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A Comparative Study of Dexmedetomidine and Clonidine in Post Spinal Anaesthesia Shivering

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Abstract
Background*: Shivering is known to be a frequent complication in patients undergoing surgery under regional anaesthesia. Dexmedetomidine and clonidine (α_2 adrenergic agonist) have been used as a sedative agent and are known to reduce the shivering threshold. The aim of this study was to evaluate and compare the efficacy, haemodynamics and adverse effects of dexmedetomidine with those of clonidine, when used for control of post spinal anaesthesia shivering.*
Methods*: A prospective , randomized and double blind study was conducted in 90 American Society of Anaesthesiologist Grade I and II patients of female sex, aged 18-45 years, scheduled for lower abdominal surgeries under spinal anaesthesia. The patients were randomised into three groups of 30 patients each. Group D received dexmeditomidine 0.5µg/kg , group C received clonidine 0.5µg/kg and group S (Control) received 5ml normal saline as intravenous bolus. Grade of shivering, onset of shivering, time of cessation of shivering, response rate and adverse effects were observed at scheduled intervals.*
Results*: Time taken for cessation of shivering was less with dexmeditomidine when compared to clonidine.. Sedation profile was more with dexmeditomidine when compared to clonidine. However, there was not much difference in the adverse effects like nausea, vomiting, hypotention and bradycardia.*
Conclusion*: Although both both dexmeditomidine and clonidine were effective in treatment of post spinal anaesthesia shivering, dexmeditomidine is more effective than clonidine with more sedation which provide comfort to the patients.*
Keywords: *Clonidine,Dexmedetomedine,Shivering.*

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I. Introduction

Regional anesthesia (spinal anesthesia) is widely used as a safe anesthetic technique for both elective and emergency operations. Shivering is known to be a frequent complication, reported in 40 to 70% of patients undergoing surgery under regional anesthesia.[1-2] Shivering is a physiological response to core hypothermia in an attempt to raise the metabolic heat production. The main cause of intra/post-operative shivering are temperature loss, increased sympathetic tone, pain, and systemic release of pyrogens.[3] Spinal anesthesia significantly impairs the thermoregulation system by inhibiting tonic vasoconstriction, which plays a significant role in temperature regulation. It also causes a redistribution of core heat from the trunk (below the block level) to the peripheral tissues. These factors predispose patients to hypothermia and shivering.[3]

Shivering is a potentially serious complication, resulting in increased metabolic rate; increased oxygen consumption (up to 100-600%) along with raised carbon dioxide (CO_2) production; ventilation and cardiac output; adverse postoperative outcomes, such as wound infection; increased surgical bleeding; and morbid cardiac events. It causes arterial hypoxemia, lactic acidosis, increased intraocular pressure (IOP), increased intracranial pressure (ICP); and interferes with pulse rate, blood pressure (BP), and electrocardiographic (ECG) monitoring.[4-5]

The treatment of shivering includes both pharmacological and non-pharmacological methods.The non-pharmacological management is by external heating like the use of forced air warming, warming blankets, warmed fluids etc. According to the results of meta-analysis, the most frequently reported pharmacological interventions include clonidine, pethidine, tramadol, nefopam and ketamine.[6]

During the last decade, Tramadol has become a favoured and commonly used drug for post-spinal anaesthesia shivering. However, it has many adverse effects like nausea, vomiting, dizziness etc. which causes further discomfort to the patient.[7-8] Clonidine is another agent which has gained popularity during the last few

years. Various studies, which have been conducted to compare them have concluded that clonidine has better efficacy and less adverse effects as compared to tramadol.[7-8] But there was 5-10% incidence of hypotension and bradycardia with clonidine.[7] Dexmedetomidine, a congener of clonidine, is a highly selective α_2-adrenoceptor agonist. It has been used as a sedative agent and is known to reduce the shivering thresold.[9] Few studies which have explored its anti-shivering potential have inferred that dexmedetomidine is an effective drug without any major adverse effect and provides good haemodynamic stability.[9-10] Hence, we planned to do a comparative study of the efficacy, haemodynamic, and adverse effects of dexmedetomidine and clonidine when used for the control of post-spinal anaesthesia shivering.

