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International Journal of Current Research Vol. 8, Issue, 12, pp.43798-43804, December, 2016 INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

A COMPARATIVE STUDY OF 0.5% BUPIVACAINE AND 0.5% BUPIVACAINE WITH DEXMEDETOMIDINE FOR SPINAL ANAESTHESIA IN LOWER LIMB ORTHOPAEDIC SURGERY

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ARTICLE INFO	ABSTRACT
Article History: Received 23 rd September, 2016 Received in revised form 26 th October, 2016 Accepted 19 th November, 2016 Published online 30 th December, 2016 Key words: Spinal anaesthesia, Dexmedetomidine, Bupivacaine, Complete and effective analgesia.	 Background and objectives: Bupivacaine is the commonly used drug for spinal anaesthesia. To improve upon the quality of analgesia and prolong the duration of its action, many adjuvants have been tried.Intrathecal dexmedetomidine has potent central antinociceptive properties with analgesic effect at spinal level. Low doses of dexmedetomidine have shown effectiveness in intensifying spinal anaesthesia. So dexmedetomidine along with local anaesthetics improves the quality of intraoperative analgesia and also provide postoperative pain relief for longer duration. Objective: To evaluate the effects of adding dexmedetomidine to hyperbaric bupivacaine for lower limb orthopaedic surgeries. Methodology: 75 ASA grade I/II patients aged between 18 - 50 years undergoing elective lower limb orthopaedic surgeries were selected and divided into three groups of 25 each. Group "A" 0.5% hyperbaric bupivacaine 15 mg + 0.5ml of normal saline. Group "B" 0.5% hyperbaric bupivacaine 15 mg + 0.5ml of normal saline. Group "B" 0.5% hyperbaric bupivacaine 7.5µg. Total volumes in all groups are kept constant at 3.5ml. Parameters: Onset and duration of sensory and motor block, Duration and quality of analgesia, perioperative hemodynamic parameters were assessed. Results: The onset of sensory and motor blockade was faster in group C than in group B than in group A. Duration of sensory block and analgesia was significantly prolonged in group C and Group B so also was the duration of motor block. There was no significant hemodynamic changes in all the three groups.
	Conclusion: Dexmedetomidine potentiates bupivacaine spinal anaesthesia by improving the quality of intra operative and post-operative analgesia.

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Citation: Naveen Kumar Naveen, Naseema V. Kanase, Soudamini Gandhi, Kunda Dimble, Bilal Mohammad, Indrajit Gupta and Tushar Munnoli, 2016. "A comparative study of 0.5% bupivacaine and 0.5% bupivacaine with dexmedetomidine for spinal anaesthesia in lower limb orthopaedic surgery", *International Journal of Current Research*, 8, (12), 43798-43804.

INTRODUCTION

The greatest gift that God has given to mankind is not happiness, but relief of pain. In pursuit of relief of pain, particularly pain during and after surgery, many attempts have been made since time immemorial. Spinal anaesthesia is one of the most popular techniques for both elective and emergency surgical procedures (Dureja and Jayalaxmi, 2000). The advantages of an a wake patient, simple technique to perform, offers rapid onset of action, minimal drug cost, relatively less side effects and rapid patient turnover has made this the choice of many for surgical procedure (Paul *et al.*, 2006). These advantages are sometimes offset by relatively short duration of

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action and uncomfortable postoperative period when its action wears off. Therefore it forms a challenging forefront in clinical and research advances, where if one can enhance sensory blockade into postoperative period by combining the lowest dose of the drugs with longer duration of action and least side effects. In order to extend intraoperative analgesia into postoperative period a number of spinal adjuvants have been added to prolong intrathecal bupivacaine action. However each drug has its own limitations, and a need for alternative methods or drugs always exist (Ghodki and Sardesai, 2010). Alpha-2(α_2) adrenergic receptor (AR) agonist have been the focus of interest due to sedative, analgesic, perioperative sympatholytic and haemodynamic stabilizing properties. Dexmedetomidine, a highly selective α_2 -AR agonist with a relative high ratio of α_2/α_1 activity (1620:1) possesses all these properties but lack respiratory depression, making it a safe adjuvant (Grewal, 2011).

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Hence, this study was designed to evaluate the effectiveness of adding dexmedetomidine to bupivacaine for spinal anaesthesia and to compare its use with that of bupivacaine.

MATERIALS AND METHODS

After approval from the hospital ethical committee and taking informed consent this clinical study was conducted on 75 patients of 18 to 50 years of ASA physical statusI &IIundergoing elective lower limb orthopaedic surgeries under spinal anaesthesia at Krishna Hospital, Karad.Patients who are physical dependent on narcotics, allergy to study group drugs, and those who are contraindicated for spinal anaesthesia are excluded. Patients were randomly divided on an alternative basis into three groups of 25 each.

