# Effect of Dexmedetomidine on Post Operative Analgesia and Haemodynamics when added to Bupivacaine 0.5% in Epidural Block for Pelvic and Lower Limb Orthopedic Surgeries

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## ABSTRACT

**Introduction:** Epidural blockade is one of the best procedures, providing better intra operative hemodynamic control, post operative pain relief and rapid recovery from surgery specially pelvic surgeries and orthopedic surgeries. Selective alpha 2 adrenergic agonist used as adjuvant in epidural blockade. Dexmedetomidine a more powerful and highly selective alpha 2 adrenoceptor agonist than clonidine. This study was designed to investigate appropriate doses 1.0, 1.5, 2.0 mcg/kg of dexmedetomidine added to bupivacaine for epidural block to prolong postoperative pain relief and reduce the requirement of rescue analgesia in pelvic and lower limb orthopedic surgeries with least side effects.

**Material and methods:** In our randomized control trial study, total 100 ASA class I and II patients of age between 15 to 65 years undergoing lower limb orthopedic and pelvic surgeries were given epidural block and studied for addition of dexmedetomidine on intra operative hemodynamic and post operative analgesia. Patients received 0.5% bupivacaine 20 ml alone in one group and with added Dexmedetomidine 1.0, 1.5, 2.0 mcg/kg in the other 3 groups respectively. All the patients were monitored for onset of sensory and motor blockade, intra operative hemodynamic, post operative analgesia, adverse effect and complications.

**Result:** Onset of sensory and motor blockade was same in all four groups. Addition of Dexmedetomidine increases the post operative pain free period significantly with all doses of dexmedetomidine. An increase of dose beyond 1.5 mcg/Kg did not further improved pain free period and in fact lowered by 1.24 hours and the incidences of complications started appearing which were absent up to 1.5 mcg/Kg dose. The incidence of side effects like hypotension, Bradycardia and shivering were not seen in patients receiving 1.0 and 1.5 mcg/Kg of Dexmedetomidine with bupivacaine. In patients receiving 2.0 mcg/Kg dexmedetomidine with bupivacaine 24 % of the patients had hypotension and Bradycardia and 4 % had shivering.

**Conclusion:** Addition of Dexmedetomidine in dose range of 1.0 to 1.5 mcg/Kg substantially prolongs postoperative analgesia without altering block characteristics offered by Bupivacaine for epidural blockade with no side effects and appears to be safe and reliable adjuvants.


**Keywords:** Epidural Anaesthesia, Bupivacaine, Dexmedetomidine, Post operative analgesia

## INTRODUCTION

Regional anaesthesia is supposed to be excellent anaesthesia in terms of safety and prolong post operative pain relief. In modern regional anaesthesia epidural blockade is one of the best procedures, providing better intra operative hemodynamic control, post operative pain relief and rapid recovery from surgery specially pelvic surgeries and orthopedic surgeries.

Many adjuvants have been used with bupivacaine to increase the post operative analgesia such as epinephrine, neostigmine, opiods with associated side effects like respiratory depression, pruritus, sedation, nausea, vomiting. Selective alpha 2 adrenergic agonist used as adjuvant in epidural blockade. Clonidine hydrochloride was the first drug from the group and was found clinically useful in peri operative period.[1]

Dexmedetomidine a more powerful and highly selective alpha 2 adrenoceptor agonist than clonidine was introduced in clinical practice in 1999 and soon became popular for variety of indications in Anesthesiology.[2-5]

The current prospective randomized double blind study was undertaken in orthopedic and pelvic surgical patients to evaluate the comparative hemodynamic, analgesic, sedative and respiratory effects of different doses of dexmedetomidine in patients receiving bupivacaine epidural anaesthesia.

## MATERIAL AND METHODS

A study of effect of dexmedetomidine on post operative analgesia when added to bupivacaine 0.5% in epidural block was carried out in 100 patients undergoing lower limb orthopedic and pelvic surgeries. Sample size was based on inclusion and exclusion criteria.

