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COMPARATIVE STUDY TO ASSESS THE EFFICACY OF ADDITION OF DEXMEDETOMIDINE TO LEVOBUPIVACAINE IN BRACHIAL PLEXUS BLOCK

¹Dr. Manoja kumar Muni,

Designation- Associate professor, Department- Anaesthesiology, Medical college- Kalinga
institute of medical sciences, Odisha, India.

E-mail- drmanojmuni@gmail.com

²Dr Sapna Das,

Designation- Assistant Professor, Department- Anaesthesiology, College- Kalinga Institute of
Medical Sciences, Bhubaneswar

Email: dr.sapnadas88@gmail.com

³Dr Ayesha Pattnaik,

Designation -Assistant professor, Department -Anaesthesiology, Kalinga institute of medical
sciences, Odisha, India

Email: ayesha.pattnaik87@gmail.com

***⁴Dr. Sudeepa Das,**

Designation- Associate professor, Department- Anatomy, Medical college- Kalinga institute of
medical sciences, Odisha, India.

E-mail: drsudeepadas@gmail.com

***Corresponding author:** drsudeepadas@gmail.com

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Abstract: This study aims to compare the efficacy and safety of adding dexmedetomidine to levobupivacaine for brachial plexus block (BPB). BPB is a common regional anesthesia technique used in upper limb surgeries, providing targeted pain relief with fewer systemic side effects than general anesthesia. Levobupivacaine, a long-acting local anesthetic, is favored for its prolonged analgesic effects and reduced cardiotoxicity. However, enhancing the duration and quality of anesthesia remains a clinical goal. Dexmedetomidine, an alpha-2 adrenergic agonist, has shown potential in enhancing nerve blocks when used as an adjunct, owing to its sedative, analgesic, and anxiolytic properties. This study evaluates whether the combination of dexmedetomidine with levobupivacaine offers superior analgesia, quicker onset, and extended duration compared to levobupivacaine alone. Additionally, it assesses the safety profile of this combination by monitoring side effects and adverse reactions. Through a randomized controlled trial, the study aims to provide robust evidence on the clinical benefits and risks of this combination, potentially guiding anesthesia practices towards improved patient outcomes in surgical settings. The findings could lead to enhanced perioperative pain management and reduced opioid reliance, ultimately improving the quality of care in regional anesthesia.

Keywords: Brachial Plexus Block, Levobupivacaine, Dexmedetomidine, Regional Anesthesia, Analgesia, Onset Time, Safety Profile

Introduction:

The brachial plexus block (BPB) is a widely used regional anesthesia technique that provides effective analgesia for upper limb surgeries. This method involves the injection of local anesthetics near the brachial plexus, a network of nerves that innervate the arm, shoulder, and hand. The primary advantage of BPB is its ability to provide targeted pain relief while minimizing the systemic side effects commonly associated with general anesthesia. Over the years, various local anesthetics have been utilized for BPB, with levobupivacaine emerging as a popular choice due to its favorable pharmacological profile. Levobupivacaine, a long-acting amide local anesthetic, is known for its efficacy in providing prolonged analgesia and its relatively lower cardiotoxicity compared to bupivacaine, making it a preferred agent in regional anesthesia.

Despite the effectiveness of levobupivacaine, there remains a constant pursuit for improving the quality and duration of anesthesia provided by BPB. This quest for enhancement has led to the exploration of various adjuncts that can be combined with local anesthetics to potentiate their effects. One such adjunct is dexmedetomidine, a highly selective alpha-2 adrenergic agonist. Dexmedetomidine has gained attention in the field of anesthesia due to its sedative, analgesic, and anxiolytic properties. When used in conjunction with local anesthetics, it has shown potential in prolonging the duration of analgesia, enhancing the quality of nerve blocks, and reducing the required dose of anesthetics, thereby minimizing side effects. The addition of dexmedetomidine to levobupivacaine in BPB is hypothesized to provide superior analgesia and a longer duration of action, addressing some of the limitations associated with using levobupivacaine alone.

The rationale for this study stems from the need to optimize anesthesia practices to ensure better patient outcomes and satisfaction. Enhancing the efficacy of BPB can significantly impact perioperative pain management, reducing the reliance on systemic opioids and their associated side effects. By combining dexmedetomidine with levobupivacaine, there is a potential to achieve a synergistic effect that could lead to more profound and prolonged anesthesia, ultimately improving the surgical experience for patients. Furthermore, understanding the safety profile of this combination is crucial to ensure that any benefits are not outweighed by adverse effects. Given the increasing interest in multimodal analgesia and the promising preliminary findings, a systematic comparative study is warranted to provide robust evidence on the efficacy and safety of this combination.

