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Comparative Evaluation of Efficacy of Levobupivacaine with Clonidine and Levobupivacaine with Dexmedetomidine in Supraclavicular Brachial Plexus Block - A Clinical Study

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Abstract:
Aims: Our aim was to study the comparison of levobupivacaine with clonidine or dexmedetomidine in supraclavicular brachial plexus block for sensory, motorblock, analgesia sedation, hemodynamics and side effects.
Methods and Material: 60 patients were subsequently randomized using 'slip in a box' technique into two groups of 30 each as under.Patients were given 30 ml of 0.5% levobupivacaine with 150 mcg of clonidine (Group LC) or 100 mcg dexmedetomidine (Group LD) respectively. Time for onset of sensory and motor block, duration of motor block and analgesia, intra operative hemodynamics and sedation, side effects, complications were assessed.
Statistical analysis used: For Statistical analysis chi-square test and independent student't' test were applied by SPSS software (version 22) and p-value <0.05 was considered as statistically significant.
Results: In Group LC and Group LD the mean onset time of sensory block was 8.87 (±1.78) min and 7.53 (±1.55) min respectively .Mean duration of motor block was 409.00 (±96.00) min while in group LD, it was 488.00 (±110.56) min. In group LC, the mean duration of analgesia was 805.00 (±114.11) min while in group LD, it was 1019.83 (±139.16) min.
Conclusions: Dexmedetomidine when added to levobupivacaine as an adjuvant in supraclavicular brachial plexus block fastens the onset and have longer duration of motor and sensory blockade ,better sedation with no side effects as compared to clonidine .
Key-words: Supraclavicular brachial plexus block, Dexmedetomidine, Clonidine,

Introduction:

Supraclavicular brachial plexus block is an established regional anesthetic technique for upper limb surgeries. Supraclavicular approach gives the most effective block for all portions of upper extremity and is carried out at the level of trunks of brachial plexus[1]. It is being routinely and efficiently used as an alternative to general anesthesia for upper limb surgeries.

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A large variety of local anesthetic agents are available commercially, differing in their clinical profiles.

Levobupivacaine is the S(-) enantiomer of racemic bupivacaine. It has less cardiotoxicity compared with bupivacaine and its pharmacological profile and duration of anesthesia are similar to those of bupivacaine[2]

There has been a search for an ideal adjuvant to local anaesthetics so as to prolong the duration of postoperative analgesia with lesser side effects. Many drugs like opioids, epinephrine and α-2 agonists etc. have been used to this effect. Clonidine, an α_2 receptor agonist has been used as an adjuvant to local anaesthetic to extend the duration of block[2], Dexmedetomidine hydrochloride, another α_2 agonist is 8 times more selective for α_2 adrenoreceptors as compared to clonidine. It is found to be safe and effective adjuvant in various neuraxial and regional anaesthetics in human[2]

This prospective study was performed to compare the effects of addition of clonidine or dexmedetomidine as adjuvants to levobupivacaine given in supraclavicular brachial plexus block in terms of onset of anaesthesia, duration of analgesia, associated motor blockade, degree of sedation and any possible side effects.

Subjects and Methods:

The present study entitled "Comparative Evaluation Of Efficacy Of Levobupivacaine With Clonidine And Levobupivacaine With Dexmedetomidine In Supraclavicular Brachial Plexus Block - A Clinical Study" was carried out in the Department of Anaesthesiology, Gandhi Medical College and Associated Hospitals, Bhopal (MP) after approval from institutional ethics committee in 60 patients of ASA grade I and II scheduled for upper limb surgeries. The study was designed as prospective randomized comparative double-blinded study.

After obtaining written and informed consent, patients were subsequently randomized using 'slip in a box' technique into two groups of 30 each as under:

1. Group LC: The patients were given 30 ml of 0.5% levobupivacaine with 150 mcg of clonidine
2. Group LD: The patients were given 30 ml of 0.5% levobupivacaine with 100 mcg dexmedetomidine

PREANAESTHETIC CHECKUP

Pre-anaesthetic checkup of these patients was done with complete history taking, general examination, and systemic examination. Following investigations were done to assess fitness for surgery: Urine (Routine & Microscopic) ,Complete blood count ,Random blood sugar ,Blood urea and creatinine ,Liver function tests ,Chest X-ray PA view ,ECG (>40 years or patients suspected of cardiac diseases)

PROCEDURE PLANNED

On arrival in the operation theatre, baseline heart rate, blood pressure, RR, ECG and SpO2 were recorded. An intravenous line was secured and Ringer Lactate infusion was started.