II. Materials And Methods

This study was a prospective, randomized and double blind placebo control, conducted in the department of Anaesthesiology, a Tertiary Care Centre in Imphal, Manipur,over a period of three year between September 2014 to August 2017. After obtaining approval from the Institutional Ethics Committee and written informed consent 90 patients of female sex with American Society of Anaesthesiologist (ASA) physical status I and II, aged 18-45 years scheduled for elective as well as emergency lower abdominal surgeries under spinal anesthesia were included in the study. In this study, patients were randomized into three groups with 30 patients in each group by using computer generated random number. Group D received 0.5µg/kg dexmedetomidine in 5ml normal saline intravenous (IV), group C received 0.5µg/kg clonidine in 5ml normal saline IV and group S received 5 ml normal saline IV. Patients with known hypersensitivity to dexmedetimidine and clonidine, pre existing cardiac or pulmonary diseases, bleeding or coagulation disorders, renal or hepatic disease, psychiatric disorder, hyperthyroidism, deformity of the spinal column, urinary tract infection, severe diabetes or autonomic neuropathies, known history of substance or alcohol abuse, patient receiving any pre-medication, cutaneous infection, and patient refusal were excluded from the study.

Based on the study of Kim YS et al[11], where the incidence of shivering were 63% and 17% in the control and dexmedetomidine group respectively, and with an assumption of α= 0.05 and β of 0.2 (power =1-β=80%) we need to recruit 22 patients for each group. Considering any dropout which may arise in our study, we have recruited 30 patients for each group.

All the patients were assessed in the pre anesthetic room and planned for spinal anesthesia. No premedication was given to the patients. After arrival in the operation theater, standard monitors were attached and base line vital parameter of heart rate (HR), electrocardiogram (ECG), pulse oximetry and non invasive arterial blood pressure (BP), and body temperature (oral, sublingual) were recorded. An intravenous(IV) line was secured and patient was preloaded with Ringer's Lactate fluid @ 20ml/kg, 15 min before initiation of spinal anesthesia. Under all aseptic and antiseptic conditions, subarachnoid anesthesia was administered with 0.5% heavy bupivacaine (15mg) with 25G Quincke's needle, using the midline approach at L_{2-3} or L_{3-4} intervertebral space. All operation theaters were maintained at an ambient temperature of around 24˚C-25˚C. Supplemental oxygen was administered to all the patients at the rate of 5 l/min with face mask and patients were covered with drapes but not actively warmed. Intravenous fluids, anesthetics drugs were administered at room temperature. Vital parameters such as HR, NIBP, and SpO_2 were recorded at intervals of every 5 min for first 30 min and every 15 min for rest of the observation period. Shivering was graded by using a four point scale as per Wrench.[12]

Grade 0: No shivering

Grade 1: One or more of the followings:-

a) Piloerection
b) Peripheral vasoconstriction
c) Peripheral cyanosis
d) 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 Grades 3 or 4 shivering were included in the study and one of the three drugs was given as slow IV bolus injection. The study drug was presented as coded syringes as per randomization list by an anesthesiologist who was not aware of the group allocation. The attending anesthesiologist record the time in minutes at which shivering started after spinal anesthesia (onset of shivering), severity of the shivering, time of disappearance of shivering and response (shivering ceasing within 15 min after treatment). Recurrence of shivering will also be noted. In case there is recurrence of shivering, patients was treated with an additional dose of dexmedetomidine (0.5µg/kg), Clonidine (0.5µg/kg) and normal saline in the respective groups.

Adverse effects such as nausea, vomiting, bradycardia ($\leq$50/min), hypotention (>20% of baseline), dizziness; and sedation score was noted. The degree of sedation was graded on a four point scale as per Filos et

al[13]

Grade 1: Awake and alert
Grade 2: Drowsy, responsive to verbal stimuli
Grade 3: Drowsy, arousable to physical stimuli
Grade 4: Unarousable

Bradycardia, hypotension and vomiting were treated with atropine, mephentermine and metoclopramide, respectively, in titrated doses when required.

