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Original Research

A Prospective Randomised Double Blind Study to Evaluate Effects of Intrathecal Levobupivacaine with Dexmedetomidine Versus Levobupivacaine in Patients Undergoing Abdominal Hysterectomies

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ABSTRACT
Background: This study was planned to compare the block characteristics, intraoperative haemodynamic changes,duration of postoperative analgesia and perioperative complications when dexmedetomidine is used as an adjuvant to intrathecal hyperbaric levobupivacaine.**Methods:**This was randomized comparative study double blind on 104 female patients who underwent hysterectomy. Hemodynamic parameters, onset and duration of sensory and motor block,postoperative analgesia, VAS score and analgesic requirementwere noted the findings were compared between 2groups.**Results:** The time of onset of sensory block, motor block , duration of sensory and motor block were significantly higher in dexmedetomidine-levobupivacaine group compared to levobupivacaine alone group. Postoperative VAS scorewas lower and analgesic requirement was lesser in dexmedetomidine- levobupivacaine group. Incidence of adverse effects was simlar in both groups.**Conclusion:** Addition of dexmedetomidine to levobupivacaine for spinal anaesthesia shortens sensory and motor block onset time and prolongs block duration, reduces VAS score and analgesia requirement postoperatively without any significant adverse effects.
Keywords: Dexmedetomidine, levobupivacaine, spinal anaesthesia, postoperative analgesia.

INTRODUCTION

Spinal anaesthesia remains simple yet most effective technique for lower abdominal surgeries including abdominal hysterectomies. It has multiple advantages including rapid onset, has ease of administration and is cost effective with lesser incidence of adverse effects. However, local anaesthetics when used alone may not have longer lasting effect and patient may have varying degree of pain which may be distressing and may require early analgesic intervention. Further, few of commonly used agent like lignocaine and bupivacaine may have more adverse effects. Introduction of levobupivacaine, which has lesser incidence of cardiovascular and neurological adverse effects, has improved safety of spinal anaesthesia[1,2]. Further, addition of various adjuvants helps to increase duration of postoperative analgesia with reduction in analgesic requirement postoperatively. Amongst various adjuvants, intrathecal α2 receptor agonists dexmedetomidine with high specificity(α2/α1 1600:1) enhances postoperative analgesia. It has antinociceptive action not only for somatic pain but also for visceral pain. Further, lack of respiratory depressant effect like opioids with good hemodynamic stability makes it more favourable agent to be used intrathecally along with local anaesthetic agent for providing postoperative analgesia[3].

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Hence we aimed to evaluate efficacy of dexmedetomidine as an intrathecal adjuvant levobupivacainein patients undergoing abdominal hysterectomies.

METHODS

It was a prospective,randomised double blind study enrolling104 adult female patients, in the age group of 18-60 years of ASA physical status grade I and II undergoing elective abdominal hysterectomies.Study was conducted in tertiary care institute after obtaining institutional ethics committee approval during period of June 2022 to December 2024. This study was conducted in accordance with Good Clinical Practice and in a manner to conform to the Helsinki Declaration of 1975, as revised in 2013 concerning human rights. Well-being and safety of patients were maintained during study.

Patients were randomly allocated in two groups of 52 each using block randomisation and computer-generated sequence.Patients refusing to give consent, allergic to local anaesthetic, local site infection, bleeding diathesis were excluded.

Patient were evaluated preoperatively including detailed airway examination and investigated according to institutional protocol.Study protocol was explained to patient and written informed consent was obtained. Patient was explained about VAS scale preoperatively. A night prior to surgery, patient was given tab alprazolam 0.25 mg and tab pantoprazole 40 mg. On day of surgery, NPO status and consent was checked. An iv line was secured and RL was started. Patients were attached with standard monitors including ECG, SPO_2, NIBP, $ETCO_2$, temperature probe and baseline parameters were recorded.

