A COMPARATIVE CLINICAL STUDY OF INTRATHECAL DEXMEDETOMIDINE 5 µg AND INTRATHECAL FENTANYL 25 µg AS AN ADJUVANT WITH 0.5% HYPERBARIC BUPIVACAINE 12.5 mg IN ELECTIVE LOWER LIMB SURGERIES

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ABSTRACT

BACKGROUND

Various adjuvants are being used with local anaesthetics intrathecally for prolongation of intraoperative and postoperative analgesia. Dexmedetomidine, the highly selective alpha-2 adrenergic agonist is a new neuraxial adjuvant gaining popularity. Fentanyl is commonly used as an opioid adjuvant to local anaesthetic for spinal anaesthesia.

AIM

The purpose of this study was to compare the onset, duration of sensory and motor block, haemodynamic effects, postoperative analgesia and adverse effects of dexmedetomidine and fentanyl used intrathecally with hyperbaric 0.5% bupivacaine for spinal anaesthesia.

METHODOLOGY

The study was conducted in prospective, double-blind manner. It included 90 American Society of Anaesthesiology (ASA) class I and II patients undergoing lower limb surgery under spinal anaesthesia. The patients were randomly allocated into three groups (30 patients each). Group C received 12.5 mg hyperbaric bupivacaine (2.5 mL) with normal saline (0. 5mL), group F received 12.5 mg bupivacaine (2.5 mL) with 25 µg fentanyl (0.5 mL) and group D received 12.5 mg bupivacaine (2.5 mL) plus 5 µg dexmedetomidine (0.5 mL). The onset time to reach peak sensory and motor level, the regression time of sensory and motor block, haemodynamic changes and side effects were studied.

RESULTS

Patients in Group D had significantly longer duration of sensory and motor block than patients in Group C and F. The mean time of two segment sensory block regression was 95.8±21 min in Group C, 130.5±17 in Group D, 131±22 in Group F (P<0.0001). The duration of motor block was 226±24.1, 626.5±48.5, 391.5±30.0 in Group C, D, and F respectively (P <0.0001). The onset time to reach maximum level of sensory block and modified Bromage 3 motor block were not significantly different between the groups. Dexmedetomidine group showed significantly less and delayed requirement of rescue analgesic.

CONCLUSION

Intrathecal dexmedetomidine is associated with prolonged motor and sensory block, haemodynamic stability and reduced demand of rescue analgesics as compared to fentanyl or lone bupivacaine.

KEYWORDS

Dexmedetomidine, Fentanyl, Bupivacaine Heavy, Spinal.

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INTRODUCTION

Subarachnoid blockade is the most commonly used regional anaesthetic technique for lower limb surgery. Various adjuvants are being used with local anaesthetics for prolongation of intraoperative and postoperative analgesia.[1]

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Adjuvants such as Morphine, Fentanyl, Clonidine and Dexmedetomidine have been used to supplement intrathecal local anaesthetics providing possible advantages, such as delayed onset of pain and reduced analgesic requirements.[2]

Dexmedetomidine, a highly selective α2 adrenergic agonist has evolved for use in critical care setting. It is also emerging as a valuable adjunct to regional anaesthesia and analgesia, where gradually evolving studies can build the evidence for its safe use in central neuraxial blocks.

Based on the earlier human studies, it is hypothesized that intrathecal 5 µg Dexmedetomidine would produce more postoperative analgesic effects with hyperbaric bupivacaine in spinal anaesthesia with minimal side effects.

Fentanyl is commonly used as an opioid adjuvant to local anaesthetic for spinal anaesthesia in our institution. A study is required to compare the traditionally used Fentanyl with

recently introduced Dexmedetomidine as adjuvant to Bupivacaine intrathecal anaesthesia.

MATERIALS AND METHODOLOGY

After approval from Institutional Ethical Committee clearance, informed written consent of 90 patients aged between 30-60 years belonging to ASA class I and class II without any co-morbid conditions posted for elective lower limb surgeries.

