

Comparison of efficacy, potency, haemodynamic effects, complications and side effects of two doses of dexmedetomidine for control of shivering intra operatively

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Abstract

Background: Shivering occurs mostly after central neuraxial blockade due to altered thermoregulatory control. Shivering is an involuntary, oscillatory muscular activity that augments metabolic heat production. Vigorous shivering increases metabolic heat production up to 600% above the basal level. **Aim:** 1.To assess the efficacy and potency of dexmedetomidine in shivering during spinal anesthesia.2.To assess hemodynamic changes in using the drug. **Methods:** This Double-Blind, Randomized, Clinically Controlled Trial Was Done In 100 Patients At department Of Anesthesiology, Vinayaka Mission's Medical College and Hospital, Karaikal. Patients were randomly allocated into two groups of 50 each.1. Group A-Dexmedetomidine 0.5mcg/kg IV.2. Group B-Dexmedetomidine 1 mcg/kg IV. A minimum of 8 hours Nil Per Oral status. **Results:** In our study the time of onset of shivering variability is compared in both the group and the mean value of group A (72.30) standard deviation (41.35) and the group B mean value(72.66) standard deviation (41.64) p-value of 0.965 which is statistically insignificant.In Severity of shivering the mean value of group A (3.8) standard deviation (0.27) and group B the mean value (3.96) standard deviation (0.12) the p-value of 0.405 which is statistically insignificant. In time to disappearance of shivering(sec) the mean value of group A (174) standard deviation (14.5) and group B the mean value (168) standard deviation (23.3) the p-value of 0.0024 which is statistically significant. **Conclusion:** Both Dexmedetomidine(0.5mcg/kg) and Demedetomidine (1mcg/kg) are useful for cessation of post Spinal shivering, but Dexmedetomidine (0.5mcg/kg) have less complication and side effects compared to Dexmedetomidine (1mcg/kg). So we conclude that Dexmedetomidine (0.5mcg/kg) is good choice. **Key Words:** Shivering, Dexmedetomidine, Vital Signs, Post Spinal Anaesthesia

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INTRODUCTION

Shivering is an involuntary, oscillatory muscular activity that augments metabolic heat production. Vigorous shivering increases metabolic heat production up to 600% above the basal level. However, a doubling of metabolic heat production is all that can be sustained over a mechanism that could determine the rhythm and frequency of motor neurons discharges. Shivering is defined as an involuntary, repetitive activity of skeletal muscles. ¹Though hypothalamic thermoregulation remains intact during regional anesthesia, it is associated

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with greater heat loss than general anesthesia which is attributed to various reasons like abnormal heat loss due to vasodilatation, impairment of shivering in the area of the block and rapid intravenous (IV) infusion of cold fluids. ²Furthermore, the incidence of shivering is comparable in volunteers and patients are given warm or cold epidural anesthetic injections. These data indicate that temperature of injected local anesthetic does not influence the incidence of shivering during major conduction anesthesia.³ The risk of shivering during neuraxial anesthesia is markedly diminished by maintaining strict normothermia. However, a distinct incidence of low-intensity, shivering-like tremor occurs in normothermic patients and is not thermoregulatory. ⁴The cause of this muscular activity remains unknown. However, it is associated with pain, and it may thus result from sympathetic nervous system activation. The same drugs that are effective for post anesthetic tremors also are useful for shivering during regional anesthesia: these include meperidine (25 mg intravenously [IV] or epidurally) clonidine (75 µg IV), dexmedetomidine, ketanserin (10 mg IV), and magnesium sulfate (30 mg/kg IV). The incidence of postoperative shivering-like tremors reportedly is approximately 40%, but it now appears to be less as more patients are kept normothermic and opioids are administered more frequently and in larger doses than in the past. ⁵

METHODOLOGY

A prospective randomized double-blinded controlled clinical study was conducted in the Department of Anaesthesia, Vinayaka Mission’s Medical College and Hospital, Karaikal after obtaining ethical committee approval from our institute, 120 patients were screened and 20 patient didn’t fit the inclusion criteria then after obtaining the consent, 100 patients were randomly allocated through computer-generated method into two groups with 50 patients in Group A who received Inj. Dexmedetomidine 0.5mcg/kg and group B received Inj.

