ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Comparative Study Between Intrathecal 0.5% Levobupivacaine With Dexmedetomidine And Intrathecal 0.5% Bupivacaine With Dexmedetomidine In Patients Undergoing Elective Infraumbilical Surgeries- A Prospective Double-Blind Randomised Controlled Trial.

S Chowndharryaa[1], Chinthavali Sujatha[2]*, Srinivasan Suganya[3], and Annamale Jeevendiran[4].

[1]Senior Resident, Department of Anaesthesiology and Critical Care, Indira Gandhi Medical College, Hospital and Research institute, Pondicherry, India.
[2]Associate Professor, Department of Anesthesiology & Critical Care, Sri Venkateswara Medical College, Hospital & Research Centre, Pondicherry, India.
[3]Associate Professor, Department of Anesthesiology & Critical care, Sri Venkateswara Medical College, Hospital & Research Centre, Pondicherry, India.
[4]Senior Resident, Department of Anaesthesiology and Critical Care, Indira Gandhi Medical College, Hospital and Research Institute, Pondicherry, India.

ABSTRACT

Spinal anaesthesia is a technique preferred in infraumbilical surgeries. It aimed at evaluating the efficacy of intrathecal levobupivacaine versus bupivacaine with dexmedetomidine in enhancing its blockade, providing sedation and analgesia, prolonging the anaesthesia duration, and reduces the need for rescue analgesia. A double-blinded, randomised controlled prospective study was done on 60 patients of ASA I & II undergoing infraumbilical surgeries under spinal anaesthesia. Randomisation was done to either of the groups; group LBD(n=30) received a total volume of 3.5 ml of 0.5% levobupivacaine, or group BD(n=30)3.5 ml of 0.5% bupivacaine with 5 micrograms dexmedetomidine to each group. The characteristics of sensory and motor blockade, haemodynamic changes, duration of analgesia, adverse effects, visual analogue score, and analgesic requirements were studied at different time intervals. The demographic and hemodynamic parameters were comparable between the groups. The mean onset time of sensory block was earlier in group BD (3.16±0.87minutes; P<0.01) compared to group LBD (7.93±0.98 minutes; P<0.01), and the mean onset time of motor block was earlier in group BD (4.80±1.06minutes; P<0.01) than the group LBD (10.57±2.06 minutes; P<0.01). The mean duration of sensory (291±29.53 minutes; P<0.01) and motor blockade (278.6±32.9 minutes; P<0.01) was longer in group LBD. The duration of analgesia was also longer in group LBD (305±29.5 minutes) with significant reduction in VAS scores at 6 hrs (0.90±0.66) and 12 hrs (0.53±0.57). The number of rescue analgesics required was lower in group LBD (56.7%) compared to group BD (50%) in 24 hours. This study concluded that levobupivacaine with dexmedetomidine provides more effective anaesthesia in terms of onset, duration of sensory and motor blockade, along with a longer period of post-operative analgesia.

Keywords: Analgesia, Anaesthesia, spinal, Bupivacaine, Dexmedetomidine, Levobupivacaine, Pain.

https://doi.org/10.33887/rjpbcs/2025.16.4.16

Corresponding author

ISSN: 0975-8585

INTRODUCTION

Spinal anaesthesia is widely preferred for infraumbilical surgeries due to its benefits over general anaesthesia, such as better perioperative hemodynamic stability, reduced opioid consumption, providing an effective anaesthesia and analgesia, and decreased postoperative complications like nausea, vomiting, and deep vein thrombosis [1]. Bupivacaine is the most commonly used intrathecal local anesthetic [2]. Levobupivacaine, a racemic mixture and S-enantiomer of bupivacaine, has a better safety profile with less cardiotoxicity, longer duration of sensory blockade, and motor blockade duration [3,4]. Adjuvants are added to enhance the effects of local anaesthetics, prolonging the duration of the blockade, limiting the cumulative dose requirements, and providing better postoperative pain relief[5]. Dexmedetomidine is preferred for its sedative qualities, analgesic effects, and better hemodynamic stability when compared to other alpha 2 adrenoreceptor agonists [6]. Hence, adding adjuvants to local anaesthetics intrathecally provides prolonged anaesthesia and analgesia and reduces the requirements of rescue analgesia [7]. The research objective aims to compare the effectiveness of levobupivacaine with dexmedetomidine and bupivacaine with dexmedetomidine in spinal anaesthesia for infraumbilical surgeries.