All the patients received brachial plexus block through supraclavicular approach by an experienced anaesthesiologist who was different from the one assessing the patient perioperatively. Both were blinded to the study drug used.

POSITION

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Patients to be operated were placed in supine position with the head turned to contralateral side and the arms were abducted and pulled towards the knee. A wedge was placed on the back a the interscapular region.

TECHNIQUE

Aftercleaning the area with antiseptics, draping was done. The midclavicular point, external jugular vein and subclavian artery pulsations were identified. After local infiltration of 2 ml of 2% lignocaine, a 22G 1.5 inches hypodermic needle was introduced 1 cm above the midclavicular point just lateral to subclavian artery pulsations, and directed downward, backward and medially until paraesthesia was elicited. After negative aspiration of blood, the study drug was injected.

OBSERVATIONS AND RESULTS

After the drug was injected, the following parameters were recorded:

1. Duration of Analgesia: The duration of analgesia was defined as the time elapsed between injection of drug and appearance of pain in post-operative period when rescue analgesia was requested by the patient. All patients were administered IM diclofenac sodium 1.5 mg/kg as rescue analgesia.

2. Cardio-respiratory Monitoring:

Pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO_2), respiratory rate (RR) and 3-lead ECG monitoring was done continuously by multi-parameter monitor throughout the operative procedure. Recording of parameters was done at 0, 5, 10, 15 and 30 minutes after injection of drug and then at 30 minutes interval up to 120 minutes and then at interval of every hour till 720 minutes (12 hours).

3. Sensory block

Sensory block was assessed by **pin prick method** graded as:

- Grade 0: sharp pin prick felt
- Grade 1: analgesia, dull sensation felt
- Grade 2: anaesthesia, no sensation felt

A. Onset of sensory block

Sensations were checked at every 1 minute interval after injection of drug until onset of sensory block. Onset of sensory block was defined as the time elapsed between injection of drug and complete loss of sensation (grade 2).

B. Duration of sensory block

Sensations were recorded every 30 minutes after injection of drug continued into post-operative period and duration of sensory block was defined as the time elapsed between injection of the drug and appearance of full sensations (grade 0).

4. Motor block:

A modified Bromage scale for the upper extremity was used to assess motor function.

A. Onset of motor block

Onset of motor block was defined as the time elapsed from injection of drug to complete motor block (Bromage grade 3). Assessment was done at every 1-minute interval from the time of injection of test drug until the block was established. Only patients with complete

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motor block (Bromage grade 3) were included in the study. Rest of the patients were excluded and new cases in equal number were added to complete the study.

B. Duration of motor block:
Motor function was recorded every 30 minutes after injection of drug continued into post-operative period and duration of motor block was defined as time elapsed from injection of the drug to the point of complete return of motor power (Bromage grade 0).

4. Assessment of Post-operative Pain :
Post-operative pain was assessed using a **Visual Analogue Scale** which consisted of a 10 cm horizontal scale with gradations marked as '0' means no pain at all and '10' means unbearable pain.VAS score was recorded every 30 minutes after injection of drug up to 120 minutes and continued in the postoperative period at the interval of every 60 minutes till 720 minutes or the VAS >2.5 when rescue analgesia was administered or such was requested by the patient.

5. Sedation score:
Sedation was assessed based on**Chernik sedation score [**Modified Observer's Assessment of Alertness/Sedation (OAA/S) Scale]
Sedation score was recorded every 30 minutes after injection of drug upto 120 minutes and continued in the postoperative period at the interval of every 60 minutes till 720 minutes or till the patient was fully alert.

6. Duration of Surgery:
It was calculated as time taken from making the incision to closure of skin incision.

7. Complications and side effects:
Careful watch was kept for complications and side effects such as nausea, vomiting, bradycardia, tachycardia, hypertension, hypotension, haematoma, headache, convulsions and respiratory distress and noted if there were any.

DATA COLLECTION METHOD
The available relevant literature was reviewed. The observations for all the patients were recorded in the prescribed proforma.

DATA ANALYSIS
The observations recorded in both groups were tabulated in the master chart and statistical analysis for comparison of the two study groups was carried out using chi-square test and independent student 't' test by SPSS software (version 22). Statistically significant difference in findings was considered when p-value was found to be <0.05. Results of this study were compared with other similar and relevant studies and conclusions were drawn.

