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# "COMPARISON OF TWO DIFFERENT DOSES OF DEXMEDETOMIDINE AS AN ADDITIVE TO SPINAL ANAESTHESIA WITH 0.5% HYPERBARIC BUPIVACAINE IN ORTHOPAEDIC PATIENTS UNDERGOING LOWER LIMB SURGERIES".

Anaesthesiology

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## ABSTRACT

Dexmedetomidine, a highly selective α2 agonist is frequently used as the choice of additive to spinal anaesthesia in view of its property to provide analgesia and sedation without respiratory depression along with a stable hemodynamic.

**Aim:** comparison of two different doses of dexmedetomidine as an additive to spinal anaesthesia with 0.5% hyperbaric Bupivacaine in orthopedic patients undergoing lower limb surgeries

**Material and method:** This was a randomized, controlled, single blinded study which included adult ASA I, II and III patients, orthopedic patients undergoing lower limb surgeries. They were allocated into two groups. Groups were designed as 3 ml 0.5% hyperbaric Bupivacaine with 0.5ml dexmedetomidine: 5mcg (A) and 10mcg (B). Data were collected in with regards to the hemodynamic stability, effect on characteristics of sensory and motor block, incidence of side effects and postoperative analgesia and any adverse effects and groups were analysed.

**Results and conclusion:** both groups were comparable in demographic data. No significant side effects. Weighing the prolongation of anesthesia and analgesia, we conclude that 10 mcg of dexmedetomidine is optimum intrathecal dose.

## KEYWORDS

Dexmedetomidine, Bupivacaine, Hemodynamics, postoperative analgesia

## INTRODUCTION:

August Bier (1898) introduced spinal analgesia in clinical practice. Since then, the technique has been widely practiced to provide anaesthesia, particularly for surgery below umbilicus. If hyperbaric Bupivacaine 0.5% is used alone in spinal anaesthesia, leading to the need to rescue with general anaesthesia if the surgical procedure exceeds beyond the drug's duration of action.

Over the years many drugs have been used as an additive to spinal anaesthesia in order to hasten its onset of sensory and motor block, decrease the time to surgical incision, prolong the duration of action and to provide adequate postoperative analgesia. These drugs include midazolam, ketamine, fentanyl, clonidine, Neostigmine, dexamethasone, many opioids and non opioids.

Dexmedetomidine, a highly selective centrally acting α2 agonist, provide analgesia and awake sedation without respiratory depression along with a stable hemodynamic. There may be dose related prolongation of duration of motor blockade along with increase in the incidence of side effects of dexmedetomidine namely hypotension and bradycardia. Avoidance of side effects of dexmedetomidine while ensuring a pain free perioperative period is vital successful outcome of any surgical procedure.

## MATERIAL AND METHOD:

After getting approval from the hospital Ethical Committee and informed consent from 60 adult patients, a single blind randomized clinical study was conducted on patients of ASA grade 1,2 and 3 belonging to the age group of 18-65 years undergoing lower limb surgeries. The study was conducted from February 2020 to December 2020. Patients presents with sensitivity to the Local anesthetics being used, age <18 years or >65years, contraindications to spinal anaesthesia like Bleeding diathesis, local skin infections, neurological diseases, Cardiac or renal insufficiency were excluded from study.

All patients will be thoroughly assessed for history, and examined in detail, both general and systemic examinations. Patient's demographic data like age, sex, weight were recorded. Patients will be kept adequately (6-8 hours) nil by mouth. Patients were randomly divided into 2 groups : all the patients received Inj. Bupivacaine 0.5% hyperbaric 3 ml with inj Dexmedetomidine 5 µg (group A) or 10 µg (group B).

Before operation patients were explained about procedure. Patients were not aware of the group allocation. Venous access will be obtained, basic monitors will be attached like NIBP, pulse oximetry, ECG and vitals of the patient will be recorded and local sensitivity testing will be done. Patients were pre-loaded with 15ml/kg of Inj Ringer Lactate IV fluid. All the patients were premedicated with Inj. Glycopyrrolate 4ug/kg IV slowly, Inj. Ondansetron 80ug/kg IV slowly, Inj. Midazolam 0.02 mg/kg IV slowly. With the patient in sitting position, lumbar puncture was performed at L3-4 intervertebral space with a 25G BD spinal needle in sitting position under all aseptic and antiseptic precautions after appearance of free flowing and clear cerebrospinal fluid. Patients were immediately placed in supine position.