Ethical approval was taken from Hospital Ethical Committee. Patients of ASA Grade I or II, aged 15-65 years, weighing 40-70 Kg were included in the study. Patients with hematological diseases, abnormal bleeding and clotting time, psychiatric disease, diabetes, sepsis at the site of injection, spinal deformities, non consenting patients and patient with allergy to local anaesthetic agent were excluded from the study. After detailed examination and informed consent, patients were randomly assigned in four groups of 25 patients each.

In the operation theatre, a good intravenous access was secured and monitoring devices were attached. Base line heart rate, electrocardiogram (ECG), pulse oximetry ($SpO_2$), non invasive blood pressure (NIBP), respiratory rate recorded. The drug syringes were prepared with all aseptic technique. After antiseptic preparation of back and sterile draping the selected

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space for epidural puncture was infiltrated with 1 ml of 2% Xylocaine solution, epidural puncture was done in the midline by using 18 gauge Touhy needle (Romsons) in sitting position and epidural space was identified by the loss of resistance to air injection technique. Procedure was conducted by same anesthesiologist every time.

After identifying the space a test dose of 2 ml lignocaine hydrochloride solution containing adrenaline 1:200000 was injected to avoid accidental intra vascular injection or massive intrathecal dose. After 2-3 minute of administering the test dose, Group A patients received local anaesthetic solution 0.5% preservative free Bupivacaine 20 ml as a single shot injection, Group B, C, and D received local anaesthetic solution 0.5% preservative free Bupivacaine 20 ml with 1.0, 1.5, 2.0 mcg/kg of Dexmedetomidine as a single dose respectively.

After injection of drug/s (as per the group assigned), patient was made to lie down supine with 10 degree head low tilt and each patient was observed for -

A. Time of onset for sensory block
B. Time of onset of motor block
C. Highest Level of sensory block achieved (by pin prick method)
D. Duration of sensory block
E. Duration of motor block
F. Intraopertaive muscle relaxation (on Bromage scale)
G. Degree of sedation on Ramsay sedation scale
H. Duration of pain free period
I. Any adverse drug effect and
J. Any complication like bradycardia, hypotension, respiratory depression and sedation.

Continuous Intra operative monitoring of vital signs (Pulse rate, NIBP, $SpO_2$, RR) was done by using multi parameters.

An independent observer who was totally unaware of the nature of the study, recorded blood pressure and heart rate just before and after surgical incision and then every five minutes interval till the end of surgery using multi parameters. Postoperatively patient was monitored for offset time of epidural block (motor and sensory regression).

## STATISTICAL ANALYSIS

Descriptive statistics were used and mean and percentage were calculated. Paired t test applied using SPSS software for analysis between four groups. P value less than 0.5 percent was considered statistically significant.

## RESULT

Demographic data of patient included in the study was comparable with respect to height, weight and mean age of patient in each group (Table-1). The time for onset of sensory and motor block was similar in all groups and no statistical significant difference noted ($p > 0.05$) (Table-2).

Two level decrease in sensory block (duration of sensory block) and offset of motor block (duration of motor block) was similar in all four groups and no statistical significant difference noted ($p > 0.05$). Post operative analgesia increased significantly in B,C and D group when compared with A group ($p<0.005$). Side effect like hypotension, bradycardia and shivering was seen in Group D only (Table-2). Highest sensory level achieved in all four groups were comparable (Table-3). All patients in control group and study group were co-operative, oriented, calm and responsive to commands and mostly remained sleepy during entire surgery (Table-4).