This study population was randomly selected based on the closed sealed opaque envelop technique into

- Group-B – 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine with 0.5 mL normal saline.
- Group-D – 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine with 5 µg of Dexmedetomidine in (0.5 mL normal saline).
- Group-F – 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine with 25 µg of Fentanyl in (0.5 mL normal saline).

The Exclusion Criteria Includes

1. Any co-morbid conditions like diabetes mellitus, asthma, hypertension, cardiac disease, haematological diseases, etc.
2. Any allergy to local anaesthetics.
3. Patients posted for emergency surgeries.
4. Patients with body mass index more than 28 kg/m^2.
5. Patients having absolute contraindication for spinal anaesthesia.

All spinal blocks were given by the same anaesthesiologist who also was the observer.

Hence, the patient and the observer were blinded for the study drug.

Patients were kept nil per oral for solids 6 hours and clear fluids 2 hours before surgery.

Patients were pre-medicated on the night before surgery with the tablet Ranitidine 150 mg and tablet Alprazolam 0.5 mg.

Patients were pre-medicated just before surgery after obtaining IV line with injection Ondansetron 4 mg. Patients were preloaded with Ringer lactate 500 mL (10 mL/kg bodyweight) half an hour before anaesthesia. Patients were connected to multi-channel monitor (Starplus Larsen and Toubro Ltd., India) for monitoring Pulse Rate (PR), Arterial Oxygen Saturation (SpO2), Electrocardiograph (ECG), Non-Invasive Blood Pressure (NIBP), Mean Arterial Blood Pressure (MAP). In a sitting position under aseptic precautions, subarachnoid block was performed at L2-L3, L3-L4 interspace through a midline approach using 25-G Quincke's spinal needle after confirming the clear and free flow of CSF and the study drug was injected into the subarachnoid space. Patients were made to lie down in supine posture, immediately supplementary oxygen was given.

The following Parameters were noted

1. Onset of sensory blockade and motor blockade.
2. Maximum level of sensory blockade attained and the time taken for the same.
3. Time for the two segment sensory regression.
4. Maximum level of motor blockade attained and the time taken for the same.
5. Total duration of the sensory blockade and motor blockade.
6. Total duration of analgesia.

The parameters were recorded every 30 seconds for first two minutes, every minute for next 5 minutes and every 5 minutes for next 15 minutes and every 10 minutes for the next 30 minutes and every 15 minutes till the end of the surgery and thereafter every 30 minutes until sensory blockade is resolved. The motor block was assessed according to modified Bromage scale.

Sedation was assessed by modified Ramsay sedation score at the end of the surgery. In the postoperative period, patients were monitored for the postoperative pain by VAS scale (0-10) initially every hour for 2 hours, then every 2 hours for the next 8 hours, then every 4 hours till 24 hours which was explained to the patients preoperatively. When the VAS was >4 patients were given rescue analgesia with Injection Diclofenac 75 mg intramuscularly.

Onset of Motor Blockade

Defined as the time required for the complete injection of the drug till the patient developed Bromage-1 quality of motor block.

Quality of the motor blockade will be assessed by modified Bromage scale.

- Bromage 0- No motor block.
- Bromage 1- Inability to raise the extended leg, able to move knee and feet.
- Bromage 2- Inability to raise extended leg and move knee, able to move feet.
- Bromage 3- Complete motor block of lower limb.

Time taken for the maximum motor blockade is defined as the time taken from the injection of test drug to the maximum motor blockade attained (Bromage 3).

Duration of motor blockade is defined as the time taken from the time of injection of the test drug to till the patient attains complete recovery.

Duration of analgesia is defined as the time taken from the time of injection of the test drug till the patient requests rescue analgesia in post-operative period.

Duration of the sensory blockade is defined as the time taken from the time of injection of test drug till the patients feel the sensation at S1 dermatome.

