


Original Research Article

Effect of oral clonidine premedication on spinal anesthesia using levobupivacaine

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Abstract

Background: The duration of spinal analgesia can be prolonged by using different techniques including oral clonidine. This study was mainly undertaken in order to study the effect of oral clonidine in levobupivacaine spinal analgesia.

Material and methods: A randomized controlled trial was undertaken in 80 patients. About 40 patients received 150 mcg of oral clonidine and 40 patients received placebo. The socio demographic characteristics, hemodynamic parameters, sedation time, time to reach maximum sensory level and time to 2 segment regression were compared between the oral clonidine and placebo groups.

Results: There was no statistically significant difference in the hemodynamic parameters between the oral clonidine and placebo groups. The mean sedation score was 1.1 in Oral clonidine group and 1.12 in the placebo group ($p=0.728$). The mean time to reach maximum sensory level was 9.92 minutes in oral clonidine group and 9.82 minutes in placebo group ($p=0.753$). The time to two segment regression in oral clonidine group was 108.85 minutes and 109.85 minutes in placebo group ($p=0.496$).

Conclusion: This study had shown no significant difference in the hemodynamic parameters, sedation score, time to maximum sensory level and time to 2 segment regression between the oral clonidine and placebo groups.

Key words

Oral Clonidine, Placebo, Spinal analgesia, Levobupivacaine, Sedation scores.

Introduction

Spinal anesthesia is a regional anesthesia which involves the injection of local anesthetic into the

subarachnoid space resulting in loss of sensation to all the nerves supplying the lower limbs [1]. A number of anesthetics will be used for the spinal anesthesia including Lidocaine, Bupivacaine,

Tetracaine, Mepivacaine and Ropivacaine. Lower toxic effect of Levobupivacaine on heart and central nervous system is well established by many studies [2].

Prolonging the duration of the spinal analgesia by alternative techniques for longer surgeries is very useful. A number of agents have been used to prolong the duration of spinal analgesia. Clonidine which is an alpha 2 adrenergic agonist has been used by anesthesiologists as a premedicant since many years. The use of premedication is advantageous including decrease in minimum alveolar anesthetic concentration (MAC) of inhaled anesthetics, decrease in the dose of narcotics and potent analgesic properties [3, 4, 5]. The reports available are scant in this part of the country to study the effect of oral clonidine as a premedicant on spinal anesthesia using Levobupivacaine. Hence this study was undertaken.

Materials and methods

A double blind randomized controlled study was undertaken in Department of Anesthesiology of a tertiary care hospital. The clearance of institutional ethics committee was taken before the study was started. An informed consent was obtained from each subject before including them in to the study. About 80 patients were included in to the study. The cases with ASA grade I and II, aged about 20 – 60 years and patients posted for elective lower abdominal and lower limb surgeries were included in to the study. The patients with coagulopathy and bleeding disorders, renal dysfunction, current use of antiplatelet medication and anticoagulants, any localized infections at the site of anesthesia, malignant and thromboembolic event were excluded from the study.

A detailed history and complete pre anesthetic examination was conducted on each patient before including them. Routine investigations were carried out in order to rule out lung pathologies and cardiac abnormalities. The study

subject were divided in to two groups where one group of 40 patients who were randomly selected received 150 mcg of oral clonidine and other group of 40 patients received placebo drug. The baseline heart rate, systolic and diastolic blood pressure, SpO₂, respiratory rates were measured before surgery, before administering premedication. The sedation score was assessed using Ramsay sedation scale.

The spinal anesthesia was administered using Levobupivacaine. The hemodynamic parameters were assessed at regular intervals during the surgery. The highest sensory levels and the time from injection to attainment of highest level of sensory block were evaluated. The time for two segment regression and recovery of sensory blockade to L1 segment were noted. Time of onset of complete motor block was assessed using modified Bromage scale. The data thus obtained was analyzed using Statistical Package for Social Sciences (SPSS vs 20).

Results

There was no statistically significant difference in age between the Clonidine and placebo groups. About 52.5% in Clonidine and 50% in the placebo group were males and statistically not significant. Diabetes Mellitus and hypertension were the comorbidities in both the groups. There was no statistically significant difference in height and weight between the Oral Clonidine and placebo groups (**Table – 1**).