Using computer generated randomization patients were randomly allocated to two groups ie group I receivingsubarachnoid block with 3.5 ml of 0.5% Hyperbaric Levobupivacaine (17.5 mg) and 0.5 ml of sterile normal saline (total 4 ml) and group II receiving 3.5 ml of 0.5% Hyperbaric Levobupivacaine (17.5 mg) with 10µg Dexmedetomidine 0.5 ml (total 4 ml). Lumbar puncture was performed under aseptic conditions, in sitting position by midline approach by using Quincke spinal needle (25G) at L3-L4 intervertebral space.Opaque sealed numbered envelopes were used to conceal randomization sequence which were opened by principal investigator just prior to administration of spinal anesthesia. A separate investigator was asked to prepare spinal drug solution who was not involved in case or study. Anesthesiologist, who was unaware of drug in syringe, performed spinal anesthesia and monitored patients perioperatively.

Continuous monitoring of hemodynamic parameters was done and readings were recorded every 0 min, 5 mins, 10 mins, 15 mins, 30 mins, 1 hour, 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 24 hours.

The onset of sensory block was tested by 'pin-prick method' using a hypodermic needle. The time of onset was taken from the time of injection of drug into subarachnoid space to loss of pinprick sensation in S1. The highest level of sensory block, duration of sensory blockade, taken as the time from onset to the time of return of pinprick sensation to S1 dermatomal area was noted.

Motor block was assessed with 'Modified Bromage Score'. The time interval between injection of drug into subarachnoid space, to the patient's inability to lift the straight extended leg was taken as onset time (Bromage grade 1). The duration of motor block was taken from time of onset to complete regression of motor block (ability to lift the extended leg) (Bromage grade 0).

Postoperatively,VAS was recorded at an interval of 2,4, 6, 8,12and 24 hours postoperatively. Duration of complete analgesia was noted and rescue analgesics were administered when VAS >4.Effective analgesia period ie time from starting the induction to 1st analgesic administration on patient demand was noted.At any point of time in postoperative period, on patients demand or VAS ≥ 4, inj tramadol 100mg IV was given as first rescue analgesic.

Side effects like sedation, nausea, vomiting, shivering, pruritus and any other complications were monitored. Hypotension (MAP< 20% from baseline) was treated using mephentermine 6mg iv and bradycardia (HR<60/min) was treated using atropine 0.6 mg iv.

The data was entered using Microsoft excel sheet and was analysed using Statistical Package for Social Sciences (SPSS) version 22.0 software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Categorical data was presented in form of frequency and proportion. As test of significance for qualitative data inform of frequency and proportion.Chi-square test was used as test of significance for qualitative data. Continuous data like VAS score was analysed using mean and standard deviation and Mann-Whitney U testA probability of $P < 0.05$ was considered statistically significant.

RESULTS

All the patients in both groups(52 each) underwent spinal anesthesia successfully and wer evaluated for results. As seen from table 1, demographic data was comparable in both groups**.**

Table 1: Comparison of Demographic parameters in Two Groups

Parameter	Group I(Mean±SD)	Group II(Mean±SD)	P value
Age (years)	47.0±6.1	46.2±5.6	0.482
Height(cm)	149.4±6.7	151.3±7.7	0.183
Weight (kg)	58.3±10.8	61.7±10.1	0.174
ASA 1: 2	32(61.5%):20(38.5%)	32(61.5%):20(38.5%)	1.00

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Duration of surgery(minutes)	114±6.7	116.1±12.5	0.375

Table 2: Comparison of onset of sensory and motor block between two groups

Parameter	Group I (Mean±SD)	Group II (Mean±SD)	P value
Sensory block	3.8±0.6	2.7±0.6	0.000
Motor block	5.6±0.6	4.0±0.6	0.000

As seen in table 2, addition of dexmedetomidine hastened the onset of sensory and motor block which resulted in earlier time to surgery compared to levobupivacine group. Further, duration of sensory blockade as well as motor blockade was significantly longer indexmedetomidine and levobupivacaine groupthan levobupivacaine alone group(Table 3). Further motor blockade intensity was better in dexmedetomidine group than levobupivacaine alone group as reportrd by surgeons. As duration of motor blockade was higher in dexmedetomidine group, ambulation was delayed in this group which may be considered as drawback as it may not suitable for day care procedures.

