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Efficacy of different doses of dexmedetomidine as an adjuvant to bupivacaine in sub-arachnoid block for patients undergoing lower limb surgeries

Muhammad Owais

Post Graduate Resident, Anesthesia Department, Hayatabad Medical Complex
Peshawar, Pakistan

Salma Jan

Assistant Professor, Anesthesia Department, Hayatabad Medical Complex
Peshawar, Pakistan

Jawad Mabood

Post Graduate Resident, Anesthesia Department, Hayatabad Medical Complex
Peshawar, Pakistan

Corresponding author email: mabood.jawad12@gmail.com

Afraseyab Rehman

Post Graduate Resident, Anesthesia Department, Hayatabad Medical Complex
Peshawar, Pakistan

Shakeeb Ahmad Jan Durrani

Medical Officer, DHQ Hospital Hangu, Pakistan

Sohaib Amin

Post Graduate Resident, Emergency Department, Hayatabad Medical Complex
Peshawar, Pakistan

Abstract--Objective: To determine the difference in efficacy of bupivacaine as adjuvant to 5 µg& 10 µg of dexmedetomidine respectively during intrathecal administration in prolongation of duration of sensory block (as a main primary variable) in lower limb orthopedic surgery. Setting: Department of anesthesia, MTI-HMC, Peshawar. Study design: Randomized controlled trails. Duration of study: From 1st Feb 2021 to 30th July 2021. Subjects & Methods: Each patient enrolled in study after proper consent in written form and counselling was subjected to complete medical history, clinical examination. Spinal column was the primary focus of examination. All

standard vitals monitoring equipment attached. Baseline readings obtained and noted. Double i/v line was secured. Patients were preloaded with 10ml/ kg of Ringer Lactate. Spinal injection of anesthetic. Conclusion: Results obtained from this study showed that adding 10 micro gram of dexmedetomidine in comparison to 5 micro gram to spinal anesthetic for lower limb traumatic orthopedic surgery significantly prolongs the sensory block, analgesia, decreased onset time for block, early rehabilitation and ambulation of patients which has various socioeconomic advantages.

Keywords---anesthesia, spinal anesthesia, bupivacaine, dexmedetomidine, lower limb surgery.

Introduction

Management of intraoperative pain in lower limbs orthopedic surgery along with postoperative pain is associated with early recovery as it leads to attenuation of endocrine, somatic and autonomic reflexes. Pain control leads to early rehabilitation, reduced opioid requirements & side effects related to opioid use.¹ Perioperative pain is managed most commonly with multiple pharmacological approaches the use of which is limited by the side effects of drug used. To prolong the duration of spinal or epidural anesthesia, opioids are most commonly added to bupivacaine or other local anesthetic used.² Dexmedetomidine is a very specific alpha-adrenergic agonist. There is a lot of debate in the current era on the role of alpha-adrenergic agonists in anesthesia and intensive care for the reason that they exhibit many functions in terms of pain management, inducing sedation and maintaining anesthesia. In Europe, the drug of choice for these requirements is clonidine which is regarded as the most useful drug in this category specifically in terms of monitoring regional anesthesia and managing opioid or alcohol withdrawal syndrome.³

Addition of different doses of dexmedetomidine to bupivacaine during spinal anesthesia prolongs onset & duration of sensory blockade. In a study conducted by SUSANTA HALDER et al, by adding 5 µg and 10 µg of dexmedetomidine respectively to bupivacaine in spinal anesthesia for orthopedic surgeries showed that sensory regression to S2 dermatome was 189.10±30.50 mins vs. 216.50±27.07 mins (p value = 0.010) respectively.⁴ Another study conducted by C NWACHUKWU, HO IDEHEN et al, showed that using bupivacaine alone vs. as an adjuvant to 7.5 µg of dexmedetomidine in spinal anesthesia for ORIF of femoral fractures resulted in time to sensory regression to S1 in bupivacaine alone group & combination group of 210.54±21.48 mins vs. 358.74±30.97 mins respectively (p value = 0.02).⁵

Materials and Methods

Study design

Randomized controlled trials.

Setting

Department of anesthesia, MTI-HMC, Peshawar.

Duration of study

Six months after synopsis approval.

Sample Size

Sample size was calculated as total no. of 60 patients (30 in each group) using WHO software with following assumptions: Significance level 5%, statistical power 80%, anticipated proportion of 189.10 ± 30.50 mints & 216.50 ± 27.07 mints.

Sampling technique

Consecutive Nonprobability sampling.