MATERIALS AND METHODS

After obtaining approval from the institutional ethics committee and registering with Clinical Trial Registry, India (CTRI/2023/02/049787), a prospective double-blinded randomized controlled trial was conducted on sixty patients in the year 2024 at Department of Anesthesiology & Critical Care, Sri Venkateswara Medical College, Hospital & research centre, Pondicherry The patients recruited for this study were between 18-60 years of age including both sexes categorized under American Society of Anaesthesiologist I and II planned for infraumbilical surgeries after obtaining informed written consent. Patients' refusal to spinal anaesthesia, allergic to local anaesthetics, contraindications for neuraxial blockade, pregnant patients, infection at the site of injection, and patients with known psychiatric illness were excluded from the study. The eligible patients were randomized into two groups to receive a total volume of 3.5 ml to either groups of 0.5% Levobupivacaine (3.4 mL) with (0.1 mL) 5mcg of Dexmedetomidine (Group LBD) or 0.5% Bupivacaine (3.4 mL) with (0.1 mL) 5mcg of Dexmedetomidine (Group BD) using computer-generated block random tables. The Sequentially Numbered, Opaque, Sealed Envelope (SNOSE) technique was used to allocate patients to either group. The participants and the anaesthetists administering the study drug in spinal anaesthesia were blinded to ensure the outcome of the study.

All patients underwent a thorough pre-anaesthetic evaluation before the procedure, and they were pre-medicated on night before surgery. Patients were shifted to the operating theatre, and American Society of Anaesthesiologists (ASA) standard monitors were attached, and baseline values were noted down. Preloading with crystalloids of 10ml/kg was done before spinal blockade.

The subarachnoid block was performed in patients in sitting position using a spinal needle of 90mm, 25 Gauge Quincke (Becton Dickinson, Madrid, Spain) at either L3-L4 or L4-L5 level**.** The study drug volume was injected after observing the free flow of CSF through the needle, and the patient was positioned supine. The primary outcome of this study included the onset of time of sensory block till T6 level achieved, and it was done using pinprick or spirit swab method, and the time of onset of motor blockade to achieve Grade 3 block was assessed using modified bromage scale. The duration of sensory block was recorded from the time of injection up to when the patient complained of pain (VAS>4), and the duration of motor block was assessed from the time taken to achieve Grade 6. The secondary outcomes were the duration of analgesia, intensity of pain using visual analogue scale (VAS), Pain scores at every 5 minutes till one hour, at 2nd hour, 4th hour, 6th hour, 12th hour, and 24th hour respectively, and the number of rescue analgesia required. Postoperatively, and incidence of Side effects – bradycardia, hypotension, vomiting, if any, were noted.

Statistical Analysis

The sample size was calculated with a confidence interval 95%, power80%, ratio between groups, and mean difference of 0.7 from the study done by Kataria et al[11]. This study sample size was 60 patients in total, with 30 in each group, which was calculated using OpenEpi V 3. The data collected were analysed with IBM SPSS Statistics for Windows, version 23.0. Armonk, NY: IBM Corp. The mean and standard deviation (S.D) were calculated for demographic, hemodynamic parameters, and the characteristics of spinal blockade. The chi-square test was employed to evaluate the number of rescue

ISSN: 0975-8585

analgesia. The Unpaired Sample t-test was used to calculate the duration of analgesia and visual analogue scale (VAS).

RESULTS

Figure 1 concluded that the demographic parameters, such as age, gender, weight, height, and ASA physical status, in both groups were comparable [Table 1]. The characteristic time of onset of sensory block and the onset time of motor block with group BD showed a faster onset than group LBD (P<0.01) [Table 2]. Whereas the duration of sensory and motor block in group LBD provided a longer duration compared to group BD, with a highly statistically significant difference (P < 0.01) [Table 2]. The duration of analgesia in this study inferred that the group LBD provided superior analgesic duration with a high statistical difference (P < 0.01) compared to group BD [Table 3]. This study indicated that group LBD demonstrated significantly less pain, as measured by VAS scores at 6 hours and 12 hours postoperatively, compared to group BD with statistical significance (P < 0.01) [Table 4]. The number of rescue analgesics required in group LBD demonstrated a better analgesic profile with a statistically significant difference (P<0.05) [Table 5]. Similarly, the hemodynamic parameters such as systolic blood pressure, diastolic blood pressure, mean arterial pressure, spo2 across different time intervals were comparable and statistically showed no significance (P>0.05).

