Original Article

ISSN (0): 2456-7388; ISSN (P): 2617-5479

To Compare the Clinical Assessment of Spinal Anaesthesia with Levobupivacaine Alone Vs A Combination of Levobupivacaine and Dexmedetomidine

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Abstract

Background: Spinal anaesthesia is a commonly used method that offers rapid initiation of action along with efficient and evenly spread numbing of both sensory and motor functions. Levobupivacaine is a favourable substitute for spinal anaesthesia since it has less cardiovascular and central nervous system effects. When administered intrathecally, dexmedetomidine is linked to a longer duration of motor and sensory block, stable hemodynamics, and reduced need for further pain relief within a 24-hour period. **Aim:** To compared the clinical assessment of spinal anaesthesia with Levobupivacaine alone vs a combination of Levobupivacaine and Dexmedetomidine. **Subjects and Methods:** A total of 160 patients, classified as American Society of Anesthesiologists physical status I or II, were included in this randomised, double-blind trial. The patients were of both sexes, aged between 20 to 60 years, with a body weight ranging from 35 to 70 kg and a height more than 150 cm. The groups were partitioned and therapy was administered in the following manner: Control Group (Group-A, N=80): 0.5% Isobaric levobupivacaine 15 mg (3 ml) mixed with 0.3 ml normal saline; Study Group (Group-B, N=80): 0.5% Isobaric levobupivacaine 15 mg (3 ml) mixed with 0.3 ml (3 µg) dexmedetomidine. The motor block is assessed using the modified Bromage score. **Results:** In Group A, the average time it took for the sensory block to reach the T10 dermatome was 9.01 ± 0.88 minutes, whereas in Group B it was 5.57 ± 0.78 minutes (P=0.03). In group A, the median maximum sensory level reached was at the T6 dermatome, taking an average of 18.11 ± 1.64 minutes. In group B, the median maximum sensory level was at the T4 dermatome, attained in an average of 10.21 ± 1.34 minutes (P=0.001). In Group A, the average length of sensory block (time until regression to S1 dermatome) was 209.99 ± 7.85 min, but in Group B it was 349.88 ± 7.63 min (P = 0.001). The differences between the two groups were statistically highly significant. The average duration required to reach maximal motor block was 13.99 ± 1.24 minutes for group A and 9.14 ± 0.88 minutes for Group B (P=0.001). In addition, the average duration of motor block in Group A was 139.82 ± 4.29 min, whereas in Group B it was 188.85 ± 5.85 min. Both differences exhibited a high level of significance (P = 0.001). 12.5% of patients in both Group A and Group B had hypotension, whereas 5% of patients in Group A and 15% of patients in Group B experienced bradycardia. However, these differences were not statistically significant (P > 0.05). **Conclusion:** The combination of levobupivacaine and dexmedetomidine has been determined to result in a sensory and motor block that starts earlier and lasts longer, as well as a longer period of postoperative pain relief compared to using levobupivacaine alone.

Keywords: Levobupivacaine, Dexmedetomidine, Sensory, Motor block.

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Received: January 2018
Accepted: March 2018

Introduction

Anesthesiologists and patients having surgical operations under the sub-arachnoid block are both greatly concerned about the lengthening of surgery and the management of pain after the operation. In addition to conventional analgesics like NSAIDs and opioids, the use of additives in combination with spinal medications is increasingly common in order to prolong the length of the block and postoperative pain relief. Optimal management of pain after surgery is a crucial aspect of providing comprehensive care to the surgical patient. 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.With the passage of time, there is a growing inclination towards using regional anaesthesia methods instead of general anaesthesia for many routine procedures. Regional anaesthesia has several advantages compared to general anaesthesia since it effectively removes both intraoperative and postoperative discomfort, provides exceptional muscular relaxation, and minimises intraoperative bleeding.[2]Regional anaesthesia approaches surpass systemic opioid drugs in terms of analgesic

effectiveness and side effects. Spinal anaesthesia 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. Levobupivacaine is a favourable substitute because to its reduced cardiovascular and central nervous system toxicity.[3,4]

Levobupivacaine is a newly available option for spinal anaesthesia due to its reduced risk of causing harm to the cardiovascular and central nervous systems.[5]Levobupivacaine is a newly introduced alternative to bupivacaine in clinical usage. It generates a sensory block that is equal in effect but has a shorter duration of motor block compared to intrathecal bupivacaine.[6]