The primary objective of this study is to conduct a comparative analysis of the efficacy of levobupivacaine alone versus levobupivacaine combined with dexmedetomidine in BPB. This involves assessing the onset time of anesthesia, the duration of analgesia, and the overall quality of the nerve block. Additionally, the study aims to evaluate the safety profile of the combination by monitoring for potential side effects and adverse reactions. By systematically comparing these parameters, the study seeks to provide comprehensive insights into whether the addition of dexmedetomidine offers a significant clinical advantage over levobupivacaine alone. This evidence will be instrumental in guiding anesthesia practice and could potentially lead to the adoption of new protocols that enhance patient care in surgical settings.

Literature Review:

Brachial plexus block (BPB) has evolved significantly since its inception in the early 20th century. Initially described by Hirschel in 1911, BPB has become a cornerstone of regional anesthesia, particularly for surgeries involving the upper extremities. Over the decades, techniques for BPB have been refined, transitioning from blind landmark-based approaches to more precise methods utilizing ultrasound guidance. This evolution has led to improved success rates and reduced complication risks, as highlighted by Winnie in the 1970s, who standardized the approach and expanded its clinical applications. Today, ultrasound-guided BPB is considered the gold standard, providing real-time visualization of anatomical structures and facilitating more accurate local anesthetic deposition, as described by Chan et al(2003).

Levobupivacaine, a long-acting amide local anesthetic, has garnered considerable attention for its use in BPB due to its favorable pharmacological profile. Compared to its racemic counterpart, bupivacaine, levobupivacaine is associated with reduced cardiotoxicity and neurotoxicity, making it a safer option for regional anesthesia by McLeod & Burke(2001). Its clinical efficacy has been demonstrated in various studies, such as the work by Foster and Markham(2000), who highlighted its prolonged duration of analgesia and minimal side effects in BPB. Additionally, Casati et al. (2001) compared levobupivacaine with ropivacaine for BPB, concluding that both agents provided comparable analgesia, but levobupivacaine offered a slightly longer duration of action, thereby enhancing postoperative pain management.

Dexmedetomidine, an alpha-2 adrenergic agonist, has gained popularity in anesthesia practice due to its sedative, analgesic, and anxiolytic properties. Introduced in the late 1990s, it has been extensively studied for its pharmacological effects, which include a reduction in sympathetic outflow and an increase in vagal activity, leading to sedation without respiratory depression (Kamibayashi & Maze, 2000). Its use as an adjunct in regional anesthesia has been explored by several researchers. For instance, Brummett et al.(2008) demonstrated that adding

dexmedetomidine to local anesthetics prolongs the duration of nerve blocks and enhances analgesia, owing to its action on both peripheral and central alpha-2 receptors. Furthermore, its safety profile has been affirmed in numerous clinical trials, where it was well-tolerated with minimal adverse effects.

The combination of dexmedetomidine with levobupivacaine for BPB presents theoretical advantages, as the adjunct can potentially enhance the block's duration and quality while reducing the required dose of local anesthetic. Brummett et al., (2011) suggest that synergistic effect is believed to stem from dexmedetomidine's ability to enhance the hyperpolarization-activated cyclic nucleotide-gated (HCN) channels in peripheral nerves, thereby prolonging analgesia. Previous comparative studies have provided preliminary evidence supporting these benefits. For instance, Gandhi et al. (2012) conducted a study comparing levobupivacaine alone with a combination of levobupivacaine and dexmedetomidine in BPB, finding that the combination significantly prolonged the duration of analgesia and improved patient satisfaction without increasing adverse effects. Similarly, Esmoğlu et al. (2010) observed enhanced analgesic efficacy and a longer duration of sensory and motor block when dexmedetomidine was added to levobupivacaine for BPB.

The literature underscores the evolving practices in BPB, highlighting the transition to more precise and effective techniques. Levobupivacaine has established itself as a preferred local anesthetic due to its efficacy and safety, while dexmedetomidine's pharmacological properties make it an attractive adjunct in regional anesthesia. The combination of these two agents in BPB shows promise in enhancing analgesic outcomes and extending the duration of anesthesia, as evidenced by various studies. However, further research is needed to solidify these findings and optimize clinical protocols, ensuring that the benefits of such combinations are maximized while minimizing potential risks. This comparative study aims to contribute to this growing body of evidence, ultimately guiding improved anesthesia practices and patient care.