The heart rate was lower in oral clonidine group which was higher than the placebo group after administration of oral clonidine and the heart rate has declined after administration of placebo. This difference was not statistically significant between the oral clonidine group and placebo groups (**Chart – 1**).

The mean arterial pressure was significantly different between the two groups before operation, administration of premedication and during surgery at different time intervals. But

after that there was no statistically significant difference between the two groups (**Chart – 2**).

The mean SPO₂% was higher in placebo group than the oral clonidine at all time periods of follow up which was not statistically significant at time points of follow up (**Chart – 3**).

Table – 1: Socio-demographic characteristics of the study groups.

Mean \pm SD	Clonidine	Placebo	T/ χ^2 value	P value, Sig
Age	25.47 \pm 3.82	25.67 \pm 3.82	0.234	0.816, NS
Males, %	21 (52.5)	20 (50.0)	0.05	0.823, NS
DM, %	6 (15.0)	6 (15.0)	0.469	0.791, NS
HTN, %	4 (10%)	6 (15.0)		
Height	154.25 \pm 154.3	154.3 \pm 3.36	0.067	0.947, NS
Weight	60.97 \pm 9.86	60.37 \pm 9.76	0.273	0.785, NS

Chart – 1: Heart rate in the study groups.

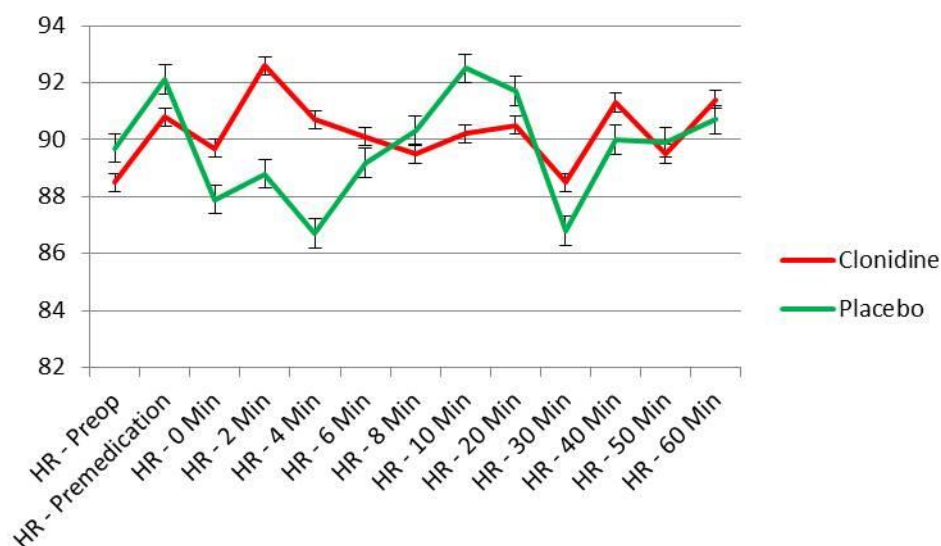


Chart – 2: Mean Arterial Pressure in the study groups.

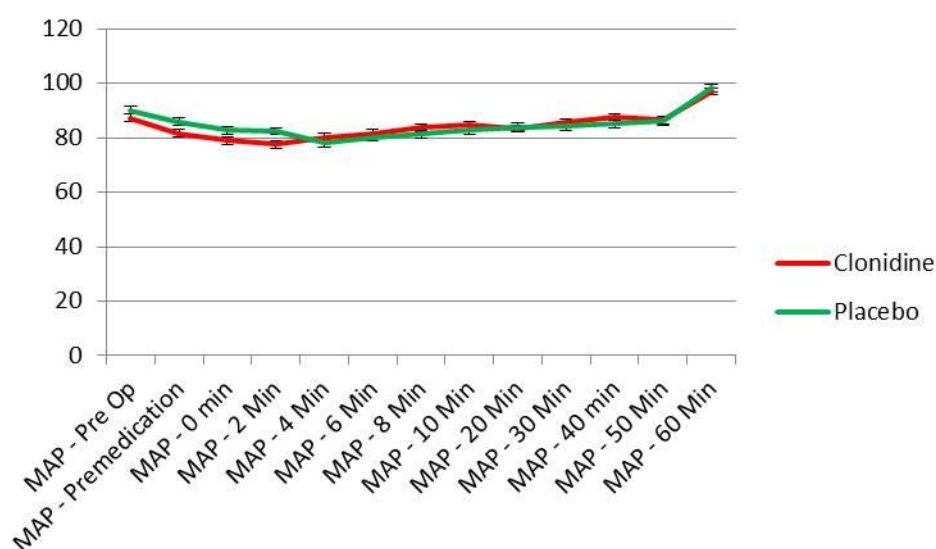


Chart – 3: SPO₂% in the study groups.

