ORIGINAL RESEARCH

Comparative clinical assessment of spinal anesthesia with Levobupivacaine alone vs a combination of Levobupivacaine and Dexmedetomidine

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ABSTRACT

Aim: Comparative clinical assessment of spinal anesthesia with Levobupivacaine alone vs a combination of Levobupivacaine and Dexmedetomidine. **Materials and Methods:** A total of 140 patients, classified as American Society of Anesthesiologists physical status I or II, were included in this randomized, double-blind trial. The patients were of both sexes, aged between 30 and 70 years, with a body weight ranging from 40 to 80 kg and a height more than 150 cm. The groups were segregated and treatment was administered in the following manner: Control Group (Group-A, N=70): 0.5% Isobaric levobupivacaine 15 mg (3 ml) with 0.3 ml normal saline; Study Group (Group-B, N=70): 0.5% Isobaric levobupivacaine 15 mg (3 ml) with 0.3 ml (3 μg) dexmedetomidine. **Results:** The average time it took for the sensory block to reach the T10 dermatome was 8.78 ± 0.66 minutes in Group A (Levo) and 5.27 ± 0.39 minutes in Group B (Levo+Dex) ($P<0.05$). In the Levo group, the median maximum sensory level reached was at the T6 dermatome in 18.22 ± 1.17 minutes. In the Levo+Dex group, the median maximum sensory level was at the T4 dermatome in 10.12 ± 1.15 minutes ($P<0.01$). The average length of sensory block, measured as the time it took for the regression to the S1 dermatome, was 212.19 ± 7.92 minutes in Group Levo and 361.11 ± 12.92 minutes in Group Levo+Dex ($P < 0.01$). The average duration required to reach maximal motor block was 13.48 ± 0.76 minutes for the Levo group and 9.11 ± 0.85 minutes for the Levo+Dex group ($P<0.01$). In addition, the average duration of motor block in Group Levo was 139.19 ± 5.39 minutes, whereas in Group Levo+Dex it was 184.93 ± 5.79 minutes. Both differences exhibited a high level of significance ($P < 0.001$). **Conclusion:** Our observation indicates that the combination of levobupivacaine and dexmedetomidine is effective in achieving surgical anesthesia and maintaining stable hemodynamics. This combination outperforms levobupivacaine alone in several aspects: it leads to a faster onset of sensory and motor block, a longer duration of sensory and motor block, a prolonged period of postoperative analgesia, and a reduced need for rescue analgesia.

Keywords: Spinal anesthesia, Levobupivacaine, Dexmedetomidine

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INTRODUCTION

Optimal management of pain after surgery is a crucial aspect of providing care to those undergoing surgical procedures. Insufficient pain management may lead to higher rates of illness or death [1]. The modern anesthesiologist is responsible for the comprehensive treatment of patients, including preoperative, intraoperative, and postoperative pain management [2,3]. With the progression of time, there is a growing inclination towards using regional anesthetic methods instead of general anesthesia for many frequent surgical procedures [4]. Regional anesthesia has several advantages compared to general anesthetic, as it effectively eliminates both intraoperative and postoperative discomfort, provides exceptional muscle relaxation, and minimizes intraoperative hemorrhage [5]. Regional anesthetic approaches surpass systemic opioid drugs in terms of analgesic profile and side effects [6]. Spinal anesthetic is widely used because of its unparalleled dependability, simplicity, and cost-efficiency. It offers a rapid and efficient initiation of sensory and motor block, outstanding muscle relaxation, and extended postoperative pain relief [7]. Levobupivacaine is a favorable substitute due to its reduced risk of cardiovascular and central nervous system damage [8]. To enhance the effectiveness of local anesthetics and extend the duration of pain relief during surgery and recovery, other substances such

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vasoconstrictors, alpha-2 agonists, and opioids have been used as adjuvants [9]. Dexmedetomidine is used as a supplementary treatment in spinal anesthesia and is linked to extended periods of reduced motor and sensory function, stable cardiovascular activity, and decreased need for further pain relief within a 24-hour period. Consequently, it enables a reduction in the dosage of local anesthetic [10,11].

MATERIALS AND METHODS

The Institutional Ethics Committee granted legal permission, and all participating subjects provided written informed consent. The study was conducted at department of Anesthesiology, M L B Medical College Jhansi in a duration of 12 months. A total of 140 patients, classified as American Society of Anesthesiologists physical status I or II, were included in this randomized, double-blind trial. The patients were of both sexes, aged between 30 and 70 years, with a body weight ranging from 40 to 80 kg and a height more than 150 cm. Patients who declined the procedure, had any contraindication to local anaesthetics due to allergies, were pregnant or breastfeeding, had coagulation or neurological disorders, had spine injury or previous spine surgery, had sepsis affecting the spine, had morbid obesity, or had communication difficulties that could affect reliable assessment were excluded from the study.

