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ORIGINAL RESEARCH

Efficacy of low dose dexmedetomidine as an adjuvant to 0.5% isobaric bupivacaine in epidural anaesthesia for elective lower limb surgeries with regards to block characteristics and postoperative analgesia

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ABSTRACT

Introduction: Early postoperative mobilization and rehabilitation with minimal pain and discomfort is the most desirable feature in modern orthopaedic surgeries.The striking feature ofDexmedetomidine is the absence of opioid related side effects like respiratory depression, pruritis, nausea and vomiting.We studied the analgesic and sedative effects of dexmedetomidine when used epidurally in low concentration (0.5µg/kg) as an adjuvant to 0.5% isobaric bupivacaine in patients undergoing elective lower limb surgeries.**Methods:** This was a prospective randomized study carried out over a period of 18 months involving 60 patients aged 20-55 years of ASA grade I & II scheduled for elective lower limb surgeries. Group D patients were administered 18 ml of 0.5% isobaric bupivacaine with 0.5 µg/kg dexmedetomidine. Group P patients were administered 18 ml of 0.5% isobaric bupivacaine with normal saline, volume made equivalent to that of dexmedetomidine.**Results:** Both groups were comparable with regards to age, weight, height distribution, and ASA grading. Duration of sensory and motor blockade: The patients in Group D had a faster onset, better sedation, prolonged time for two-segment regression, and longer duration of sensory and motor blockade. The incidence of side effects such as hypotension and bradycardia was comparable in both groups.**Conclusion**: Low dose (0.5µg/kg) epidural dexmedetomidine is an effective adjuvant to epidural bupivacaine for prolonged surgeries, with minimal side effects and excellent postoperative analgesia.

Keywords: Dexmedetomidine,Epidural,Low Dose.

INTRODUCTION

Early postoperative mobilization and rehabilitation with minimal pain and discomfort is the most desirable feature in modern orthopedic surgeries. Epidural anesthesia is the most commonly used technique for providing not only perioperative surgical anesthesia but also postoperative analgesia in lower limb surgeries.[1,2]

Dexmedetomidine is a highly selective α2 adrenergic agonist that acts on both pre- and post-synaptic sympathetic nerve terminals and the CNS. It reduces sympathetic outflow and norepinephrine release causing sedative, anti-anxiety, analgesic, sympatholytic, and hemodynamic effects. The striking feature of this drug is the absence of opioid-related side effects like respiratory depression, pruritis, nausea, and vomiting.[2-5]

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Based on the above-established facts, we designed a randomized controlled study with the aim to analyzethe analgesic and sedative effects of dexmedetomidine when used epidurally in low concentration (0.5 µg/kg) as an adjuvant to 0.5% isobaric bupivacaine in patients undergoing elective lower limb surgeries.

METHODS

This was a prospective randomized study carried out over a period of 18 months involving 60 patients aged 20-55 years of ASA grade I & II scheduled for elective lower limb surgeries, divided equally into Group D & Group P. Group D patients were administered 18 ml of 0.5% isobaric bupivacaine with 0.5 µg/kg dexmedetomidine. Group P patients were administered 18 ml of 0.5% isobaric bupivacaine with normal saline, volume made equivalent to that of dexmedetomidine.

Those with a BMI ≤19 & ≥ 30.0, an international normalized ratio >1.3, platelets <100,000, patients on anticoagulant therapy, with neurological disease, cardiac or renal insufficiency, spinal deformities, allergy or intolerance to local anesthetics, and ASA grade III and above were excluded from the study.

Time of onset of sensory blockade was recorded as the time in minutes from the time of injection of study drug/placebo to achieve loss of sensation to pin prick in the midline using a 27 G blunt hypodermic needle every 2 minutes interval until T10 dermatome is reached. Time to achieve maximum sensory level was the time in minutes to achieve loss of sensation to pinprick using a 27 G blunt hypodermic needle tested every 5 minutes until the highest level has been stabilized from the T10 dermatome. Duration of sensory blockade was noted as the time taken from the onset of sensory block at T10 to the time of pain sensation at the surgical site with a visual analogue scale score of > 3. Time for two-segment dermatomal regression was the time in minutes taken to regress the level of loss of sensation to pinprick to two lower sensory dermatomal levels.