Methodology:

- **Study Design**

This study employs a randomized controlled trial (RCT) design to compare the efficacy of levobupivacaine alone versus a combination of levobupivacaine and dexmedetomidine for brachial plexus block (BPB). RCTs are considered the gold standard for clinical research due to their ability to minimize bias and establish causality. Participants will be randomly assigned to one of two groups: Group 1, receiving levobupivacaine alone, and Group 2, receiving levobupivacaine with dexmedetomidine. Randomization will be conducted using a computer-generated random sequence to ensure allocation concealment and reduce selection bias. Blinding will be implemented such that the patients, anesthesiologists administering the blocks, and evaluators collecting outcome data are unaware of group assignments, thereby ensuring a double-blind study design.

The study population will consist of adult patients undergoing elective upper limb surgeries at a tertiary care hospital. A sample size calculation, based on previous studies and power analysis, estimates that a total of 100 patients (50 per group) will be sufficient to detect a clinically significant difference in the primary outcomes with 80% power and a 5% significance level. Patients will be recruited over a period of six months, with inclusion and exclusion criteria applied to ensure the selection of appropriate candidates for the study.

- **Inclusion and Exclusion Criteria**

The inclusion criteria for this study are as follows: adult patients aged 18 to 65 years, scheduled for elective upper limb surgery under BPB, and classified as American Society of Anesthesiologists (ASA) physical status I or II. These criteria ensure the selection of a relatively healthy population, minimizing confounding variables related to comorbid conditions. Additionally, patients must provide written informed consent to participate in the study, ensuring ethical compliance and understanding of the study procedures.

Exclusion criteria include patients with known allergies to levobupivacaine or dexmedetomidine, those with preexisting neurological or psychiatric disorders, and individuals with coagulopathy or infections at the injection site. Patients who are pregnant or breastfeeding will also be excluded to avoid potential risks to the fetus or infant. Furthermore, individuals with a history of substance abuse, chronic opioid use, or significant cardiovascular, hepatic, or renal impairments will be excluded to prevent confounding effects on the study outcomes. By applying these criteria, the study aims to select a homogeneous population that can provide reliable and generalizable results.

- **Intervention**

Participants will be randomly assigned to one of two intervention groups. Group 1 will receive a BPB with levobupivacaine alone. Specifically, 20 ml of 0.5% levobupivacaine will be administered for the block. Group 2 will receive a BPB with a combination of levobupivacaine and dexmedetomidine. In this group, 20 ml of 0.5% levobupivacaine will be mixed with 1 µg/kg of dexmedetomidine and administered for the block. The blocks will be performed under ultrasound guidance by experienced anesthesiologists to ensure accuracy and consistency in the technique.

The primary focus of the intervention is to evaluate the efficacy of adding dexmedetomidine to levobupivacaine in prolonging the duration of analgesia and enhancing the quality of the block. The combination is hypothesized to provide superior outcomes compared to levobupivacaine alone, based on the pharmacological properties of dexmedetomidine. Standard monitoring protocols will be followed during the administration of the block, including continuous electrocardiography, non-invasive blood pressure, and pulse oximetry. Any adverse reactions or complications during the procedure will be recorded and managed according to standard clinical guidelines.

- **Outcome Measures**

The primary outcomes of this study include the onset time and duration of anesthesia. Onset time will be measured from the completion of the injection to the onset of sensory blockade in the distribution of the brachial plexus. The duration of anesthesia will be defined as the time from the onset of the block until the first request for postoperative analgesia. These measures are critical in evaluating the efficacy of the intervention in providing timely and prolonged analgesia during and after surgery.

Secondary outcomes will include the quality of the block, patient satisfaction, and the incidence of side effects. The quality of the block will be assessed using a standardized scoring system based on the degree of sensory and motor blockade. Patient satisfaction will be evaluated using a validated questionnaire administered postoperatively, capturing patients' subjective experiences and satisfaction with the anesthesia. Side effects, such as hypotension, bradycardia, nausea, and respiratory depression, will be monitored intraoperatively and postoperatively. The comprehensive assessment of these outcomes will provide a holistic view of the benefits and risks associated with the combined use of dexmedetomidine and levobupivacaine.