In majority of the patient degree of muscle relaxation in study and control group was acceptable and provide smooth intra operative period (Table-5). Incidence of decrease in heart rate (35.2% ) was seen in group D only (Table-6). Incidence of

| Group | Group A | Group B | Group C | Group D |
|---|---|---|---|---|
| Age in years | 41.4 ± 13.3 | 45.9 ± 11.1 | 33.76 ± 9.1 | 33.9 ± 8.8 |
| Sex | | | | |
| Male | 9 | 20 | 23 | 16 |
| Female | 16 | 5 | 2 | 9 |
| Weight in kg | 51.6 ± 3.9 | 51.04 ± 2.07 | 52.08 ± 4.64 | 49.2 ± 4.8 |
| Height in cm | 153.2 ± 3.8 | 153.1 ± 3.6 | 152.8 ± 2.3 | ± 4.7 |

**Table-1:** Showing demographic data

| Group | Group A | Group B | Group C | Group D |
|---|---|---|---|---|
| Mean time onset of sensory block (seconds) | 715.20 | 686.40 | 688.80 | 696.80 |
| Mean time onset of motor block (seconds) | 919.20 | 890.40 | 864.00 | 854.40 |
| Duration of sensory block (Minutes) | 259.20 | 251.20 | 257.60 | 250.00 |
| Duration of motor block(Minutes) | 180.40 | 182.40 | 186.40 | 182.00 |
| Post operative analgesia hrs | 4.47 | 10.71 | 10.89 | 10.85 |
| Hypotension | - | - | - | 6 |
| Bradycardia | - | - | - | 6 |
| Shivering | - | - | - | 1 |
| Vomiting( | - | - | - | - |

**Table-2:** Showing duration and Adverse Effect

| Dermatome Height | Group A (n=25) | Group B (n=25) | Group C (n=25) | Group D (n=25) |
|---|---|---|---|---|
| T4-T8 | 8 | 7 | 9 | 9 |
| >T9 | 17 | 18 | 16 | 16 |

**Table-3:** Highest sensory level achieved

decrease in blood pressure was seen in group B, C and D over group A but were not statistically significant (Table-7).

## DISCUSSION

It is well established that Bupivacaine offer good anaesthesia in Epidural Block. However anesthesiologists persistently attempted to improve the quality of block by adding adjuvant drugs to local anesthetics. Adjuvants enhance the effectiveness and quality of analgesia offered by local anesthetics alone and also prolongs the post operative pain free period and decrease the requirement of systemic analgesics with minimum and no side effects and least possible effect on hemodynamic.

Dexmedetomidine is alpha two adrenoceptor agonist and has been introduced for clinical use in our country recently. Paracelsus very correctly stated that "There is no safe drug, only safe doses". Dexmedetomidine being a new introduction in anesthesia armamentarium, it is important to find a dose of drug that would cause acceptable intra-operative sedation and enhancement of post-operative pain free period without significant side effects. Hence, the present study is aimed to determine an optimum dose.

Patients included in the study had a mean age of 38.7 years (20 – 60 years). Male / female ratio was 68/32. The patients included in the study were adults and had vital signs within normal limits with no co morbid condition and thus belonged to grade I/II as per ASA classification.

The time for onset of sensory block was similar in all group and clinically insignificant changes were noticed. Mean time for onset of sensory block was found to be 715.2 ± 119.9 seconds in control group. After addition of dexmedetomidine the mean time for onset of sensory block was not altered significantly in dose range of 1.0 and 2 mcg/kg. Salgado PF and colleagues[6] administered dexmedetomidine with 20 ml 0.75% ropivacaine and found that addition of dexmedetomidine in dose of 1 mcg/Kg did not alter onset time for sensory block. Experimental study of epidural dexmedetomidine in rabbits was shown to have no effect sensory and motor effects by Konakci S et al.[7]

Mean time for onset of motor block in patients receiving bupivacaine without dexmedetomidine was found to be 919.2 ± 139.3 seconds and in other group marginal early onset occurred. In group B, C and D mean time of onset of motor block is 890.40 seconds, 864 seconds and 854.40seconds respectively which is statistically insignificant (p >0.005). Similar findings were observed by Salgado PF et al[6] and by Konakci S[7] in experimental study on rabbits.

| Sedation score | Group A (n=25) | Group B (n=25) | Group C (n=25) | Group D (n=25) |
|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 |
| 2 | 0 | 7 (28%) | 8 (32%) | 13 (52%) |
| 3 | 25 (100%) | 18 (72%) | 17 (68%) | 12 (48%) |
| 4 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 |