Dexmedetomidine 1mcg/kg in Elective Lower abdominal surgeries, orthopedic, gynecological surgeries under post-spinal anesthesia shivering were chosen for this study. Inclusion Criteria: ASA grade 1 and 2 patients, of either sex, Age 18-60yrs, Scheduled for elective lower abdominal, orthopedic, and gynecological surgeries. Exclusion Criteria: Patients with known history of alcohol or substance abuse, hyperthyroidism, cardiovascular diseases, psychological disorder, severe diabetes or autonomic neuropathies and urinary tract infection. Patients with known hypersensitivity to DEXMEDETOMIDINE. ASA grade III and IV, Pregnant and lactating women, Age: <18yrs and >60yrs

GRADING OF SHIVERING [1,6,9]

- Grade 0: No shivering.
- Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction, peripheral cyanosis without other cause, but without visible muscle activity.
- Grade 2: Visible muscle activity confined to one muscle group.
- Grade 3: Visible muscle activity in more than one muscle group.
- Grade 4: Gross muscle activity involving the whole body.

Patients who developed either Grade 3 or Grade 4 of shivering were included in the study. The same criteria were used for grading shivering during recurrence and patients with Grade 3 or 4 shiverings were included.

STATISTICAL ANALYSIS

Students Independent sample size t-test were used to find the significant difference between the age, duration of surgery, Heart rate, Systolic Blood pressure, Diastolic Blood Pressure, Mean Arterial Pressure, SpO₂, respiratory rate, time of onset of shivering, severity of shivering, time to disappearance of shivering and time of recurrence with treatment of shivering groups and these expressed as mean and standard deviation. P<0.05 considered statistically significant.

RESULTS

Table 1: Demographic profile of patients of both groups

Parameter	GroupA (n=50)	GroupB(n=50)	P value
Age(years)	36.54 ± 10.92	39.74 ± 9.72	0.125
Gender(M/F)	39/11	32/18	0.123
Weight(kgs)	71.6 ± 8.5	73.3 ± 9.3	0.424
Height(cm)	173.6 ± 7.3	171.7 ± 6.5	0.329
ASA I/ASA II	15/35	13/37	0.482
Duration of surgery(hours)	1.28 ± 0.65	1.12 ± 0.55	0.185
Duration of spinal anesthesia(mins)	136.2 ± 14.1	132.7 ± 11.6	0.295
Crystalloids infused	1553 ± 527.2	1483 ± 392.7	0.372

TABLE: 1 In our study the basic variables as time weight(kgs) in group A with the mean (71.6) standard deviation (8.5) and in group B with the mean of (73.3) standard deviation of (9.3) was compared and the p-value of 0.424 which is statistically insignificant. In our study, the basic variables as height in group A with the mean (173.6) standard deviation

(7.3) and in group B with the mean of (171.7) standard deviation of (6.5) were compared and the p-value of 0.329 which is statistically insignificant. In our study the basic variables as time duration of surgery in group A with the mean (1.28) standard deviation (0.65) and in group B with the mean of (1.12) standard deviation of (0.55) were compared and the p-value of 0.185 which is statistically insignificant

Table 2: Comparison of heart rate variables between two groups

	Group A	Group B	P-Value
	Mean \pm SD	Mean \pm SD	
Baseline	80.40 \pm 13.74	77.76 \pm 11.17	0.294
0 Minute	79.72 \pm 11.14	76.84 \pm 10.81	0.193
2 Minutes	79.72 \pm 9.88	72.82 \pm 9.12	0.001
5 Minutes	80.12 \pm 10.83	71.40 \pm 9.74	<0.001
10 Minutes	79.84 \pm 10.63	68.44 \pm 8.48	<0.001
20 Minutes	79.71 \pm 10.58	67.22 \pm 9.14	<0.001
30 Minutes	79.05 \pm 9.92	67.58 \pm 8.43	<0.001
45 Minutes	78.83 \pm 9.75	68.19 \pm 8.94	<0.001
60 Minutes	78.59 \pm 10.12	71.71 \pm 8.78	0.014
120 Minutes	70.0 \pm 10.36	73.0 \pm 7.07	0.441

TABLE: 2 In our study the heart rate variability is compared in both the group and at the 2mins the mean value of group A (79.72) standard deviation (9.88) and the group B mean value(72.82) standard deviation (9.12) p-value of 0.01 which is statistically significant. At 5 mins the mean value of group A (80.12) standard deviation (10.83) and group B the mean value (71.40) standard deviation (9.74) the p-value of < 0.001 which is statistically highly significant. At 10, 20, 30,45 mins in both groups A and B were compared and the p-value of 0.001 which is statistically highly significant. At 60,120mins in both groups, A and B were compared and the p-value of 0.014 and 0.441 which are statistically insignificant.