Sensory testing was assessed by loss of pinprick sensation to 23 G hypodermic needle and dermatome levels were tested every min until the highest level had stabilized by consecutive testing. After this sensory level was tested every 10 minutes till the effect regressed by 2 segments. Thereafter the level was tested every 20 minutes till the sensation was felt at S1 dermatome. Highest level of sensory blockade, Time to reach this level after injection, Time to S1 regression and side effect if any were recorded. The motor block was assessed using the modified Bromage Scale. The duration of analgesia was considered as the period from the injection of the study drug to the first request made by the patient for rescue analgesics. Intravenous injection of Diclofenac sodium 75 mg was given, which was repeated after 12 hours, if needed. Hypotension defined as a decrease of systolic blood pressure by >20% from baseline or a fall below 90 mm Hg, was treated with incremental iv doses of 6 mg of injection mephentermine and iv fluid as required. Bradycardia, defined as heart rate (HR) below 50 bpm, was treated with 0.3-0.6 mg of iv atropine. HR, mean arterial blood pressure (MAP) and oxygen saturation were monitored and recorded after the block every 5 minutes for 30 minutes; then at 15min interval thereafter. The incidence of adverse effects such as headache, hypotension, nausea, vomiting, tachycardia, bradycardia, shivering, urinary retention were recorded.

Statistical tests used for comparison is unpaired *t*-test. Results are presented as mean (standard deviation (SD)) and number (%) of cases as appropriate. The level of significance was set at $P < 0.05$, and 95% confidence intervals were calculated for the main outcome measures.

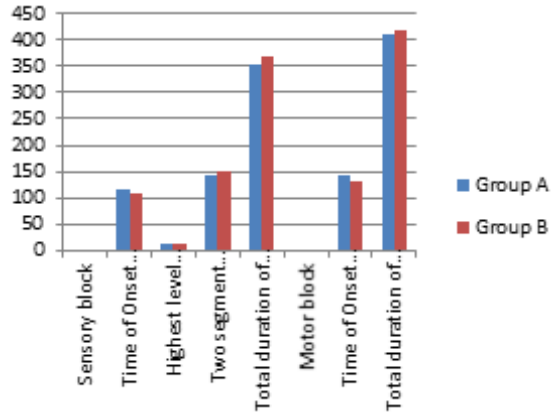
**Table 1: Patients' characteristics and surgical duration**

| | Group A | Group B | P Value |
|---|---|---|---|
| Age (years) | 38.86 ± 11.68 | 39.57 ± 13.56 | >0.05 |
| Sex (M/F) | 20/10 | 21/9 | >0.05 |
| Weight (kg) | 64.7 ± 8.88 | 65.33 ± 7.65 | >0.05 |
| Surgical duration (min) | 105.5 ± 10.03 | 99.5 ± 16.93 | >0.05 |

**Table 2 : comparison of motor and sensory blockade in two groups**

| | Group A | Group B | P value |
|---|---|---|---|
| **Sensory block** | | | |
| **Time of Onset (seconds)** | 117.27 ± 21.04 | 107 ± 15.91 | **<0.05** |
| **Highest level achieved (minutes)** | 13.4 ± 1.86 | 12.1 ± 1.21 | **<0.05** |
| **Two segment regression time (minutes)** | 144.2 ± 6.77 | 150.93 ± 9.49 | **<0.05** |
| **Total duration of block (minutes)** | 352.86 ± 12.28 | 366.87 ± 16.44 | **<0.05** |
| **Motor block** | | | |
| **Time of Onset (seconds)** | 141.4 ± 15.28 | 130.6 ± 16.13 | **<0.05** |
| **Total duration of block (minutes)** | 408.93 ± 10.87 | 418.2 ± 14.15 | **<0.05** |