Isobaric solutions of this product are now accessible in India. However, due to its recent introduction, there have been few research conducted on its use in spinal anaesthesia. Arterial hypotension is the most common negative outcome after subarachnoid anaesthesia due to changes in hemodynamics. Isobaric solutions of anaesthetic agent may counteract the more dense and longer-lasting motor blockage that would be provided by a hyperbaric solution. To enhance the efficacy of local anaesthetics and extend the duration of pain relief during surgery and after surgery, other substances such vasoconstrictors, alpha-2 agonists, and opioids have been used as adjuvants.[7]Dexmedetomidine is used as a supplementary treatment in spinal anaesthesia and is linked to extended periods of reduced motor and sensory function, stable blood flow, and decreased need for further pain relief within a 24-hour period. Consequently, it allows for a reduction in the dosage of the local anaesthetic used.[8]Therefore, we conducted a research to examine the effects of two different doses of isobaric levobupivacaine (0.5%, 15 mg) in combination with dexmedetomidine (0.3 ml, 3 µg) for infraumbilical procedures performed under spinal anaesthesia.

Subjects and Methods

This research was conducted at the department of anesthesiology, after approval from the institutional ethics board. A total of 160 patients, classified as American Society of Anesthesiologists physical status I or II, were included in this randomised, double-blind trial. The patients were of both sexes, aged between 20 to 60 years, with a body weight ranging from 35 to 70 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

All patients had a 6-hour fasting period. 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 anaesthesia. 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 dosage of Levo-bupivacaine was 15.2±4.0mg.[9]Therefore, in the current investigation, a dose of 15mg (equivalent to 3ml of 0.5%) isobaric levobupivacaine solution was administered for spinal anaesthesia. The research medication for anaesthesia and pain relief after surgery was prepared by a distinct anesthesiologist. The anaesthesiologist, surgeon, patient, and personnel involved in the trial were unaware of the medicine being administered. To ensure impartiality in the trial, the medication was administered in a consistent amount of 3.3 ml to both groups. The groups were partitioned and therapy was administered in the following manner: Control Group (Group-A, N=80): 0.5% Isobaric levobupivacaine 15 mg (3 ml) mixed with 0.3 ml normal saline; Study Group (Group-B, N=80): 0.5% Isobaric levobupivacaine 15 mg (3 ml) mixed with 0.3 ml (3 µg) dexmedetomidine.

The clinical effectiveness was assessed by examining the time at which the sensory block began, the time at which the greatest motor block occurred, and the duration of analgesia. A visual analogue scale (VAS) consisting of a 0-10 cm line was used to assess the degree of pain relief in the 24-hour postoperative period. 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" indicates the presence of intense agony. Analgesia was administered for rescue purposes when the Visual Analogue Scale (VAS) score exceeded 3. The sensory block is evaluated by determining the absence of feeling to a pinprick using a blunt hypodermic needle with a gauge size of 22. The motor block is assessed using the modified Bromage score. Bromage scale.[10]0 - Full range of motion in knees and feet, capable of lifting legs when extended. 1 - Incapable of lifting extended legs, but able to flex knees and feet. 2 - Incapable of flexing knees, but able to flex feet. 3 - Complete inability to move legs and feet.

Hemodynamic response was assessed by measuring respiratory rate, heart rate, noninvasive systolic and diastolic blood pressure, and SpO2. Recordings were taken before the operation, then during the surgery at 0 and 5 minutes, and subsequently at intervals of 10 minutes up to 30 minutes, 15 minutes up to 120 minutes, every half hour up to 180 minutes, every hour until 12 hours, and every 3 hours thereafter until 24 hours in both groups.

Statistical analysis

SPSS Version 25.0 was used for statistical analysis. Information was gathered from every patient in both groups and entered into a Microsoft Excel Worksheet. The mean and standard deviation were calculated for the variables of age, weight, operation time, and analgesia duration. The mean values of the two groups were compared using a Student's t-test. A significance level of $P < 0.05$ was deemed statistically significant.

Results

The gender, age, and weight of the two groups do not exhibit statistically significant differences. Similarly, the systolic

blood pressure, diastolic blood pressure, mean respiratory rate, and SpO2 during the surgery and after the surgery were likewise similar. The observed differences do not show statistical significance.Table 1 and Table 2

The moment at which the sensory block began was determined based on the timing of medication delivery. In Group A, the average time it took for the sensory block to reach the T10 dermatome was 9.01 ± 0.88 minutes, whereas in Group B it was 5.57 ± 0.78 minutes (P=0.03). In group A, the median maximum sensory level reached was at the T6 dermatome, taking an average of 18.11 ± 1.64 minutes. In group B, the median maximum sensory level was at the T4 dermatome, attained in an average of 10.21 ± 1.34 minutes (P=0.001). In Group A, the average length of sensory block (time until regression to S1 dermatome) was 209.99 ± 7.85 min, but in Group B it was 349.88 ± 7.63 min (P = 0.001). The differences between the two groups were statistically highly significant, as seen in Table 3.