Post-operative Sedation Scoring was done as per Ramsay Sedation Scale

1= Anxious and agitated.
2= Cooperative and tranquil.
3= Drowsy but responds to commands.
4= Asleep but responds to tactile stimulation.
5= Asleep and no response.

Hypotension

Is defined as reduction in the systolic blood pressure of more than 30% below the baseline or fall in systolic blood pressure less than 90 mmHg and was treated with increased IV fluids and Injection mephentermine 6 mg IV in incremental doses.

Bradycardia

Is defined as heart rate of less than 60 beats per minute and was treated with Injection Atropine 0.6 mg IV.

Desaturation
SpO_2<92% in room air.

Hypoventilation
Respiratory rate less than 10.

Adverse Effects
Like nausea, vomiting, shivering, itching, respiratory depression and hypotension were recorded.

THE RESULTS OF THE STUDY WERE STATISTICALLY ANALYSED BETWEEN THE GROUPS

Purposive Sampling was done by Using Formula,

S= z2pq/d2 where z is constant, p is prevalence, q is (1-p) and d is constant.

In this study considering hospital prevalence of 4% and confidence interval of 95%, z will be 1.96 and d will be 0.05 and applying this formula, sample size was 90 patients (30 patients in each group). The results obtained from the above study was analysed for statistical significance (p) using statistical parameters like mean, standard deviation, percentage, etc. The significance level was determined by using descriptive statistics, t-test – paired/independent samples, repeated measure ANOVA and contingency coefficient analysis using SPSS for windows (version 20.0).

Crosstabs (Contingency Table Analysis)
The Crosstabs procedure forms two-way and multi-way tables and provides a variety of tests and measures of association for two-way tables. The structure of the table and whether categories are ordered determine what test or measure to use.

Independent Samples 't' Test
The Independent - Samples "t" test procedure compares means for two groups of cases. Ideally, for this test the subjects should be randomly assigned to two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors.

Chi-Square Test
Chi-square test (χ^2 test) is a statistical test of significance for categorical variables. This test is used to test the statistical significance of the association between two categorical variables when the sample sizes are large and independent. When the sample sizes are small, i.e. if the expected frequencies are less than 5, Fisher's exact test will be used.

Repeated Measures ANOVA
GLM repeated measures analyses groups of related dependent variables that represent different measurements of the same attribute. This dialog box lets you define one or more within-subjects factors for use in GLM repeated measures. Note that the order in which you specify within-subjects factors is important. Each factor constitutes a level within the previous factor. All the statistical calculations were done through SPSS for windows (Version 20.0).

