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A study to evaluate the effect of low dose Intrathecal dexmedetomidine as adjuvant to low dose bupivacaine (H) Spinal Anaesthesia in elderly patients undergoing Infraumbilical Surgery

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Abstract

Background: Elderly patients pose a serious challenge to anaesthesia not only because of associated co-morbidities but also due to physiological changes during aging. Therefore lower doses of local anesthetics along with Intrathecal α_2 -adrenoceptor agonists have been shown to decrease the required doses of local anesthetics and are devoid of major side effects. Hence this study evaluates spinal anaesthesia characteristics in elderly patients.

Methods: 120 Patients aged more than 60 years belonging to ASA I,II and III physical status and posted for infraumbilical surgeries were randomized into 2 groups, Group B(Bupivacaine) and Group BD (Bupivacaine + Dexmedetomidine). Under aseptic conditions lumbar puncture was performed in sitting position at L₃₋₄ / L₄₋₅ interspace and 2.1 ml of study agents were administered. Group B received 10mg of 0.5% hyperbaric Bupivacaine and Group BD received 10mg of 0.5% hyperbaric Bupivacaine and 5mcg of Dexmedetomidine. In all cases monitoring of Blood pressure, ECG, Oxygen saturation and Respiratory rate was done at regular intervals intra-operatively. Sensory block and motor blocks were assessed periodically.

Results: There were no clinically and statistically significant changes in heart rate and blood pressure and the mean max fall in HR, SBP, DBP and MAP. However, it was observed that there was a statistically significant ($P<0.001$) decrease in the time of onset of sensory block and motor block in Group BD(1.68 ± 0.96 and 2.42 ± 1.12) when compared to Group B(2.24 ± 0.81 and 3.33 ± 1.06). Duration of analgesia and the time for first rescue analgesia was prolonged in Group BD ($P<0.001$). There were no side effects except for mild sedation in Group BD.

Conclusion: Addition of Dexmedetomidine 5 mcg to intrathecal Bupivacaine(H) in elderly patients causes minimum hemodynamic changes, prolongs sensory and motor block.

Keywords: spinal anaesthesia, dexmedetomidine, bupivacaine, intrathecal

Introduction

Aging is an irreversible and progressive physiological phenomena characterized by degenerative changes in the structure and functional reserve of organs and tissue¹. In almost every country, the proportion of people aged over 65 years is growing faster than any other age Group, as a result of both longer life expectancy and declining fertility rates. By the year 2040, persons aged 65 years or older are expected to comprise 24% of the population and account for 50% of health care expenditures^[2]. With the rising longevity and 1/3rd of the surgical patients being elderly, geriatric anaesthesia has come into prominence^[3].

Elderly patients pose a serious challenge to anaesthesia not only due to associated co-morbidities but also due to natural changes during aging. Both the peripheral and central nervous system degenerate with advancing age. A reduction in the number of neurons within the spinal cord, deterioration of myelin sheaths and connective tissue barriers and slowing of the conduction velocity in peripheral nerves, especially the motor nerves, all these changes contribute to altered nerve block characteristics (dose-response relationship)^[4]. Thus reduction in the intrathecal dose (fixed volume and concentration) of local anaesthetic may prevent major changes in the vital parameters and further modification of the given dose by use of spinal adjuvants like Dexmedetomidine may be rewarding^[5].

Dexmedetomidine by acting on the α_2 adrenoreceptors located on the primary afferent terminals of neurons in spinal cord, brain stem and peripheral tissue, will exhibit synergistic

effects with Local anaesthetics and will also produce analgesic effects [6]. In this background we undertake to evaluate spinal anaesthesia characteristics in elderly patients due to the effect of 5mcg of Dexmedetomidine as an adjuvant to low dose Bupivacaine (H) 10mg.