Another criteria for evaluation was the time at which maximal motor block occurred, as shown in Table 4. The average duration required to reach maximal motor block was 13.99 ± 1.24 minutes for group A and 9.14 ± 0.88 minutes for Group B (P=0.001). In addition, the average duration of motor block in Group A was 139.82 ± 4.29 min, whereas in Group B it was 188.85 ± 5.85 min. Both differences exhibited a high level of significance (P = 0.001).

The VAS (Visual Analogue Scale) in Group A showed a significant rise at 120 minutes after the procedure. Patients in this group requested their first dosage of rescue analgesia at an average of 181.25 ± 4.58 minutes after the surgery. There was a further rise in the VAS score at the 10th hour, and a second dosage of rescue analgesia was administered at the 12th hour. The third administration of rescue analgesia occurred during the 18th hour, followed by the fourth administration at the 24th hour.

Group B had a rise in VAS at 240 minutes, and the first administration of rescue analgesia occurred in the 6th hour after the surgery (401.22 ± 6.85 minutes). The second administration of rescue analgesia occurred at the 14th hour, whereas the third administration took place at the 22nd hour. Group B had considerably lower postoperative VAS ratings at various time intervals compared to Group A, suggesting greater analgesic effects.

The time at which the first dosage of rescue analgesia was requested was delayed in Group B, occurring at 401.22 ± 6.85 minutes, whereas in Group A it occurred at 181.25 ± 4.58 minutes. The disparity between the two groups was quite substantial (P = 0.001). Our research saw a decrease in the amount of rescue analgesia needed, which was directly related to the dosage administered. The number of rescue analgesia doses in Group A was 4.33 ± 0.54, whereas in Group B it was 2.42 ± 0.33. The difference between the two groups was statistically significant (P = 0.001).

12.5% of patients in both Group A and Group B had hypotension, whereas 5% of patients in Group A and 15% of patients in Group B experienced bradycardia. However, these differences were not statistically significant (P > 0.05). Urinary retention was absent in all patients in Group A, but it was found in only 2.5% of patients in Group B. However, this difference was not statistically significant. None of the patients in either group had adverse symptoms such as pruritus, nausea, vomiting, headache, backache, local anaesthetic toxicity, or respiratory depression.

Table 1: Gender and age of the participants

Gender and age	Group A=80		Group B=80		P value
Gender	Number	Percentage	Number	Percentage	0.21
Male	49	61.25	50	62.5	
Female	31	38.75	30	37.5	
Age in years					0.18
Below 35	9	11.25	12	15	
35-45	39	48.75	40	50	
45-55	21	26.25	19	23.75	
Above 55	11	13.75	9	11.25	
Mean Age	44.25±3.96		45.25±3.61		

Table 2: Basic parameter of the participants

	Group A=80		Group B=80		P value
	Mean	SD	Mean	SD	
Weight (kg)	54.11	4.29	53.31	3.28	0.14
Heart rate/Min	82.04	3.74	83.15	3.96	0.21
Systolic BP (mmHg)	123.58	5.85	121.59	5.33	0.19
Diastolic BP (mmHg)	78.85	3.96	78.52	3.39	0.23
SpO2 (%)	100.05	4.58	99.25	4.39	0.11
Respiratory rate/min	16.54	1.25	17.41	1.69	0.09

Table 3: Difference in the sensory block between two groups

	Group A=80		Group B=80		P value
	Mean	SD	Mean	SD	
Onset of sensory block (Min)	9.01	0.88	5.57	0.78	0.03
Median maximum sensory block (Min)	18.11	1.64	10.21	1.34	0.001
Mean duration of sensory block (Min)	209.99	7.85	349.88	7.63	0.001

Table 4: Difference in the motor block between two groups

	Group A=80		Group B=80		P value
	Mean	SD	Mean	SD	
Onset of maximum motor block	13.99	1.24	9.14	0.88	0.001
Total duration of motor block	139.82	4.29	188.85	5.85	0.001

Table 5: Side effect

Side effect	Group A=80		Group B=80		P value
Hypotension	10	12.5	10	12.5	0.11
Bradycardia	4	5	12	15	0.26