Table 1: Demographic parameters

Parameter	Group LBD(n=30) (Mean ± SD)		Group BD(n=30) (Mean ± SD)		P value
Age(years)	39.63±12.65		38.06±10.21		0.600
Gender Males Females	No of cases 8 22	% 26.7% 73.3%	No of cases 17 13	% 56.7% 43.3%	0.18
Weight	66.93±8.808		64.30±8.192		0.235
Height	157.57±6.393		152.40±17.504		0.134
ASA grade	1.40±0.498		1.33±0.479		0.599

*$P \leq 0.05$ (statistically significant). ASA = American Society of Anaesthesiologists - Physical status, SD = standard deviation

Table 2: Comparison of onset and duration of sensory and motor blockade

Parameter	Group LBD (N=30)	Group BD (N=30)	P value
	Mean ± SD	Mean ± SD	
Onset of Sensory Blockade (min)	7.93 ± 0.98	3.16 ±0.87	0.000

*$P \leq 0.05$ (statistically significant), SD - standard deviation

Table 3: Comparison of duration of Analgesia between the two groups

Parameter	Group LBD (N=30)	Group BD (N=30)	P value
	Mean ± SD	Mean ± SD	
Duration of Analgesia (min)	305 ± 29.5	207.3 ± 11.2	0.000

*$P \leq 0.05$ (statistically significant), SD - standard deviation

Table 4: Comparison of VAS at various Time intervals in the study groups

VAS	Group LBD (N=30)		Group BD (N=30)		P value
	Mean ±SD		Mean ± SD		
0 minutes to 120 minutes	0.00 ±0.00		0.00±0.00		-
4 hours	0.53±0.50		0.53±0.50		1.000
6 hours	0.90 ±0.66		1.37±0.55		**0.004**
12 hours	0.53±0.571		0.93±0.691		**0.012**
24 hours	0.23±0.571		0.07±0.254		0.111

*$P \leq 0.05$ (statistically significant), SD - standard deviation

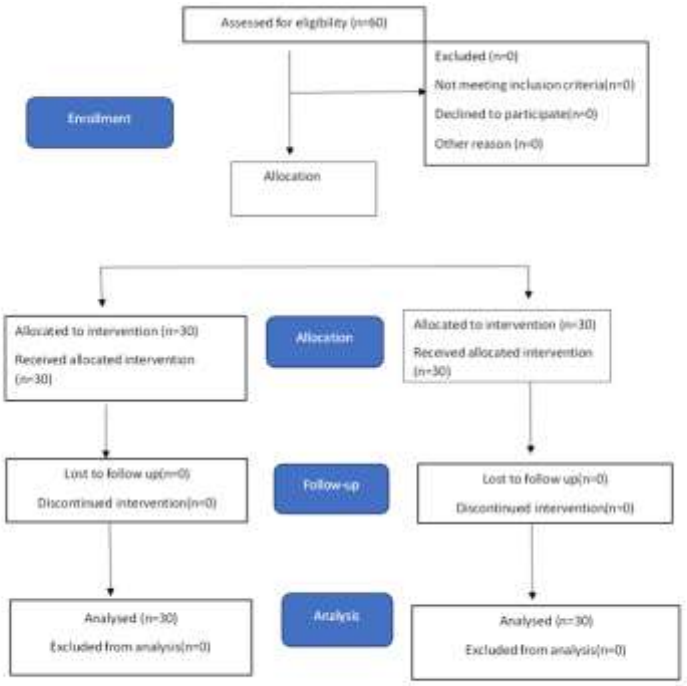
ISSN: 0975-8585

Table 5: Comparison of the number of rescue analgesics between the two groups

Number of Rescue Analgesics in post-operative 24 hrs		Groups		Total	Chi Square
		Group LBD	Group BD		
0	**Frequency**	10	6	16	13.24 P<0.05
	%	33.3%	20.0%	26.7%	
1	**Frequency**	17	8	25	
	%	56.7%	26.7%	41.7%	
2	**Frequency**	3	15	18	
	%	10.0%	50.0%	30.0%	
3	**Frequency**	0	1	1	
	%	0.0%	3.3%	1.7%	
Total	**Frequency**	30	30	60	
	%	100.0%	100.0%	100.0%	

*$P \leq 0.05$ (statistically significant)

Figure 1: Consort Diagram



DISCUSSION

The advantages of spinal anaesthesia over other regional anaesthetic techniques for infraumbilical surgeries include effective sensory and motor blockade, resulting in improved surgical conditions and patient comfort, it facilitates sufficient muscle relaxation, it does not require airway manipulation, avoiding polypharmacy and offering better postoperative analgesia [1,2]. Levobupivacaine, a racemic mixture of bupivacaine, was developed to decrease the incidence of cardio-neurotoxicity and provide greater hemodynamic stability [3,4]. Generally, adjuvants are mainly added to local anaesthetics to lower the dosage and further potentiate their effect. The alpha 2 agonists like clonidine and dexmedetomidine are increasingly being employed. Dexmedetomidine is proposed to be a favourable local anaesthetic adjuvant among alpha 2 agonists by prolonging the duration of spinal blockade and increasing the duration of analgesia by maintaining better hemodynamic stability [5-7]. The demographic parameters and hemodynamic parameters were comparable in this study.