**Table-4:** Sedation Score

| Muscle power grading | Group A (n=25) | Group B (n=25) | Group C (n=25) | Group D (n=25) |
|---|---|---|---|---|
| 1 | 19 | 19 | 16 | 18 |
| 2 | 6 | 6 | 9 | 7 |
| 3-6 | 0 | 0 | 0 | 0 |

**Table-5:** Showing degree of muscle relaxation.

| Groups | Preoperative HR/ bpm | Minimum HR/ bpm | RR / min |
|---|---|---|---|
| Group A (n=25) | 83.1 ± 5.4 | 67.0 ± 9.4 | 16.8± 1.0 |
| Group B (n=25) | 82.2 ± 8.7 | 64.0 ± 9.3 | 17.0± 1.1 |
| Group C (n=25) | 88.2 ± 6.3 | 60.7 ± 6.5 | 16.2± 0.7 |
| Group D (n=25) | 84.0 ± 9.3 | 54.4 ± 10.4 | 16.6± 0.9 |

**Table-6:** Showing Changes in Heart rate and Respiratory Rate

| Groups | Pre-block SBP (mmHg) | Pre-block DBP (mmHg) | SBP minimum (mmHg) | DBP minimum (mmHg) |
|---|---|---|---|---|
| Group A (n=25) | 135.2 ± 11.1 | 78.0 ± 7.9 | 99.3 ± 10.9<br>35.9<br>(-26.5%) | 62.6 ± 8.3<br>15.4<br>(-19.7 %) |
| Group B (n=25) | 137.6 ± 11.6 | 79.9 ± 8.4 | 92.0 ± 18.6<br>45.6<br>(-33.1%) | 63.5 ± 9.2<br>12.4<br>(-24.6 %) |
| Group C (n=25) | 139.4 ± 8.4 | 81.0 ± 8.2 | 98.4 ± 6.5<br>41.0<br>(-29.4 %) | 65.2 ± 9.9<br>15.8<br>(-24.2%) |
| Group D (n=25) | 132.4 ± 11.5 | 74.3 ± 7.4 | 91.2 ± 9.9<br>41.2<br>(-31.2%) | 56.1 ± 11.4<br>18.5<br>(-24.4 %) |

**Table-7:** Showing Changes in Systolic and diastolic Blood Pressure

In our study offset time for sensory block 2 segments below the highest level of dermatome block in control group was found to be 259.2 ± 22.3 minutes. In group B, C, D offset of sensory block time was 251.20, 257.60, 250.00 minutes respectively which was statistically insignificant. ($p > 0.05$). Salgado PF et al[6] observed in his study that duration of sensory block is prolonged when Dexmedetomidine was added with 20 ml of 0.75% ropivacaine in epidural anaesthesia for hernia repair.

Mean time for offset of motor block in control group was 180.4 ± 18.9 minutes. In study group B, C and D patients the offset of motor block was 182.4, 186.40 and 182 minutes respectively which was not statistically significant ($p>0.05$), this observation is not supported by findings of Sabbage et al[8] and Kanazi et[9] al. In their study it was found that addition of dexmedetomidine prolonged the duration of motor block in epidural anaesthesia.

Highest time for pain free period was recorded in group C patients and it was found to be 10.89 ± 2.39 hours which was followed by group B patients who had pain relief for 10.71 ±1.75 hours. In control group patients shortest pain free period was seen and it was 4.47 ± 1.27 hours in group D (10.85 ± 2.31). From the finding of our study it can be observed that dose beyond 1.5 mcg/Kg did not enhance the post operative analgesia. The results observed in our study are comparable with the findings of several studies which show that addition of Dexmedetomidine increased post operative pain free period and also the time for demand of first rescue dose of systemic analgesic. Sukhminderjit singh[13] 2011, Vijay G Anand[10], Harsoor SS et al[11], A.M.El- Hennawy et al[12], Salgado PF et al.[6]

In none of the patients from control and study group (B and C) complication like hypotension, bradycardia, vomiting and shivering were seen whereas Group D patients who received 2 mcg/Kg of Dexmedetomidine showed occurrence of hypotension, bradycardia. Sukhminderjit singh[13] et al used the mephentermine and atropine in their study for treating low HR and blood pressure. Salgado et al[6] noticed low incidence of shivering in their study with 1 mcg/kg of Dexmedetomidine. In one study by Michael Smith and Marrof[14] used Dexmedetomidine successfully to prevent shivering associated with anaesthesia.