T-Te: Control vs Dexmedetomidine

Independent Samples Test				
	t-Test for Equality of Means			
	t	**df**	**Sig. (2-Tailed)**	**Mean Difference**
HR Basal	1.353	58	.181	4.90000
HR_0	1.234	58	.222	5.33333
HR_2	1.021	58	.311	3.56667
HR_4	.424	58	.673	1.30000
HR_6	1.173	58	.246	4.16667
HR_8	1.643	58	.106	5.06667
HR_10	1.149	58	.255	3.90000
HR_15	1.337	58	.186	4.23333
HR_20	2.179	58	.033	5.86667
HR_25	2.831	58	.006	6.60000
HR_30	2.346	58	.022	5.86667
HR_45	3.830	58	.000	11.10000
HR_60	2.781	58	.007	7.20000
HR_75	2.871	58	.006	6.60000
HR_90	2.309	58	.025	5.86667
HR_105	2.352	58	.022	5.33333
HR_120	3.087	58	.003	7.46667
SBP Basal	.688	58	.494	2.23333
SBP_0	1.354	58	.181	4.23333
SBP_2	-.745	58	.459	-5.16667
SBP_4	-.473	58	.638	-3.38667
SBP_6	2.106	58	.040	8.63333
SBP_8	2.442	58	.018	8.86667
SBP_10	1.101	58	.276	4.30000
SBP_15	1.979	58	.053	7.86667
SBP_20	2.968	58	.004	10.76667
SBP_25	3.072	58	.003	10.23333
SBP_30	2.928	58	.005	11.26667
SBP_45	2.934	58	.005	10.76667
SBP_60	2.706	58	.009	8.46667
SBP_75	2.221	58	.030	6.30000
SBP_90	2.740	58	.008	7.96667
SBP_105	2.801	58	.007	8.66667
SBP_120	2.739	58	.008	8.43333
DBP Basal	.113	58	.911	.26667
DBP_0	1.061	58	.293	2.13333
DBP_2	2.185	58	.033	4.53333
DBP_4	1.335	58	.187	2.83333
DBP_6	1.817	58	.074	5.00000
DBP_8	2.319	58	.024	6.33333
DBP_10	.666	58	.508	2.00000
DBP_15	1.113	58	.270	2.50000
DBP_20	3.154	58	.003	6.23333
DBP_25	2.669	58	.010	5.36667
DBP_30	2.067	58	.043	4.90000
DBP_45	2.239	58	.029	5.33333
DBP_60	2.935	58	.005	5.00000
DBP_75	1.964	58	.054	3.36667
DBP_90	2.454	58	.017	3.73333
DBP_105	1.417	58	.162	2.56667
DBP_120	1.627	58	.109	2.26667
MAP Basal	1.001	58	.321	2.56667
MAP_0	2.055	58	.044	4.46667
MAP_2	2.830	58	.006	6.40000
MAP_4	1.678	58	.099	4.13333
MAP_6	2.221	58	.030	6.90000
MAP_8	2.826	58	.006	7.83333
MAP_10	.969	58	.337	3.16667
MAP_15	2.018	58	.048	5.83333
MAP_20	3.110	58	.003	8.10000
MAP_25	3.360	58	.001	8.53333
MAP_30	2.887	58	.005	6.86667
MAP_45	3.018	58	.004	8.86667
MAP_60	3.054	58	.003	7.03333
MAP_75	2.472	58	.016	5.16667
MAP_90	2.934	58	.005	5.93333
MAP_105	1.717	58	.091	3.86667
MAP_120	2.848	58	.006	5.20000

Table 1

T-Test

Independent Samples Test				
	t-Test for Equality of Means			
	t	df	Sig. (2-Tailed)	Mean Difference
Sen_para TOSB	-1.680	58	.098	-.20000
TOMLSB	-2.483	58	.016	-.53333
TTSSB	-6.922	58	.000	-34.66667
TCSR	-41.797	58	.000	-398.33333
TDA	-40.476	58	.000	-400.50000
TRA	-40.725	58	.000	-416.50000
TOMB	-.918	58	.362	-.13333
TDMB	-22.509	58	.000	-276.00000

Table 2

Notes		
Output Created		21-APR-2016 08:10:08
Comments		
Input	Data	C:\Users\user\Desktop\med \Dr Prathibha 3grp.sav
	Active Dataset	DataSet 1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	60
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics for each table are based on all the cases with valid data in the specified range(s) for all variables in each table.
Syntax		CROSSTABS /TABLES=MLSB Bradycardia Hypotension BY Grp /FORMAT=AVALUE TABLES /STATISTICS=PHI /CELLS=COUNT COLUMN /COUNT ROUND CELL
Resources	Processor Time	00:00:00.00
	Elapsed Time	00:00:00.00
	Dimensions Requested	2
	Cells Available	174762

Table 3

Maximum Level Sensory Block * Group

Crosstab					
			Grp		Total
			Cont	Dexem	
MLSB	T6	Count	9	8	17
		% within Grp	30.0%	26.7%	28.3%
	T8	Count	7	11	18
		% within Grp	23.3%	36.7%	30.0%
	T10	Count	12	11	23
		% within Grp	40.0%	36.7%	38.3%
	T12	Count	2	0	2
		% within Grp	6.7%	0.0%	3.3%
Total		**Count**	**30**	**30**	**60**
		% within Grp	**100.0%**	**100.0%**	**100.0%**