- **Group A**: Patients received intrathecal 0.5% hyperbaric bupivacaine 15mg (3 mL) + normal saline 0.5ml and total volume 3.5 mL
- **Group B**: Patients received intrathecal 0.5% hyperbaric bupivacaine 15mg (3 mL) +dexmedetomidine 5µg and total volume 3.5 mL
- **Group** C: Patients received intrathecal 0.5%hyperbaric bupivacaine15mg (3mL) +dexmedetomidine 7.5µg and total volume 3.5 mL

Method of study

Pre anaesthetic check-up was carried out pre operatively and relevant investigations were done. Patients were premedicated with tab diazepam 5 mg and tab ranitidine 150 mg orally at night before surgery.

Procedure

Patient was shifted to the OT table; Intravenous (IV) access was obtained with 18 Gauge IV cannula and Ringer Lactate solution 500 mL was infused before sub arachnoid block (SAB) and continued at rate of 10 ml/kg/hr. The monitors connected to the patient included non-invasive blood pressure (NIBP), oxygen saturation using pulse oximeter. Baseline pulse rate (PR), blood pressure (BP), respiratory rate(RR), SpO2 was recorded. Under strict aseptic precautions, spinal anaesthesia was given in sitting position by midline approach using 25 gauge Quincke spinal needle at L3-L4 intervertebral space. Patients were monitored continuously using NIBP, pulse oximeter and electrocardiogram. HR, B.P, RR and SpO2 monitored at 1,3,5,10,15,20,25,30,45,60,120,180 minutes.

Assessment of Sensory Blockade

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 pin prick sensation. The level of sensory block to T10 and time required to achieve it was noted. The time for two dermatomal segments regression of sensory level was noted. The duration of sensory blockade was taken as time from onset to time of return of pinprick sensation to S1 (heel) dermatomal area.

Assessment of Motor Blockade: This was assessed by using Bromage scale.

Assessment of Analgesia

Pain was assessed by visual analogue score (VAS) (Camorcia *et al.*, 2005). Patient simply marks the line to indicate the pain

intensity and the provider then measures the length of the line to mark a point scale. All the patients were instructed about the VAS and to point out the intensity of pain on the scale 0-no pain, 10-worst pain (Figure 1). Duration of complete analgesia was defined as the time from the intrathecal injection to VAS>0 -<4 and duration of effective analgesia as the time to VAS >4. Analgesics were avoided until demanded by the patient and the time taken for the first pain medication was also noted (ie, when VAS >6) VAS was also recorded 3, 6, 12 hours postoperatively. Sedation scores were assessed every 15 minutes both intra and post operatively using a four point score described by B.S.sethi (Joshi et al., 2013). Post operatively, monitoring of vital signs, VAS scores and sedation scores was continued every 30 minutes until the time of regression of sensory block to L1 dermatome. The incidence of hypotension (arterial blood pressure < 20 % of baseline), and was treated with Inj. Ephedrine 6 mg intravenous increments and bradycardia as pulse rate < 60/ min was treated by atropine 0.6 mg intravenous stat. Side effects like sedation, nausea, vomiting, urinary retention were monitored in the recovery room.

Statistical analysis

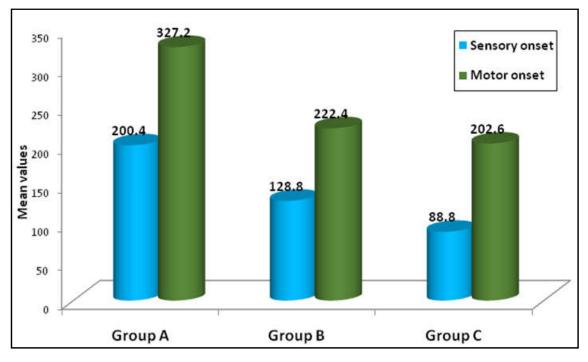
The distribution of age, height, weight, sensory onset, motor onset, and VAS was checked by the Kolmogorov-Smirnov test. They followed a normal distribution. Age, weight, heart rate, SBP, DBP and VAS were compared between three groups by one way ANOVA. The repeated measures analysis of variance was used to assess the differences of VAS for pain in three groups and the changes of them over time in each group. To compare them between three groups in each time of measurement, chi-square and Fisher exact tests (when appropriated) were used. Two tailed p<0.05 was taken as significant. Statistical analysis was performed using SPSS 18 for Windows (SPSS Inc., Chicago, Illinois).