Results:

Table 1 . Demographic Variable

S. No.	Variable	Group LC	Group LD	p-value
1.	Age (Years)	36.13 (±11.61)	36.23 (±10.90)	**0.973**
2.	Sex Ratio (M:F)	17:13	19:11	**0.598**
3.	Weight (Kilograms)	65.60 (±13.56)	65.27 (±10.87)	**0.917**

Table 2

Variable	Group LC	Group LD	p-value

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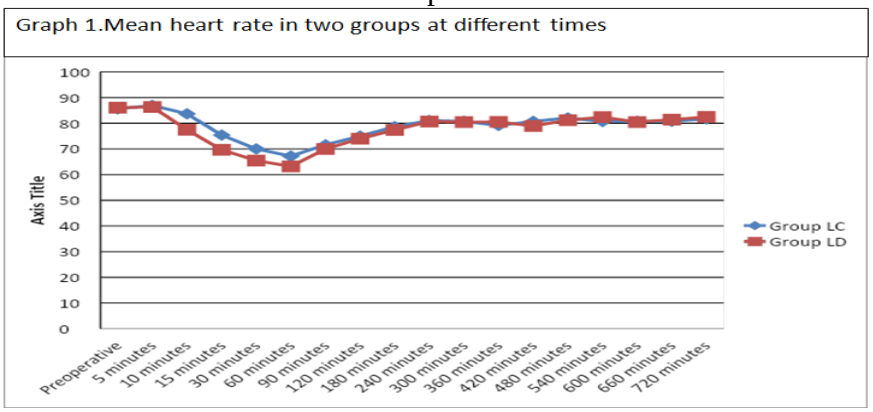
Duration of Surgery (in minutes)	101.67 (±37.95)	103.50 (±38.29)	**0.853**
Onset of Sensory Block (in minutes)	8.87 (±1.78)	7.53 (±1.55)	**0.003***
Onset of Motor Block (in minutes)	14.57 (±2.24)	12.60 (±2.13)	**0.001***
Duration of Analgesia (in minutes)	805.00 (±114.11)	1019.83 (±139.16)	**<0.001***

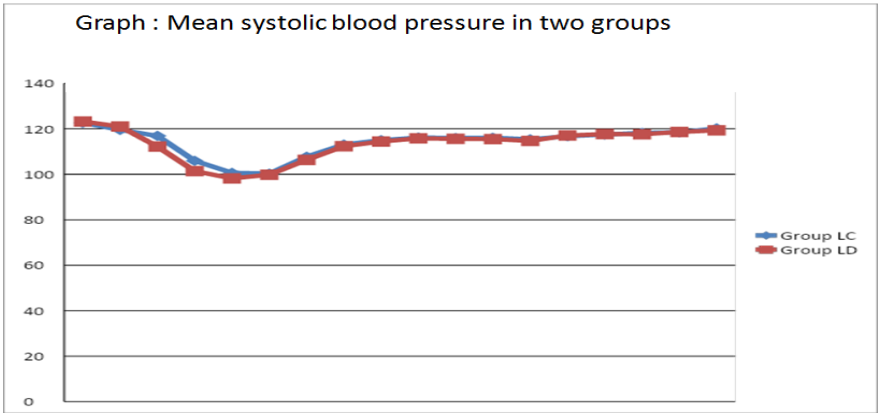
Table 3 . Incidence of Side Effects

Side Effect	**Number of Patients in Group LC (%)**	**Number of Patients in Group LD (%)**
Headache	1 (3.33%)	1 (3.33%)
Nausea	3 (10%)	1 (3.33%)
Dry Mouth	1 (3.33%)	0
Sedation	0	1 (3.33%)
Total incidence of side effects	**5 (16.67%)**	**3 (10%)**
No side effect reported	25 (83.33%)	27 (90%)
Grand Total	**30 (100%)**	**30 (100%)**