Values are expressed as mean ± standard deviation (SD). Group A = Inj. Bupivacaine 0.5% hyperbaric 3 ml with inj Dexmedetomidine 5 µg Group B = Inj. Bupivacaine 0.5% hyperbaric 3 ml with inj Dexmedetomidine 10 µg Figure 1: comparison of characteristics of sensory and motor blockade between two groups




## RESULTS:

The demographic data and surgical characteristics were similar in each group [Table 1]. Sensory and motor block onset time was earlier in group B as compared with group A [Table 2] ($P < 0.05$).Total durations for Sensory and motor blockade were longer in group B than in group A [Figure 1]. Duration of analgesia was significantly longer in group B than in group A [Table 3]. Mean arterial pressure and mean pulse rate in group A and group B were statistically insignificant ($P > 0.05$). Incidence of side effects like Bradycardia, nausea and vomiting is comparable in both groups while hypotension and shivering is more in group B as compare to group A.

## DISCUSSION:

Bupivacaine, when used alone in regional anaesthesia, is adequate for surgeries lasting 2-3 hours. But if we require regional anaesthesia for longer duration we have to use some additive. There are number of adjuvant have been studied to prolong the effect of spinal anaesthesia. Dexmedetomidine is one among them.

Dexmedetomidine is a specific and selective alpha 2 adrenoceptor agonist. Activation of receptors in the brain and spinal cord inhibits neuronal firing and leads to sympatholytic effect, causing hypotension, bradycardia, sedation and analgesia.

Al-Mustafa et al., studied effect of dexmedetomidine 5 and 10 mcg with Bupivacaine in urological procedures and found that dexmedetomidine prolongs the duration of spinal anaesthesia in a dose-dependent manner.(1)

A Comparative study of hyperbaric 0.5% bupivacaine and hyperbaric 0.5% Bupivacaine with low dose dexmedetomidine in spinal anaesthesia done by **Kamat et al.**(2) This study was a prospective, randomized controlled, single blind, study conducted in 100 patients of ASA grade I and II undergoing elective surgeries under spinal anaesthesia. The patients were divided randomly into two groups, containing 50 patients in each group. Dosages of drugs selected are divided as Group B: Patients received 3 ml of 0.5% hyperbaric Bupivacaine (15mg) and Group BD: Patients received 3 ml of 0.5% hyperbaric Bupivacaine (15mg) plus 10 µg Dexmedetomidine. Spinal block characteristics, Mean arterial pressure, Mean pulse rate, sedation and side effects were studied during intra-operative and postoperative period. It was found from present study that in Dexmedetomidine group time to reach T10 sensory blockade and complete motor blockade was earlier and a higher level of sensory blockade compared to control group achieved. Duration of sensory, motor blockade and duration of analgesia was significantly prolonged in the Dexmedetomidine group compared to the control group. Hemodynamic parameters were preserved both intra-operatively and postoperatively. However there were a small percentage of patients who developed hypotension and bradycardia which were easily managed without any untoward effect.

| | Kamat et al Study | | Present study | |
|---|---|---|---|---|
| Spinal Block characteristics | Group B Mins. (Mean±S.D) | Group BD Mins. (Mean±S.D) | Group A Mins. (Mean±S.D) | Group B Mins. (Mean±S.D) |
| Time to reach maximum level of sensory blockade | 8.940±1.007 | 6.520±0.863 | 13.4 ± 1.86 | 12.1 ±1.21 |
| Duration of two segment regression | 92.56±11.846 | 137±13.062 | 144.2 ± 6.77 | 150.93 ± 9.49 |
| Total duration motor blockade | 149.22± 10.469 | 256.30± 36.897 | 408.93 ± 10.87 | 418.2 ± 14.15 |
| Duration of analgesia | 187.32± 16.448 | 357.46± 30.642 | 416.97 ± 12.79 | 433.6 ± 19.72 |

A Comparative study of intrathecal dexmedetomidine and fentanyl as adjuvant to Bupivacaine conducted by **Gupta et al**.(3) Sixty patients classified in American Society of Anesthesiologists classes I and II scheduled for lower abdominal surgeries were studied. Patients were randomly allocated to receive either 12.5 mg hyperbaric Bupivacaine plus 5 $\mu$g dexmedetomidine (group D, $n = 30$) or 12.5 mg hyperbaric Bupivacaine plus 25 $\mu$g fentanyl (group F, $n = 30$) intrathecal. The mean time of sensory regression to S1 was 476±23 min in group D and 187±12 min in group F ($P<0.001$). The regression time of motor block to reach modified Bromage 0 was 421±21 min in group D and 149±18 min in group F ($P<0.001$). Intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h as compared to fentanyl.