Time of onset of motor blockade was the time in minutes taken from the time of injection to the achievement of grade 3 motor blockade in the lower limbs. The degree of motor block was assessed every 5 minutes for the first 60 minutes and then every 15 minutes till completion of surgery by the modified Bromage score. Duration of motor blockade was noted as the time taken in minutes from the time of injection till the patient attains complete motor recovery of the lower limb, i.e., modified Bromage Score.

Time to rescue analgesia was the time taken in minutes from the time of injection to the time when the patient complains of pain at surgical site. Analgesia was monitored by using VAS score. VAS score was recorded 5 minutes before epidural, at the start of surgery and then every 15 minutes interval till the end of surgery. Postoperatively, VAS was recorded 30 minutes for first 1 hr, then hourly for 12 hr and then third hourly for next 12 hr till 24 hr. When patients had VAS score (verbal) of more than 3, rescue analgesia in the form of epidural top up with 8ml of 0.125% isobaric bupivacaine was given. The time at which patient demanded first dose of rescue analgesia was the primary end point of this study because at that time the effect of epidural anaesthesia would have weaned off.

Data was entered into Microsoft excel data sheet and was analysed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chisquare test was the test of significance. Continuous data was represented as mean and standard deviation. Chi square test and independent t test was the test of significance to identify the mean difference between two groups. p-value of < 0.05 was considered as statistically significant.

RESULTS

Majority of the participants (43% and 30%) were in the age group of 41-50 years in group D and group P. This was followed by 51-60 years, 23.3%, and 26.7% in group P and group D, respectively. In total, the majority (36.7%) were 41-50 years of age. There was no significant difference in age group distribution of group P and group D (P=0.653). Both the P and D groups were comparable in terms of age distribution. The mean age ± standard deviation was 42.90 ± 10.19 and 41.60 ± 11.99 in the P and D groups, respectively, and in total it was 42.25 ± 11.05.

Age (in Years)	Group P	Group D	Total	P-Value
20-24	2 (6.6%)	5 (16.6%)	7 (11.6%)	0.551
25-34	4 (13.3%)	5 (16.6%)	9 (15%)	
35-44	7 (23.3%)	4 (13.3%)	11(18.4%)	
45-55	17 (56.6%)	16 (53.3%)	33 (55%)	
Total	30(100%)	30(100%)	60(100%)	
Mean ± SD	42.90±10.19	41.60±11.99	42.25±11.05	

Table 1: Age Group Distribution among Participants in Both Groups

Majority of the participants (70%) were males in both the P and D groups. There was no significant difference in sex distribution of P and D groups (p = 1.000). Both the P and D groups were comparable in terms of sex distribution. Both groups were comparable with respect to ASA grade distribution.

The mean and standard deviation of height in groups P and D were 163.90±1.48 and 167.03±1.52,

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respectively. There was no significant difference in height of P and D groups (p = 0.145). Both groups were comparable in terms of height distribution. The mean and standard deviation of weight in groups P and D were 61.77±1.63 and 64.17±1.76, respectively. There was no significant difference in the weight of the P and D groups (p = 0.322). Both groups were comparable in terms of weight distribution.

	Group P	Group D	Total	P-Value
Height(cm)	163.90±1.48	167.03±1.52	165.47±1.07	.0145
Weight(kg)	61.77±1.63	64.17±1.76	62.97±1.20	0.322

Table 2: Comparison of Height and Weight of Patients in Two Groups Studied

Majority of participants in both groups had maximum sensory block at T6, 86.7% and 70% in groups P and D had T6 level sensory block. 13% in group P and 27% in group D had maximum sensory block at T8 level. Though more participants in group P had maximum sensory block at T6, this difference was not statistically significant with p = 0.209.