In this study, we used dexmedetomidine of 5 micrograms as an additive with the concentration of 0.5% hyperbaric levobupivacaine and 0.5% hyperbaric bupivacaine with the same total volume of

totally in both groups. A similar study by Rai et al[8] inferred that the dose of 5 micrograms as an additive has a maximal beneficial effect compared to 3 micrograms of dexmedetomidine in spinal anaesthesia with an acceptable safety profile [8]. We observed from this study, on comparing the mean time of onset of sensory block and motor block, the onset of sensory blockade was found to be significantly earlier in group BD (3.16 ± 0.87 minutes; P < 0.01) than the group LBD (7.93 ± 0.98 minutes; P < 0.01) and the onset time of motor block was significantly earlier in group BD (4.80 ± 1.06 minutes; P < 0.01) than group LBD (10.57 ± 2.06 minutes; P < 0.01). The result of the other randomised study by Phaneendra et al [9] was similar, that the mean onset time of sensory block in the bupivacaine with dexmedetomidine group was earlier when compared to the levobupivacaine with dexmedetomidine group, with P value of <0.001 and in another study by Patro et al[12], similar results were observed. Likewise, in this study, the onset time of motor blockade in group BD (4.80 ± 1.06 minutes; P< 0.01) was significantly earlier when compared to group LBD (10.57 ± 2.06 minutes; P < 0.01). The results of this study were coherent in terms of the onset time of motor block, with the study by Deepa et al [10] demonstrating the mean onset time of motor block in the buprenorphine group 75 micrograms with 0.5% levobupivacaine was earlier compared to the 5 micrograms dexmedetomidine group. The mean duration of sensory blockade in this study was found to be significantly longer in group LBD (291±29.53 minutes; P<0.01) when compared to group BD (199.50±12.8 minutes; P<0.01). Correspondingly, the group LBD (278.6 ± 32.9 minutes; P<0.01) exhibited prolonged duration of motor blockade when compared to group BD (190.17±12.21 minutes; P<0.01), and the differences were considered to be statistically significant. A similar study by Kataria et al [11] concluded that the levobupivacaine with dexmedetomidine group 3mcg exhibited a prolonged duration of sensory and motor blockade than the isobaric levobupivacaine group. Another comparable study by Neepa S patel et al [15] randomised 44 patients undergoing vaginal hysterectomy, they added 10 micrograms of dexmedetomidine to either 0.5% levobupivacaine (LD) or 0.5% bupivacaine (BD), their study concluded that the duration of sensory and motor blockade was longer with the group LD (162.33± 10.56 and 310±32.9) compared to group BD (145.5± 11.01 and 168.9± 24.2) respectively. In contrast to their study, this study concluded that adding 5 micrograms of dexmedetomidine to 0.5% levobupivacaine offered a considerably longer duration of sensory and motor blockade. The other study by Gupta et al [14] observed that adding adjuvants like dexmedetomidine and fentanyl to 0.5% bupivacaine concluded that the dexmedetomidine group (476± 23 minutes and 421± 21minutes) had a prolonged duration of sensory and motor blockade than the fentanyl group 187± 12 minutes and 149±18 minutes, respectively. The pain scores at various time points were compared between the two groups in this study. Group LBD shows less significant VAS scores of (0.90 ± 0.66) at 6 hours and (0.53 ± 0.57) at 12 hours than the group BD with VAS scores of (1.37± 0.55) at 6 hours and (0.93 ±0.69) at 12 hours, respectively. Other studies by Patro et al [12] randomized 60 patients; their study patients had better pain relief in the bupivacaine with dexmedetomidine group in the postoperative period. From this study, the duration of analgesia in group LBD (305.00 ± 29.595 minutes) was higher than in group BD (207.33±11.275 minutes). Hence, the results imply that group LBD showed significantly increased duration of analgesia (P<0.01) when compared to group BD. Another similar study by Hadiya et al [13], their result showed duration of analgesia was prolonged in the dexmedetomidine group. On comparing the number of rescue analgesics required in the study groups. The Majority in group LBD (56.7%) required one rescue analgesic in 24 hours, whereas the majority of the patients in Group BD (50%) required two analgesics in 24 hours in this study. In similar studies, Patro et al[12], rescue medication was given for the bupivacaine group when compared to the bupivacaine with dexmedetomidine group