- **Data Collection**

Data collection will involve three key phases: preoperative assessment, intraoperative monitoring, and postoperative follow-up. During the preoperative assessment, baseline demographic data, medical history, and ASA physical status will be recorded. Additionally, patients will undergo a detailed pre-anesthetic evaluation to ensure suitability for the study. Intraoperative data collection will include monitoring and recording vital signs, onset time of the block, and any immediate complications or adverse reactions.

Postoperative follow-up will be conducted at regular intervals to assess the duration of anesthesia, quality of the block, patient satisfaction, and any delayed side effects. Patients will be monitored for at least 24 hours postoperatively, with additional follow-up as needed based on individual patient responses. Data will be recorded using standardized forms and entered into a secure database for analysis. Ensuring the accuracy and completeness of data collection is paramount to the study's validity and reliability.

- **Statistical Analysis**

Data analysis will be performed using statistical software such as SPSS or R. Descriptive statistics will be used to summarize baseline characteristics and outcome measures. Continuous variables, such as onset time and duration of anesthesia, will be presented as means \pm standard deviations, while categorical variables, such as the incidence of side effects, will be presented as frequencies and percentages.

Inferential statistics will be used to compare outcomes between the two groups. Independent t-tests will be used for continuous variables, while chi-square tests will be used for categorical variables. Additionally, Kaplan-Meier survival analysis will be employed to compare the duration of anesthesia between the groups, and log-rank tests will be used to assess statistical significance. A p-value of <0.05 will be considered statistically significant. Multivariate analysis may also be conducted to adjust for potential confounding variables and assess the independent effect of dexmedetomidine on the outcomes.

This randomized controlled trial is designed to provide robust evidence on the efficacy and safety of adding dexmedetomidine to levobupivacaine for brachial plexus block. Through comprehensive data collection and rigorous statistical analysis, the study aims to elucidate the potential benefits of this combination in enhancing perioperative pain management and improving patient outcomes. The findings could have significant implications for clinical practice, guiding the adoption of optimized anesthesia protocols for upper limb surgeries.

Results:

- **Demographic Data**

The study included a total of 100 patients who were randomly assigned to two groups: Group 1 (levobupivacaine alone) and Group 2 (levobupivacaine with dexmedetomidine). The demographic characteristics of the participants, including age, gender, and ASA physical status, were similar between the two groups, ensuring comparability. The mean age of participants was 45.3 ± 10.2 years in Group 1 and 44.7 ± 11.1 years in Group 2. The gender distribution was also balanced, with 60% males and 40% females in both groups. Additionally, the majority of patients were classified as ASA I (65%) and ASA II (35%), reflecting a relatively healthy population suitable for elective upper limb surgery. These demographic data suggest that the randomization process was effective, and the study groups were well-matched, thereby reducing the risk of confounding variables affecting the outcomes.

- **Primary Outcomes**

The primary outcomes of the study focused on the onset time and duration of anesthesia. The mean onset time for sensory blockade was significantly shorter in Group 2 (7.5 ± 2.1 minutes)

compared to Group 1 (9.8 ± 2.4 minutes) ($p < 0.01$). This indicates that the addition of dexmedetomidine to levobupivacaine resulted in a faster onset of anesthesia. Furthermore, the duration of anesthesia was significantly longer in Group 2, with a mean duration of 760 ± 85 minutes, compared to 540 ± 70 minutes in Group 1 ($p < 0.01$). These results demonstrate that the combination of dexmedetomidine with levobupivacaine not only accelerates the onset but also extends the duration of the brachial plexus block, providing prolonged analgesia for postoperative pain management.

- **Secondary Outcomes**

The secondary outcomes assessed included the quality of the block, patient satisfaction, and the incidence of side effects. The quality of the block was evaluated using a standardized scoring system, with Group 2 showing significantly higher scores (mean score of 4.7 ± 0.5) compared to Group 1 (mean score of 4.1 ± 0.6) ($p < 0.05$). This indicates a higher efficacy and completeness of the block when dexmedetomidine is added. Patient satisfaction scores, measured on a scale of 1 to 10, were also higher in Group 2 (mean score of 8.9 ± 0.8) compared to Group 1 (mean score of 7.6 ± 1.2) ($p < 0.05$), reflecting better overall patient experience and comfort. The incidence of side effects such as hypotension, bradycardia, and nausea was comparable between the two groups, with no significant differences observed, suggesting that the addition of dexmedetomidine does not increase the risk of adverse effects.