Level of Maximum Sensory Block	Group P	Group D	Total	P-Value
T10	0(0%)	1(3.3%)	1(1.7%)	0.209
T8	4(13.3%)	8(26.7%)	12(20%)	
T6	26(86.7%)	21(70%)	47(78.3%)	
Total	30(100%)	30(100%)	60(100%)	

Table 3: Level of Maximum Sensory Block-Frequency Distribution of Patients in Two Groups Studied

All participants (100%) in group P had a sedation score of 1. In group D, 80% had a sedation score of 2, and the remaining 20% had a sedation score of 3. This difference was statistically significant with p<0.001.

Sedation Score	Group P	Group D	Total	P-Value
1	30(100%)	0(0%)	30(50%)	<0.001
2	0(0%)	24(80%)	24(40%)	
3	0(0%)	6(20%)	6(10%)	
Total	30(100%)	30(100%)	60(100%)	

Table 4: Sedation Score-Frequency Distribution of Patients in Two Groups Studied

The onset of sensory block was early in group D, which is 8.2 minutes, while in group P it was 15.5 minutes. Also, the onset of motor block was early in group D, which was 16.5 minutes, while in group P it was 25.7 minutes. Both the onset of sensory and motor block was early in group D and was statistically significant (p<0.001).

The time for maximum sensory block was 15 minutes in group D compared to 24 minutes in group P. The time for maximum sensory block was early in group D and was statistically significant (p<0.001).

The time for two segment regression was 315.6 minutes in group D compared to 87.6 minutes in group P. The time to two-segment regression was early in group P and was statistically significant (p<0.001).

Variables	Group P	Group D	Total	P-Value
Onset of Sensory Block (minutes)	15.53±0.55	8.27±0.22	11.90±0.56	**<0.001**
Onset of Motor Block (minutes)	25.77±0.73	16.53±0.45	21.15±0.74	**<0.001**
Time for Max Sensory Block (minutes)	23.97±0.68	15.60±0.33	19.78±0.66	**<0.001**
Time to Two Segment Regression	87.67±1.53	315.67±1.59	201.67±14.88	**<0.001**

Table 5: Comparison of Study Variables in Two Groups of Patients Studied

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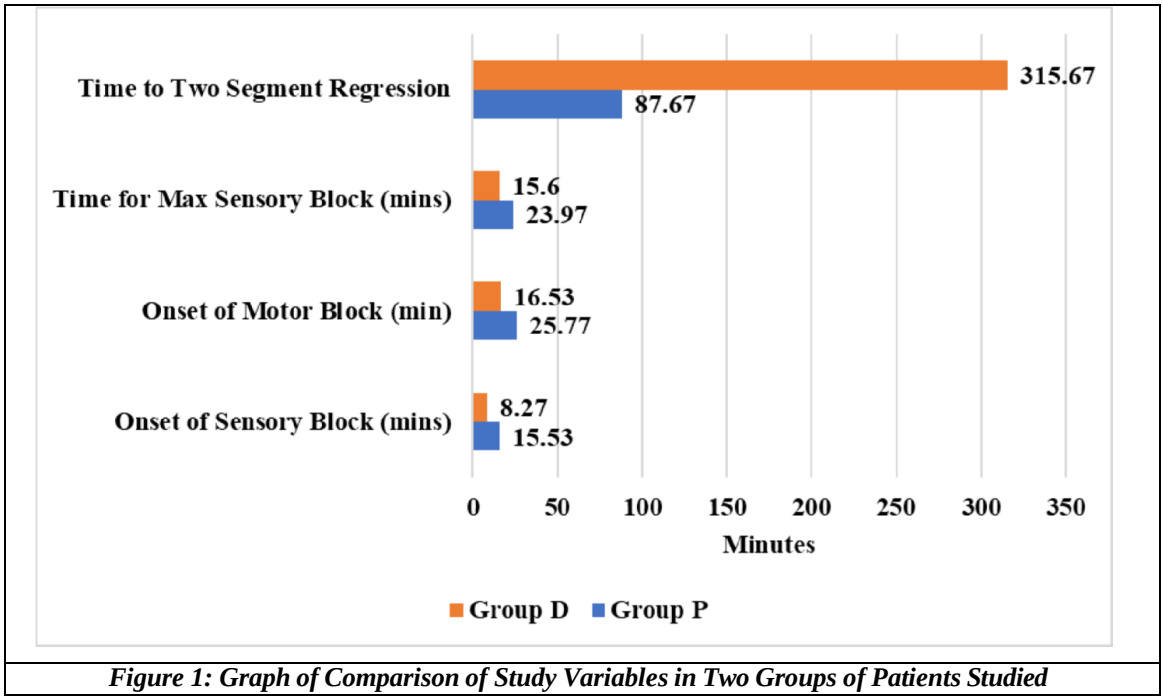