Table3: Comparison of duration sensory, motor block and analgesia between two groups

Parameter	GroupI (Mean±SD)	Group II(Mean±SD)	P value
Duration of sensory block (min)	**179.9±3.3**	**325.3±9.9**	**0.000**
Duration ofmotor block (min)	**150.5±3.8**	**289.3±4.1**	**0.000**
Analgesia duration (min)	**203.3±6.8**	**353.2±13.8**	**0.000**

VAS score was significantly lower in dexmedetomidine group at all intervals postoperatively(table 4) and patients experience more pain free period. Further postoperative analgesic requirement was also lesser in dexmedetomidine group(Table 5).

Table 4: Comparison of Postoperative VAS score of patients. P<0.05 significant

Postoperative time	Group I(Mean±SD)	Group II(Mean±SD)	P value
2 hours	0.0	0.0	NA
4 hours	7.3±1.4	0.9 ±0.5	0.000
6 hours	5.2±2.2	2.5±1.3	0.000
8 hours	6.6±1.3	2.8±1.2	0.000
12 hours	5.2±2.0	2.5 ±1.1	0.000
24 hours	3.4±1.0	2.9±0.6	0.011

Table 5: Comparison of Supplemental Analgesic dose requirement between two groups

Total supplemental analgesics requirement	Group I(Mean±SD)	Group II(Mean±SD)	P value
	189.4±30.3	**113.5±34.5**	**<0.001**

Nausea and vomitting was higher(Table 6) in levobupivacaine alone group than dexmedetomidine-levobupivacaine group. However, difference was not statistically significant. None of the patients in both group had shivering, pruritus, or respiratory depression. Further, patients were hemodynamically stable in both groups and few patients dropped mean heart rate below 60 bpm (15.38 % cases) in LD group as against 7.69% cases in leobupivacaine group. This was noted after 4 hours of giving spinal anesthesia. Howeevr, none of these patients required intervention using atropine. None of the patients in either group were drowsy

Table 6: Comparison of complications of two Groups

Complications	Group I	Group II	P value
Nausea	4 (7.7%)	2 (3.8%)	0.708
Vomiting	1 (1.9%)	1 (1.9%)	0.707

DISCUSSION

Spinal anaesthesia is well accepted regional technique for hysterectomy , a commonly performed gynaecological procedure.Although most patients find themselves comfortable under spinal anesthesia, 50% of patients reported pain or discomfort as shown by study conducted by Alahuhta*et al.*[4]. This pain can be taken care of by iv supplemental analgesics or conversioninto general anaesthesia. Further, increasing dose of bupivacaine may also be useful to avoid such pain. However, Pederson *et al.* reported occurrence of pain and increased incidence of side effects in one third of patients even after increasing dose of bupivacaine[5].Further, most patient of hysterectomy are elderly which may have some or other comorbidities in which higher doses of

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bupivacaine can further complicate situation. Level of sensory blockade required for hysterectomy is usually up to T6 dermatome and duration of surgery last for about one to two hours. Using higher doses may cause hypotension, myocardial depression and arrhythmias. Also postoperative analgesia remains limited when local anaesthetic agent is used alone. Addition of adjuvant like dexmedetomidine will help to reduce dose of local anaesthetic and prolong postoperative analgesiathan alone will local anaesthetic will do[6]. Hence we evaluated effect of intrathecal dexmedetomidinealong with levobupivacaine for abdominal hysterectomy.

Directly acting α2 adrenergic agonist prolongs duration of analgesia however its mechanism remains still unclear. It may be an additive or synergistic effect secondary to the different mechanisms ofaction the local anesthetics and intrathecal α2 adrenoceptor agonist. α2 adrenoceptor act by binding to presynaptic C-fibres and postsynaptic dorsal hornneurons. Analgesia is produced by inhibiting release of neurotransmitters from C fibres and postsynaptic dorsal horn neurons hyperpolarisation.α2 adrenoceptor complement action of local anaesthetic and cause profound analgesia. Motor block prolongation may be result of binding of drug to motor neurons of dorsal horn of spinal cord[7].

