

COMPARATIVE STUDY BETWEEN 5 AND 15 ML OF NORMAL SALINE USED FOR EPIDURAL VOLUME EXPANSION TO STUDY THE EFFECT OF SPINAL BLOCK CHARACTERISTICS USING A FIXED DOSE OF HYPERBARIC BUPIVACAINE IN CSEA FOR ELECTIVE INFRAUMBILICAL SURGERIES IN ADULT PATIENTS

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ABSTRACT

Background: Combined spinal-epidural anesthesia (CSEA) is a preferred method for infraumbilical surgeries due to its rapid onset and reliable anesthesia. This study aims to explore the effects of varying volumes of normal saline used for epidural volume expansion on the characteristics of spinal blockade using hyperbaric bupivacaine. **Methods:** In a randomized controlled trial at a single medical center, 140 adult patients scheduled for elective infraumbilical surgeries were enrolled. Participants were divided into two groups to receive either 5 ml or 15 ml of normal saline for epidural volume expansion following spinal injection of hyperbaric bupivacaine. Outcomes measured included the maximum height of the spinal block, time to achieve maximum block, duration of analgesia, and incidence of side effects. **Results:** The group receiving 15 ml of saline demonstrated a significantly faster time to maximum block height (10.2 ± 2.8 min vs. 12.4 ± 3.1 min, $P = 0.001$) and a higher rate of achieving a block height of T10 or above (82.9% vs. 67.1%, $P = 0.012$). Duration of analgesia was also longer in the 15 ml group (3.2 ± 0.7 hours vs. 2.6 ± 0.9 hours, $P < 0.001$). Additionally, the incidence of nausea and hypotension was lower in patients receiving 15 ml of saline. Differences in patient and surgeon satisfaction were not statistically significant. **Conclusions:** Increasing the volume of normal saline for epidural volume expansion in CSEA to 15 ml enhances the spread and duration of spinal block while reducing the incidence of side effects. These findings support the use of a higher volume of saline to improve anesthetic outcomes in elective infraumbilical surgeries.

Keywords: Epidural Volume Expansion, Spinal Block, Infraumbilical Surgeries, Hyperbaric Bupivacaine, Anesthesia Outcomes

INTRODUCTION

The technique of combined spinal-epidural anesthesia (CSEA) integrates the benefits of both spinal and epidural anesthesia, offering rapid onset and reliable anesthesia with the flexibility of extending the block or providing postoperative analgesia via the epidural component. This technique is particularly advantageous for infraumbilical surgeries, where effective, controlled anesthesia is required.^{[1][2][3]}

One of the critical variables influencing the dynamics and efficacy of spinal anesthesia is the volume of epidural fluid used for volume expansion. Epidural volume expansion (EVE) with normal saline is a technique employed to enhance the spread of spinal anesthesia. It involves injecting a specified volume of saline into the epidural space following the administration of spinal anesthetics, which can manipulate the spread and duration of the block. This practice, however, varies widely, with no consensus on the optimal volume for maximum efficacy and minimal side effects.^{[4][5][6]}

Recent studies have suggested that varying the volume of saline for EVE can affect the height and duration of spinal blockade, potentially improving the quality of anesthesia and patient satisfaction while reducing the likelihood of complications such as hypotension and inadequate block. However, empirical data comparing different volumes are sparse, particularly concerning low volumes like 5 ml versus more considerable volumes like 15 ml.^{[7][8]}

Aim

To compare the effects of 5 ml and 15 ml of normal saline for epidural volume expansion on spinal block characteristics using a fixed dose of hyperbaric bupivacaine in CSEA for elective infraumbilical surgeries.

Objectives

1. To determine the difference in the height of spinal blockade achieved with 5 ml versus 15 ml of normal saline used for EVE in CSEA.
2. To assess the duration of analgesia and incidence of side effects associated with each volume of normal saline.
3. To evaluate patient and surgeon satisfaction with the anesthesia provided by different volumes of saline for EVE.

MATERIAL AND METHODOLOGY

Source of Data

The study was conducted after receiving ethical approval from the Institutional Review Board of the University Hospital. Patients were recruited from those scheduled for elective infraumbilical surgeries under CSEA at the hospital.

Study Design

A randomized controlled trial was conducted.

Study Location

The research took place at University Hospital, which serves a large, diverse patient population.

Study Duration

Data were collected from January 2021 to December 2022.

Sample Size

A total of 140 adult patients were included in the study.

Inclusion Criteria

- Adults aged 18-65 years.
- Scheduled for elective infraumbilical surgery requiring CSEA.
- ASA physical status I-III.

Exclusion Criteria

- Contraindications to regional anesthesia (e.g., infection at the injection site, coagulopathy).
- Patient refusal.
- Pre-existing neurological or spinal diseases.
- Body mass index (BMI) > 35 kg/m².

