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Comparison of Efficacy of Intrathecal Addition of Dexmedetomidine and 0.5% Levobupivacine Heavy with 0.5% Levobupivacine alone in Infra Umbilical Surgeries

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ABSTRACT

Background: Intrathecal α2 agonists lessen the dosage needed while extending the duration of action of local anaesthetics. As an α2 receptor agonist, dexmedetomidine has eight times more α2/α1 selectivity than clonidine.

Aim: To compare the efficacy of intrathecal addition of dexmedetomidine to 0.5% levobupivacaine heavy with 0.5% levobupivacaine heavy alone in infraumbilical surgeries. Methods: This was a prospective, randomized, double-blinded clinical study. Patients were randomized into two groups. Group L (n=41) patients received 3ml (15mg) of 0.5% levobupivacaine with 0.1ml of normal saline. Group LD (n=41) patients received 3ml (15mg) of 0.5% levobupivacaine with 0.1ml (10mcg) dexmedetomidine. The onset time and duration of sensory and motor blocks, as well as the time to two-segment sensory regression and the time to first rescue analgesia, were recorded. Adverse effects were also monitored.

Results: Sensory and motor block onset times were significantly shorter in Group LD than in Group L ($p<0.000$). The regression of the sensory block to L1 dermatome and Bromage 0, as well as the duration of the two-dermatome regression, were significantly longer in Group LD than in Group L ($p<0.000$). There was no statistically significant difference between the groups when adverse effects were compared.

Conclusion: We conclude that the intrathecal addition of dexmedetomidine to levobupivacaine for spinal anaesthesia results in the rapid onset of sensory and motor blockade with a prolonged duration of postoperative analgesia without significant adverse effects.

KEYWORDS: Dexmedetomidine, Levobupivacaine, Spinal anaesthesia, Infraumbilical surgery, Postoperative analgesia.

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INTRODUCTION

Spinal anaesthesia, also known as sub-arachnoid block, is a widely used and effective technique for lower limb and infraumbilical surgeries. It offers several advantages over general anaesthesia, including the patient's ability to maintain spontaneous respiration and retain protective airway reflexes [1, 2]. An ideal regional anaesthetic for these procedures should provide sufficient operative time, excellent postoperative analgesia, and minimal intraoperative and postoperative side effects. Bupivacaine is a commonly used local anaesthetic for spinal anaesthesia, known for its rapid onset and adequate motor blockade. However, its use is associated with a risk of cardiotoxic and neurotoxic effects. Levobupivacaine, the pure S-enantiomer of racemic bupivacaine, has a similar long duration of action but with a lower risk of these side effects. Despite its advantages, adjuvants are often added to local anaesthetics to prolong the duration of the block and reduce the need for early postoperative analgesics. α2-adrenergic agonists have emerged as effective adjuvants to local anaesthetics, providing enhanced analgesia without the side effects associated with opioids, such as respiratory depression [3, 4]. Dexmedetomidine is a highly selective α2-adrenergic agonist, which is approximately eight times more potent than clonidine due to its higher α2/α1 receptor selectivity (1:1620 for dexmedetomidine vs. 1:220 for clonidine). Dexmedetomidine produces analgesia by inhibiting descending pain pathways and reducing the release of nociceptive substances.

The primary aim of this study was to compare the efficacy of intrathecal addition of 10 mcg of dexmedetomidine to 0.5% levobupivacaine heavy with 0.5% levobupivacaine heavy alone in patients undergoing infraumbilical surgeries. The primary objective was to compare the duration of sensory blockade, while secondary objectives included comparing the onset of sensory and motor blockade, the duration of motor blockade, postoperative analgesia, and the incidence of side effects.

MATERIALS AND METHODS

Study Design:

This was a prospective, parallel-group, randomized, double-blinded clinical trial.

Study Duration:
The study was conducted from May 2023 to November 2024.

Study Population and Setting:
The study population comprised patients undergoing elective infraumbilical surgeries. The study was conducted in the Department of Anaesthesiology and Critical Care at Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry.

