A CLINICAL STUDY TO EVALUATE THE EFFECTS OF INTRATHECAL DEXMEDETOMIDINE 10 MCG ON LOW DOSE HYPERBARIC 0.5% BUPIVACAINE (5 MG) FOR SADDLE BLOCK ANAESTHESIA IN ADULT PATIENTS POSTED FOR ELECTIVE PERIANAL SURGERIES

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ABSTRACT

AIMS AND OBJECTIVES

Saddle block anaesthesia is most commonly used technique for perineal surgeries, i.e. haemorrhoids, fissure-in-ano, etc., as it is most economical and easy to administer. Spinal anaesthesia by bupivacaine may be too short for providing postoperative analgesia. Hence, various adjuvants have been used with Local anaesthetics to provide good intraoperative anaesthesia and to prolong postoperative analgesia. The aim of our study was to evaluate the effects of intrathecal administration of dexmedetomidine 10 µg on low dose bupivacaine 0.5% (5 mg), to know the onset and duration of sensory and motor blockade, the haemodynamic effects, duration of analgesia and the occurrence of side effects.

METHODOLOGY

This prospective randomized double blind study included 60 patients. Patients were randomly allocated into two groups of 30 patients each. Group D received 5 mg of 0.5% hyperbaric with dexmedetomidine 10 µg (0.5 mL) and Group N received 5 mg of 0.5% hyperbaric bupivacaine with 0.5 mL of normal saline. The onset of sensory and motor block, haemodynamic effects, duration of analgesia and occurrence of side effects were noted.

RESULTS

The mean time taken for the onset of sensory block was 6.36±1.2 min and 8.23±1.7 significantly rapid with D Group compared to group N. The total duration of analgesia (360±15 min and 210±30 min in Group D and Group N respectively, P <0.000) and time to first rescue analgesic (370.85±15 min, 230.8±15 min in Group D and Group N respectively, P <0.001) were increased significantly by addition of dexmedetomidine without significant motor block and with minimal side effects.

CONCLUSION

Dexmedetomidine added intrathecally for saddle block had favourable effects on onset of sensory and total duration of analgesia and rescue analgesia.

KEYWORDS

Spinal, Dexmedetomidine, Surgeries.

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INTRODUCTION

Saddle block anaesthesia is most commonly used technique for perineal surgeries, i.e. haemorrhoids, fissure-in-ano, etc., as it is most economical and easy to administer. Low dose local anaesthetics can limit the block level and induce rapid recovery from anaesthesia. The recommended dose for anorectal surgery is 1–1.5 mL of hyperbaric 0.5% bupivacaine or 5% lidocaine. These patients after perineal surgeries will have severe pain if only local anaesthetics are used, as the duration of action of local anaesthetics will not be prolonged to manage post-operative analgesia. Various adjuvants have been used along with local anaesthetic agents to prolong the block duration with reduced rate of adverse effects.

Alpha-2(α2) adrenergic receptor agonists like clonidine and dexmedetomidine have been the focus of interest as adjuvants to intrathecal local anaesthetics due to their sedative, analgesic, perioperative sympatholytic and haemodynamic stabilizing properties.[1]

Dexmedetomidine (DXM) is an S-enantiomer of medetomidine with a highly selective α_2 adrenergic receptor agonistic activity with a relatively high ratio of α_2/α_1 activity (1620:1) compared to clonidine (220:1).[2] Dexmedetomidine has been safely used as an adjuvant for subarachnoid block in urological, orthopaedic and lower abdominal surgical procedures. As adjuvant neuraxial administration is the appropriate route to dexmedetomidine, because the analgesic effect of α2 agonists mostly occurs at spinal level, binding to spinal cord α2 adrenergic receptor.

Though intrathecal Dexmedetomidine has been used for various surgeries as an adjuvant to local anaesthetics, its use for saddle block is not extensively studied.

The present study is designed to evaluate the effects of addition of Dexmedetomidine (10 µg) to hyperbaric

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bupivacaine 0.5% for saddle block anaesthesia in terms of onset and duration of sensory block, post-operative analgesia.