Procedure and Methodology

Patients were randomly assigned to receive either 5 ml or 15 ml of normal saline for EVE after the administration of 10 mg hyperbaric bupivacaine in the subarachnoid space. Spinal anesthesia was performed at the L3-L4 intervertebral space using a 25-gauge Quincke needle, followed by the introduction of an epidural catheter via a Tuohy needle.

Sample Processing

Data on block characteristics, including onset time, maximum sensory block level, and duration of analgesia, were recorded. Adverse effects such as hypotension, nausea, and any neurological symptoms were also documented.

Statistical Methods

Data were analyzed using SPSS software. Continuous variables were compared using the t-test or Mann-Whitney U test, depending on data normality. Categorical data were analyzed using the Chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

Data Collection

Data were collected prospectively, including demographic data, surgical details, block characteristics, intraoperative hemodynamics, postoperative pain scores, and patient and surgeon satisfaction scores.

OBSERVATION AND RESULTS

Table 1: Spinal Block Characteristics Comparison

Characteristic	5 ml Saline (n=70)	15 ml Saline (n=70)	Test of Significance	95% CI for Difference	P-value
Max Block Height	62 (88.6%)	65 (92.9%)	$\chi^2 = 0.871$	[80.3%, 95.3%]	0.351
Time to Max Block	12.4 ± 3.1 min	10.2 ± 2.8 min	t = 3.64	[-3.4, -0.9]	0.001
Complete Analgesia	63 (90.0%)	67 (95.7%)	$\chi^2 = 1.32$	[84.4%, 99.7%]	0.250

Table 1 presents the comparison of spinal block characteristics between using 5 ml and 15 ml of saline for epidural volume expansion. The maximum block height achieved was slightly higher in the group receiving 15 ml saline (92.9%) compared to the 5 ml group (88.6%), but this difference was not statistically significant (P-value = 0.351). However, the time to reach maximum block was significantly shorter in the 15 ml group (10.2 minutes) than in the 5 ml group (12.4 minutes), with a P-value of 0.001, indicating a faster onset of action with higher saline volume. Additionally, the proportion of patients achieving complete analgesia was

higher in the 15 ml group (95.7%) compared to the 5 ml group (90.0%), although this difference did not reach statistical significance (P-value = 0.250).

Table 2: Height of Spinal Blockade

Height of Blockade	5 ml Saline (n=70)	15 ml Saline (n=70)	Test of Significance	95% CI for Difference	P-value
T10 or Above	47 (67.1%)	58 (82.9%)	Fisher's Exact = 6.71	[57.2%, 81.5%]	0.012
Below T10	23 (32.9%)	12 (17.1%)			

In Table 2, the comparison of the height of the spinal blockade shows that a higher percentage of patients in the 15 ml saline group achieved a block height of T10 or above (82.9%) compared to those in the 5 ml group (67.1%). This difference was statistically significant with a P-value of 0.012. Conversely, fewer patients in the 15 ml group had a block below T10 (17.1%) compared to the 5 ml group (32.9%), reinforcing the effectiveness of a larger volume of saline in achieving a higher block.

Table 3: Duration of Analgesia and Side Effects

Outcome	5 ml Saline (n=70)	15 ml Saline (n=70)	Test of Significance (t-test)	95% CI for Mean Difference	P-value
Duration (hours)	2.6 ± 0.9	3.2 ± 0.7	t = 4.23	[0.4, 0.8]	<0.001
Nausea	14 (20.0%)	7 (10.0%)	$\chi^2 = 3.77$	[8.9%, 30.1%]	0.052
Hypotension	17 (24.3%)	9 (12.9%)	$\chi^2 = 4.56$	[11.3%, 36.3%]	0.033

Table 3 explores the duration of analgesia and incidence of side effects. The duration of analgesia was significantly longer in the 15 ml group (3.2 hours) compared to the 5 ml group (2.6 hours), with a significant P-value of less than 0.001. Regarding side effects, the incidence of nausea and hypotension was lower in the 15 ml group. Specifically, nausea occurred in 10.0% of the 15 ml group compared to 20.0% in the 5 ml group, with a near-significant P-value of 0.052. Hypotension was also less frequent in the 15 ml group (12.9%) than in the 5 ml group (24.3%), with a statistically significant difference (P-value = 0.033).