Urinary retention	0	0	2	2.5	0.34

Discussion

Regional anaesthesia approaches surpass systemic opioid drugs in terms of analgesic efficacy and unwanted effects. Levobupivacaine is a favoured local anaesthetic because it has a rapid start and long-lasting effect on sensory block, a shorter period of motor block, and a reduced risk of heart toxicity. Prior research has shown that the inclusion of dexmedetomidine with levobupivacaine results in efficient pain relief and extends the period of both motor and sensory block, while also improving postoperative pain management and reducing the occurrence of adverse effects.[11]There was no significant difference in the change in respiratory rate at various time intervals between the two groups ($P > 0.05$). The absence of respiratory depression associated with dexmedetomidine has been confirmed in trials conducted by Esmaoğlu et al,[12]and Basuni et al.[13]Similarly, the average heart rate throughout different time periods during the surgery was found to be similar in both groups.

Levobupivacaine is a highly favoured choice for a local anaesthetic medication. These effects may be due to the sensory block starting early and lasting for a long time, the motor block being shorter in length, and the decreased occurrence of toxicity related to the heart and central nervous system. The study conducted by Sell A et al aimed to determine the least efficacious dosage of isobaric levobupivacaine and ropivacaine, delivered using a spinal catheter, during hip replacement surgery. The dosage of Levobupivacaine was 15.2±4mg, as reported in reference.[9]Therefore, in the current investigation, a dosage of 15mg (equivalent to 3ml of 0.5%) isobaric levobupivacaine solution was administered for spinal anaesthesia. Previous reports have shown that the administration of dexmedetomidine in combination with levobupivacaine results in efficient pain relief, as well as an extended period of reduced motor and sensory function. Additionally, this combination has been shown to provide improved pain relief after surgery and fewer adverse effects. 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. Prior research has also shown that dexmedetomidine does not cause respiratory depression and does not affect blood pressure.[12]The discrepancy in levobupivacaine dosage between the trial conducted by Basuni and Ezz (4 mg) and the current research (15 mg) might account for this difference.[13]Nevertheless, both investigations found no statistically significant disparity in the average heart rate between the two groups during the perioperative and postoperative periods ($P > 0.05$). Studies conducted by Esmaoğlu et al,[12] have shown that the intrathecal administration of dexmedetomidine with levobupivacaine does not result in considerable hypotension.

The current investigation established that the administration of 0.5% levobupivacaine combined with 3 µg dexmedetomidine resulted in sufficient spinal anaesthesia 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 sensory block effects of this combination are corroborated by prior research.[14,15]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 more effective option for spinal block and post-operative pain control. Similar to a sensory block, the combination of levo+Dex also has an impact on the motor block. Nevertheless, the inclusion of dexmedetomidine with levobupivacaine resulted in an extension of the motor block, as stated in the report.[12]

The research recorded the length of pain relief following the administration of these anaesthetics, either alone or in combination, using the objective pain score known as the Visual Analogue Scale (VAS). The findings demonstrate that the combination of levobupivacaine and Dex effectively extended the duration of pain relief after surgery and substantially decreased the need for further pain relief after surgery by over 50% as 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 B 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.[16]Regarding side effects, we found no disparities in the safety profile of the patients in both groups. No disparities were seen in the motor block, surgical sedation, or urine retention. None of the groups had significant issues with nausea and vomiting.

The inclusion of dexmedetomidine with levobupivacaine enhanced the postoperative pain relief, leading to a decrease in the quantity of analgesic dosages needed inside the 24-hour period after the surgery. The enhanced level of pain relief seen in Group B 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. This finding aligns with the research undertaken by Basuni and Ezz,[13]as well as Amer et al.[16]Esmaoğlu et al,[12] noted that there was no statistically significant difference ($P > 0.05$) in the occurrence of hypotension between Group A and Group B, with 12.5% of patients experiencing hypotension in each group. Similarly, the occurrence of bradycardia was also not statistically significant ($P > 0.05$), with 5% of patients in Group A and 15% in Group B experiencing bradycardia.

Conclusion

The combination of levobupivacaine and dexmedetomidine has been determined to result in a sensory and motor block that starts earlier and lasts longer, as well as a longer period of postoperative pain relief compared to using levobupivacaine alone.

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How to cite this article: P Pradeep, JoshiD S, Rao W. M U,to compared the clinical assessment of spinal anaesthesia with Levobupivacaine alone vs a combination of Levobupivacaine and Dexmedetomidine.Acad. Anesthesiol. Int. 2018;3(1):26-30.

DOI: dx.doi.org/10.21276/aan.2018.3.1.7

Source of Support: Nil, **Conflict of Interest:** None declared.