Our aim was to evaluate the effect of low dose intrathecal Dexmedetomidine (5mcg) as an adjuvant to Bupivacaine (H) (10mg) in Elderly regarding,

1. Hemodynamic stability
2. Time of onset of sensory and motor block
3. Duration of Sensory and Motor block
4. Time for first rescue analgesia
5. Side effects if any

Materials and Method

Following ethics committee approval, informed consent was obtained from the patients. Detailed pre-anaesthetic evaluation was done. Patient aged more than 60 years of either sex who are fit for spinal anaesthesia undergoing Infra umbilical surgeries belonging to ASA physical status I, II and III were included in the study. Those patients with bleeding diathesis and coagulopathy, Severe hepatic failure, Heart blocks, dysrhythmias, ASA IV patients, having Infection at the site of spinal anaesthesia and Known allergy to local anaesthesia or Dexmedetomidine were excluded from the study.

Sample size was calculated based on the study by Seop Chang Y *et al* (2015) and considering the mean difference 6.1mmHg and SD 11.7 in mean blood pressure between study and control Group, with 95% CI and 80% power, sample size will be 43 in each Group⁷. Considering the nonresponsive rate of 20% We have included 60 patients in each Group. Hence 120 Patients were randomly allocated to 2 Groups of 60 each by computer generated randomization table, Group B(Bupivacaine) and Group BD (Bupivacaine + Dexmedetomidine). Under aseptic conditions lumbar puncture was performed in sitting position at L₃₋₄ / L₄₋₅ interspace using a para- median approach with a 25-G Quincke spinal needle and 2.1 ml of study agents were administered. Group B received 10mg of 0.5% hyperbaric Bupivacaine and Group BD received 10mg of 0.5% hyperbaric Bupivacaine and 5mcg of Dexmedetomidine. The solution was injected over 6 seconds with no barbotage followed by immediate placing the patient in supine position with the operating table in neutral position.

In all cases monitoring of Blood pressure, ECG, Oxygen Saturation and Respiratory rate was done at regular intervals intra-operatively. Sensory block and motor blocks were assessed periodically. Intraoperative fluid requirement was managed taking into account the cardiopulmonary status of

the patients. Hypotension was defined as a decrease in Systolic blood pressure (SBP) of >20% of the Basal SBP and was initially treated with crystalloids and if necessary Vasopressors. Bradycardia defined as a decrease in heart rate of > 20% of the Basal value and was treated with intravenous atropine(0.6mg). At 10 mnts after spinal injection, the inability to reach a sensory block at T12 and a Modified Bromage Score of 0 was considered as a block failure and was excluded from further study. In case of intra-operative discomfort or pain patients were administered appropriate anaesthesia based on the patients physical status and was excluded from the study.

At the end of surgery patients were shifted to post-anaesthesia care unit. The duration of analgesia was considered as the period from the injection of the study drug to patient perceiving sensation and time for first rescue analgesia was considered as period from the injection of the study drug to the first request made by the patient for analgesics. For rescue analgesia intravenous infusion of Diclofenac 75 mg was given. which was repeated after 12 hours, if needed.

Vital signs(ECG, Pulse rate, NIBP, Respiratory rate, SpO₂) were recorded at intervals of 2, 4, 6, 8, 10, 15, 20, 30, 40, 50, 60 75 and 90 minutes, Onset of sensory and motor blockade, Duration of analgesia and motor block, Time to first rescue analgesic (Diclofenac), VAS at 4th and 8th hour post operatively and adverse effects like Bradycardia, Hypotension/Hypertension, sedation, Nausea/vomiting, Desaturation, Dry mouth and Others were monitored.

Descriptive statistics done for all data and suitable statistical tests of comparison were applied. Data was entered in MS Excel and analysed in SPSS v20. Continuous variables were summarised as mean or median with standard deviation (SD) or interquartile range (IQR). Categorical variables were expressed as percentages with 95% confidence interval (95% CI). T test was used to test the statistical significance of difference between the groups in continuous variables. Two way ANOVA was used to test the statistical significance of difference in variation of heart rate, systolic, diastolic, and mean arterial blood pressure. Chi square test was used test the statistical significance of deference in distribution of categorical variable. P value less than 0.05 was considered as statistically significance.

Results

All the patients included in the study received the assigned intervention and were followed up till the end of study. Patient demographic characteristics were comparable in both groups (age, gender, BMI).