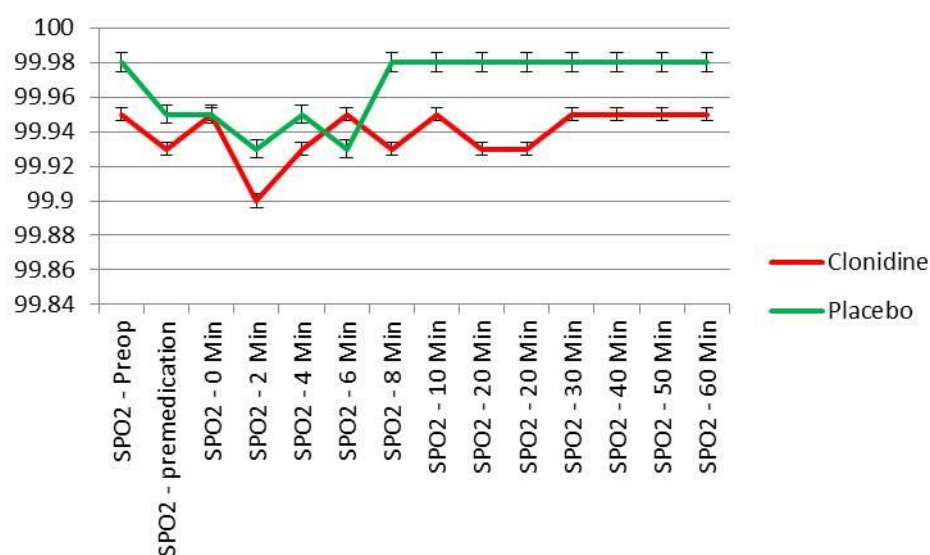


Chart – 4: Respiratory rate in the study groups.

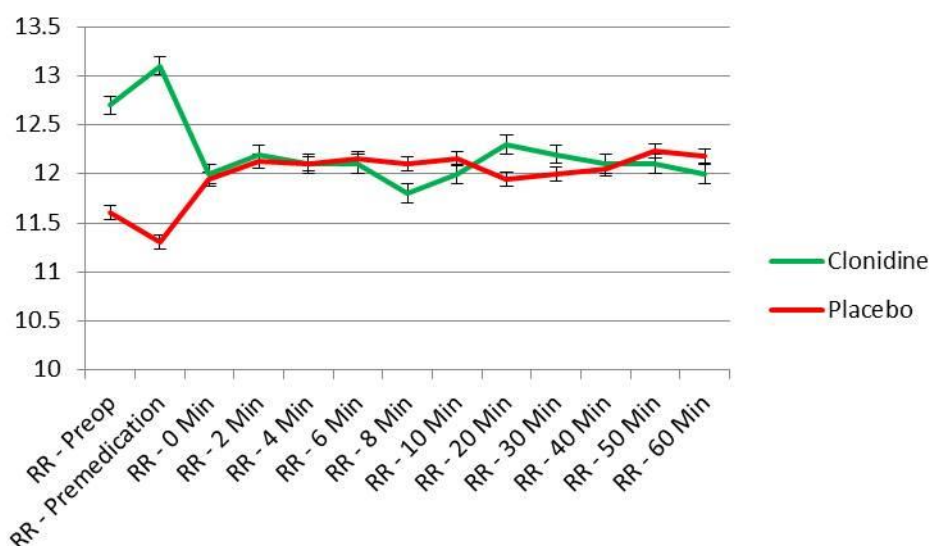


Table – 2: Comparison and block characteristics of two groups.

Mean ± SD	Clonidine	Placebo	T value	P value, Sig
Sedation score	1.1 ± 0.3	1.12 ± 0.33	0.350	0.728, NS
Time to maximum sensory level	9.92 ± 1.4	9.82 ± 1.43	0.316	0.753, NS
Time to 2 segment regression	108.85 ± 10.63	109.85 ± 11.56	0.684	0.496, NS

The mean respiratory rate in oral group was higher at pre-operative and pre medications time periods and at some time intervals. After 60 minutes of follow up, the placebo group had higher respiratory rate than the oral clonidine group (**Chart – 4**).