RESULTS

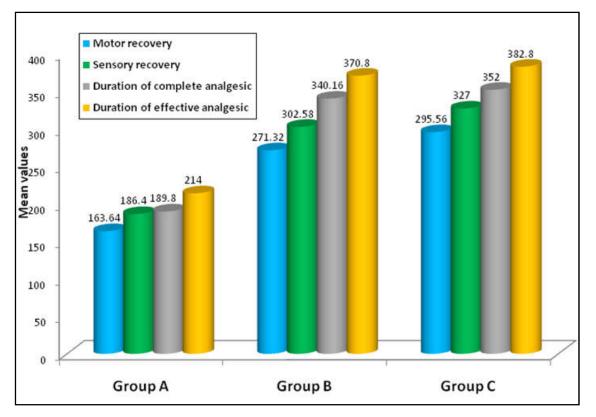
Patients were comparable demographically as shown in Table -1. The onset of sensory block in group c was earlier as compared to group B and group A. There is significant difference between mean values of sensory onset between Group A with Group B, Group A with Group C and Group B with Group C (p<0.01) .The onset of motor block in group c was earlier as compared to group B and group A. There is significant difference between mean values of motor onset between Group A with Group B, Group A with Group C and Group B with Group C (p<0.01) (Graph 1). With regard to the highest sensory level patients in Group C achieved higher sensory level block with p=0.33 which is not significant (Table -2). There is a significant difference between mean values of Motor recovery, Sensory recovery, Duration of complete analgesic and Duration of effective analgesic, when Group A compared with Group B, Group A compared with Group C and Group b compared with Group C (p<0.01) and no significant for duration of effective analgesic in comparison of Group A v/s Group B and Group B v/s Group C (p>0.05) (Graph 2). There is a significant difference between mean values of postoperative VAS when Group A compared with Group C and Group B compared with Group C (p<0.01) and no significant when Group A compared with Group B (p>0.05). VAS were statically significant at 3, 6, and 12 hours implying patients in Group C has better pain relief than Group B and Group A.

Table 1. Age and sex wise distribution in group A, B and C

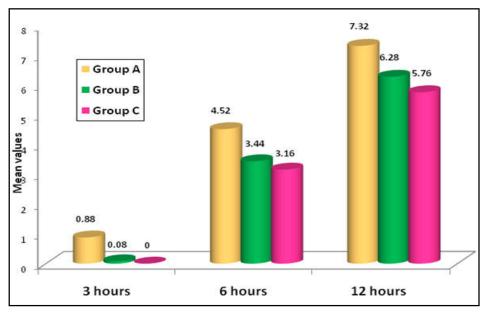
Age in years	Group A		Group B		Group C	
-	Male	Female	Male	Female	Male	Female
<20	1	1	1	0	1	0
20-30	5	1	8	2	2	3
30-40	6	2	1	2	4	7
40-50	4	4	4	3	6	2
>50	1	0	4	0	0	0
Total	17	8	18	7	13	12
Mean \pm SD	36.88 yrs. :	± 9.08yrs.	37.52yrs. ±	: 8.93yrs.	38.68yı	s. ±8.79



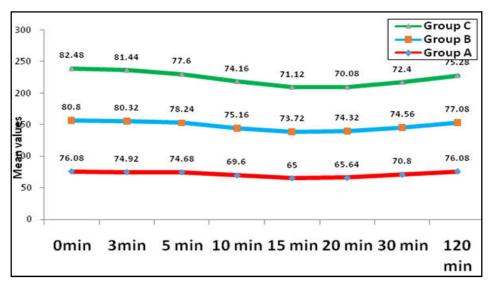
Graph 1. Distribution of Mean values of sensory onset and motor onset in group A, B and C



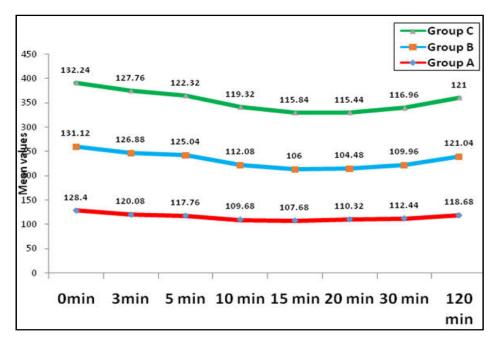
Graph 2. Distribution of Mean values of motor recovery, sensory recovery, duration of complete analgesic and duration of effective analgesic in group A, B and C