The data collected were entered in a computer and statistical analysis was performed using Statistical Pakage for Social Sciences (SPSS-version 20 Chicago, IL, USA). Numerical/continuous variables were presented as Mean ± SD (standard deviation) and qualitative/categorical variables were again described as number of cases and percentages. The three means, one from each group, for every parameter were compared by *ANOVA (Analysis of Variance Ratio) test*, commonly known as *F-test* and for multiple comparisons of means *Post Hoc Tests of Bonferroni* was advocated whenever applicable. For categorical variables, the information was exhibited in terms of number of cases along with percentages and χ^2*-test* was applied if data permit. All comparisons were two-sided and the P-values of < 0.05 and < 0.01 are treated as the cut off values for significance and highly significance respectively.

III. Results And Observation

All the patients in the study groups were female of ASA I, therefore, sex-wise as well as ASA-wise comparisons are not required. Other profiles like age, height and weight were comparable and statistically not significant among the three groups with P value of >0.05 as shown in Table 1.

Table – 1 Demographic profile

Parameters	Mean±SD				F-value	P-value
	Group C (n=30)	Group D (n=30)	Group S (n=30)	Total (n=90)		
Age (years)	29.10±6.22	27.43±5.83	29.20±5.23	28.58±5.77	0.884	0.417
Weight(Kg)	67.53±5.00	64.87±5.32	65.07±5.18	65.49±5.33	2.920	0.053
Height(cm)	157.23±4.40	156.37±6.04	158.97±6.32	157.52±5.69	1.643	0.199

Mean ± SD: mean ± standard deviation; n: number of cases;
F: ANOVA (analysis of variance ratio); P: probability of difference due to chance factors.

Table – 2: Group-wise mean±SD of heart rate (HR) at different stages

Parameters	Group C (n=30)	Group D (n=30)	Group S (n=30)	Total (n=90)	F-value	P-value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
HR0	88.20±12.51	86.87±9.02	81.97±8.96	82.34±11.20	9.107	0.079
HR5	86.20±13.34	77.63±9.59	78.77±9.45	80.87±11.47	5.421	0.006
HR10	84.57±14.95	80.00±11.93	78.00±10.15	80.86±12.66	2.174	0.120
HR15	84.10±14.06	79.83±12.22	77.80±10.34	80.58±12.44	2.049	0.135
HR20	83.90±14.39	77.80±10.97	78.17±9.55	79.96±12.01	2.514	0.087
HR25	83.97±14.75	77.43±9.81	78.93±7.90	80.11±11.42	2.800	0.066
HR30	82.23±14.34	77.03±10.66	78.43±7.72	79.23±11.33	1.719	0.185
HR45	81.90±13.26	77.97±9.85	78.87±8.37	79.58±10.71	1.114	0.333
HR60	83.17±12.63	77.57±9.00	79.53±7.57	80.09±10.12	2.437	0.093

Mean ± SD: mean ± standard deviation; n: number of cases;
F: ANOVA (analysis of variance ratio); P: probability of difference due to chance factors.

Table-2 shows the mean and standard deviation of heart rates (HR) at 9 different stages after infusion of the study drug, taking 0 minute as at the time of infusion upto 60 minutes thereafter in all the three groups. We observed that despite some visible variation, none of the difference except at 5 minute after infusion of the study drugs was found to be significant.

Table – 3: Group-wise mean±SD of mean arterial pressure (MAP) at different stages

Parameters	Group C (n=30)	Group D (n=30)	Group S (n=30)	Total (n=90)	F-value	P-value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
MAP0	90.13±8.50	88.03±9.08	92.17±5.60	90.11±7.97	2.064	0.133
MAP5	86.97±9.53	87.57±8.16	86.47±6.94	87.00±8.20	0.133	0.876
MAP10	83.17±9.50	83.87±7.75	83.67±6.71	83.57±7.98	0.060	0.942

MAP15	82.93±8.82	83.17±7.48	81.37±7.04	82.49±7.77	0.470	0.627
MAP20	82.40±7.05	83.27±7.95	81.27±6.95	82.31±7.29	0.561	0.573
MAP25	83.70±6.85	83.47±7.63	82.83±6.04	83.33±6.80	0.128	0.880
MAP30	81.80±7.93	84.70±7.35	84.50±6.38	83.67±7.29	1.497	0.230
MAP45	81.40±8.01	85.07±7.59	85.03±6.52	83.83±7.52	2.431	0.094
MAP60	83.90±8.53	86.00±6.52	87.07±7.21	85.66±7.50	1.396	0.253

Mean ± SD: mean ± standard deviation; n: number of cases;
F: ANOVA (analysis of variance ratio); P: probability of difference due to chance factors.