Table 3: Comparison of mean arterial pressure variables between two groups

	Group A	Group B	P-Value
	Mean \pm SD	Mean \pm SD	
Baseline	93.98 \pm 1.79	92.29 \pm 4.14	0.009
0 Minute	93.20 \pm 2.32	89.42 \pm 3.74	<0.001
2 Minutes	91.48 \pm 2.89	87.62 \pm 5.18	<0.001
5 Minutes	84.50 \pm 2.65	84.20 \pm 5.83	0.741
10 Minutes	81.84 \pm 3.59	84.18 \pm 7.17	0.042
20 Minutes	75.48 \pm 3.14	76.90 \pm 4.61	0.075
30 Minutes	78.88 \pm 4.52	74.16 \pm 1.86	<0.001
45 Minutes	78.78 \pm 6.53	72.94 \pm 2.18	<0.001
60 Minutes	83.66 \pm 4.91	71.85 \pm 2.19	<0.001
120 Minutes	84.36 \pm 5.42	72.86 \pm 4.13	<0.001

TABLE :3 In our study the Mean Arterial Pressure variability is compared in both the group and at the baseline in the mean value of group A (93.98) standard deviation (1.79) and the group B mean value(92.29) standard deviation (4.14) p-value of 0.009 which is statistically significant. At initial (0) min the mean value of group A (93.20) standard deviation (2.32) and group B the mean value (89.42) standard deviation (3.74) the p-value of < 0.001 which is statistically highly significant. At 2 min the mean value of group A (91.48) standard deviation (2.89) and group B the mean value (87.62) standard deviation (5.18) the p-value of < 0.001 which is statistically highly significant. At 10 min the mean value of group A (81.84) standard deviation (3.59) and group B the mean value (84.18) standard deviation (7.17) the p-value of 0.042 which is statistically significant. At 30,45,60,120 mins in both groups, A and B were compared and the p-value of 0.001 which is statistically highly significant.

Table 4: Comparison of spo2 variables between two groups

	Group A	Group B	P-Value
	Mean \pm SD	Mean \pm SD	
Baseline	99.22 \pm 0.65	97.94 \pm 1.13	<0.001
0 Minute	98.24 \pm 0.48	97.98 \pm 0.99	0.100
2 Minutes	98.44 \pm 0.76	97.98 \pm 1.13	0.019
5 Minutes	98.64 \pm 0.66	98.20 \pm 1.21	0.027

TABLE: 4 In our study the Spo2 variability is compared in both the group and at the baseline min the mean value of group A (99.22) standard deviation (0.65) and the group B mean value(97.94) standard deviation (1.13) p-value of < 0.001 which is statistically highly significant. At initial (0) min the mean value of group A (98.24) standard deviation (0.48) and group B the mean value (97.98) standard deviation (0.99) the p-value of 0.100 which is statistically insignificant. At 2 min the mean value of group A (98.44) standard deviation (0.76) and group B the mean value (97.98) standard deviation (0.99) the p-value of 0.019 which is statistically significant. At 5 min the mean value of group A (98.64) standard deviation (0.66) and group B the mean value (98.20) standard deviation (1.21) the p-value of 0.027 which is statistically significant.

Table 5: Comparison of mean respiratory rate variables between two groups

	Group A Mean ± SD	Group B Mean ± SD	P-Value
Baseline			
0 Minute			
2 Minutes	13.46 ± 1.59	13.46 ± 1.37	1.000
5 Minutes	13.54 ± 1.36	13.86 ± 2.06	0.362
10 Minutes	13.64 ± 1.60	12.92 ± 1.38	0.018

TABLE: 5 In our study the Mean Respiratory Rate variability is compared in both the group and at the 2 min the mean value of group A (13.46) standard deviation (1.59) and the group B mean value(13.46) standard deviation (1.37) p-value of 1.000 which is statistically insignificant. At 5 min the mean value of group A (13.54) standard deviation (1.59) and group B the mean value (13.86) standard deviation (2.06) the p-value of 0.362 which is statistically insignificant. At 10 min the mean value of group A (13.64) standard deviation (1.60) and group B the mean value (12.92) standard deviation (1.38) the p-value of 0.018 which is statistically significant.