Graph 1



Graph 2



Graph 3

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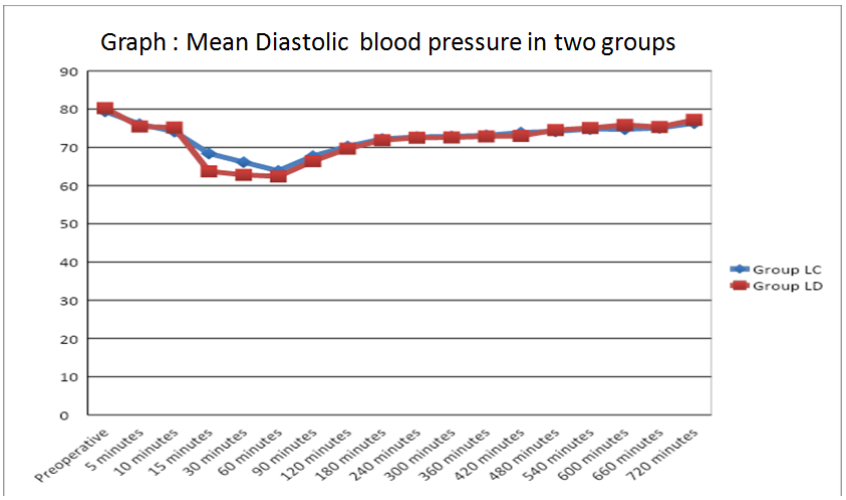
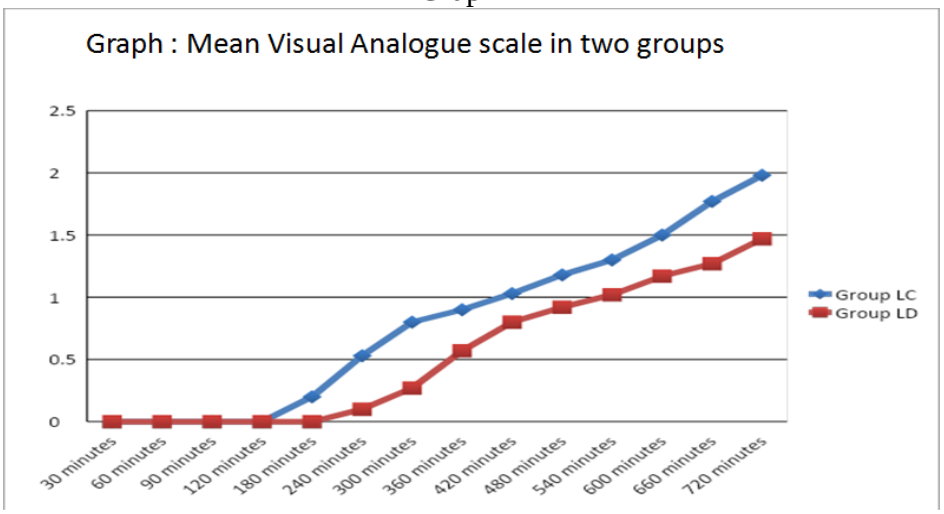
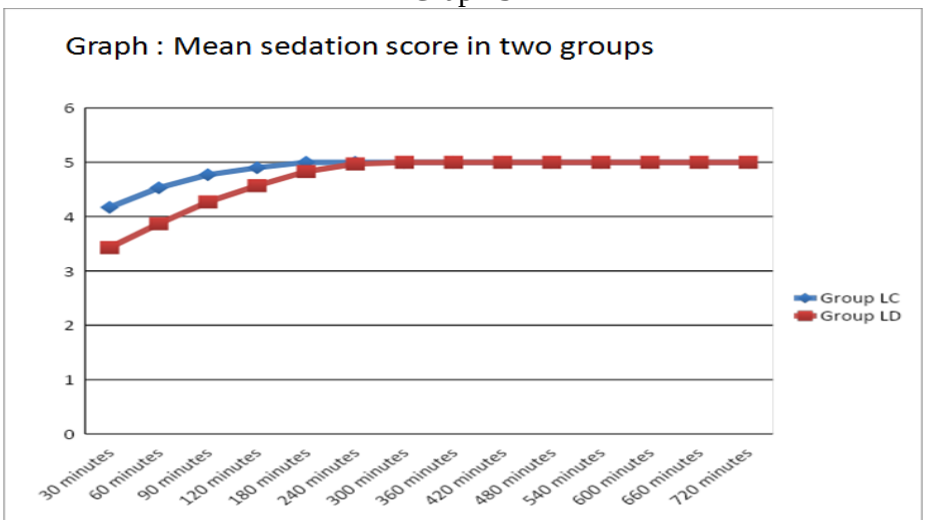


Graph 4



Graph 5



Discussion:

(Table 1) Both study groups were statistically comparable to each other in terms of demographic characteristics (namely age, gender distribution and weight of patients) and

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(Table 2) the mean duration of surgery was statistically comparable to each other in the two study groups.
(Table 2) indicates that the onset of sensory block was significantly rapid in group LD as compared to group LC.

Our results were in accordance with following studies:

- **Esmaoglu et al**[7] evaluated the effect of dexmedetomidine added to levobupivacaine for brachial plexus block and observed that the onset of sensory blockade was shorter [9.03 (±1.15) min] in dexmedetomidine group than in control group [10.46 (±1.30) min] which was statistically significant.
- Similar results were found by **Kaygusuz et al**[8]**, Ammar et al**[10]**, Dar et al**[12]and **Aggarwal et al**[14].