Table 1: Distribution of anthropometric parameters

Characteristics	N	Group B		Group BD		P value
		Mean	±S.D	Mean	±S.D	
Age (years)	60	68.08	4.91	69.3	5.75	0.4
Height (cms)	60	166.58	5.15	160.95	8.30	0.1
Weight (kgs)	60	64.26	5.10	61.50	7.31	0.3
BMI (kg/m ²)	60	23.16	1.69	23.78	2.88	0.9

In Group B the mean basal HR was 79.43±8.74 bpm and at 90th minute was 71.58±7.20 bpm with a difference of 7.85. In Group BD the mean basal HR was 78.75±11.15 bpm and

at 90th minute was 70.38±7.75 bpm with mean difference of 8.37. The mean difference in the HR between Group B and Group BD was statistically insignificant (P= 0.067).

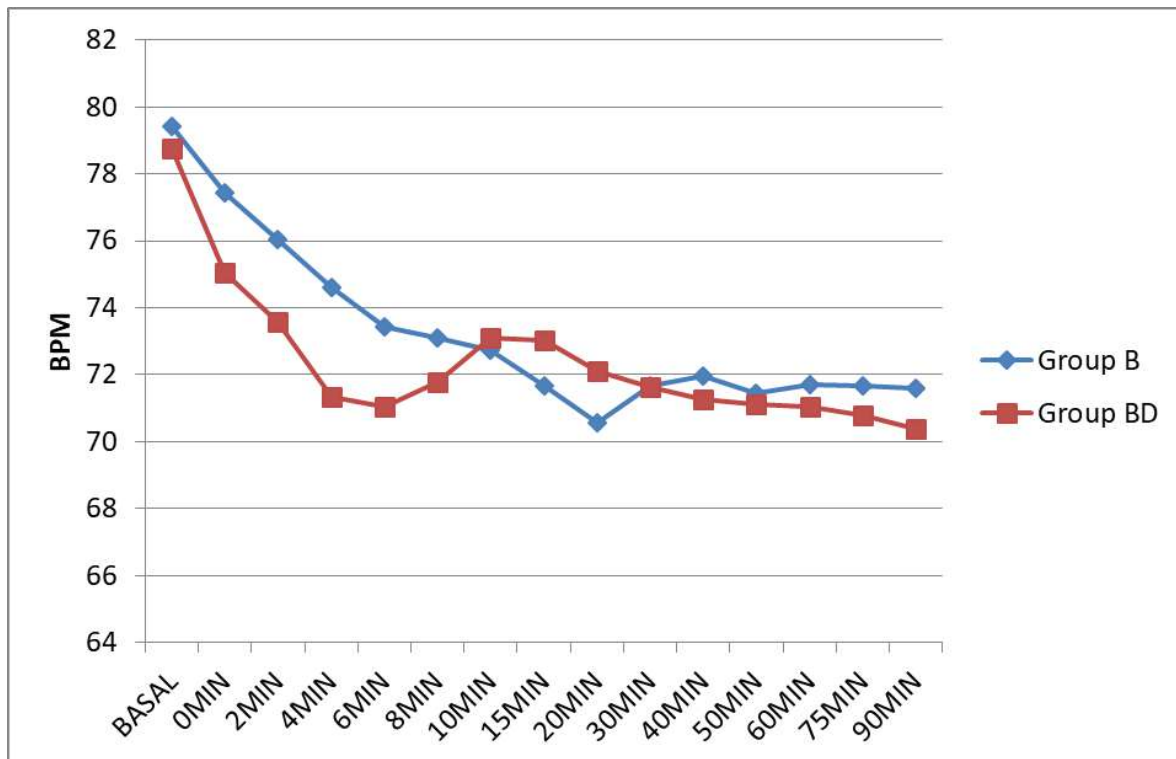


Fig 1: Graph showing comparison of mean heart rate between the Groups at various time intervals

In Group B the mean basal SBP was 138.53 ± 13.45 mm hg and at 90th minute was 121.15 ± 7.133 . In Group BD the mean basal SBP was 139.73 ± 15.61 mm hg and at 90th minute was 123.53 ± 11.587 . Even though there was a

statistically significant fall in SBP from the baseline value to the 90th minute in both the Groups, the mean difference in the fall of SBP was statistically insignificant (P value = 0.601).