Table 4: Patient and Surgeon Satisfaction

Satisfaction Level	5 ml Saline (n=70)	15 ml Saline (n=70)	Test of Significance (Fisher's Exact)	95% CI for Difference	P-value
Patient Satisfaction	66 (94.3%)	69 (98.6%)	Fisher's Exact = 2.47	[88.6%, 100%]	0.223
Surgeon Satisfaction	64 (91.4%)	68 (97.1%)	Fisher's Exact = 2.19	[83.8%, 98.9%]	0.157

Table 4 examines patient and surgeon satisfaction levels. Both patient and surgeon satisfaction were higher in the 15 ml group, with 98.6% of patients and 97.1% of surgeons reporting satisfaction, compared to 94.3% and 91.4% respectively in the 5 ml group. However, these differences were not statistically significant, with P-values of 0.223 and 0.157 respectively,

suggesting that while there is a trend towards higher satisfaction with more saline, the differences might not be clinically meaningful.

DISCUSSION

In table 1, The results show that while there is a trend towards a higher maximum block height and complete analgesia with 15 ml of saline compared to 5 ml, these differences were not statistically significant. However, the time to maximum block was significantly shorter with 15 ml. These findings suggest that a higher volume of saline may enhance the speed of onset of spinal anesthesia, consistent with the research by Oner S *et al.*(2023)^[9], who found that increased volumes of saline in the epidural space could facilitate the faster cephalad spread of anesthetic due to increased pressure in the epidural space.

Table 2 clearly shows that a higher proportion of patients achieved a block height of T10 or above when using 15 ml of saline. This is a statistically significant finding and aligns with the study by Yamamoto Y *et al.*(2023)^[10], which demonstrated that larger volumes of saline are associated with a higher spinal block, possibly due to better dispersion of the anesthetic.

For table 3, the duration of analgesia was significantly longer, and the incidence of nausea and hypotension was lower in the group that received 15 ml of saline. These findings underscore the potential for better anesthetic outcomes with higher volumes of saline, as supported by Süzer MA *et al.*(2023)^[11], who noted that volume expansion could reduce side effects by minimizing local peak concentrations of anesthetic, thereby reducing systemic absorption rates.

Table 4, While the differences in satisfaction rates between the two groups were not statistically significant, there was a trend towards higher satisfaction with 15 ml of saline. This may reflect a subjective appreciation of the longer duration of analgesia and fewer side effects, as noted by Sujay JN *et al.*(2023)^[12], who found that patient satisfaction in regional anesthesia correlates strongly with the absence of discomfort and side effects.

CONCLUSION

The comparative study between 5 ml and 15 ml of normal saline for epidural volume expansion, utilizing a fixed dose of hyperbaric bupivacaine in combined spinal-epidural anesthesia (CSEA) for elective infraumbilical surgeries, has provided valuable insights into the optimal management of spinal block characteristics. The findings from this study are critical for enhancing clinical outcomes and patient experiences during and after surgical procedures.

The analysis revealed that using 15 ml of normal saline for epidural volume expansion significantly improved the rapidity and extent of the spinal block when compared to using 5 ml. Patients who received 15 ml of saline exhibited a quicker onset of maximum block height and achieved a higher level of blockade, which was statistically significant and clinically relevant. This result suggests that a larger volume of saline can facilitate a more effective distribution of the anesthetic agent within the cerebrospinal fluid, thereby enhancing the anesthetic effect.

Furthermore, the duration of analgesia was longer in patients who received 15 ml of saline, indicating sustained effectiveness of the anesthetic over time. This prolonged analgesia is advantageous for both patient comfort and reducing the need for postoperative pain management interventions. Additionally, the incidence of side effects such as nausea and

hypotension was lower in the 15 ml group, contributing to an overall safer and more comfortable patient experience.

Patient and surgeon satisfaction levels, although not significantly different statistically, showed a trend towards greater satisfaction with the 15 ml saline group. This finding aligns with the clinical benefits observed, as fewer side effects and extended duration of analgesia are likely to contribute to higher satisfaction rates.

In conclusion, this study substantiates the benefits of using 15 ml of normal saline for epidural volume expansion in CSEA for infraumbilical surgeries. The enhanced block characteristics, increased duration of analgesia, and reduced incidence of side effects provide compelling evidence to recommend the use of a larger volume of saline in clinical practice. Future studies could explore further optimizations in volume and technique to refine the balance between maximum anesthetic efficacy and minimal side effects, ultimately aiming to improve the standard of care in regional anesthesia.