Figure 1: Graph of Comparison of Study Variables in Two Groups of Patients Studied

The duration of sensory block was 356.8 minutes in group D and 120 minutes in group P. The duration of motor block was 345.5 minutes in group D and 155 minutes in group P. The time for rescue analgesia was 355 minutes in group D and 120 minutes in group P. The duration of sensory and motor block and time for rescue analgesia were all greater in group D than in group P; this difference was statistically significant with p<0.001.

Variables	Group P	Group D	Total	P-Value
Duration of Sensory Block	120.00±1.79	356.83±1.93	238.42±15.47	**<0.001****
Duration of Motor Block	155.00±2.35	345.50±1.48	250.25±12.48	**<0.001****
Time for Rescue Analgesia	120.00±1.79	355.50±2.44	237.75±15.40	**<0.001****

Table 6: Comparison of Study Variables in Two Groups of Patients Studied

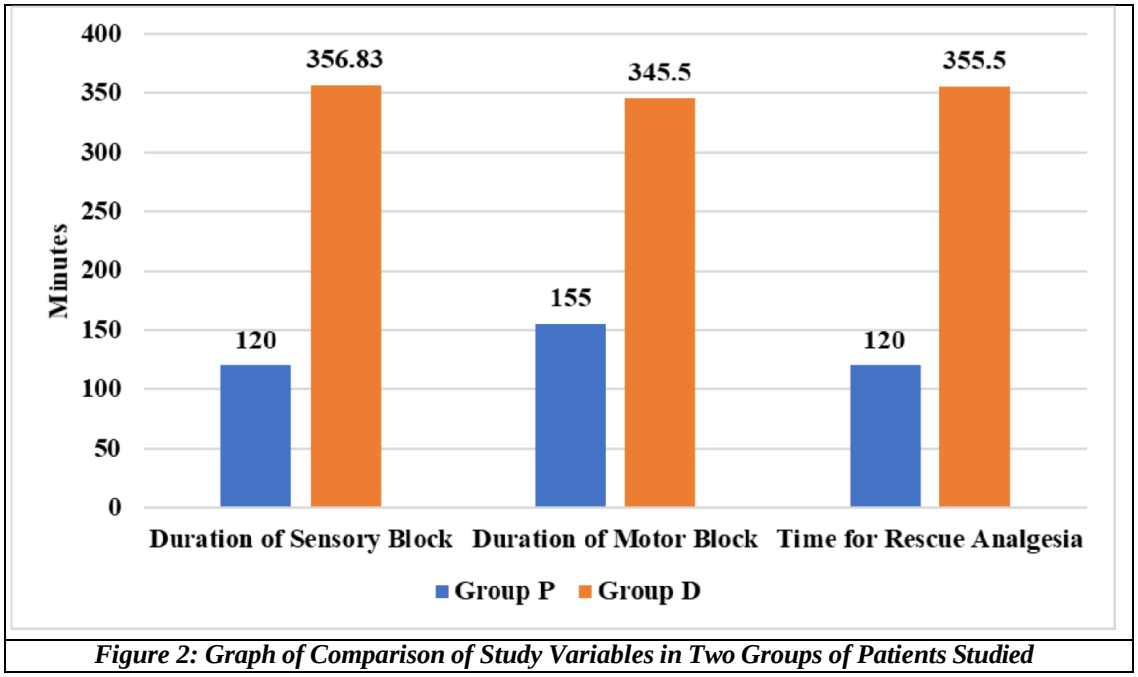

Figure 2: Graph of Comparison of Study Variables in Two Groups of Patients Studied

30% of participants in group D and 13.3% of participants in group P had side effects. 10% of the participants in group D had bradycardia and 20% had hypotension. 10% and 3.3% in group P had hypotension and bradycardia, respectively. Overall, hypotension was the common side effect (15%) followed by bradycardia (6.7%).