Limitations

The study is primarily concerned with short-term results, healing during the hospital stay, and rapid postoperative pain alleviation. The sedative property of dexmedetomidine was not evaluated. The need for analgesia varied among different surgeries due to early ambulation in lower abdominal surgeries rather than in orthopaedic surgeries. Hence, the number of analgesia required due to visceral pain and somatic pain is not taken into account. An alternate type of needle, the size of the needle, and other approaches could potentially affect outcomes at other departments or institutions.

CONCLUSION

This study concluded that intrathecally adding dexmedetomidine to levobupivacaine was found to be more effective with regard to prolongation of sensory and motor blockade, duration of analgesia, by maintaining equipotent hemodynamic stability. It offered better patient satisfaction by a significant reduction in the number of rescue analgesics postoperatively. Although other parameters were superior,

the time of onset of sensory and motor blockade was earlier in the bupivacaine with dexmedetomidine group.

REFERENCES

[1] Casey WF. Spinal anaesthesia practical guide. Update Anaesth 2000;12:1-7.

[2] Bardsley H et al. A comparison of the cardiovascular effects of levobupivacaine and rac□ rac-bupivacaine following intravenous administration to healthy volunteers. British Journal Of Clinical Pharmacology 1998;46(3):245-9.

[3] Gristwood R et al. Reduced cardiotoxicity of levobupivacaine compared with racemic bupivacaine (Marcaine): new clinical evidence. Exp Opin Invest Drugs 1994 ;3:1209-12.

[4] Bajwa SJ and Kaur J. Clinical profile of levobupivacaine in regional anesthesia: A systematic review. Journal of Anaesthesiology Clinical Pharmacology 2013;29(4):530-9.

[5] Swain A et al. Adjuvants to local anesthetics: Current understanding and future trends. World journal of clinical cases. 2017 Aug 8;5(8):307.

[6] Jaakola ML et al. The analgesic action of dexmedetomidine—a novel α2-adrenoceptor agonist in healthy volunteers. Pain 1991;46(3):281-5.

[7] Afshani N. Clinical application of dexmedetomidine. Southern African Journal of Anaesthesia and Analgesia 2010;16(3):50-6.

[8] Rai A and Bhutia MP. Dexmedetomidine as an additive to spinal anaesthesia in orthopaedic patients undergoing lower limb surgeries: A randomized clinical trial comparing two different doses of dexmedetomidine. Journal Of Clinical And Diagnostic Research 2017;11(4):UC09.

[9] Babu et al. A Comparative Study Between 0.5% Levobupivacaine with Dexmedetomidine and 0.5% Bupivacaine with Dexmedetomidine In Subarachnoid Block, International Journal of Scientific Research 2019, 8(6),68-69.

[10] Deepa T et al. Comparison of dexmedetomidine v/s buprenorphine as an adjuvant to levobupivacaine in spinal anesthesia for infraumbilical surgeries. IJMA 2018;1(2):37- 41.

[11] Kataria AP et al. Comparison of levobupivacaine and levobupivacaine with dexmedetomidine in infraumbilical surgeries under spinal anesthesia. Anesthesia Essays and Research 2018 ;12(1):251-5.

[12] Patro SS et al. Evaluation of dexmedetomidine as an adjuvant to intrathecal bupivacaine in infraumbilical surgeries. Journal of Clinical and Diagnostic Research 2016;10(3): UC13.

[13] Hadiya J et al. Effect of adding dexmedetomidine versus fentanyl to intrathecal hyperbaric bupivacaine on spinal block for infraumbilical elective surgeries. Journal of Population Therapeutics and Clinical Pharmacology 2023;30(19):1683-91.

[14] Gupta R et al. A comparative study of intrathecal dexmedetomidine and fentanyl as adjuvants to bupivacaine. Journal of Anaesthesiology Clinical Pharmacology 2011 ;27(3):339-43.

[15] Neepa S Patel et al. A comparative evaluation of intrathecal bupivacaine and dexmedetomidine versus intrathecal levobupivacaine and dexmedetomidine in vaginal hysterectomy. MedPulse International Journal of Anesthesiology 2021; 17(2): 39-43