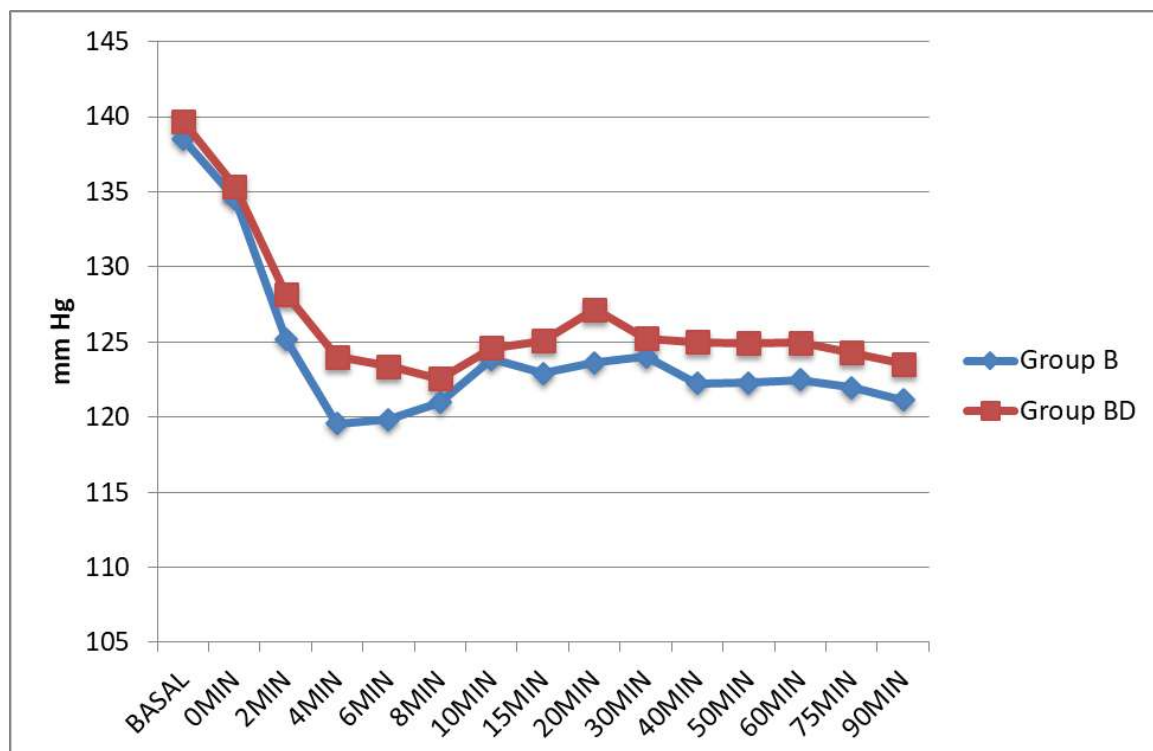


Fig 2: Graph showing comparison of mean SBP between the Groups at various time intervals

In Group B the mean basal DBP was 80 ± 7.717 mm hg and at 90th minute was 74.55 ± 6.593 . In Group BD the mean basal DBP was 83 ± 8.525 mm hg and at 90th minute was

72.88 ± 6.284 . The mean maximum fall from the Basal DBP was 14.81 ± 5.50 in Group B and 16.88 ± 8.66 in Group BD. There was a statistically significant fall in DBP (P = 0.04).

