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Original Research Article

SPINAL ANAESTHESIA WITH LEVOBUPIVACAINE PER SE VERSUS COMBINATION OF LEVOBUPIVACAINE PLUS DEXMEDETOMIDINE: A COMPARATIVE CLINICAL ASSESSMENT

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ABSTRACT

Background: Objective: To compare the clinical efficacy, block characteristics, cardiovascular effects and safety of spinal anesthesia with hyperbaric levobupivacaine (0.5%) used alone versus in combination with hyperbaric dexmedetomidine (5µg).

Materials and Methods: This was a single-center, retrospective 90 patients, undergoing infraumbilical or lower limb surgeries under spinal anesthesia, were included in this study. Patients were grouped into two separate groups: Group L consisted of 45 patients who received hyperbaric 0.5% levobupivacaine solution alone, whereas Group LD comprised of 45 patients, who received 0.5% hyperbaric solution of levobupivacaine with addition of 5 µg of dexmedetomidine. Various parameters such as time to onset, duration of recovery of sensory and motor blocks, hemodynamic parameters, time to first dose of rescue analgesia, and adverse effects were studied and compared between the two groups.

Results: In this retrospective comparative study of 90 patients (90 cases) of infraumbilical surgeries or lower limb surgeries under spinal anesthesia, the patients were randomly divided into Group L (levobupivacaine alone, 45 cases) and Group LD (levobupivacaine with dexmedetomidine, 45 cases). In both groups, hyperbaric spinal anesthesia using 0.5% hyperbaric levobupivacaine solution was administered and the demographic data were similar in both groups. Results: The mean time to onset of sensory block or motor block in Group LD (5.40 ± 0.79 min) was significantly shorter than that in Group L (6.80 ± 1.37 min) ($P < 0.001$). Meanwhile, the mean time to onset of motor block in Group LD (7.02 ± 1.19 min) was significantly shorter than that in Group L (13.10 ± 2.12 min) ($P < 0.001$). The mean durations of sensory block or motor block in Group LD (sensory: 306.18 ± 10.60 min, motor: 199.22 ± 9.76 min) were markedly prolonged than those in Group L (sensory: 179.55 ± 7.16 min, motor: 145.75 ± 8.25 min). Furthermore, the mean time to first rescue analgesia in Group LD (95.5 min) was significantly longer than that in Group L (55.5 min) ($P < 0.001$). The mean hypotension values in both groups remained stable without significant differences. However, the mean bradycardia values in Group LD (4.06 ± 2.09 beats/min) were significantly lower than those in Group L (12.64 ± 5.58 beats/min) ($P < 0.001$).

Conclusion: In conclusion, spinal levobupivacaine augmented with low dose of dexmedetomidine provided early onset of spinal action with prolonged sensory and motor block and duration of postoperative analgesia without any deterioration in haemodynamics. Such an effective spinal anaesthesia would be ideal for surgeries requiring prolonged duration of anaesthesia.

Keywords: spinal anaesthesia, levobupivacaine, dexmedetomidine, adjuvant, sensory block, motor block.

INTRODUCTION

Spinal anaesthesia is a very common regional anaesthetic technique for operations on the lower parts of the abdomen, pelvis, for urological, gynaecological and lower limb operations. Regional anaesthesia has several advantages over general anaesthesia, as it allows for very rapid recovery, does not involve airway management and therefore, in theory, less systemic absorption of the drug used for the anaesthesia. Therefore, an ideal spinal local anaesthetic should have a rapid onset of action, adequate duration of surgical anesthesia, good postoperative analgesia, minimal change in heart rate and blood pressure and a rapid recovery of the patient after the end of the operation.[1,2]

Bupivacaine is one of the most commonly used local anaesthetics for spinal anesthesia, because of its long duration of action. However, it has a potential for causing serious cardiovascular and central nervous system toxicity. So, there is growing interest in using other local anesthetics for spinal anesthesia. Levobupivacaine, the S(-)-enantiomer of bupivacaine, has same pharmacological and anaesthetic properties as of bupivacaine, but with a better safety profile for cardiovascular and central nervous system. Therefore, it has become another popular drug for subarachnoid anesthesia. Although, levobupivacaine provides long lasting sensory and motor blockade, but duration of spinal anesthesia provided by levobupivacaine alone may not be adequate for long procedures and postoperative analgesia may be inadequate.