In present study, we evaluated dexmedetomidine efficacy in patients undergoing hysterectomies. We found differences in various anestheticparametersperticularlyonset and duration of sensory block and duration of analgesia which was better in dexmedetomidine –levobupivacaine group(LD group). Onset ofsensory block was faster in LD group 2.7±0.6 minutes compared to levobupivacaine group which was 3.8±0.6 mins and was statistically significant(p value <0.05). Stastically significant faster onset of motor block was also reported in LD 4.0±0.6 minutes compared to levobupivacine 5.6±0.6 mins alone group. Further, mean duration of sensory block in LD group was 325.3±9.9 minutes and was staistically significant and higher than levobupivacaine alone groupwhich was 179.9±3.3 minutes. Similarly,mean duration of motor blockwas significantly higher in LD group(289.3±4.1 mins) as compared tolevobupivaciane alone group(150.5±3.8 mins) (p value <0.05).

Esmaoğlu*et al.*[8]used similar drugs in patients posted for elective transurethral endoscopic surgery. They found statistically significant shorter onset time for sensory and motor block in LD group compared to levobupivacaine alone group. Further duration of sensory and motor block was also prolonged in LD group.Our finding were consistent with the results of this study. Similarly study conducted by Kataria *et al.*[9] also had similar finding in their study in LD group.

Our study, could also demonstrate statistically siginificant difference between mean duration of analgesia of both groups i.e. time from injection of drug in subarachnoid space to time of first supplemental analgesic requirement when VAS ≥ 4. This was 353.2±13.8 minutes in LD group compared to levobupivacaine alone group which was 203.3±6.8 minutes. Higher duration of analgesia also reduced postoperative analgesic consumption and was much lower in LD group(113.5±34.5 mg) compared levobupivacaine alone group (189.4±30.3 mg) and was significant statistically(p value <0.05).

SS Patro *et al.*[10] also demonstrated statistically significant difference in duration of analgesia observed between the two groups ie.dexmedetomidinegroup(333.6±20.6 minutes) and normal saline group (193.67±7.06 minutes).This also lead to decreased analgesic consumption postoperatively.

Addition of dexmedetomidine prolonged the pain free period postoperativelyand improved postoperative analgesia. Many of the studies are consistent with these findings.Kanazi*et al.*[11] added 3µg dexmedetomidine to bupivacaine in spinal block and found to have prolongessensory and motor block. Similar finding were reported by Al-Mustafa *et al.* who added 5 µg and 10 µg dexmedetomidine to spinal bupivacaine and found earlier onset of sensory and motor block with prolonged effects for same[12].

We also compared VAS score in two groups postoperatively at various time intervals as noted in table.. We noted significantly lower VAS scores in LD group compared to levobupivacaine alone group.

We could not find statistically significant difference in hemodyanmic parameters particularly syatolic, diastolic and mean arterial blood pressure in two groups. Although hemodynamics were more stable in LD group compared to levobupivacaine alone group, but difference was not statistically significant. We found drop in mean heart rate below 60 bpm in 15.38 % cases in LD group as against 7.69% cases in leobupivacaine group. This was noted after 4 hours of giving spinal anesthesia. This could be attributed to lower VAS scores in LD group. However, none of them required treatment with atropine and hence was not clinically significant.

Similar findings were reported in earlier studies conducted by SS Patro *et al.*[10] and Kataria *et al.*[9] which had more incidence of bradycardia in LD group.

Occurrence of complications were lower in Group II (5.8%) compared to Group I (9.6%) but this difference was not significant (p value 0.702). In group I, 7.7% patients had nausea, 1.9% had vomiting and in group II, 3.8% patients had nausea, 1.9% had vomiting.

CONCLUSION

Addition of 10 mcg of dexmedetomidine to 0.5% hyperbaric levobupivacaine as an intrathecal adjuvant in spinal anaesthesia significantly decrease the time of onset, prolongs the duration of both sensory and motor blockade, improves quality and duration of post

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operative analgesia with better heamodynamic stability and without significant increase in side effects as compared to levobupivacaine alone in patients undergoing elective abdominal hysterectomies.

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