According to the Table-3 there was no significant difference of mean arterial pressures among the three groups over the stages considered in the present study with P value > 0.05.

Table-4: Group-wise Shivering graded by scale

Shivering (Scale)		**Group C (n=30)**	**Group D (n=30)**	**Group S (n=30)**	**Total (n=90)**
S0	0	-	-	-	0
	4	28(93.3%)	30(100.0%)	30(100.0%)	88(97.8%)
S5	0	23(76.7%)	29(96.7%)	18(60.0%)	70(77.8%)
	3	1(3.3%)	-	-	1(1.1%)
	4	6(20.0%)	1(3.3%)	12(40.0%)	19(21.1%)
S10	0	27(90.0%)	30(100.0%)	19(63.3%)	76(84.4%)
	1	-	-	2(6.7%)	2(2.2%)
	2	-	-	2(6.7%)	2(2.2%)
	3	2(6.7%)	-	4(13.3%)	6(6.7%)
	4	1(3.3%)	-	3(10.0%)	4(4.4%)
S15	0	29(96.7%)	29(96.7%)	28(93.3%)	86(95.6%)
	2	1(3.3%)	-	-	1(1.1%)
	3	-	1(3.3%)	-	1(1.1%)
	4	-	-	2(6.7%)	2(2.2%)
S20	0	30(100.0%)	29(96.7%)	30(100.0%)	89(98.9%)
	4	-	1(3.3%)	-	1(1.1%)
S25	0	30(100.0%)	29(96.7%)	30(100.0%)	89(98.9%)
	4	-	1(3.3%)	-	1(1.1%)
S30	0	30(100.0%)	30(100.0%)	30(100.0%)	90(100.0%)
S45	0	30(100.0%)	30(100.0%)	30(100.0%)	90(100.0%)
S60	0	30(100.0%)	30(100.0%)	30(100.0%)	90(100.0%)

Due to most of theoretical cell frequencies are less than 5,
the test statistic especially χ^2 could not be applied.

It was observed that at baseline shivering scale was "4" is all the groups whereas at 5^{th} minute after infusion the shivering scale "0" and "4" was common in all the groups but it was "0-scale" at 10^{th}, 15^{th}, 20^{th} and 25^{th} minutes after infusion of the drugs in most of the patients. However at 30^{th}, 45^{th} and 60^{th} minutes, scale "0" was the only shivering scale found in all the groups.(Table-4)

Table 5: Group-wise adverse effects

Adverse effects	Group C n=30	Group D n=30	Group S n=30
Nausea	1	0	0
Vomiting	0	0	2
Sedation	7	10	0
Hypotention	0	0	0
Bradycardia	0	0	0
Respiratory depression	0	0	0

One patient in group C had nausea. Seven patients in group C and 10 patients in group D had sedation. Two patients in group S had vomiting but no nausea or sedation in this group. No hypotention, bradycardia or respiratory depression in all the three groups.

IV. Discussion

The results of our study indicates that both clonidine and dexmedetomidine (0.5µgm/kg) were effective in treating patients with post spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to clonidine.

The mechanism which leads to shivering after regional anaesthesia is not very clear, but the probable mechanism could be decrease in core body temperature secondary to sympathetic block; peripheral vasodilatation; increase cutaneous blood flow, which leads to increase heat loss through skin; cold temperature of the operation theatre; rapid infusion of cold IV fluids; and effects of cold anaesthetic drugs upon the

thermosensitive receptors in the spinal cord.[14,15]