METHODOLOGY

After Institutional Ethical Committee approval and informed consent, 60 patients in the age group between 18 and 50 years belonging to ASA class I and II undergoing elective haemorrhoidectomy under saddle block were randomly allocated into two equal groups using shuffled sealed opaque envelope technique. Patients with known hypersensitivity to local anaesthetics or dexmedetomidine, subjects having any absolute contraindications for spinal anaesthesia like raised intracranial pressure, severe hypovolaemia, bleeding diathesis, local infection, patient refusal, comorbidities like diabetes, hypertension, epilepsy, morbid obesity, pregnant women were excluded from the study. All patients were pre-medicated on the night before surgery with Tablet Ranitidine 150 mg and were kept nil per oral 6 hours for solid food and 2 hours for clear fluids. On arrival to operation theatre, IV access was taken using 18G cannula on non-dominant hand.

Patients were connected to multi-parameter monitor having Electrocardiography (ECG), Non-Invasive Blood Pressure (NIBP) and arterial pulse saturation (SPO_2). Under aseptic precautions, lumbar puncture was performed at the level of L2-L3/L3-L4 through a midline approach using 25G Quincke's spinal needle and study drug was injected after confirmation of needle tip in the subarachnoid space by clear and free flow of Cerebrospinal Fluid. Patients were kept in sitting position for 5 minutes and then brought to supine posture. After 10 minutes, patients were placed in lithotomy posture.

Dexmedetomidine for intrathecal use was prepared by diluting 1 mL (containing 100 µg) to 5 mL with normal saline; 0.5 mL of this diluted solution (containing 10 µg) was taken using 1 mL insulin syringe and added to syringe containing 1 mL of 0.5% hyperbaric bupivacaine, which was given for group D patients. For Group N patients, 0.5 mL of normal saline taken in insulin syringe added to 1 mL of 0.5% hyperbaric bupivacaine. Both the test drugs were prepared by senior anaesthesiologist under sterile technique who was not involved in the study. Saddle block anaesthesia for all patients in study was given by the same anaesthesiologist who was the observer too. Thus both the observer and subjects were blinded to the study drugs.

Sensory blockade was tested using pinprick method with a blunt 27G hypodermic needle every 15 seconds till the onset of sensory blockade and thereafter at 2 mins intervals till the maximum level of sensory blockade was achieved. Time taken for sensory block to reach L1 dermatome and motor block were noted. Pain was assessed by Verbal Rating Score (VAS) at 1st, 2nd, 4th and 6th hours post-operatively, where patients were given a scale marked from 0 to 10 and were asked to mark the degree of pain experienced ranging from 'No pain' at 0 to 'Maximum pain' at 10 point. At VRS >4, Inj. diclofenac 75 mg IM was given as rescue analgesic and study ended. Duration of analgesia measured from the time of intrathecal injection to the first request of analgesia [VRS >4] was monitored. Sedation was assessed using Ramsay Sedation Score (RSS) and baseline sedation score was noted. Incidence of side effects like nausea, vomiting, hypotension, bradycardia were noted.

The statistical analysis of data was done by using Statistical Package for Social Science (SPSS) evaluation version 20. Data were expressed as either mean and standard deviation or numbers and percentages. The demographic data of the patients were studied for each of the two groups. Continuous covariates (Age, duration of surgery, height, weight) were compared using Analysis Of Variance (ANOVA). For categorical covariates (Gender, ASA class), Chi-square test was used with p-value reported at 95% confidence interval. For the time to reach L1 dermatome, Bromage, time taken to rescue analgesia ANOVA test followed by Tukey's multiple post-hoc test was used. The level of significance used was $p<0.05$.

RESULTS

The groups were comparable with respect to age, weight, height, sex distribution and operative time. The onset of sensory block was 6.36±1.2 min and 8.23±1.7 min in group D and group N respectively, $p <0.000$. All the patients achieved sensory level of at least S1 dermatome block and motor blockade of modified Bromage score 0, that is, no detectable weakness of lower limb when they were made supine after completion of 5 min after subarachnoid block; however, in 4 patients motor blockage of Bromage score 1 was noticed. There was no difference between Group D and N in the maximum level of blocks achieved (T10). In all the patients, maximum sensory level recorded at 20 min was similar to or higher than the sensory level recorded immediately post-operatively. Time for regression of sensory level to S1 (360±15 min and 210±30 min in Group D and Group N respectively, $P <0.000$) and time for first administration of analgesic (370.85±15 min, 230.8±15 min in Group D and Group N, respectively, $P <0.001$) were clinically and statistically prolonged in Group D. The duration of motor blockade noticed in four patients (180 min in Group D, which were not significant. The post-operative VAS scores were higher in Group N than in Group D after 180 min in the post-operative period. Intraoperative HR and BP were comparable between the two groups. All patients in both the groups were calm and cooperative and no undue sedation (Sedation score >3) was observed intra-operatively. The incidence of side effects was not statistically significant in both the groups.