Table 6: Comparison of the time of onset of shivering, severity of shivering, time to disappearance of shivering and time of recurrence in the two study groups

	GroupA (n=50)	GroupB(n=50)	P
Time of onset of shivering(min)	72.30 ± 41.35	72.66 ± 41.64	0.965
Severity of shivering	3.8 ± 0.27	3.96 ± 0.12	0.405
Time to disappearance of shivering(Sec)	174 ± 14.5	168 ± 23.3	0.0024
Time of recurrence	70 ± 17.3	75 ± 21.17	0.42

TABLE: 6 In our study the time of onset of shivering variability is compared in both the group and the mean value of group A (72.30) standard deviation (41.35) and the group B mean value(72.66) standard deviation (41.64) p-value of 0.965 which is statistically insignificant. In the Severity of shivering the mean value of group A (3.8) standard deviation (0.27) and group B the mean value (3.96) standard deviation (0.12) the p-value of 0.405 which is statistically insignificant. In time to disappearance of shivering(sec) the mean value of group A (174) standard deviation (14.5) and group B the mean value (168) standard deviation (23.3) the p-value of 0.0024 which is statistically significant.

Table 7: Comparison of complications in both groups

Complication	Group A (n=50)	Group B (n=50)
Hypotension	15(30%)	30(60%)
Bradycardia	12(24%)	35(70%)
Nausea	2(4%)	6(12%)
Vomiting	0(0)	3(6%)
Sedation Grade1	30(60%)	40(80%)
Grade2	15(30%)	10(20%)
Dry mouth	2(4%)	6(12%)

TABLE: 7 In our study complications like hypotension, bradycardia, nausea, vomiting, Sedation Grade1, Sedation Grade2, Dry mouth are compared in both Groups. The percentage of complications are more in Group B than Group A.

DISCUSSION

Shivering is known to be a frequent complication in patients undergoing surgery under neuraxial anesthesia. K.S. Filos *et al.* have reported the incidence of shivering in patients undergoing surgery under regional anesthesia

at 40–70% based on previous studies. The incidence of shivering in our study was 41%. In this study, we studied the efficacy of dexmedetomidine in the treatment of post-SA shivering in adults and compared its efficacy with dexmedetomidine for the treatment of shivering after SA

in patients undergoing various elective surgeries. Although tramadol is an established drug in the treatment of shivering, in this study, we found that dexmedetomidine (0.5mcg/kg) is equally effective as dexmedetomidine (1mcg/kg) in treating post-SA shivering.⁶ Prevention of post-anesthetic shivering (PAS) mainly entails preventing perioperative heat loss by increasing the ambient temperature of the operative room, using conventional war air blankets and using warmed intravenous (I.V.) fluids. Although the neurotransmitter pathways involved in the mechanism of PAS are complex and still anonymous, there are various pharmacological drugs available for the management of PAS such as meperidine, clonidine, tramadol, and ketamine. However, every drug has its own adverse effect and the ideal anti-shivering still not found.⁷ The efficacy of dexmedetomidine is similar to that of a previous study by Sessler DI, *et al* who studied the role of dexmedetomidine in the treatment of postoperative shivering in adults. In our study, the time of onset of shivering variability is compared in both the group and the mean value of group A (72.30) standard deviation (41.35) and the group B mean value(72.66) standard deviation (41.64) p-value of 0.965 which is statistically insignificant. In Severity of shivering the mean value of group A (3.8) standard deviation (0.27) and group B the mean value (3.96) standard deviation (0.12) the p-value of 0.405 which is statistically insignificant. In time to disappearance of shivering(sec) the mean value of group A (174) standard deviation (14.5) and group B the mean value (168) standard deviation (23.3) the p-value of 0.0024 which is statistically significant. In our study the basic variables as age in group A with the mean (36.54) standard deviation (10.92) and in group B with the mean of (39.74) standard deviation of (9.72) was compared and the p-value of 0.125 which is statistically insignificant.⁸ In our study the heart rate variability is compared in both the group and at the 2mins the mean value of group A (79.72) standard deviation (9.88) and the group B mean value(72.82) standard deviation (9.12) p-value of 0.01 which is statistically significant. At 5 mins the mean value of group A (80.12) standard deviation (10.83) and group B the mean value (71.40) standard deviation (9.74) the p-value of < 0.001 which is statistically highly significant. At 10, 20, 30,45 mins in both groups A and B were compared and the p-value of 0.001 which is statistically highly significant. At 60,120mins in both groups A and B were compared and the p-value of 0.014 and 0.441 which are statistically insignificant.^{9,10} In our study the Mean Arterial Pressure variability is compared in both the group and at the baseline min the mean value of group A (93.98) standard deviation (1.79) and the group B mean value(92.29) standard deviation (4.14) p-value of 0.009