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Variables	Group P	Group D	Total
Nil	26(86.7%)	21(70%)	47(78.3%)
Yes	4(13.3%)	9(30%)	13(21.7%)
Bradycardia	1(3.3%)	3(10%)	4(6.7%)
Hypotension	3(10%)	6(20%)	9(15%)

Table 7: Side Effects–Frequency Distribution of Patients in Two Groups Studied

DISCUSSION

Epidural analgesia offers superior pain relief and early mobilization especially when local anaesthetic is combined with an adjuvant.[6] Alpha 2 agonists have evolved as panacea for various applications/procedures with promising multiple delivery routes. Epidural administration of these drugs is associated with sedation, analgesia, anxiolysis, hypnosis and sympatholysis.[7,8] Alpha 2 agonists may provide an attractive alternative to anesthetic adjuvants in current use because of their anesthetic-sparing and haemodynamic stabilizing effects.[9,10]The complementary action of local anaesthetics and alpha 2 adrenoceptor agonists accounts for their profound analgesic properties. Dexmedetomidine is eight times more specific and highly selective Alpha 2 adrenoceptor agonist. [9,11] The prolongation of motor block of local anaesthetics may be the result of binding of Alpha 2 adrenoceptor agonists to the motor neurons in the dorsal horn.[12]

In the present study, the two groups were comparable with respect to age distribution (p = 0.653), sex distribution (p = 1.000), ASA distribution (p = 1.000), height distribution (p = 0.145), and weight distribution (p = 0.322). We found no statistical significance (p=0.209) in the maximum level of analgesia achieved in both groups. Our findings were in concordance with Salgado et al.[13]Unlike our study, Bajwa et al.,[1]found that dexmedetomidine provided a significantly higher dermatomal spread T5 – T6 compared to clonidine when added as adjuvant to epidural ropivacaine. This could be attributed to the lower dose of dexmedetomidine (0.5µg/kg) used in our study.

In this study the onset of sensory and motor blockade was earlier in Group D and was statistically significant with p<0.001 when compared to Group P. Similar results were seen in study done by Shaikh S et al.[14]

The results of our study clearly indicated the effectiveness of epidural dexmedetomidine as adjuvant to bupivacaine in providing sedation. More patients in Group D had sedation score 2 and 3 compared to the number in Group P with a statistically significant p value (<0.001). Similar results were seen in study done by Saravana Babu M et al.[3]

Our study showed that the time for two-segment regression was earlier in Group P than in Group D. This was statistically significant (p<0.001) and was in concordance with the study done by Bajwa S et al.[1]

The dexmedetomidine group showed visible superiority over isobaric bupivacaine group in various postoperative block characteristics such as wearing off of sensory and motor block, and prolonged postoperative analgesia. Similar to this study, Safiya et al,[14]found significant prolongation of time to two segmental dermatomal regression and regression to Modified Bromage 1 in dexmedetomidine group when compared to isobaric bupivacaine group. Salgado et al,[13]also found that the duration of motor block was significantly higher in the dexmedetomidine group (P > 0.05).