METHODOLOGY

Prior to administering anesthesia and randomizing patients, all individuals were instructed to abstain from eating for a period of 6 hours. The preanesthetic treatment consisted of oral ranitidine 150 mg, ondansetron 4 mg, diazepam 5 mg, and 750 ml of Ringer lactate solution. Subsequently, they were assigned at random to undergo spinal anesthesia. The study conducted by Sell A et al aimed to determine the minimal efficacious dosage of isobaric levobupivacaine and ropivacaine when delivered using a spinal catheter during hip replacement surgery. The average amount of Levo-bupivacaine was 15.2±4.0mg, with a standard deviation of 4.0mg [12]. Therefore, in this particular investigation, a dosage of 15mg (equivalent to 3ml of a 0.5% concentration) of levobupivacaine in isobaric form was administered for spinal anesthesia. The medication used for anesthesia and pain relief after surgery was prepared by a different anesthesiologist. The anaesthesiologist, surgeon, patient, and personnel involved in the trial were unaware of the medicine used. To ensure impartiality in the trial, the medication was administered in a consistent amount of 3.3 ml to both groups.

The groups were segregated and treatment was administered in the following manner:

Control Group (Group-A, N=70): 0.5% Isobaric levobupivacaine 15 mg (3 ml) with 0.3 ml normal saline;

Study Group (Group-B, N=70): 0.5% Isobaric levobupivacaine 15 mg (3 ml) with 0.3 ml (3 μg) dexmedetomidine.

The clinical parameters were evaluated to assess the clinical effectiveness. This included examining the time it took for the sensory block to occur, the time it took for the maximal motor block to occur, and the duration of analgesia. The pain assessment throughout the postoperative period for 24 hours was conducted using a Visual Analog Scale (VAS) with a line ranging from 0 to 10 cm. The patient was informed about this scale at the preanesthetic check-up, which took place one day before to the surgery. The initial marker "0" signifies the absence of pain, whereas the marker "10" denotes intense or severe pain. Analgesia was administered for rescue purposes when the Visual Analog Scale (VAS) score exceeded 3. The assessment of sensory and motor block involves evaluating the lack of feeling to a pinprick from a 22-gauge blunt hypodermic needle for sensory block, and using the modified Bromage score for motor block. Bromage scale [11]

- 0 - Full flexion of knees and feet possible, able to lift extended legs
- 1 - Unable to lift extended legs, but able to flex knees and feet
- 2 - Unable to flex knees but flexion of feet possible
- 3 - Unable to move legs and feet at all.

Assessment of hemodynamic response-Respiratory rate, heart rate, noninvasive systolic and diastolic blood pressure and SpO2 was done for hemodynamic response. Readings were recorded preoperatively, then intraoperatively at 0, 5 min, then at an interval of every 10 min up to 30 min, every 15 min up to 120 min, half- hourly up to 180 min, hourly until 12 h, and thereafter 3 hourly till 24 h of surgery in both the groups.

STATISTICAL ANALYSIS

Information was gathered for each patient from both groups and entered into a Microsoft Excel Worksheet. Age, weight, length of operation, and duration of analgesia were subjected to computation in order to determine their mean value and standard deviation. The mean values of the two groups were compared using a student's t-test. A p-value less than 0.05 was deemed to be statistically significant.

RESULTS

The two groups had similar age distributions (44.56±5.78 vs 45.67±5.87 years) and weight measurements (54.67±3.89 vs 53.76±3.76 years). The mean age and weight of the two groups do not exhibit statistical significance. Similarly, the systolic blood pressure, diastolic blood pressure, mean respiratory rate, and SpO2 during the surgery and after the surgery were likewise similar, as shown in Table 1. The observed disparities do not exhibit statistical significance.