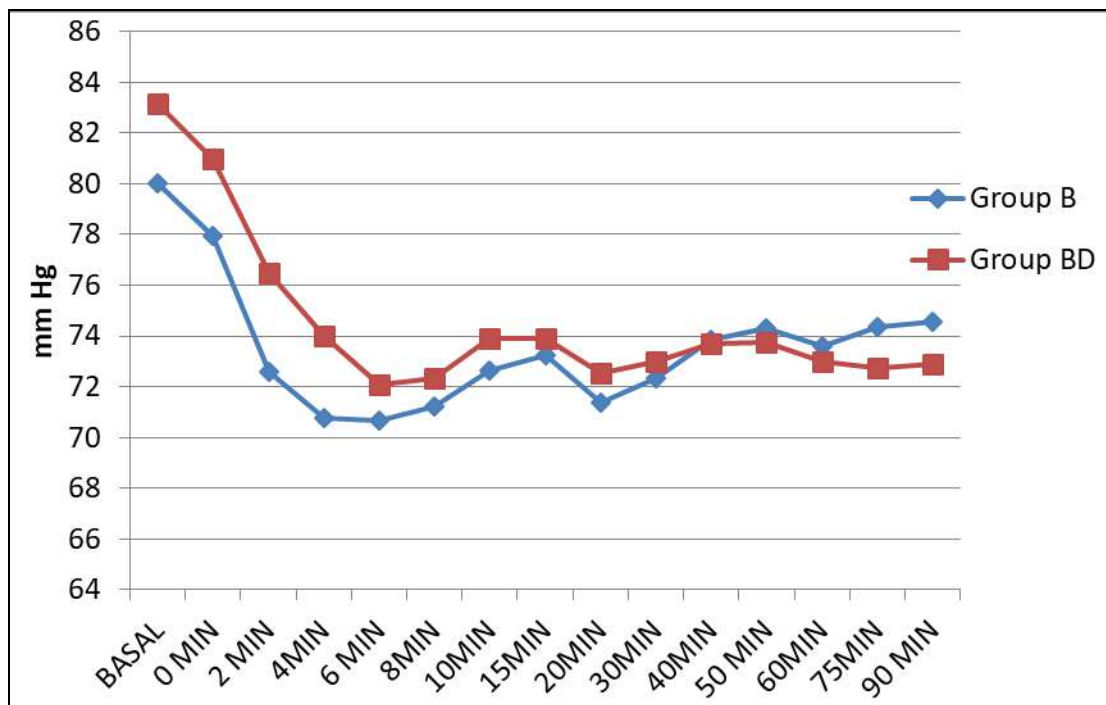


Fig 3: Graph showing comparison of mean DBP between the Groups at various time intervals

In Group B the mean basal MAP was 99.51 ± 8.28 mm hg and at 90th minute was 90.08 ± 5.29 . In Group BD the mean basal MAP was 102.02 ± 9.87 mm hg and at 90th minute was 89.76 ± 6.83 . Even though there was a statistically

significant fall in MAP, the mean difference in the fall of MAP from the basal to the 90th minute between the two Groups was statistically insignificant ($P=0.30$).

