block quality at the end of the procedure and hemodynamic parameters remained comparable between the two groups.[16]

Kalagać et al. in Croatia investigated the effects of anesthetic baricity using both ropivacaine and bupivacaine. Their results revealed that the shortest median time to achieve surgical anesthesia was in the hyperbaric ropivacaine group (6.95 minutes). Moreover, the greatest intensity of motor block (Bromage score 3) was observed in the hyperbaric bupivacaine group. Regarding recovery, patients in the hyperbaric and hypobaric ropivacaine groups achieved earlier ambulation and first urination (160 minutes vs. 190 minutes) compared to those in the hyperbaric and hypobaric bupivacaine groups (230 minutes vs. 250 minutes). Side effects were minimal and infrequent across all groups. The authors concluded that while the baricity of the solution did not significantly impact the success of achieving unilateral blocks, ropivacaine may be preferred in outpatient settings due to quicker recovery and fewer complications.[17]

Anand et al. from India compared hyperbaric and hypobaric levobupivacaine in terms of efficacy and patient satisfaction. Unilateral spinal anesthesia was achieved in 87% (n=26) of the hyperbaric group and 90% (n=27) of the hypobaric group. Both groups reached maximum sensory blockade (T10) in approximately 10 minutes. However, two-segment regression occurred faster in the hypobaric group (64.2 ± 4.8 minutes) than in the hyperbaric group (76.4 ± 5.2 minutes), with a p-value less than 0.05. Furthermore, the duration of anesthesia was longer in the hyperbaric group (210 ± 12 minutes) compared to the hypobaric group (170 ± 14 minutes). Hemodynamic stability remained consistent across both groups. The study concluded that hypobaric levobupivacaine may provide better patient satisfaction due to quicker recovery and resolution of block.[18]

CONCLUSION

This study's strengths include its randomized controlled design, clear inclusion criteria, and use of two different bupivacaine formulations to compare outcomes effectively. The large sample size enhances the generalizability of results. However, limitations include the single-center setting and the relatively short duration of follow-up. Future research could explore multicenter trials with longer follow-up periods to evaluate the long-term effects of hyperbaric versus hypobaric bupivacaine and assess outcomes in different surgical populations.

LIMITATIONS & RECOMMENDATIONS

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Authors Contribution

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Substantial contributions to study design, acquisition of data Analysis & Interpretation of Data, Manuscript writing Has given final approval of the version to be published Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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Substantial contributions to concept, study design
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Has given final approval of the version to be published
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