Time of onset of sensory blockade was 6.36±1.2 min and 8.23±1.7 min with group D and C respectively.

Duration of Analgesia in Minutes	Group-D	Group-C	P value
Mean±SD	6.36±1.2	8.23±1.7	0.000

Table 1: Time of Onset of Sensory Block

There was significant difference between two groups, group D has faster onset of sensory blockade compared to Group N, $p <0.000$.

			Group D	Group C	
Analgesia	L1	Count	19	6	25
		% within Grp	63.3%	20.0%	41.7%
	S4	Count	3	4	7
		% within Grp	10.0%	13.3%	11.7%
	S3	Count	5	10	15
		% within Grp	16.7%	33.3%	25.0%
	T10	Count	3	1	4
		% within Grp	10.0%	3.3%	6.7%
	S2	Count	0	2	2
		% within Grp	0.0%	6.7%	3.3%
	S1	Count	0	7	7
		% within Grp	0.0%	23.3%	11.7%
Total		**Count**	**30**	**30**	**60**
		% within Grp	**100.0%**	**100.0%**	**100.0%**

Table 2: Maximum Levels of Sensory Blockade

Group Statistics					
	Grp.	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Dura_ analgesia	DXM	30	360	.36636	.06689
	Normal	30	210	.53738	.09811

Table 3: Duration of Analgesia

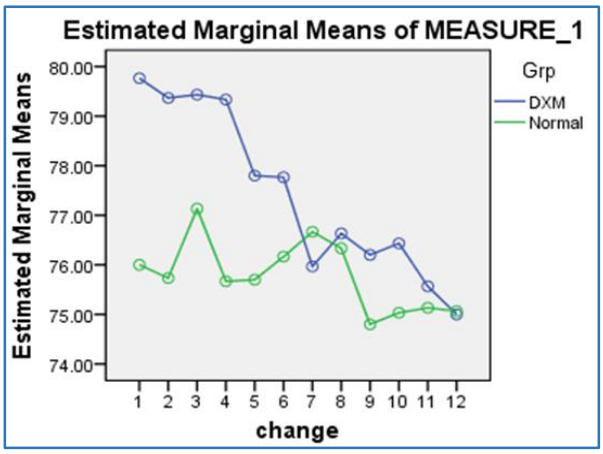
Duration of analgesia between two groups, 360±15 min and 210±30 min with group D and C respectively. There was significant difference between two groups with prolonged duration of postoperative analgesia with group D compared to group N.

Mean Heart Rate in bpm at Various Intervals in Minutes

HR in bpm at Various Intervals (Minutes)	Group N	Group D
Basal	76.0±9.823	79.8±9.280
0	75.7±9.526	79.4±8.876
2	77.1±10.868	79.4±7.713
4	75.7±9.568	79.3±8.922
6	75.7±9.952	77.8±9.193
8	76.2±10.389	77.8±8.016
10	76.7±9.824	76.0±9.349
15	76.3±9.223	76.6±10.118
20	74.8±7.627	76.2±10.138
25	75.0±7.650	76.4±9.261
30	75.1±7.519	75.6±7.342
35	75.0±6,826	75.0±5.376

Table 4: Heart Rate

There was no significant difference in the heart rate in between two groups.



SBP at Various Intervals	Group-C	Group-D
Basal	124.1±10.823	122.6±10.404
0	122.8±8.849	123.5±9.247
2	122.2±8.772	122.9±8.943
4	119.8±7.912	122.0±8.845
6	119.7±6.762	122.0±10.327
8	120.2±6.623	121.5±10.295
10	118.4±6.856	121.4±9.733
15	117.3±6.507	120.3±9.667
20	117.6±6.404	121.0±9.812
25	118.9±6.625	121.8±7.851
30	119.6±4.854	121.8±7.937
35	120.4±4.530	118.5±19.659

Table 5: Mean Systolic Blood Pressure at Various Interval in mmHg

DBP at Various Intervals	Group-C	Group-D
Basal	78.3±6.809	80.7±5.299
0	78.7±6.977	81.2±6.206
2	79.8±6.226	81.0±6.327
4	79.5±6.447	80.3±6.147
6	79.2±6.071	81.1±5.944
8	79.1±6.511	78.4±6.095
10	79.0±6.729	80.0±4.944
15	78.1±5.741	78.7±5.785
20	78.0±5.696	78.3±6.362
25	77.5±5.450	79.2±5.027
30	77.9±5.406	79.7±5.688
35	78.7±4.852	79.4±5.757