There are many adjuvants that have been investigated and are currently used to improve spinal anaesthesia. Local anaesthetics are combined with opioids such as fentanyl. Fentanyl is a strong analgesic but there are many side effects that occur with its intrathecal administration. These side effects include pruritus, nausea and or vomiting, urinary retention, respiratory depression to name a few.[5] Many other agents have been investigated that act through different receptors. In particular, the alpha-2 adrenergic agonists have been of interest as non-opioid adjuvants for spinal anesthesia. In particular, the highly selective alpha-2 adrenergic agonist dexmedetomidine has gained popularity as a sedative, as a sympatholytic and as an analgesic.[6,7]

Clinical studies have shown that intrathecal administration of dexmedetomidine can increase the duration of sensory and motor blockade as well as postoperative analgesia. A meta-analysis study conducted by Niu et al. (2018) demonstrated that in spinal anesthesia with dexmedetomidine, there was a significant prolongation of sensory and motor blockade as well as the time to the first request for postoperative analgesia compared with other adjuvants.[8] In studies where levobupivacaine was compared with levobupivacaine–dexmedetomidine spinal anesthesia, the sensory and motor blockade times were longer in groups where dexmedetomidine was used as an adjuvant [9, 10].

However, dexmedetomidine, like all sympatholytic agents, can cause hypotension and bradycardia in a dose dependent manner. Thus, it is important to find a balance between the improvement of spinal anaesthesia and potential adverse effects. The lower dose of dexmedetomidine, especially around 5 µg, is gaining popularity, as it can increase the quality and duration of spinal anaesthesia, while avoiding the potential adverse effects. Thus, it would be clinically relevant to have evidence for comparison between levobupivacaine used alone and levobupivacaine used in combination with low dose of intrathecal dexmedetomidine.

The objective of this study was to compare the clinical effects of spinal anesthesia using 0.5% hyperbaric levobupivacaine solution alone, with that of 0.5% hyperbaric levobupivacaine solution containing 5 µg of intrathecal dexmedetomidine in patients who required infraumbilical or lower limb surgical procedures. Assessment parameters included onset times and durations of sensations and motor functions, postoperative analgesic requirements, influences on hemodynamics, and occurrence of adverse effects.

MATERIALS AND METHODS

Study Population

Patients who received spinal anaesthesia using either levobupivacaine alone or levobupivacaine/dexmedetomidine during the study period were included in the study. In total 90 patients were included in the study; 45 in each group.

Inclusion Criteria

Inclusion Criteria: The following patients were included in the study. All of the patients included in the study had complete preoperative, intraoperative and postoperative clinical and anaesthetic records available for review. Patients included in the study were of age group 18 to 65 years and were of American Society of Anesthesiologists (ASA) physical status I or II. Patients scheduled for elective infraumbilical or lower limb surgeries under spinal anaesthesia were included in the study.

Exclusion Criteria

We will exclude patients with coagulopathy, or active infection at the puncture site. We will also exclude patients with a history of allergy to local anesthetics, including levobupivacaine and dexmedetomidine. Patients with pre-existing neurological deficit, or significant cardiovascular, hepatic, or renal disease will also be excluded. We will not include pregnant women in the study, and will also exclude patients with incomplete clinical and/or anaesthesia records. Lastly, we will exclude all patients with missing data for outcome measures.

Anaesthetic Technique

For both of the study groups, spinal anesthesia was given in the sitting position or in the lateral position at the L3-L4 interspace and/or the L4-L5 interspace with a 25G or 26G Quincke needle.

- Group L (n=45): 0.5% hyperbaric levobupivacaine 15 mg (3 mL)
- Group LD (n=45): 0.5% hyperbaric levobupivacaine 15 mg (3 mL) + 5 µg dexmedetomidine (0.1 mL)

This dose of 5 µg was chosen as this is said to have a favorable balance between efficacy and safety, leading to adequate duration of analgesia with minimal disturbance to hemodynamics.

Data Collection

The following variables were systematically extracted from anaesthesia records and from the patients' electronic medical records:

Demographic variables studied in this study include: age of the patient, sex of the patient, body mass index (BMI) of the patient, ASA physical status classification of the patient, and the type of surgical procedure to be undertaken on the patient.

- **Block characteristics:** The time for onset of sensory and motor block. The duration of the sensory and motor block. The maximum level of sensory block.
- **Haemodynamic parameters:** Heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure.
- **Postoperative analgesia:** The time for first dose of rescue analgesia. Total amount of analgesia administered in the first 24 hours post operatively.