Sampling Method and Sample Size: A convenient sampling method was used. The sample size was calculated using the formula: $$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \cdot 2 \cdot (\text{s.d.})^2}{d^2}$$Given Z1−α/2=1.96 (for a 95% confidence interval), Z1−β=0.84 (for 80% power), standard deviation (s.d.) = 3.2, and difference (d) = 2.1, the calculation was: n=(2.1)2(1.96+0.84)2·2·(3.2)2=4.41(2.8)2·2·10.24≈36.3

This was rounded up to 37 per group. Accounting for a 10% dropout rate, the sample size was set at 41 patients in each group. Ethical Considerations: After obtaining approval from the Institutional Ethical Committee, the study was conducted on 82 patients with ASA physical status I or II. All patients were fully informed about the procedure, and written informed consent was obtained.

Inclusion Criteria:

- ASA I and II patients
- Both genders
- Age 18-60 years
- BMI 25-40 kg/m2
- Height above 150 Cms

Exclusion Criteria:

- Patient refusal
- Pregnant and lactating women
- History of bleeding diathesis
- Infection at the site of injection
- Allergy to local anaesthetic agents
- Fixed stenotic valvular lesions
- Inadequate spinal blockade due to supplementation of other drugs
- Complicated surgery
- Pre-existing neurological diseases

Eighty-two patients were randomly allocated to one of two groups (n=41 each) using a computer-generated random table. The study was double-blinded, where neither the patient nor the anaesthesiologist administering the drug was aware of the group allocation. A senior anaesthesiologist (with five years of experience) performed the spinal block in the sitting position using a 25-gauge Quincke needle.

- Group L: Received 15 mg of 0.5% levobupivacaine with 0.1 ml of normal saline (total volume: 3.1 ml).
- Group LD: Received 15 mg of 0.5% levobupivacaine with 0.1 ml (10 mcg) of dexmedetomidine (total volume: 3.1 ml). The time of rescue analgesia, total dose of rescue analgesia, hemodynamic parameters, and side effects were recorded.

Statistical Analysis
The collected data was entered into MS Excel and analyzed using SPSS software Version 24.0. The distribution of study variables was analyzed using mean, standard deviation, proportion, median, and interquartile range. The Chi-square test and Student's t-test were used to compare categorical and continuous variables, respectively. A p-value of less than 0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference in demographic data or duration of surgery between the two groups. Haemodynamic parameters (SpO2 and vital signs) showed no significant difference intraoperatively and postoperatively.

Table 1:

Characteristic	Group LD (Mean ± SD)	Group L (Mean ± SD)	p-value
Onset of Sensory Block (mins)	1.78±1.46	3.39±1.00	<0.000
Onset of Motor Block (mins)	2.05±1.09	4.05±1.32	<0.005
Two-Segment Regression (mins)	177.44±15.69	152±26.45	<0.000
Duration of Sensory Block (mins)	292±13.65	221±53	<0.000

Duration of Motor Block (mins)	292±13.65	221±53	<0.000
Time to First Rescue Analgesia (mins)	292.68±18.7	212.2±39.6	<0.000

Sensory Block Characteristics:

- The mean time for the onset of sensory blockade was significantly shorter in Group LD (1.78±1.46 mins) compared to Group L (3.39±1.00 mins), with a highly significant p-value of less than 0.000.
- The highest sensory blockade level was observed in Group LD (T4) compared to Group L (T6). The highest level was attained by 92.6% of patients in Group LD versus 85.3% in Group L, which was statistically significant.
- The mean time for two-segment sensory regression was significantly longer in Group LD (177.44±15.6 mins) compared to Group L (152±26.45 mins), with a p-value of less than 0.000.
- The mean duration of sensory blockade was significantly longer in Group LD (292±13.65 mins) compared to Group L (221±53 mins), with a p-value of less than 0.000.