Highest Level of block achieved in these patients was up to T 9 dermatome in most of the cases, in all groups. Addition of dexmedetomidine did not affect the height of block in majority of patients. Similar observation was made by Salgado PF et al.[6] Whereas SukhminderJit Singh Bajwa et al[13] 2011 found that dexmedetomidine not only provided a higher dermatomal spread but also helped in achieving the maximum sensory anesthetic level in shorter period in comparison to clonidine.

No patient in control and study group had clinically significant respiratory depression. Oxygen saturation was maintained during entire surgery and post operative period.

None of the patient from any group had sedation score 1, 4, 5 and 6. All 25 patients in control had Ramsey score of 3. In group B 72% of cases had score of 3 and rest of the patient means 28% had score 2. In group C patients 32% and 68% of the cases had score of 2 and 3 respectively. For group D sedation score of 2 and 3 was observed in 52% and 48%. The same sedation scoring was seen in studies of Sukhminderjit singh et al[13], Vijay G Anand[10] and Saadawy et al[6] when they used the Dexmedetomidine as a adjuvant with local anaesthetic for epidural anaesthesia. Elhakim et al[12] 2010, noted a decrease in narcotic requirements after epidural dexmedetomidine during combined epidural and general anesthesia for thoracic surgery employing one lung ventilation.

In majority of the patient degree of muscle relaxation in study and control group was acceptable and provide smooth intra operative period. Total time taken by group D patients to achieve bromage scale 1 (33.3 ± 5.5) minutes whereas in control group it took more time (36.7 ± 5.5 minutes) and similar results found by Sukhminderjit Singh et al[13], in his study of epidural block by using 17 ml of 0.75 % ropivacaine with 1.5 mgm/kg of Dexmedetomidine.

decrease of mean heart rate by 35.2% of preoperative mean pulse rate was seen in Group D patients. In groups B, and C, fall in mean heart rate was 22.1% and 29.9% of the mean preoperative heart rate. Bradycardia was responsive to injection Atropine 0.6 mg given intra operatively. No patient in group A, B, and C, had pulse rate 30 % lower than his own pre-operative value. Sukhminder jit singh[13], Taylor Brandao Schnaider et al[15] showed a drop in pulse rate by 20% to 30% in their studies.

Changes noticed in respiratory rate were not clinically significant in any group when compared with their base line preoperative respiratory rate. During the whole period of observation $SpO_2$ remained more than 98 %.

In all group patients mean preoperative systolic and diastolic pressure was between 132.4 and 139.4 and 74.3 and 79.9 mm of Hg. Maximum lowering of 33.1% in systolic pressure and 19.7% in diastolic pressure was seen in Group B patients. Greater than 30% fall from preoperative mean systolic pressure was noticed in group D patients as 31.2%. Hypotension well responded to mephentermine 3- 6 mg IV bolus. In other groups A, and C, fall in blood pressure remained below 30%. Sukhminder jit singh et al[13], Taylor Brandao Schnaider et al[15] also observed fall in systolic blood pressure more than 20% when they used Dexmedetomidine in a dose of 1.0 to 2.0 mcg/kg in their studies.

## CONCLUSION

Addition of Dexmedetomidine, an alpha 2 agonist to local anaesthetic solution for conduct of lumbar epidural block in the dose range of 1.0 to 1.5 mcg/Kg substantially prolongs postoperative analgesia without altering block characteristics offered by Bupivacaine without any significant side effects and appears to be safe and reliable adjuvant.

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