The mean sedation score was 1.1 in Oral clonidine group and 1.12 in the placebo group

and this difference was not statistically significant between the two groups. The mean time to reach maximum sensory level was 9.92 minutes in oral clonidine group and 9.82 minutes in placebo group which was statistically not significant. The time to two segment regression in oral clonidine group was 108.85 minutes and 109.85 minutes in placebo group which was statistically not significant (**Table – 2**).

Discussion

This study was mainly undertaken to study the effect of oral clonidine as a pre medication in Levobupivacaine spinal anesthesia. Many researchers have shown that the use of vasoconstrictors can prolong the effect of spinal anesthesia. The age was comparable between the two groups. There was no statistically significant difference in sex between the two groups. There was no statistically significant difference in height and weight between the Oral Clonidine and placebo groups in this study. A study by Maheshwari, et al. also noted similar findings in their study in patients undergoing Caesarean section [6]. In a comparative study of clonidine and gabapentin in ropivacaine spinal anesthesia by Singh et al, the demographical characteristics were comparable between the clonidine and gabapentin groups similar to the results of this study [7].

The heart rate was lower in oral Clonidine group which was higher than the placebo group after administration of oral Clonidine and the heart rate has declined after administration of placebo which was statistically not significant between the two groups. In a study by Maheshwari, et al., the mean pulse was 89.13 per minute in Levobupivacaine with 15 mcg of clonidine (Group A) group, 96.5 per minute in Levobupivacaine with 30 mcg of clonidine (Group B) and 90.07 in Levobupivacaine with 45 mcg of clonidine (Group C) [6]. In a study, Gupta et al also noted no significant change in intra operative heart rate between the gabapentin and oral clonidine groups [7].

The mean arterial pressure was significantly different between the two groups before operation, administration of premedication and during surgery at different time intervals. In a study by Maheshwari, et al., the mean arterial pressure was 93.74 mm of Hg in group A, 97.35 in Group B and 96.49 in Group C [6]. In a study by Gupta et al, the mean systemic arterial blood pressure had shown an intraoperative decline which was statistically not significant [7].

The mean SPO₂% was higher in placebo group than the oral Clonidine at all time periods of follow up which was not statistically significant at time points of follow up. In a study by Gupta, et al., no significant change in oxygen saturation between the clonidine and gabapentine groups [7].

The mean respiratory rate in oral group was higher at pre-operative and pre medications time periods and at some time intervals. After 60 minutes of follow up, the placebo group had higher respiratory rate than the oral clonidine group. A study by Gupta, et al. had noted no significant change in respiratory rate between the clonidine and gabapentine groups [7].

The mean sedation score was 1.1 in Oral clonidine group and 1.12 in the placebo group and this difference was not statistically significant between the two groups. The mean time to reach maximum sensory level was 9.92 minutes in oral clonidine group and 9.82 minutes in placebo group which was statistically not significant. The time to two segment regression in oral clonidine group was 108.85 minutes and 109.85 minutes in placebo group which was statistically not significant. In a study by Maheshwari, et al., the sedation score was higher in higher doses of clonidine used. The for onset of sensory blockade was 208.33 seconds in Group A, 164.43 seconds in group B and 154.3 seconds in group C. The mean time for two segment regression was 4337.4 seconds in group A, 4984.2 seconds in group B and 5550.0 seconds with group C [6]. In a study by Gupta et al, the sedation scores had shown that most of the patients in clonidine group were awake and anxious. There was no significant difference in time required to achieve complete sensory analgesia, mean time to reach maximum cephalic dermatome level for sensory block, mean time taken for complete motor block and duration of sensory and motor analgesia [7]. In a study by Jetley, et al., there was no significant difference in onset of sensory block, time for two segment regression and duration of analgesia between demedetomidine and clonidine groups. The

patient in dexmedetomidine group had highest sedation scores [8].

This study had noted fewer side effects in Oral Clonidine group when compared to the placebo group. Maheshwari and Singh et al also noted similar findings [6, 7].

Conclusion

This study noted no significant difference in the hemodynamic parameters, sedation scores, time to maximum sensory level and time to two segment regression between the oral clonidine and placebo.

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