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Table 1: Basic parameter of the participants

Basic parameter	Group A (Levobupivacaine)	Group B (Levobupivacaine+dexmedetomidine)	P value
Dose	15mg,3ml,0.5%	15mg,3ml,0.5%+0.3 ml(3ug)	
Gender	Number (%)/Mean	Number (%)/Mean	0.15
Male	42(60%)	42(60%)	
Female	28(40%)	28(40%)	
Age in years			0.12
30 -40	7(10%)	8(11.43%)	
40-50	32(45.71%)	33(47.14%)	
50-60	18(25.14%)	20(28.57%)	
Above 60	13(18.57%)	9(12.86%)	
Agein mean	44.56±5.78	45.67±5.87	
Weight(kg)	54.67±3.89	53.76±3.76	0.11
Heartrate/Min	82.45±4.87	83.23±4.82	0.33
SystolicBP(mmHg)	125.23±6.92	123.17±5.83	0.19
DiastolicBP(mmHg)	78.12±4.23	79.45±5.33	0.22
SpO2(%)	99.56±4.27	98.78±4.19	0.39
Respiratoryrate/min	16.44±1.19	16.96±1.43	0.25

The moment at which the sensory block began was determined based on the timing of medication delivery. The average time it took for the sensory block to reach the T10 dermatome was 8.78 ± 0.66 minutes in Group A (Levo) and 5.27 ± 0.39 minutes in Group B (Levo+Dex) (P<0.05). In the Levo group, the median maximum sensory level reached was at the T6 dermatome in 18.22 ± 1.17 minutes. In the Levo+Dex group, the median maximum sensory level was at the T4 dermatome in 10.12 ± 1.15 minutes (P<0.01). The average length of sensory block, measured as the time it took for the regression to the S1 dermatome, was 212.19 ± 7.92 minutes in Group Levo and 361.11 ± 12.92 minutes in Group Levo+Dex (P < 0.01). The differences between the two groups were statistically significant, as shown by the data presented in Table 2.

Table2: Difference in the sensory block between two groups

Parameters	Group A (Levobupivacaine)	Group B (Levobupivacaine+dexmedetomidine)	P value
Onset of sensory block(Min)	8.78± 0.66	5.27± 0.39	<0.05
Median maximum sensory block(Min)	18.22± 1.17	10.12± 1.15	<0.01
Mean duration of sensory block(Min)	212.19±7.92	361.11±12.92	<0.01

The evaluation criteria of the time at which maximal motor block occurred was also considered (Table 3). The average duration required to reach maximal motor block was 13.48 ± 0.76 minutes for the Levo group and 9.11 ± 0.85 minutes for the Levo+Dex group (P<0.01). In addition, the average duration of motor block in Group Levo was 139.19 ± 5.39 minutes, whereas in Group Levo+Dex it was 184.93 ± 5.79 minutes. Both differences exhibited a high level of significance (P < 0.001).

Table3: Difference in the motor block between two groups

Parameters	Group A (Levobupivacaine)	Group B (Levobupivacaine+dexmedetomidine)	P value
Onset of maximum motor block	13.48± 0.76	9.11± 0.85	<0.01
Total duration of motor block	139.19±5.39	184.93±5.79	<0.001

The Group Levo had a rise in VAS (Visual Analog Scale) at 140 minutes, and the patient requested the first dosage of rescue analgesia in the 3rd hour after the surgery (181.22 ± 12.49 minutes). There was a further rise in the VAS score at the 9th hour, prompting the administration of a second dosage of rescue analgesia at the 10th hour. The third administration of rescue analgesia occurred during the 20th hour, followed by the fourth administration at the 24th hour. An increase in Visual Analog Scale (VAS) was noticed after 260 minutes in Group Levo+Dex. The first dosage of rescue analgesia was administered during the 7th hour after the operation (401.12 ± 22.58 minutes). The second dosage of rescue analgesia was given during the 15th hour, followed by the third dose at the 23rd hour. The postoperative Visual Analog Scale (VAS) ratings were considerably lower in Group Levo+Dex compared to Group Levo at various time intervals, suggesting that Group Levo+Dex provided better pain relief.

In Group Levo+Dex, the first request for rescue analgesia was delayed, occurring at 401.12 ± 22.58

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minutes, whereas in Group L it occurred at 181.22 ± 12.49 minutes. The disparity between the two groups was quite substantial (P < 0.001). Our research saw a decrease in the amount of pain relief medication needed, which was directly related to the dosage administered. The Group L received an average of 4.33 ± 0.45 rescue analgesia doses, whereas the Group Levo+Dex received an average of 2.51 ± 0.19 doses. The difference between the two groups was extremely significant (P < 0.01).