which is statistically significant. At initial (0) min the mean value of group A (93.20) standard deviation (2.32) and group B the mean value (89.42) standard deviation (3.74) the p-value of < 0.001 which is statistically highly significant. At 2 min the mean value of group A (91.48) standard deviation (2.89) and group B the mean value (87.62) standard deviation (5.18) the p-value of < 0.001 which is statistically highly significant. At 10 min the mean value of group A (81.84) standard deviation (3.59) and group B the mean value (84.18) standard deviation (7.17) the p-value of 0.042 which is statistically significant. At 30,45,60,120 mins in both groups A and B were compared and the p-value of 0.001 which is statistically highly significant.^{10,11} In our study the Spo2 variability is compared in both the group and at the baseline min the mean value of group A (99.22) standard deviation (0.65) and the group B mean value(97.94) standard deviation (1.13) p-value of < 0.001 which is statistically highly significant. At initial (0) min the mean value of group A (98.24) standard deviation (0.48) and group B the mean value (97.98) standard deviation (0.99) the p-value of 0.100 which is statistically insignificant. At 2 min the mean value of group A (98.44) standard deviation (0.76) and group B the mean value (97.98) standard deviation (0.99) the p-value of 0.019 which is statistically significant. At 5 min the mean value of group A (98.64) standard deviation (0.66) and group B the mean value (98.20) standard deviation (1.21) the p-value of 0.027 which is statistically significant.¹² In our study the Mean Respiratory Rate variability is compared in both the group and at the 2 min the mean value of group A (13.46) standard deviation (1.59) and the group B mean value(13.46) standard deviation (1.37) p-value of 1.000 which is statistically insignificant. At 5 min the mean value of group A (13.54) standard deviation (1.59) and group B the mean value (13.86) standard deviation (2.06) the p-value of 0.362 which is statistically insignificant. At 10 min the mean value of group A (13.64) standard deviation (1.60) and group B the mean value (12.92) standard deviation (1.38) the p-value of 0.018 which is statistically significant.¹³ Six percent patients in dexmedetomidine group in the present study had recurrence of shivering. However, none of the patients had recurrence of shivering after receiving dexmedetomidine in earlier study conducted by Anne Miu Han Chan *et al*.¹⁴ Chaturvedi S conducted by Blaine Easley *et al*. the surgeries were conducted under general anesthesia, while in our study the surgeries were performed under SA. complications like hypotension, bradycardia, nausea, vomiting, Sedation Grade1, Sedation Grade2, Dry mouth are compared in both Groups. The percentage of complications are more in Group B than Group A. There was no incidence of hypotension in either

group, which is similar to previous studies. Similarly, none of the patients in either group had itching.¹⁵

CONCLUSION

Both Dexmedetomidine (0.5mcg/kg) and Demedetomidine (1mcg/kg) are useful for cessation of post-spinal shivering, but Dexmedetomidine (0.5mcg/kg) have less complication and side effects compared to Dexmedetomidine (1mcg/kg).so we conclude that Dexmedetomidine (0.5mcg/kg) is a good choice. Comparison of age,sex as mean and standard deviation between two groups Pvalue is statistically insignificant .comparison of heart rate,Systolic blood pressure,Diastolic blood pressure, mean arterial pressure, Spo2, Respiratory rate, time of onset of shivering (min), Severity of shivering, time to disappearance of shivering (sec) as mean deviation between two groups, p-value is statistically significant.

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