Table 4

Bradycardia Group

Crosstab					
			Grp		Total
			Cont	Dexem	
Bradycardia	Prs	Count	2	1	3
		% within Grp	6.7%	3.3%	5.0%
	Abs	Count	28	29	57
		% within Grp	93.3%	96.7%	95.0%
Total		**Count**	**30**	**30**	**60**
		% within Grp	**100.0%**	**100.0%**	**100.0%**

Table 5

Hypotension Group

Crosstab					
			Grp		Total
			Cont	Dexem	
Hypotension	Prs	Count	6	9	15
		% within Grp	20.0%	30.0%	25.0%
	Abs	Count	24	21	45
		% within Grp	80.0%	70.0%	75.0%
Total		**Count**	**30**	**30**	**60**
		% within Grp	**100.0%**	**100.0%**	**100.0%**

Table 6

T-Test: Control vs Fentanyl

t- Test for Equality of Means				
t	df	Sig. (2-Tailed)	Mean Difference	
HR Basal	-1.083	58	.283	-5.66667
HR_0	-.577	58	.566	-3.16667
HR_2	-.979	58	.332	-5.10000
HR_4	-.919	58	.362	-4.13333
HR_6	-1.029	58	.308	-5.00000
HR_8	-.965	58	.338	-4.60000
HR_10	-.746	58	.459	-3.83333
HR_15	-1.022	58	.311	-4.93333
HR_20	-.538	58	.592	-2.36667
HR_25	.176	58	.861	.73333
HR_30	.589	58	.558	2.36667
HR_45	1.299	58	.199	5.40000
HR_60	.287	58	.775	1.16667
HR_75	.916	58	.363	3.10000
HR_90	.285	58	.776	1.00000
HR_105	.292	58	.771	1.06667
HR_120	.037	58	.970	.13333
SBP Basal	-2.758	58	.008	-9.90000
SBP_0	-2.677	58	.010	-8.43333
SBP_2	-2.082	58	.042	-14.36667
SBP_4	-1.706	58	.093	-12.28667
SBP_6	-.898	58	.373	-3.50000
SBP_8	-.218	58	.828	-.76667
SBP_10	-.253	58	.801	-1.03333
SBP_15	.129	58	.898	.50000

SBP_20	1.006	58	.319	3.53333
SBP_25	.651	58	.517	2.33333
SBP_30	.073	58	.942	.26667
SBP_45	.303	58	.763	1.10000
SBP_60	.341	58	.734	1.10000
SBP_75	-.086	58	.932	-.26667
SBP_90	.078	58	.938	.23333
SBP_105	.042	58	.967	.13333
SBP_120	.331	58	.742	1.13333
DBP Basal	-2.430	58	.018	-6.40000
DBP_0	.199	58	.843	.80000
DBP_2	-.962	58	.340	-2.56667
DBP_4	-.745	58	.459	-1.76667
DBP_6	-1.726	58	.090	-5.23333
DBP_8	-.628	58	.533	-1.76667
DBP_10	-2.078	58	.042	-6.33333
DBP_15	-1.284	58	.204	-3.33333
DBP_20	-.280	58	.781	-.66667
DBP_25	-.382	58	.704	-.96667
DBP_30	-.652	58	.517	-1.86667
DBP_45	-1.019	58	.312	-2.60000
DBP_60	-1.646	58	.105	-3.83333
DBP_75	-1.774	58	.081	-4.20000
DBP_90	-1.134	58	.261	-2.30000
DBP_105	-.464	58	.644	-.90000
DBP_120	-.506	58	.615	-.83333
MAP Basal	-2.672	58	.010	-7.83333
MAP_0	-1.673	58	.100	-3.90000
MAP_2	-.873	58	.386	-2.23333
MAP_4	-.805	58	.424	-2.13333
MAP_6	-1.392	58	.169	-4.40000
MAP_8	-.412	58	.682	-1.13333
MAP_10	-1.475	58	.146	-4.90000
MAP_15	-.532	58	.597	-1.60000
MAP_20	.146	58	.884	.40000
MAP_25	.242	58	.810	.70000
MAP_30	-.403	58	.688	-1.10000
MAP_45	-.022	58	.982	-.06667
MAP_60	-1.000	58	.321	-2.73333
MAP_75	1.233	58	.223	5.70000
MAP_90	-.771	58	.444	-1.80000
MAP_105	-.057	58	.954	-.13333
MAP_120	.170	58	.865	.36667