Alpha-2 adrenergic agonists are widely used nowadays in anaesthesia and intensive care settings. Dexmedetomidine is an α_2 adrenoceptor agonist, with antihypertensive, sedation, analgesic, and anti-shivering properties.[16] The anti-shivering effects of alpha adrenoceptor agonists are mediated by binding to α_2 receptors that mediate vasoconstriction and the anti-shivering effect. It also has hypothalamic thermoregulatory effects. Dexmedetomidine comparably reduces the vasoconstriction and shivering thresholds, thus suggesting that it acts on the central thermoregulatory system rather than preventing shivering peripherally.[17] It has been successfully used as an adjunct to local anaesthetics in spinal anaesthesia and peripheral nerve blockade, for the sedation of mechanically ventilated patients in the Intensive Care Unit, as well as supplementation of post-operative analgesia.[18,19]

Clonidine is a centrally acting selective α_2 agonist. Clonidine exerts its anti shivering effects at three levels: hypothalamus, locus coeruleus and spinal cord. At hypothalamus level, it decreases thermoregulatory threshold for vasoconstriction and shivering, because hypothalamus has high density of α_2 adrenoreceptors and hence is effective in treating post anaesthetic shivering. It also reduces spontaneous firing in locus coeruleus- a pro-shivering centre in pons. At spinal cord level it activates the α_2 adreno receptors and release of dynorphine, norepinephrine and acetylcholine.[20]

Our study was conducted to compare the effects of intravenous dexmedetomidine with intravenous clonidine for treatment of post spinal anaesthesia shivering in 90 patients who were divided into three groups, group C (clonidine), group D (dexmedetomidine) and group S (normal saline) as controlled.

In this study, we observed both dexmedetomidine and clonidine were effective for the treatment of post spinal anaesthesia shivering. Most of the patients had cessation of shivering after single bolus dose except for few patients in clonidine group. Cessation of shivering was faster in dexmedetomidine group where shivering stops after 5 minutes of infusion of the drug, where as shivering was still present after 5 minutes in Clonidine group in some patients. The oxygen saturation in the dexmedetomidine group was in the lower side which indicates that dexmedetomidine has higher sedative property than clonidine.

A case of nausea was present in clonidine group but there was no case of nausea or vomiting in dexmedetomidine group. In a study done by Usha et al,[7] the complications of nausea were found to be higher in case of tramadol compared to clonidine. From our study we can concluded that α2-receptor agonists has lesser side effects then tramadol.

In a study by Easley et al[21] all children who had post-anaesthesia shivering were treated with a single IV bolus dose of dexmedetomidine 0.5μg/kg over 3-5 min. All children had cessation of shivering behavior within 5 min following the completion of dexmedetomidine administration. There were no recurrence of shivering and no adverse effects occurred. In our study in adult patients above 18 years of ages no recurrence of shivering was present in dexmedetomidine group.

In a study by Sahi et al.[22] they compared the efficacy of dexmedetomidine (1μg/kg), clonidine(2μg/kg), and tramadol(1mg/kg) in preventing postoperative shivering in patients undergoing laparoscopic cholecystectomy under general anesthesia[27] and found that tramadol was the most effective drug among the study drugs. In our study, the most effective drug in the control of shivering was dexmedetomidine in patients undergoing lower abdominal surgeries under spinal anesthesia. This might be due to the reduction in the threshold for shivering and vasoconstriction without influencing the core and peripheral body temperature distribution by dexmedetomidine which is in accordance to the study of Geeta et al.[23]

In the present study, the factors that influence the occurrence of shivering, like temperature of IV fluids and drugs, were not tightly controlled, but this should not affect the validity of our study because the present study is focused on response to treatment used rather than incidence of shivering; and by randomization, all the three groups were subjected to similar degrees of influence of these factors.

Limitation of the study: The major limitation of our study is the short duration of the surgeries as the mean duration of the surgeries were less than one hour in all the groups. The anti-shivering effect of the study drugs needs longer duration where chance of developing shivering are more. The temperature were not well under controlled during the surgery.Small sample size is also a limitation in our study. A bigger sample size would have increased the robustness of the result.

V. Conclusion

Both dexmedetomidine (0.5 μg/kg) and clonidine (0.5 μg/kg) are effective in treating patients with post-spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to clonidine. Furthermore, dexmedetomidine causes fewer adverse effects like nausea and vomiting. Sedation caused by dexmedetomidine provides additional comfort to the patient. Further studies are needed to compare the effectiveness of various drugs in the treatment of shivering in patients undergoing surgery under spinal anaesthesia.

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