In **April 2016**, **Shagufta Naaz et al** (4) conducted a study to find out the optimum dose of dexmedetomidine to be used in lower abdomen surgery intrathecally. This was a randomized, controlled, double blinded study which included adult ASA I and II patients. They were allocated into five groups (n=20). Groups were designed as 2.5ml hyperbaric Bupivacaine with 0.5ml saline (Control) or 0.5ml dexmedetomidine: 5mcg (D1), 10mcg (D2), 15 mcg (D3) and 20mcg (D4). Data were collected for 10 point VRS for pain, Bromage motor block, Ramsay sedation score, hemodynamic, time of first rescue analgesia (TRA) and any adverse effects and groups were analysed. The mean duration of analgesia and need of first rescue analgesics are 201.5±29.1 mins in control group but in D1 group 259.1±15.2 mins, D2 310.7±48.1mins, D3 540.3±51.6 mins and D4 702.4±52 mins. p=0.003. The mean highest VRS score along with analgesic requirements were significantly reduced in dexmedetomidine groups, but D3 and D4 had hypotension which needed correction. Weighing the prolongation of anesthesia and analgesia and side effects they conclude that 10 mcg of dexmedetomidine is optimum intrathecal dose.

In **2016**, A Prospective Randomized Double Blind Dose Response Trial on the Effect of 3 Different Doses of Intrathecal Dexmedetomidine (2.5µg, 5µg, and 10 µg) on Subarachnoid Block Characteristics is conducted by **Mayank Gupta et al.**. (5). Ninety adult (18 – 60 years) patients undergoing elective lower abdominal and lower limb surgeries were randomized into 3 groups to receive intrathecal 0.5% Bupivacaine 3 mL with 2.5 µg (group BD2.5), 5µg (group BD5), or 10 µg (group BD10) dexmedetomidine in 0.5 mL normal saline. The onset of sensory block was significantly earlier in group BD10 compared with group BD5 (P = 0.035) and BD2.5 (P = 0.010) while the onset of motor block was significantly earlier in group BD10 compared with BD2.5 (P = 0.020). There was a significant and dose-dependent prolongation of the duration of sensory block (127.50, 149.17, and 187.50 minutes; P < 0.001), motor block (258.50, 331, and 365 minutes; P < 0.001), analgesia (306.17, 396.50, and 512 minutes; P

< 0.001), and DA (47.67, 65.50, and147 minutes; P < 0.001) with escalating doses of ITD, respectively. Group BD10 required significantly fewer rescue analgesics compared with other 2 groups (P = 0.001). Except for mild sedation which was significantly higher in group BD10; all the groups were comparable with respect to hemodynamic and other adverse effects.

In our study there were significant increases in the duration of sensory and motor block of spinal anaesthesia and prolonged postoperative analgesia. The effect was more as the dose increased. This effect can be utilized in patients undergoing prolonged surgery and it can be a good alternative to epidural anaesthesia which requires a much higher dose of drug and to general anaesthesia. But one has to be vigilant because a good number of patients had a fall in heart rate and BP when 15 and 20 mcg dose of dexmedetomidine were used intrathecally.

In our study, 3% patients developed bradycardia in each groups. Shivering was noticed in 6% patients of Group B as compared to 3 % patients in group A patients.

## CONCLUSION:

Dexmedetomidine significantly enhances the onset of sensory and motor block in a dose dependant manner. This randomized single blind clinical study comparing Dexmedetomidine in different dose of 5 µg and 10 µg added to hyper baric Bupivacaine for the lower limb surgeries shows all technique provide safe and effective anaesthesia but 10 µg of dexmedetomidine provide long duration of anaesthesia and analgesia as compared to 5 µg dexmedetomidine.

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