Table 7

RESULTS

	Group C (n=30)	Group D (n=30)	Group F (n=30)	p value
Age(Years)	37.6±12.7	35.7±11.8	35.7±11.8	0.73
Weight(Kg)	61.8±7.8	62.1±6.9	62.1±6.9	0.99
Height(cms)	164.5±7.2	165±8.8	165±8.8	0.96
SEX (M:F)	21:9	19:11	19:11	0.821

Table 8: Demographic Data, Values are the Mean±Standard deviation M=Male, F=Female, C=Control, D=Dexmedetomidine, F=Fentanyl

Variable (min)	Group C	Group D	Group F	P value
Time of onset of sensory block	2.03±0.413	2.23±0.504	2.10±0.607	0.314
Time of onset of motor block	2.2±0.504	2.3±0.614	2.2±0.406	0.419
Time to reach maximum level of sensory block (T_6)	4.3±0.844	4.8±0.819	5.4±1.357	0.000
Time of rescue analgesia	235.5±25.675	652±49.785	394±28.987	0.000
Time for sensory regression by two segments	95.8±21.33	130.5±17.238	131.5±22.748	0.000
Duration of sensory block	226±24.154	626.5±48.515	391.5±30.854	0.000
Duration of motor block	158±20.744	434±63.874	292±24.835	0.000

Table 9: Characteristics of Spinal Block

Data shown are shown in mean±standard deviation.

Adverse Effect	Group-C		Group-D		Group-F		
	No. of Pts	Percentage	No. of Pts	Percentage	No. of Pts	Percentage	P value
Bradycardia	2	6.7%	1	3.3%	0	0.0%	0.355
Hypotension	6	20.0%	9	30.0%	1	3.3%	0.024
Vomiting	0	0%	0	0%	0	0.0%	0.006
Pruritus	0	0%	0	0%	0	0%	0.006
Hypoventilation	0	0%	0	0%	0	0%	0.006
Desaturation	0	0%	0	0%	0	0%	0.006

Table 10: Adverse Effects

NS- Not Statistically Significant

In our study there was no statistically significant difference in the adverse effects except hypotension throughout the procedure when group D and group F were compared with group C and there was no statistically significant difference when group D was compared with group F. There were 6 patients in group C, 9 patients in group D and 1 patient in group F developed hypotension which was managed with injection mephentermine 6 mg intravenously in incremental dosage.

DISCUSSION

Hypothesis Done Before the Study

We hypothesised that Dexmedetomidine when added as an adjuvant to 0.5% hyperbaric Bupivacaine intrathecally would produce a prolonged duration of sensory blockade, motor blockade and duration of analgesia when compared to Fentanyl added as an adjuvant.

Demographic Data

In our study there was no significant difference among the three groups, i.e. Control group, Dexmedetomidine group and Fentanyl group regarding the age, height and weight of the patients.

We also did not find any statistically significant difference regarding the mean duration of surgery.

In our study, the mean time taken for the onset of sensory block was 2.03±0.413, 2.23± 0.504, 2.10±0.607 min in group C, group D and group F respectively. There was no statistically significant difference in onset time of sensory blockade among the groups (p >0.314).