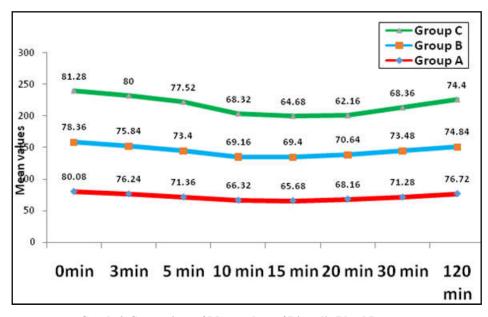
Graph 3. Comparison of Mean values of VAS at 3, 6 and 12 hours in group A, B and C



Graph 4. Comparison of Mean values of Heart Rate



Graph 5. Comparison of Mean values of Systolic Blood Pressure



Graph 6. Comparison of Mean values of Diastolic Blood Pressure

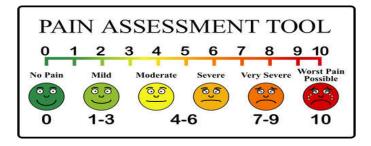


Figure 1. Linear Visual Analogue Scale Score

Table 2. Distribution of Highest sensory level in group A, B and C

Highest sensory	Group A	Group B	Group C
level	No. (%)	No. (%)	No. (%)
T8	4(16%)	5(20%)	6(24%)
T10	15(60%)	16(64%)	17(68%)
T12	6(24%)	4(16%)	2(8%)

Table 3. Side effects

Adverse effects	Group A n (%)	Group B n (%)	Group C n (%)
Nausea/Vomiting	3(12)	2(8)	2(8)
Drowsiness	0	0	0
Bradycardia	3(12)	4(16)	5(20)
Hypotension	2(8)	4(16)	5(20)
Respiratory depression	Ò	0	0
Shivering	4(16)	2(8)	2(8)

There was no statistical significance between Group A and Group B however patients in Group B have better pain relief than Group A (Graph 3). There is no significant difference between mean values of heart rate (min) from 0 min to after 120 min in Group A, and significant in Group B, and highly significant in group C (p<0.01) There is a no significant difference between mean values of Heart rate (min) when Group A compared with Group B, Group A compared with Group C (p>0.05) (Graph 4). There is a significant difference between mean values of SBP from 0 min to after 120 min in Group A, and B and highly significant in Group C (p<0.01) The systolic blood pressure when Group C is compared to Group A and Group B is statistically significant but clinically insignificant.

There is also statistical significance when Group B is compared to Group A but clinically insignificant. Not significant when Group B compared with Group C (p>0.05) (Graph 5). There is a significant difference between mean values of DBP from 0 min to after 120 min in Group B, and C (p<0.01) and significant in Group A (p<0.05) There is a no significant difference between mean values of DBP when Group A compared with Group B, Group B compared with Group C and no significant difference seen in Group A compared with Group C (p<0.05). The diastolic blood pressure when Group C is compared to Group A and Group B is statistically significant but clinically insignificant. There is also statistical significance when Group B is compared to Group A but clinically insignificant (Graph 6).

DISCUSSION

Spinal anaesthesia with hyperbaric bupivacaine 0.5% is a popular method. The duration of spinal analgesia can be prolonged by the adjuvants like vasoconstrictors, opioids, neostigmine, ketamine, midazolam, etc. Vasoconstrictors prolong the duration of action of the local anaesthetic by decreasing systemic absorption but have been found to induce neurological signs and symptoms due to reduced blood supply to the spinal cord (Aho et al., 1992). Intrathecal midazolam produces sedation, ketamine results in psychomotor symptoms and neostigmine causes excessive nausea and vomiting. A variety of perineural adjuvants, including clonidine, dexamethasone etc. Have been used to prolong the duration of analgesia of nerve blocks. Dexmedetomidine, a highly selective α_2 -AR agonist with a relatively high ratio of α_2/α_1 activity (1620:1 as compared to 220:1 for clonidine), possesses all these properties but lacks respiratory depression, making it a useful and safe adjunct in diverse clinical applications (Grewal, 2011). The aim of this study was to evaluate the effects of dexmedetomidine added to hyperbaric bupivacaine for spinal anaesthesia.

The following parameters were observed

 Sensory and motor blockade - Onset, Highest level of sensory blockade and Time to achieve peak sensory blockade.

- Analgesia Duration of complete analgesia, effective analgesia and Quality of analgesia
- Haemodynamic parameters in the perioperative period

Demographic profile across the group

Our study is demographically comparable with respect to age, gender, height, weight and type of surgery.