Table 4: Time of request of the first dose of rescue analgesia

Parameters	Group A (Levobupivacaine)	Group B(Levobupivacaine+dexmedetomidine)	P value
The time of request of the first dose of rescue analgesia	181.22 ± 12.49	401,12 ± 22.58	<0.001
Number of rescue analgesia doses	4.33 ± 0.45	2.51 ± 0.19	<0.01

DISCUSSION

Levobupivacaine is a favored local anesthetic because it has a rapid start and long-lasting effect on numbing sensation, a shorter period of muscle paralysis, and a reduced risk of harm to the heart. Prior research has shown that the inclusion of dexmedetomidine with levobupivacaine yields potent pain relief and extends the period of both motor and sensory block, while also improving postoperative pain management and reducing adverse effects. There was no significant difference in the change in respiratory rate at various time intervals between the two groups (P > 0.05)[13]. Levobupivacaine is associated with the prompt initiation and extended duration of sensory block, shorter duration of motor block, and reduced risk of cardiac and central nervous system damage. Sell and colleagues determined the least effective dosage of isobaric levobupivacaine and ropivacaine when delivered via a spinal catheter during hip replacement surgery. The average dosage of Levobupivacaine was 15.2±4mg, with a standard deviation of 4mg [12]. Therefore, in this particular investigation, a dosage of 15mg (equivalent to 3ml of a 0.5% concentration) of isobaric levobupivacaine solution was administered for spinal anesthesia. Previous reports have shown that the administration of dexmedetomidine in combination with levobupivacaine results in efficient pain relief, as well as a longer duration of both motor and sensory block. Additionally, this combination has been shown to provide improved postoperative pain management and a reduced occurrence of adverse effects [14]. The preoperative and postoperative physiological measures, including heart rate, systolic and diastolic blood pressure, saturation oxygen level, and respiratory rate, did not show any statistically significant differences between the two groups. Previous studies have shown that dexmedetomidine does not cause respiratory depression and does not affect blood pressure [14]. The disparity in levobupivacaine dosage between the trial conducted by Basuni and Ezz (4 mg) and the current research (15 mg) accounts for this discrepancy [15]. Nevertheless, both investigations found no statistically significant disparity in the average heart rate between the two groups during the perioperative and postoperative periods (P > 0.05). According to experiments conducted by Esmaoğlu et al [14], the intrathecal administration of dexmedetomidine together with levobupivacaine did not result in considerable hypotension.

Liu et al. administered dexmedetomidine at a dose of 5 µg in combination with 0.5% hyperbaric bupivacaine in the sub-arachnoid block. Their study shown that this combination resulted in an extended duration of sensory and motor blocks, as well as a delayed need for the first postoperative analgesic [16]. Jagtap and Bhure demonstrated that dexmedetomidine has a prolonged duration of action, providing efficient postoperative pain relief, and presents a reduced incidence of adverse effects in comparison to fentanyl [17]. In their study, Mohammed et al. (16) shown that adding 5µg of dexmedetomidine is more effective than using 25 µg of fentanyl in prolonging sensory and motor blocks and extending analgesia [18]. The current investigation established that the administration of 0.5% levobupivacaine combined with 3 ug dexmedetomidine resulted in sufficient spinal anesthesia for surgical procedures and pain control. The average duration until the start of motor block is shorter when using the combo compared to using levobupivacaine alone. The median maximum degree of sensory block was considerably lower in the combination group, and the mean duration of sensory block was prolonged in the combination group. The previous investigations [19,20] provide evidence for the sensory block effects of this combination. This enables anesthesiologists to administer and contemplate this combination for extended surgical procedures. These findings align with previous studies indicating that the combination of levobupivacaine and dexmedetomidine may provide a superior option for spinal anesthesia and the treatment of pain after surgery. Similar to a sensory block, the combination of levo+Dex also has an impact on the motor block. Nevertheless, the use of dexmedetomidine with levobupivacaine resulted in an extension of the motor block, as stated in the paper [13].

The research recorded the length of pain relief after administering these anesthetics either alone or in combination, using the objective pain score (VAS). The findings suggest that the combination of levobupivacaine and Dex effectively extended the duration of pain relief after surgery and greatly

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decreased the need for further pain relief after surgery by over 50% when compared to using levobupivacaine alone. It leads to a decrease in the number of pain-relieving dosages needed within the 24 hours after surgery. The enhanced level of pain relief seen in Group LD in our investigation may be attributed to the combined action of dexmedetomidine and levobupivacaine, as well as the efficacy of dexmedetomidine in eliminating visceral discomfort. Comparable findings are seen in the individuals mentioned before [21]. Regarding side effects, we found no disparities in the safety profile of the patients from both groups. There were no observed variations in the motor block, postoperative sedation, or urine retention. None of the groups had significant issues with nausea and vomiting.

CONCLUSION

Our observation indicates that the combination of levobupivacaine and dexmedetomidine is effective in achieving surgical anesthesia and maintaining stable hemodynamics. This combination outperforms levobupivacaine alone in several aspects: it leads to a faster onset of sensory and motor block, a longer duration of sensory and motor block, a prolonged period of postoperative analgesia, and a reduced need for rescue analgesia.

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