Intensity of postoperative pain was assessed using VAS and analgesia was provided when VAS was >3. The time of requirement for rescue analgesia was significantly delayed in dexmedetomidine group (355.50±2.4 minutes) when compared to isobaric bupivacaine group (120±1.79 minutes). The duration of sensory, motor block and time for rescue analgesia were all greater in group D compared to group P, and were statistically significant with p<0.001. Although the prolonged duration of sensory blockade with dexmedetomidine improved postoperative pain management, the delayed recovery of motor function may have its disadvantages and may be inappropriate for day care surgeries, which may be considered a disadvantage. This was in concordance with the study done by Vaibhav shahi et al.[15]

The incidence of side-effects like vomiting, headache, shivering and dizziness were comparable in both the groups and statistically insignificant. 30% of participants in group D and 13.3% of participants in group P had side effects.10% of the participants in group D had bradycardia and 20% had hypotension. 10% and 3.3% in group P had hypotension and bradycardia respectively. Overall, hypotension was the common side effect (15%) followed by bradycardia (6.7%). Similar to this study, Bajwa et al.,[1]] and El-Hennawy et al [16] also found the incidence side-effects to be statistically insignificant on comparison..

Most of the previous studies have used a higher dexmedetomidine dose and found superior results. This study clearly showed the superiority of low dose of dexmedetomidine (0.5µg/kg), when compared to isobaric bupivacaine without any additives, without a compromise on the quality of block.

Addition of 0.5µg/kg dexmedetomidine as adjuvant to epidural bupivacaine led to early onset of analgesia, faster achievement of maximum sensory level and motor blockade. It not only prolonged the duration of analgesia but also provided a good sedation level during the surgical procedure without significant hemodynamic effects. Our data thus supports the findings of the previous studies enumerated herewith.

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Safiya I. Shaikh and Sarala B Mahesh[14] conducted a study comparing the efficacy and clinical profile of dexmedetomidine and clonidine as an adjuvant to bupivacaine with special emphasis on their quality of analgesia, sedation, and the ability to provide a smooth intraoperative and postoperative course. The study concluded that dexmedetomidine is a superior neuraxial adjuvant to bupivacaine when compared to clonidine for early onset of analgesia, superior intraoperative analgesia, stable cardiorespiratory parameters, prolonged postoperative analgesia, and providing patient comfort.

Shilpi Agarwal et al.,[17] studied that α2 agonists are being extensively evaluated as an alternative to neuraxial opioids as adjuvants in regional anesthesia. The study concluded that dexmedetomidine is a better adjuvant than clonidine for providing early onset of sensory analgesia, superior sedative properties, and prolonged postoperative analgesia.

Sarabjit Kaur et al.,[18] conducted a study to compare the hemodynamic, sedative and analgesia potentiating effects of epidurally administered dexmedetomidine when combined with ropivacaine. The study concluded that epidural dexmedetomidine as an adjuvant to ropivacaine is associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia, and reduced demand for rescue analgesics when compared to plain ropivacaine.

SruthiArunkumar et al.,[19] conducted a study to compare the effect of clonidine and dexmedetomidine when used as an adjuvant to epidural ropivacaine in lower abdominal and lower limb surgeries. The study concluded that dexmedetomidine at doses of 1 µg/kg is an effective adjuvant to ropivacaine for epidural anesthesia, which is comparable to clonidine.

Seema ShreepadKarhade et al.,[20] conducted a study comparing the onset of action, duration of action, highest dermatomal level achieved, degree of motor blockade, sedation, intraoperative and postoperative anesthesia, and analgesia achieved by epidural bupivacaine versus bupivacaine with dexmedetomidine for vaginal hysterectomy. They concluded that epidural dexmedetomidine 0.5 µg/kg is a good adjuvant providing early onset of sensory and motor block, adequate sedation, and prolonged postoperative analgesia with minimal side effects.

Mohammadrezagousheh et al [21] conducted a study aimed to compare the analgesic effects of dexmedetomidine and morphine as adjuvants to bupivacaine for epidural anaesthesia in leg fracture surgery. They concluded that the findings of their study showed that bupivacaine-dexmedetomidine combination results in prolonged sensory and motor block and effective postoperative pain control. Thus, this combination could be appropriate for epidural anaesthesia in leg fracture surgery.

CONCLUSION

In conclusion, low dose (0.5µg/kg) epidural dexmedetomidine is an effective adjuvant to epidural bupivacaine for prolonged surgeries, with minimal side effects and excellent postoperative analgesia. Further evaluation is needed for better utilisation of dexmedetomidine in other surgical groups.

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