Our study compared with the study conducted by Mahendru V et al[3], who have also found statistically there was no significant difference in the mean onset of sensory block group BS (Bupivacaine+saline) 7.8±1.8, group BF (Bupivacaine+Fentanyl) 8.6±1.5, group BC (Bupivacaine+Clonidine) 8.3±2.8, group BD (Bupivacaine+Dexmedetomidine) 8.3±2.4 with p<0.113.

Our study also compared with SL Solanki et al[4], Al-Ghanem SM et al[5], Gupta R et al[6] and Khan AL et al[7], wherein the authors of these studies have not found any significant difference in the onset of sensory block in both Dexmedetomidine group and Fentanyl group.

In our study, subarachnoid block was given in sitting posture and then patients were positioned in supine posture soon after the completion of the subarachnoid injection.

In our study, mean time taken for maximum level of sensory blockade was 4.3±0.844, 4.8±0.819, 5.4±1.357 min in group C, group D, group F respectively (p<0.000). There was statistically significant difference among the groups. Our study compared with Singh et al[8], they have found statistically significant difference among the group C and group B. In their study, the concentration of the drug used was 0.75% Bupivacaine instead of 0.5% Bupivacaine unlike our study.

In our study, maximum level of sensory blockade was not significant statistically. Our results were comparable with Mahendru V et al[3], Al-Ghanem SM et al[5], Gupta R et al[6], Tarbeeh GA et al.[9] They have also not found statistically significant difference between dexmedetomidine and fentanyl group. In our study, mean time taken for the sensory regression by two segments 95.8±21.3, 130±17.238, 131±22.748 min in group C, group D, group F respectively. p<0.000. Statistically, there was significant increase in mean time taken for two segment sensory regression in group D in group F as compared to group C.

Statistically, there was significant increase in time taken for sensory regression in group F when compared to group D. Our study compared with the study conducted by Gupta R et al[6], the mean time taken for the sensory regression by two segments in group D 120±22.2 mins, group F 76±20.2 mins. The reason probably is the maximum level of sensory blockade in their study with Fentanyl group was T6 when compared to our study (T4). Our study also compared with Kanazi et al[10], Khan AL et al[7], Singh et al[8], studies who also found significant difference in Dexmedetomidine group and fentanyl group than control group.

In our study the mean duration of rescue analgesia 235±25.675, 652±49.785, 394±28.987 in group C, group D, group F respectively. Statistically significant difference between group D compared to group F and group C and statistically significant in group F compared to group C. Our study is compared with Solanki SL et al[4] study; in that they found group D 824±244, group C 678±178, group B 406±119 mins, which was statistically significant in group D and group C when compared to B. We also compared with Mahendru V et al[3] study; in their study they also noticed statistically significant duration of rescue analgesia in group D when compared to group F and C. We also compared our study with Gupta R et al[6]; they also found significant increase in analgesia in dexmedetomidine group.

In our study time taken for onset of motor blockade 2.2±0.50 4 min, 2.3±0.614, 2.2±0.406 in group C, group D, group F respectively; p >0.419 which was not statistically significant.

In our study, the duration of motor blockade was 158±20.744, 434±63.874, 292±24.835 mins in group C, group D, group F respectively; p <0.000. Statistically, there was significant increase in mean duration of motor blockade in Group-D and Group-F as compared to Group-C. Statistically, there was significant increase in mean duration of motor blockade in Group-D as compared to Group-F. Our study compares with the study conducted by Tarbeeh GA et al[9], who also found statistically significant difference in mean time taken for duration of motor blockade between Dexmedetomidine group and Fentanyl group compared with Bupivacaine group.

In our study, mean duration of motor blockade was prolonged in Group-D and statistically significant compared with Group-F. Our study compares with studies conducted by Al-Ghanem SM et al[5], Gupta R et al[6], Mahendru V et al[3] and Tarbeeh GA et al[9], who also have found statistically significant difference when Dexmedetomidine group was compared with Fentanyl group.