Inclusion Criteria in sample selection

- Patients having ASA physical status of 1 & 2.
- Age 20-50 years.
- Both sexes i.e. male-female
- Patients undergoing any lower limb traumatic orthopedic surgery.

Exclusion Criteria

- Rejection to participate in study by patients.
- Allergic to any anesthetic drugs.
- Contraindication to drugs under study.
- Vertebral column deformities

Data Collection Procedure

After permission & approval from research committee of CPSP and hospital ethical committee, this study will be conducted in the Orthopedics Operation Theatre of MTI- HMC, Peshawar. Patients meeting inclusion criteria will be taken in for the study after their written informed consent. Enrolled patients will be divided into two groups, Group D5 & D10 ($n=30$ per group) by blocked randomization. History of patient to be taken followed by clinical examinations (specifically spine & airway). Baseline vitals will be recorded. I/V line to be passed. Patient will be preloaded with R/L 10ml/kg.

After seating the patient comfortably, L3 L4 lumbar space to be identified. Under aseptic condition 25 G spinal needle will be introduced. Free flow of CSF to be confirmed and drug will be injected. Immediately patient will be made recumbent. Patient allocated to group D5 will receive dose of hyperbaric bupivacaine 15 mg 2cc + 5µg dexmedetomidine. Patients allocated to group D10 will be injected with hyperbaric bupivacaine 15 mg 2cc + 10µg dexmedetomidine.

Sensory testing will be done with 23 G hypodermic needle and will be assessed by loss of pinprick sensation until the T8 level of dermatome anesthetized. Dermatome level will be assessed every 2 minutes after intrathecal injection of drug. Surgery will be started after T8 sensory blockade level. Testing of sensory block level will be then conducted every 30 minutes. The time to reach the T8 dermatome before surgery will be recorded, and the time to regression to S2 dermatome in PACU will be recorded. All durations will be calculated with reference to time of spinal injection as time zero

Data Analysis

Data will be analyzed by using SPSS version 24.0. Standard deviation and mean will be calculated for quantitative variables like Age, BMI, and duration of surgery. For Categorical variables like Gender (male, female) ASA class, a chi square test will be used with p value reported at 95% of confidence interval. The time to reach T8 dermatome, and the regression of the sensory block to S2 dermatome, t-test will be used for analysis. A probability value (p-value) less than 0.05 will be considered statistically significant. All the results will be presented as tables and graphs

Results

This study was conducted at the Department of Anesthesia, MTI-HMC, Peshawar. Results are as follows:- Frequency wise gender distribution of study participant are given in table no.1. Mean and standard deviation for Age was 34.43 ± 8.05 years. Mean and standard deviation for BMI was 25.20 ± 5.71 kg/m². Mean and standard deviation for total duration of surgery was 100.70 ± 6.38 minutes. (Table no.2). Pearson Chi-square test for Gender & ASA class showed insignificant association between the two parameters, $X^2 (1, N=60) = 1.88$, P-Value of 0.170. (Table no.3). An independent samples t-test was conducted to compare block onset time to T8 dermatome between the two groups. There was significant differences [$t(58) = 10.681, p < 0.001$] in the block onset time with Mean & standard deviation of 2.66 ± 0.33 mints for group D5 which was slower than Mean & SD of 1.66 ± 0.38 mints for group D10. The magnitude of difference in the means (mean difference = 1.007 mints, 95% CI: 0.8188 to 1.1965). (Table no.4). Same independent samples t-test was conducted to compare block regression to S2 dermatome between the two groups. There was significant differences [$t(51.429) = 11.819, p < 0.001$] in the block regression time with Mean & standard deviation of 212.43 ± 14.25 mints for group D10 which was slower than Mean & SD of 175.10 ± 9.80 mints for group D5. The magnitude of difference in the means (mean difference = 37.33 mints, 95% CI: 30.99336 to 43.67331). Since Null Hypothesis was rejected (H_0) (Table no.5).

Parameter	Frequency	Percentage
Male	35	58.3
Female	25	41.7
Total	60	100
[Table-1] Gender wise frequency of study participants		

0	3	5	4.11	0.47	11.8	51.4	0.000	37.333	3.158	30.99	43.6
D	175.1	9.80	2		19	2					7
5	0										

[TABLE-5] Independent sample t-test for Block regression time to S2 dermatome between two groups D5 & D10 in minutes

Discussion

Spinal anesthesia in the form of a minimal dose of dexmedetomidine augmented with bupivacaine has been shown to decrease motor and sensory sensations along with reasonable sedation while maintaining hemodynamic stability⁸. This theory is supported by Al - Ghanem *et al.*'s⁹ and his colleagues in their study mentioning that this combination has negligible side effect profile along with providing splendid quality of analgesia.