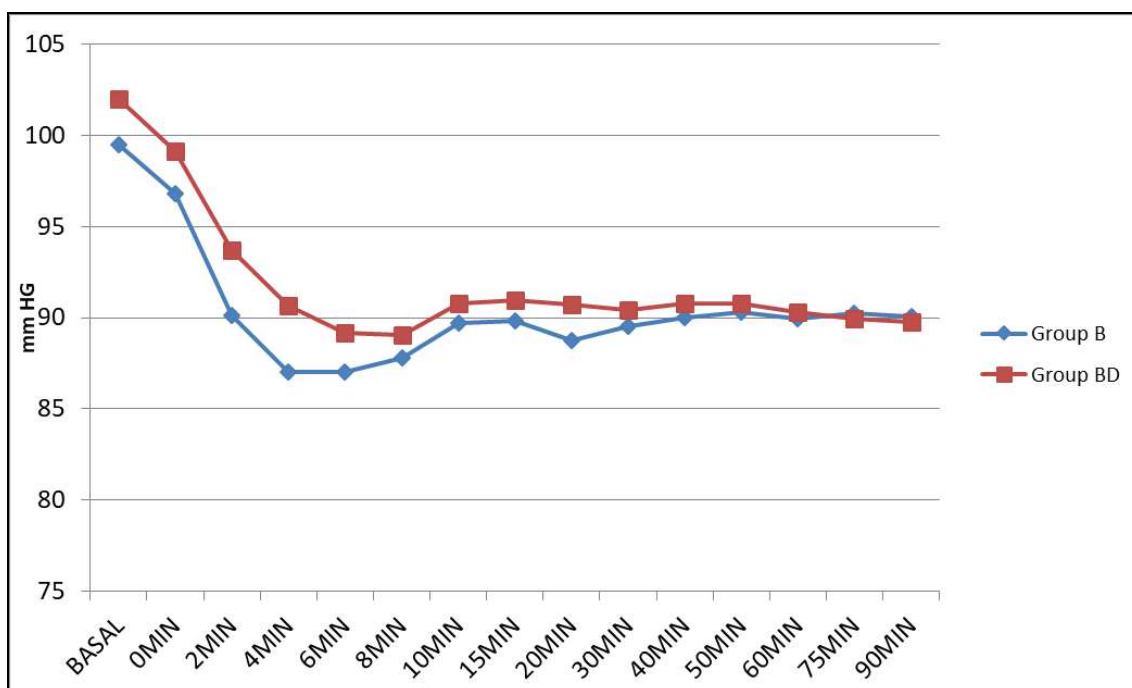


Fig 4: Graph comparing mean of the MAP between the Groups at various time intervals

The mean time of onset of sensory block (TOSB) was 2.24 ± 0.81 minutes in Group B and 1.68 ± 0.96 minutes in Group BD and was statistically significant with a P value of < 0.001 . The mean time of onset of motor block (TOMB) was 3.33 ± 1.06 minutes in Group B and 2.42 ± 1.12 minutes in Group BD and was statistically significant with a P value of < 0.001 . The total duration of motor block (TDMB) was 299.56 ± 59.66 minutes in Group B and 416.30 ± 79.61 minutes in Group BD and was statistically significant with a

P value of < 0.001 . The total duration of analgesia (TDA) was 323.61 ± 59.87 minutes in Group B and 457.23 ± 77.31 minutes in Group BD and was statistically significant with a P value of < 0.001 . The time for first rescue analgesia (TRA) was 377.60 ± 56.37 minutes in Group B and 520.85 ± 87.93 minutes in Group BD and was statistically significant with a P value of < 0.001 .

Table 2: Characteristics of sensory and motor block of the studied Groups (minutes).

	N	Group B		Group BD		P value
		Mean	±S.D	Mean	±S.D	
TOSB	60	2.24	0.81	1.68	0.96	<0.0001
TOMB	60	3.33	1.06	2.42	1.12	<0.0001
TDMB	60	299.56	59.66	416.30	79.61	<0.0001
TDA	60	323.61	59.87	457.23	77.31	<0.0001
TRA	60	377.60	56.37	520.85	87.93	<0.0001

The VAS score after 4 hours of surgery in Group B was 3.26 ± 2.34 and that of Group BD was 2.01 ± 1.34 . The VAS score after 8 hours of surgery in Group B was 5.98 ± 2.16 and that of Group BD was 2.56 ± 1.82 .

Three patients in Group B and Five patients in Group BD had bradycardia which required treatment with atropine 0.6mg iv. And 9 patients in Group B and 12 in Group BD had hypotension and required injection mephentermine in addition to iv fluids.

Discussion

Elderly patients pose a serious challenge to anaesthesia not only due to associated co-morbidities but also due to natural changes during aging. Thus reduction in the intrathecal dose (fixed volume and concentration) of local anaesthetic may prevent major changes in the vital parameters. Low-dose local anesthetics can limit the block level and induce rapid recovery from anesthesia. Hence lower doses of local anesthetics along with an adjuvant are preferred for spinal anesthesia in elderly patients [8]. Various adjuvants are frequently co-administered with local anesthetics to improve the anesthetic quality and postoperative analgesia and to reduce the incidence of hypotension after spinal anaesthesia. Adjuvants like intrathecal opioids can cause several problems, including respiratory depression, pruritus, and central nervous system excitation. Intrathecal α_2 -adrenoceptor agonists as adjuvant drugs have been shown to decrease the required doses of local anesthetics and are devoid of these side effects [9].