In our study, the mean duration of motor blockade was prolonged in Fentanyl group compared with Bupivacaine group. Our study compares with the study conducted by Mahendru V et al[3], who also found statistically significant difference (Bupivacaine group - 161±19 min and Fentanyl group - 196±26 min).

In our study, mean sedation score was assessed using Ramsay sedation scale. There was no statistical significant difference among the groups (p=0.155).

Our study compares with the studies conducted by Mahendru V et al[3], who also found no statistical significant difference among three 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 when Group-D and Group-F was compared with Group-C and also there is no statistical significant difference when Group-D compared with Group-F.

In our study, there was no statistically significant difference in the adverse effects throughout the procedure when Group-D and Group-F compared with group-C and also there was no statistical significant difference when Group-D was compared with Group-F.

CONCLUSION

From the present study, we conclude that both Fentanyl and Dexmedetomidine will delay the onset of sensory and motor block, prolong the time of regression by two segments,

prolong the duration of sensory block, motor block and duration of analgesia compared to bupivacaine alone.

However, Dexmedetomidine as an adjuvant produces more prolonged duration of sensory block and motor block and duration of analgesia compared to Fentanyl as an adjuvant.

Both Fentanyl and Dexmedetomidine as adjuvants do not produce significant haemodynamic changes with minimal effects on ventilation and oxygenation. They produce lesser incidence of pruritus and postoperative nausea and vomiting. Hence, it is concluded that Dexmedetomidine is better than Fentanyl as an adjuvant to 0.5% hyperbaric bupivacaine for spinal anaesthesia.

REFERENCES

1. Cousins MJ. Neural blockade in clinical anaesthesia and pain medicine. 4th edn. Philadelphia: Lippincott Williams and Wilkins 2009:p 213.
2. Corby MP, Bach AB. Transient radicular irritation (TRI) after spinal anaesthesia in day-care surgery. Acta Anaesthesiol Scand 1998;42(4):425-9.
3. Mahendru V, Tewari A, Katyal S, et al. A comparison of intrathecal dexmedetomidine, clonidine, and fentanyl as adjuvants to hyperbaric bupivacaine for lower limb surgery: a double blind controlled study. J Anaesthesiol Clin Pharmacol 2013;29(4):496-502.
4. Solanki SL, Bharti N, Batra YK, et al. The analgesic effect of intrathecal dexmedetomidine or clonidine, with bupivacaine, in trauma patients undergoing lower limb surgery: a randomised, double-blind study. Anaesth Intensive Care 2013;41(1):51-6.
5. Al-Ghanem SM, Massad IM, Al-Mustafa MM, et al. Effect of adding dexmedetomidine versus fentanyl to intrathecal bupivacaine on spinal block characteristics in gynaecological procedure: a double blind controlled study. American Journal of Applied Science 2009;6(5):882-7.
6. Gupta R, Verma R, Bogra J, et al. A comparative study of intrathecal dexmedetomidine and fentanyl as adjuvants to Bupivacaine. Journal of Anaesthesiol Clinical Pharmacolol 2011;27(3):339-43.
7. Khan AL, Singh RB, Tripathi RK, et al. A comparative study between intrathecal dexmedetomidine and fentanyl as adjuvant to intrathecal bupivacaine in lower abdominal surgeries: a randomized trial. Anaesthesia: Essays and Researches 2015;9(2):139-48.
8. Singh R, Shukla A. Randomized, controlled study to compare the effect of intrathecal clonidine and dexmedetomidine on sensory analgesia and motor block of hyperbaric bupivacaine. Indian Journal of Fundamental and Applied Life Sciences 2012;2(4):24-33.
9. Tarbeeh GA, Mohamed AA. Effect of intrathecal bupivacaine-fentanyl versus bupivacaine dexmedetomidine in diabetic patients. Egyptian Journal of Anaesthesia 2013;29(1):13-8.
10. Kanazi GE, Aouad MT, Jabbour-Khoury SI, et al. Effect of low-dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block. Acta Anaesthesiol Scand 2006;50(2):222-7.