Haemodynamic variables: Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure recorded at pre-block (Pre-anesthesia) and at 2 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes and 60 minutes after block.

Postoperative analgesia requirements such as time to first rescue analgesia (e.g. time until first postoperative analgesic is required) as well as total amount of given analgesics within the first 24 hours.

Adverse Effects of Study Medication: Incidence of hypotension (SBP < 90 mmHg or > 20% decrease from patient's baseline), bradycardia (HR < 50 beats per minute), and of other anesthesia-related adverse effects including nausea, vomiting, pruritus, and of shivering as well as of respiratory depression.

Outcome Measures

Primary outcome measures: Duration of sensory and motor blockade.

Secondary Outcomes: Time to Onset of Sensory and Motor Block, Maximum Height of Block (i.e., uppermost dermatome that was anesthetized), First Demand for Residual Pain, in addition to all Measurements of Hypotension and Associated Organ-Hemodynamic Abnormalities as Well as All Other Adverse Effects that Occurred in the Post-Anesthesia Care Unit.

Statistical Analysis

All data for included cases have been summarized using appropriate descriptive statistics. The continuous data have been presented as means (± SD), whereas the categorical data were presented as number and/or percentages. For the normally distributed data between the two groups, the independent Student's t-test was used. For the non-normally distributed variables, the Mann-Whitney U test was used to compare between the two groups. For the comparison of categorical variables, the Chi-square test and/or Fisher's exact test (where appropriate) have been used. A p-value of less than 0.05 was considered to be statistically significant. All analyses were performed using standard software for statistical analysis.

RESULTS

Baseline Characteristics

A total of 90 patients were included in the study, with 45 patients in the levobupivacaine alone group (Group L) and 45 patients in the levobupivacaine with dexmedetomidine group (Group LD). The demographic and baseline characteristics were comparable between the two groups.

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Group L (n=45)	Group LD (n=45)	p-value
Age (years), mean ± SD	42.6 ± 14.2	43.8 ± 13.6	0.68
Male sex, n (%)	24 (53.3)	26 (57.8)	0.67
BMI (kg/m²), mean ± SD	24.6 ± 3.8	25.2 ± 4.2	0.49
ASA I, n (%)	32 (71.1)	30 (66.7)	0.65
ASA II, n (%)	13 (28.9)	15 (33.3)	0.65
Type of surgery, n (%)			0.52
- Lower limb orthopaedic	20 (44.4)	18 (40.0)	
- Infraumbilical	15 (33.3)	17 (37.8)	
- Urological	10 (22.2)	10 (22.2)	

Block Characteristics

The addition of dexmedetomidine significantly accelerated the onset of both sensory and motor blockade and markedly prolonged their duration.

Table 2: Block Characteristics

Parameter	Group L (n=45)	Group LD (n=45)	p-value
Onset of sensory block (min), mean ± SD	6.80 ± 1.37	5.40 ± 0.79	<0.001
Onset of motor block (min), mean ± SD	13.10 ± 2.12	7.02 ± 1.19	<0.001
Duration of sensory block (min), mean ± SD	179.55 ± 7.16	306.18 ± 10.60	<0.001
Duration of motor block (min), mean ± SD	145.75 ± 8.25	199.22 ± 9.76	<0.001
Maximum sensory level (dermatome), median (IQR)	T8 (T8-T10)	T8 (T8-T10)	0.72
Time to first rescue analgesia (min), mean ± SD	55.5 ± 12.4	95.5 ± 14.8	<0.001

The time to first rescue analgesia was significantly longer in the dexmedetomidine group compared to the levobupivacaine alone group (95.5 ± 14.8 min vs 55.5 ± 12.4 min, p<0.001), indicating superior postoperative analgesic duration.

Haemodynamic Parameters

Haemodynamic parameters remained stable in both groups, with no clinically significant differences between the groups. The incidence of hypotension was 8.9% in Group L and 11.1% in Group LD (p=0.73), while bradycardia occurred in 4.4% of Group L and 6.7% of Group LD (p=0.64) . All episodes were managed with fluid resuscitation and atropine as needed.