Table 6: Mean Diastolic Blood Pressure at Various Interval in mmHg

Adverse Effect	Group-N		Group-D	
	No. of pts.	Percentage	No. of pts.	Percentage
Bradycardia	0	0.0%	1	3.3%
Hypotension	0	0.0%	1	3.3%
Vomiting	0	0.0%	0	0.0%

Table 7: Adverse Effects

The heart rate, blood pressure, respiratory rate assessed at various time interval showed no statistically significant differences. Episodes of hypotension and bradycardia were treated with Inj. mephentermine 6 mg and Inj. atropine 0.3 mg respectively.

DISCUSSION

Dexmedetomidine has been used as an intrathecal adjuvant for spinal anaesthesia in various doses from 3-15 µg.[3] Various clinical studies using dexmedetomidine as an adjuvant with bupivacaine have found to be safe without producing any neurological deficit.[4,5,6] Dexmedetomidine is more specific to α2 adrenergic receptor and recently introduced in India.

Halder S et al,[7] conducted a study with different doses of intrathecal dexmedetomidine, they concluded that addition of 10 µg in comparison to 5 µg dexmedetomidine to hyperbaric bupivacaine 0.5% more efficiently hastens the onset and prolongs the duration of sensory and motor blockade and reduces the requirement of rescue analgesic in post-operative period for the patients undergoing traumatized lower limb

orthopaedic surgery. Hence, we have selected the dosage of 10 µg of dexmedetomidine with 5 mg of intrathecal bupivacaine in perianal surgeries, as it is saddle block. In our study, there was no significant difference among the groups regarding the age, height, weight and sex of the patients.

In our study, the mean time taken for the onset of the sensory block was 6.36±1.2 with group D and with group N 8.23±1.7 min respectively. Statistically, there was a highly significant shorter onset time of sensory blockage in group D as compared to group N (P<0.001). Our study compares with the study conducted by Kanazi et al.[6] who also have found statistically significant difference in the mean onset of sensory block between group D and group C 8.6±3.7 and 8.6±4.4 min respectively. Our study compares with the study conducted by AL-Mustafa MM et al,[8] Halder S et al,[7] who also have found statistically significant difference in mean onset of sensory block between dexmedetomidine group and bupivacaine group.

In our study, the mean duration of analgesia in groups 360±15 min and 210±30 min with group D and C respectively. There was significant difference between two groups with prolonged duration of post-operative analgesia with group D compared to group N. We could compare our study with Gupta M et al.[9] The duration of analgesia was 306.17±24.34, 396.5±35.60, 512.0±23.55; in group D 2.5 µg, group D 5 µg, group D 10 µg respectively. There was significantly prolongation of duration of analgesia depending on the dosage. We could also compare our study with Halder S et al.[7] The duration of analgesia was group D5 227.0±19.85 and group D10 241.8±42.10 respectively, which was prolonged with group D10, which was statistically significant.

We could also compare our study with Gupta R et al,[4] the duration of analgesia was 478.4±20.9 min with group D and 241.67±21.67 min with group R, which was statistically significant with group D, but they have used Ropivacaine instead of bupivacaine. The duration of sensory block and post-operative analgesia were prolonged, so this was comparable to the results of the study conducted by Abdelhamid SA et al,[10] Kim JE et al,[11] and Eid HEA.[12]

In our study, there was no statistical significance in motor block among the group. In our study, the mean sedation score was assessed using Ramsay sedation scale. There was no statistical significant difference among the groups. In our study, there was no statistically significant difference in the haemodynamic parameters like Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial blood pressure throughout the surgery among the groups. In our study, there was no statistically significant difference in the adverse effects like Bradycardia, Hypotension, Nausea, Vomiting throughout the procedure among the groups.

CONCLUSION

On the basis of our study, we conclude that addition of dexmedetomidine to hyperbaric bupivacaine intrathecally produces a rapid onset of sensory block and prolongs the postoperative analgesia and the time to first analgesic requirement significantly together with stable haemodynamic parameters and minimal side effects. Dexmedetomidine seems to be an attractive adjuvant to spinal bupivacaine, especially in the perianal surgeries.

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