Motor Block Characteristics:

- The mean time for the onset of motor blockade was significantly shorter in Group LD (2.05±1.09 mins) compared to Group L (4.05±1.32 mins), with a p-value of less than 0.005.
- The mean total duration of motor block was significantly longer in Group LD (292±13.65 mins) compared to Group L (221±53 mins), with a p-value of less than 0.000.

Postoperative Analgesia and Side Effects:

- The mean time to first rescue analgesic was significantly longer in Group LD (292.68±18.7 mins) compared to Group L (212.2±39.6 mins), with a p-value of less than 0.000.
- The incidence of side effects, including nausea, vomiting, bradycardia, hypotension, and shivering, was comparable between the two groups, with no statistically significant differences noted. No postoperative nausea, vomiting, or respiratory depression was reported in either group.

DISCUSSION

Our findings demonstrate that the intrathecal addition of dexmedetomidine to 0.5% levobupivacaine significantly enhances the efficacy of spinal anaesthesia for infraumbilical surgeries. The results regarding the rapid onset of sensory blockade in the dexmedetomidine group are consistent with findings from other studies. Our mean onset time of 1.78 minutes for Group LD aligns with the observations of Shukla D *et al*. [5], who reported an onset time of 2.27 minutes with dexmedetomidine. The faster onset may be attributed to the combined effects of dexmedetomidine's sedative properties and its modulation of local anaesthetic action. Our results also concur with Monisha D *et al*. [6] and Kataria *et al*. [7], who stated that the onset of sensory blockade is significantly shorter when dexmedetomidine is added to levobupivacaine. The highest sensory blockade level observed in our study is consistent with the findings of Zameer Farooq *et al*. [8] and Sudheesh k *et al*. [9]. Our findings also concur with Nethra *et al*. [10], demonstrating that the highest blockade was seen with the dexmedetomidine group.

The prolonged duration of both sensory and motor blockade observed in our study is a crucial finding. The mean sensory block duration of 292 minutes and motor block duration of 292 minutes in Group LD were significantly longer than in Group L. This is consistent with previous research by Eid HEA *et al*. [11], Binod *et al*. [12], and Mohammed *et al*. [13], who also reported a dose-dependent prolongation of both sensory and motor block duration with intrathecal dexmedetomidine. This prolongation is beneficial as it provides extended intraoperative anaesthesia and prolonged postoperative pain relief. Our findings for two-segment regression were concurrent with those of Gupta R *et al*. [14], Nayagam *et al*. [15], and Keles *et al*. [16].

Furthermore, our finding that the time to first rescue analgesia was significantly longer in the dexmedetomidine group corroborates the results of Gupta R *et al*. [14], Nayagam *et al*. [15], and Soeun *et al*. [17]. This suggests that the analgesic properties of dexmedetomidine, mediated through its α2-adrenergic receptor agonism, contribute to a notable reduction in the need for postoperative analgesics.Importantly, the incidence of side effects was not significantly different between the two groups. This aligns with the findings of Bhagyesh Suchendra *et al*. [18], Bindu *et al*. [19], Binod *et al*. [12], Jitendra *et al*. [20], and Heba Omar *et al*. [21], indicating that the benefits of adding dexmedetomidine are not accompanied by a higher risk of adverse events such as hypotension, bradycardia, or respiratory depression.

LIMITATIONS OF THE STUDY:

A limitation of our study is the relatively small sample size. Future studies with larger, multicenter populations would be beneficial to further support the evidence and generalize these findings.

CONCLUSION

In conclusion, the intrathecal addition of 10 mcg of dexmedetomidine to 15 mg of 0.5% levobupivacaine for spinal anaesthesia in infraumbilical surgeries provides a rapid onset of both sensory and motor blockade and a significantly prolonged duration of postoperative analgesia. This enhanced efficacy is achieved without a corresponding increase in the incidence of adverse effects. Therefore, dexmedetomidine is a safe and effective adjuvant to levobupivacaine for spinal anaesthesia.

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