Onset of sensory and motor blockade

In our study addition of 7.5 μ g (Group C) of dexmeditomedine to bupivacaine accelerated the onset of sensory by 112 seconds and motor blockade by 125 seconds whereas addition of 5 μ g (Group B) of dexmeditomedine to bupivacaine accelerates onset of sensory and motor blockade by 72 seconds and 105 seconds respectively when compared to control group (Group A). This results correlates well with the studies done by Al-Mustafa *et al.*, 2009 with different doses of dexmedetomidine (D5) 5 μ g and 10 μ g (D10) with hyperbaric bupivacaine in spinal anaesthesia and compared the results with control. Which shows onset of sensory and motor blockade faster in dexmedetomidine group when compared to control group.

Highest sensory level blockade

With regard to the highest sensory level attained, Group C achieved higher sensory level block with p=0.33 which is not significant. This results correlates with study done by Rajni Gupta *et al.*, 2011 which shows dexmedetomidine group patient had higher sensory level of T5 compared to T8 in control group.

Time for complete sensory and motor recovery

In our study, we observed that adding 7.5 μ g dexmedetomidine (Group C) to bupivacaine prolonged sensory and motor blockade by 141 minutes and 132 minutes respectively while adding 5 μ g dexmedetomidine (Group B) to bupivacaine prolonged sensory and motor blockade by 116 minutes and 108 minutes respectively control group (Group A).Hence adding the dexmedetomidine to bupivacaine prolonged the duration of both sensory and motor blockade and it is dose dependent. This results correlates with study done byAl-Mustafa *et al.*, 2009 who concluded that sensory recovery in group D was 277 min and group B was 165 min. The motor blockade in group D 246 min and group B was 140 min.

Duration of analgesia

We found that the duration of complete analgesia (time from injection of bupivacaine intrathecally to first complaint of pain) in group C was 352.0 minutes, group B 340.16 minutes and 189.80 minutes in group A. The duration of effective analgesia (time to first rescue analgesia) was 382.80 minutes in group C, 370.80 minutes group B and 214.0 minutes in group A, thereby reducing the requirement of analgesics in the early postoperative period. The quality of analgesia was better as the VAS was lower in group C than in group B < group A. Sharif AAbdelhamid *et al.*, 2013 demonstrated that the time for first rescue analgesia was 380±16 min in Dexmedetomidine group and 259±14 in controlgroup. Rajni Gupta et al⁹concluded that the time for first rescue analgesia was significantly prolonged in dexmedetomidine group (D) which is consistent with our study.

Postoperative analgesia

In our study there was significant reduction in the VAS scores of the patients receiving dexmedetomidine in compared with higher VAS scores in patients receiving bupivacaine alone in the first 12 hours post operatively. This implies better quality of analgesia postoperatively, and reduced need of analgesics with the use of intrathecal dexmedetomidine. Gehan *et al.*, 2013 showed that VAS score was lower in dexmedetomidine group in first 3 hour of postoperative period compared to control group. Hence, our result is comparable to the above studies.

Heart rate

In our study, there is no significant difference between mean values of heart rate (min) from 0 min to after 120 min in Group A, while there is statistically significant change in mean heart rate in group B and group C but it is clinically insignificant. Sherif Abdelhemid *et al.*, 2013 showed that difference in heart was statistically significant at 10, 15, 20, 30 min but clinically insignificant. Our results were consistent to above study.

Blood pressure

In our study, the changes in mean systolic blood pressure was statistically insignificant at any time interval except at 30 min but it was clinically insignificant.Whereas changes in mean diastolic blood pressure was also statistically insignificant at any interval of time except at 20 mins but it was clinically insignificant.Our results with respect to changes in mean systolic and diastolic blood pressure was comparable with studies of Sharif Abdelhamid *et al.*, 2013; GE Kanazi *et al.*, 2006 and Rampl Singh *et al.*, 2012.

Side effects

In our study, we found lower incidence of side effects with small doses of dexmedetomidine but are not statistically significant. Sharif Abdelhamid *et al.*, 2013 concluded that small dose intrathecal dexmedetomidine causes minimal side effects and prolong postoperative analgesia, which is in accordance with our study.

Conclusion

The addition of dexmedetomidine to 0.5% hyperbaric Bupivacaine in spinal anesthesia significantly decreases the onset time, prolongs the duration of both sensory and motor blockade. It also prolongs the duration and improves the quality of postoperative analgesia with better hemodynamic stability as compared to bupivacaine alone. It is an attractive adjuvant for prolonging spinal anesthesia. Thus, the study concluded that "Addition of dexmedetomidine potentiates bupivacaine spinal anesthesia."

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