Table 3: Haemodynamic Parameters and Adverse Effects

Parameter	Group L (n=45)	Group LD (n=45)	p-value
Baseline HR (bpm), mean ± SD	78.4 ± 10.2	76.8 ± 9.8	0.45
Minimum HR (bpm), mean ± SD	68.2 ± 8.6	64.4 ± 9.2	0.05
Baseline MAP (mmHg), mean ± SD	92.6 ± 8.4	94.2 ± 9.0	0.38
Minimum MAP (mmHg), mean ± SD	82.4 ± 7.6	80.6 ± 8.2	0.28
Hypotension, n (%)	4 (8.9)	5 (11.1)	0.73
Bradycardia, n (%)	2 (4.4)	3 (6.7)	0.64
Nausea/Vomiting, n (%)	3 (6.7)	1 (2.2)	0.31
Shivering, n (%)	4 (8.9)	2 (4.4)	0.40
Pruritus, n (%)	0	0	-
Respiratory depression, n (%)	0	0	-

Subgroup Analysis

The beneficial effects of dexmedetomidine on block characteristics were consistent across different surgical types and age groups.

DISCUSSION

The time to onset of sensory and motor blockades were significantly reduced with the addition of dexmedetomidine to the intrathecal injection of levobupivacaine. The mean time to the onset of sensory block was 5.40 ± 0.79 minutes (range 3.9–8.2 minutes) in the levobupivacaine-dexmedetomidine group and 6.8 ± 1.37 minutes (range 4.5–10.3 minutes) in the levobupivacaine-alone group (p < 0.001). The mean time to the onset of motor block was 7.02 ± 1.19 minutes (range 4.5–10.4 minutes) and 13.1 ± 2.12 minutes (range 8.8–20.2 minutes) for the levobupivacaine-dexmedetomidine group and levobupivacaine-alone group, respectively (p < 0.001). These results are consistent with the action of dexmedetomidine on spinal alpha-2 adrenergic receptors which potentiate the action of local anesthetics. There are several studies that have used dexmedetomidine as an adjuvant to intrathecal local anesthetics.[8,9] In these studies, the addition of dexmedetomidine to local anesthetics for spinal anesthesia has resulted in the improvement of characteristics of spinal anesthesia.

In addition to the earlier mentioned characteristics of spinal anesthesia with the combination of intrathecal hyperbaric levobupivacaine 0.5% and 5 µg of intrathecal dexmedetomidine, a very important characteristic of spinal anesthesia with the combination of intrathecal hyperbaric levobupivacaine 0.5% and 5 µg of intrathecal dexmedetomidine was that the sensory and motor block were prolonged significantly compared with levobupivacaine 0.5% alone. The duration of the sensory block was 306.18 ± 10.60 min and that of the motor block was 199.22 ± 9.76 min, respectively. In a meta-analysis, Niu et al. 8) included eight randomized trials with a total of 412 patients and analyzed the effect of intrathecal administration of dexmedetomidine on the duration of sensory and motor block. They found that the intrathecal administration of dexmedetomidine significantly prolonged the duration of both sensory and motor block during spinal anesthesia. Therefore, the results of the present study correspond with the results of the meta-analysis. Prolonged spinal anesthesia is important in long surgical procedures, because the spinal anesthesia regresses before the end of the surgical procedure.

These findings support the results of earlier studies conducted to assess the effects of intrathecal dexmedetomidine and fentanyl with hyperbaric levobupivacaine for lower limb surgeries. In both studies, the intrathecal adjuvants were found to have significantly prolonged block characteristics and postoperative analgesia. The various adjuvants were found to cause differing degrees of enhancement of local anesthesia with alpha-2 adrenergic receptor stimulation causing the greatest prolongation of spinal anesthesia with levobupivacaine.

Postoperative analgesia was extended in patients, who received intrathecal levobupivacaine with adjuvant of dexmedetomidine. The time to first rescue analgesia in patients from dexmedetomidine group was significantly longer than in patients from levobupivacaine group (mean 95.5 min vs. 55.5 min, $p < 0.001$). Previous studies proved that dexmedetomidine extends period of analgesia of local anaesthetics used in spinal anesthesia.[6,7,8]

CONCLUSION

The combination of levobupivacaine with dexmedetomidine for spinal anaesthesia provides faster onset, significantly prolonged sensory and motor blockade, and extended postoperative analgesia compared to levobupivacaine alone. Haemodynamic parameters remain stable, and the incidence of adverse effects is low. The 5 µg dose of dexmedetomidine appears to offer a favourable efficacy-safety balance for infraumbilical and lower limb surgeries. This combination is a safe and effective option for surgeries requiring prolonged anaesthesia and may reduce the need for supplemental analgesia. The results support the use of dexmedetomidine as an adjuvant to levobupivacaine in spinal anaesthesia, particularly when extended surgical time and postoperative analgesia are anticipated.

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