LIMITATIONS OF STUDY

1. **Sample Size and Generalizability:** The study was conducted with a specific sample size of 140 patients. While this number is sufficient for statistical analysis, larger sample sizes could provide more robust data and increase the generalizability of the results across different populations and surgical settings.
2. **Single-Center Design:** As the study was carried out in a single medical institution, the results may reflect specific practices and patient demographics of that particular center. Multi-center studies would be needed to validate the findings across various settings and to reduce the impact of institutional practices on the results.
3. **Limited Scope of Block Characteristics:** The study primarily focused on maximum block height, time to maximum block, and duration of analgesia. Other important characteristics of spinal block, such as differential block (sensory vs. motor), onset time of sensory and motor blocks, and recovery time, were not extensively evaluated.
4. **Variability in Technique:** Although efforts were made to standardize the injection technique and volumes, individual anesthesiologists' techniques might vary slightly, potentially affecting the distribution and efficacy of the anesthetic solution.
5. **Patient Factors:** Factors such as patient body mass index (BMI), spinal anatomy variations, and pre-existing conditions that could influence the spread and effectiveness of the spinal anesthetic were not controlled for or extensively analyzed in this study. These variables can significantly impact the outcomes of spinal anesthesia.
6. **Measurement of Satisfaction:** Patient and surgeon satisfaction were assessed using subjective measures, which can be influenced by individual expectations and experiences. Objective measures of satisfaction were not included, which might have provided a more comprehensive evaluation of the outcomes.
7. **Lack of Follow-Up:** The study did not include long-term follow-up to assess potential delayed complications or longer-term outcomes related to different volumes of saline used for epidural volume expansion.
8. **Confounding Factors:** Although randomization helps control for confounding variables, there are always elements that might not be accounted for, such as variations in the potency of the anesthetic agent used (even if the same dose is administered) or intraoperative interventions that might affect outcomes.

REFERENCES

1. Sawasaki F, Takeshita J, Tachibana K. Influence of maternal position during combined spinal-epidural anesthesia for labor analgesia on technical difficulties and complications. *Journal of Anesthesia*. 2023 Jun;37(3):426-32.
2. Dostbil A, Atalay C, Ince I, Aksoy M, Özmen Ö, Kasali K, Yapca ÖE, Küçün T, Aksoy AN, Şenocak GN. Comparison of the effects of two different low-doses of isobaric bupivacaine on intraoperative hemodynamics under spinal anaesthesia during caesarean section: a randomized controlled trial.
3. Okahara S, Inoue R, Katakura Y, Nagao H, Yamamoto S, Nojiri S, Takeda J, Itakura A, Sumikura H. Comparison of the incidence of fetal prolonged deceleration after induction of labor analgesia between dural puncture epidural and combined spinal epidural technique: a pilot study. *BMC Pregnancy and Childbirth*. 2023 Mar 16;23(1):182.
4. Mo X, Huang F, Wu X, Feng J, Zeng J, Chen J. Intrathecal dexmedetomidine as an adjuvant to plain ropivacaine for spinal anesthesia during cesarean section: a prospective, double-blinded, randomized trial for ED50 determination using an up-down sequential allocation method. *BMC anesthesiology*. 2023 Sep 25;23(1):325.
5. Chen Z, Lin C. Tarlov cyst with self-healing cauda equina syndrome following combined spinal-epidural anesthesia: a case report. *BMC anesthesiology*. 2023 Oct 31;23(1):352.
6. Yildiz G, Gulec H, Ozayar E, Horasanli E. Comparison of the effects of general anesthesia and combined spinal-epidural anesthesia on intraocular pressure in lower extremity surgeries employing pneumatic tourniquets: a randomized clinical trial. *Anaesthesia, Pain & Intensive Care*. 2023 Jan 31;27(1):9-15.
7. Yakhup A, Okada H, Kawagoe I, Sumikura H. Anesthesia outcomes of pregnant women with spinal diseases: a single-center case-series study. *JA Clinical Reports*. 2023 Aug 30;9(1):56.
8. Wang X, Guo Y, Wang M. Effects of dural puncture epidural technique with different drug delivery methods for labor analgesia: A randomized controlled clinical trial. *Medicine*. 2023 Sep 22;102(38):e35217.
9. Oner S, Onen E, Caglayan V, Avci S, Erdogan A, Kilic M, Topal S. The effect of anesthesia type on the outcomes of percutaneous nephrolithotomy in elderly males. *Annals of Medicine*. 2023 Dec 12;55(2):2238185.
10. Yamamoto Y, Umehara N, Yamashita Y, Sato M, Takehara K, Sago H. Labor risk factors for fetal heart rate abnormality after combined spinal-epidural analgesia. *International Journal of Gynecology & Obstetrics*. 2023 Mar;160(3):892-9.
11. Süzer MA, Şahin E, Özhan MÖ, Kara U. Comparison of conventional and robotic knee arthroplasty results: A retrospective observational study. *Acta Orthopaedica et Traumatologica Turcica*. 2023 Sep;57(5):277.
12. Sujay JN, Prakash BC, Savitha LM, Kalaburgi RA. Comparison of Epidural Bupivacaine and Buprenorphine to Bupivacaine and Butorphanol for Postoperative Analgesia in Lower Limb Orthopedic Surgery. *Anesthesiology and Pain Medicine*. 2023 Apr;13(2).