Effective intraoperative and post operative pain management of lower limb orthopedic surgery is the key component of early postoperative recovery¹⁰. Epidural anesthesia which is a form of spinal local anesthetic block can also be utilized for long term control of pain reducing in need for post operative other intravenous analgesics¹¹. Depending upon the patients' requirements the anesthetist can select a local anesthetic agent that will provide adequate and satisfying spinal anesthesia.¹². The dose, site of injection, lipophilicity and the acid-base milieu of the site of drug deposition determine the extent of efficacy of the block.^{13,14,15}. However, their adverse effects persist irrespective of the route of administration.^{16,17,18}. Dexmedetomidine is sympatholytic drug which is notable for its ability to provide sedation, analgesia and amnesia without the risk of respiratory depression¹⁹. It reduces delirium and preserves respiratory function which adds benefits to its use.²⁰

Addition of different doses of dexmedetomidine to bupivacaine during spinal anesthesia prolongs onset & duration of sensory blockade.⁴ We injected patients with 10 microgram & 5 microgram dexmedetomidine as adjuvant to bupivacaine, in lower limb orthopedic surgeries and studied the efficacy of adjuvant drug in prolongation of sensory and motor blockade. Total duration of sensory blockade with mean & standard deviation was 175.10±9.80 minutes in D5 group & in D10 group with mean & SD was 212.43±14.25 minutes, resulting in 17% of increase in block time in minutes when compared to D5 group. P value was reported to be less than 0.001. In a study conducted by Halder, Susanta et al showed that addition of dexmedetomidine as adjuvant to bupivacaine in 5 micro gram and 10 microgram doses resulted in Onset of both sensory and motor block to be earlier in D5 group (addition of 5 microgram of dexmedetomidine) than group D10 (addition of 10 microgram of dexmedetomidine), (2.56±1.15 & 2.10±1.11 mints respectively) and they were statistically significant (p<0.05). Sensory and motor block durations were also significantly greater in the group D5 (p<0.05) than D10 group. (189.10±30.50 & 216.50±27.07). There was 12.5% difference of increased sensory block duration in minutes in group receiving larger of amount of drug dosage.⁴ These results were quite comparable to our findings in study.

In the present study, Mean and standard deviation for Age was 34.43±8.05 years. Mean and standard deviation for BMI was 25.20 ± 5.71 kg/m². Mean and

standard deviation for total duration of surgery was 100.70 ± 6.38 minutes. (Table no.2). Pearson Chi-square test for Gender & ASA class showed insignificant association between the two parameters, $X^2 (1, N=60) = 1.88$, P-Value of 0.170. (Table no.3) Block onset time upto T8 dermatome between D5 & D10 groups showed $p < 0.001$ and was statistically significant. (table no.4). Block regression to S2 dermatome in D5 group with mean & standard deviation was 175.10 ± 9.80 minutes & in D10 group with mean & SD was 212.43 ± 14.25 minutes, comparing mean with help of T-test showed p value of < 0.001 . (table no.5).

A paper by Gupta et al⁶ and coworkers related to the benefits of dexmedetomidine on postoperative analgesia was performed on 100 patients in 2011. In contrast to ropivacaine alone, it was shown that block regression was noticeably slower with addition of intrathecal dexmedetomidine and time to two segment regressions and time to S2 regression were significantly more with intrathecal dexmedetomidine.⁶ Relatively similar findings were documented by Esmaglu et al and colleagues who experimented with addition of dexmedetomidine to intrathecal levobupivacaine and they found out that this combination gave satisfactory results by inducing proper motor and sensory blockade along with very minimal list of side effects⁷.

A thorough research has been done on the above mentioned topic. Results of our study can be extrapolated to the general population receiving spinal anesthetics for lower limb traumatic orthopedic surgeries but still there are some limitations. The sample size we calculated was based on small population & further research over large population and sample size is needed to establish the efficacy of above mentioned drugs used.

Conclusion

Therefore, we deduce that addition of double amount dosage of dexmedetomidine to hyperbaric bupivacaine 0.5% is quite effective in shortening the onset and increasing the motor and sensory blockade for patients undergoing traumatized lower limb orthopedic surgeries. There is dose dependent prolongation of sensory & motor blockade by dexmedetomidine when added to bupivacaine in spinal anesthetics.

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