We conducted a study to assess the effect of dexmedetomidine with bupivacaine for spinal anaesthesia and found that there were no significant change in hemodynamic parameters. But the mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD, and the requirement of analgesics in the post operative period was also less in group BD when compared to group B.

Songir S *et al* (2016) [10] conducted a randomised controlled study on of 60 patients to know the effects of intrathecal Dexmedetomidine as an adjuvant in spinal anaesthesia with hyperbaric Bupivacaine 0.5% for gynecological surgeries and variables of vital parameters, onset and duration of sensory and motor block, intra and post-operative pain and adverse effects. Control Group received intrathecal 3.0 ml of 0.5% hyperbaric Bupivacaine with 0.5 ml of normal saline and Dexmedetomidine Group received identical volume of intrathecal Dexmedetomidine 5 mcg with hyperbaric Bupivacaine. They found that post-operative analgesia was significantly longer in Dexmedetomidine Group (9.6 hours) than in the control Group (3.55 hours) (p-value<0.01). Heart rate and blood pressure were significantly less in Dexmedetomidine Group (p-value<0.05). Hence they concluded that Dexmedetomidine 5 mcg to intrathecal Bupivacaine prolongs the duration of spinal

anaesthesia and analgesia. Similarly in our study there were no significant change in hemodynamic parameters. But the mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD.

Farhad Safari *et al* (2016) [11] studied Intrathecal Dexmedetomidine and Fentanyl as Adjuvant to Bupivacaine on Duration of Spinal Block in Addicted Patients. Addicted patients have innate tolerance to local anesthetics in both neuraxial and peripheral blocks. A total of 84 patients posted for elective surgeries less than 3 hours were selected and randomly allocated into 3 Groups. Group DEX (Dexmedetomidine 5mcg additive) and Group F (fentanyl 25mcg additive) and Group C (normal saline). They found that onset of sensory block and duration of sensory block was significantly longer in DEX Group compared to fentanyl and control Group. They concluded that Dexmedetomidine to Bupivacaine in spinal anesthesia is more effective to increase duration of block, providing more appropriate sedation and less postoperative pain scale and post-operative nausea and vomiting (PONV) compared to fentanyl additive. Similarly in our study mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD.

Shujun Sun *et al* (2017) [12] conducted a systematic review and meta-analysis to compare the effects of Dexmedetomidine and fentanyl as local anesthetic adjuvants in spinal anesthesia. A total of 639 patients from nine studies were included in this meta-analysis. They found that Dexmedetomidine resulted in statistically significant longer duration of stable sensory block, motor block and pain free period, reducing the incidence of pruritis when compared to fentanyl. They observed that there was no statistical significance in onset of sensory and motor block, the time to peak sensory level, and the incidence of hypotension and bradycardia, and the side effects (nausea, vomiting, shivering and respiratory depression) in both Groups. Similarly in our study there were no significant change in hemodynamic parameters. But the mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD.

Taznim Mohamed *et al* (2017) [13] conducted a prospective observational study on 90 patients to compare the difference in spinal block characteristics and hemodynamic effects of hyperbaric Bupivacaine combined with 5mcg Dexmedetomidine and to find out the optimum dose that would provide satisfactory block and hemodynamic stability for lower limb orthopedic surgeries. Patients were allocated to 3 Groups of 30 each. Group A received 7 mg, Group B 8 mg and Group C 9 mg 0.5% hyperbaric Bupivacaine along with Dexmedetomidine 5mcg. The onset of analgesia was slower and peak sensory level lower in Group A. The onset of motor block, time to attain peak sensory levels, duration of analgesia, maximum pain scores, and requirement of rescue analgesics were comparable among Groups. Duration of motor block and time of regression of sensory level were more in Group C. they concluded that Dexmedetomidine with lower doses of Bupivacaine produces satisfactory anesthesia without hemodynamic instability. Similarly in our study there were no significant change in hemodynamic parameters. But the mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD.

Limitations of our study were that identical surgeries could

not be studied; United State Food and Drug Administration has no approval for perineural application of Dexmedetomidine. Also a lower dose of Bupivacaine (H) and Dexmedetomidine as adjuvant could have been studied.

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