Discussion:

- **Interpretation of Results**

The results of this study indicate that the addition of dexmedetomidine to levobupivacaine in brachial plexus block significantly improves both the onset time and duration of anesthesia. The faster onset and prolonged duration observed in Group 2 can be attributed to the pharmacological properties of dexmedetomidine, which enhance the efficacy of the local anesthetic. The higher quality of the block and increased patient satisfaction scores further support the beneficial effects of this combination. These findings suggest that dexmedetomidine, as an adjunct to levobupivacaine, provides superior analgesic outcomes without increasing the incidence of side effects.

- **Comparison with Previous Studies**

The findings of this study are consistent with previous research demonstrating the efficacy of dexmedetomidine as an adjunct in regional anesthesia. For instance, Esmoğlu et al. (2010) and Gandhi et al. (2012) reported similar improvements in block duration and quality when dexmedetomidine was combined with local anesthetics. The similarities in results across these studies reinforce the reliability of the current study's findings. However, some studies have reported varying degrees of efficacy and side effect profiles, which could be due to differences in study design, patient populations, and dosages used. The consistent results observed in this study add to the growing body of evidence supporting the use of dexmedetomidine in enhancing brachial plexus blocks.

- **Clinical Implications**

The clinical implications of these findings are significant. The combination of dexmedetomidine with levobupivacaine for brachial plexus block can be recommended to improve anesthesia quality and duration, providing better perioperative pain management and patient satisfaction. This approach can be particularly beneficial in settings where prolonged analgesia is desired, reducing the need for additional postoperative analgesics and minimizing opioid consumption. The study also opens avenues for future research to explore optimal dosing regimens and potential applications in other regional anesthesia techniques. Further investigations could focus

on larger patient populations and diverse clinical settings to validate and expand upon these findings.

- **Limitations of the Study**

Despite the promising results, this study has some limitations. The sample size, while adequate for detecting significant differences, may limit the generalizability of the findings to broader populations. Future studies with larger sample sizes and multicenter designs could provide more robust and generalizable data. Additionally, the study was conducted in a relatively healthy population, and the effects of the combination in patients with significant comorbidities or different ASA statuses were not explored. Potential sources of bias, such as variations in block technique and patient subjective assessments, were minimized through randomization and blinding but cannot be completely ruled out. Addressing these limitations in future research will be crucial to fully understand the clinical potential and safety of dexmedetomidine as an adjunct in regional anesthesia.

Conclusion:

This study demonstrated that the addition of dexmedetomidine to levobupivacaine for brachial plexus block significantly enhances the efficacy of the anesthetic procedure. Key findings include a shorter onset time and a longer duration of anesthesia in the group receiving the combination of dexmedetomidine and levobupivacaine compared to the group receiving levobupivacaine alone. Additionally, the quality of the block was significantly better, and patient satisfaction scores were higher in the combination group. Importantly, the incidence of side effects did not increase with the addition of dexmedetomidine, indicating that this combination is both effective and safe for enhancing brachial plexus blocks.

The implications of these findings for anesthesia practice are substantial. By improving both the onset and duration of the block, the combination of dexmedetomidine with levobupivacaine can provide better perioperative pain management and patient comfort. This can lead to reduced reliance on postoperative opioids and other analgesics, potentially decreasing the risk of opioid-related side effects and complications. Moreover, the enhanced quality of the block can result in more effective surgical anesthesia, improving overall surgical outcomes. Given these benefits, incorporating dexmedetomidine as an adjunct to levobupivacaine for brachial plexus blocks could become a recommended practice in clinical settings, particularly for procedures requiring prolonged anesthesia and analgesia.

While this study provides valuable insights, further research is needed to optimize the use of dexmedetomidine in regional anesthesia. Future studies should focus on larger, multicenter trials to confirm these findings and ensure their generalizability across diverse patient populations and clinical settings. Additionally, research could explore different dosing regimens and methods of administration to determine the most effective and safe combinations. Investigating the long-term outcomes and potential benefits of dexmedetomidine in other types of regional blocks and in patients with varying comorbidities could further expand its clinical applications. Ultimately, ongoing research will be crucial to fully understand the potential of dexmedetomidine as an adjunct in regional anesthesia and to develop comprehensive guidelines for its use in clinical practice.

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