Our results were at variance with following studies:

- Studies by **Zhang et al**[15]and **Gandhi et al**[9] in which they showed no statistically significant difference in onset of sensory block with added dexmedetomidine to local anaesthetic in brachial plexus block.
- **Swami et al**[11]observed no statistically significant difference in onset of sensory block between dexmedetomidine and clonidine groups.

(Table 2) Shows that the duration of sensory block was significantly longer in group LD as compared to group LC.

Our results were in accordance with following studies:

- **Esmaoglu et al**[7] found a statistically significant prolongation of duration of sensory blockade [887 (±66.23) min in Group LD and 673 (±73.77) min in Group L ($p < 0.01$)].
- **Kaygusuz et al**[8] observed in their study that addition of dexmedetomidine to levobupivacaine in axillary brachial plexus block significantly prolonged the duration of sensory blockade [664.62 (±61.70) min in group L vs. 924.15 (±78.27) min in group D].
- **Ammar et al**[10] also observed significant prolongation of duration of sensory block when dexmedetomidine was added to bupivacaine in ultrasound guided infraclavicular brachial plexus block.
- **Dar et al**[12]**, Aggarwal et al**[14]**, Zhang et al**[15]and **Gandhi et al**[9] also found in their study that addition of dexmedetomidine to local anaesthetic significantly prolonged the duration of sensory blockade.
- **Swami et al**[11] also found statistically significant longer duration of sensory block in dexmedetomidine group [227.00 (±48.36) min in group C vs. 413.97 (±87.31) min in groupD ($p < 0.001$)].
  (Table 2) onset of motor block was found to be rapid in Group LD as compared to Group LC. These findings were found to be statistically significant.

Our results were in accordance with following studies:

- **Chakraborty et al**[6] evaluated effect of clonidine as an adjuvant in bupivacaine induced supraclavicular brachial plexus block and found significantly faster onset of motor block in the group receiving clonidine.
- **Esmaoglu et al**[7] observed that the onset of motor blockade was shorter [9.50 (±1.04 min)] in group LD than in group L [11.10 (±1.24) min].

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- **Ammar et al[10], Dar et al[12]** and **Aggarwal et al[14]** also concluded in their study that dexmedetomidine, when added to local anaesthetic in brachial plexus block, shortens the onsets time for motor block.

Our results were at variance with following studies:

- **Duma et al[4], Baj et al[13]**and **Patel et al[16]** showed no statistically significant difference in onset of motor block with added clonidine to local anaesthetic.
- **Zhang et al[15]**and **Gandhi et al[9]** also showed no statistically significant difference in onset of motor block.

Duration of Motor Blockade

(Table 2) This indicates that the duration of motor block was significantly rapid in group LD as compared to group LC.

Our results were in accordance with following studies:

- **Ammar et al[10]** found that addition of 0.75 mcg/kg dexmedetomidine to 0.33% bupivacaine significantly prolonged the duration of motor blockade compared to control group [155.5 (±15.8) min vs. 105.7 (±16.2) min respectively] and similar findings were observed in our study.
- **Swami et al[11]** also observed that dexmedetomidine added to local anaesthetic agent enhanced the duration of motor block [292.67 (±59.13) min in group C vs. 472.24 (±90.06) min in group D].

DURATION OF ANALGESIA

(Table 2) indicates that the duration of analgesia was significantly longer in group LD as compared to group LC.

Our results were in accordance with following studies:

- **Esmaoglu et al[7]** observed that adding dexmedetomidine (100 mcg) to levobupivacaine significantly increased the duration of analgesia from 887.14 (±260.82) min to 1008.69 (±164.04) min.
- **Swami et al[11]** also found in their study that duration of analgesia was significantly prolonged in dexmedetomidine group than in clonidine group.
- **Kaygusuz et al[8], Ammar et al[10], Dar et al[12]**and **Aggarwal et al[14]** also concluded in their study that dexmedetomidine when added to local anaesthetic for brachial plexus block significantly prolongs the duration of analgesia.
- **Singh et al[5], Patel et al[16]**and **Chakraborty et al[6]**also had similar findings in their study.

3

HEMODYNAMIC CHANGES

Heart Rate

(Graph 1) In the present study, themean (±SD) preoperative HR (in beats per minute) was 85.60 (±11.71) in group LC and 86.07 (±10.99) in group LD. The observations and obtained p-values indicate that in both study groups, initially the mean heart rate was statistically comparable at preoperative level and after interval of 5 minutes but from 10 minutes to 60 minutes, the mean heart rate was significantly lower in LD group as compared to LC group. Thereafter, mean heart rates again were statistically comparable throughout till the conclusion of observations.

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Our results were in accordance with following studies:

- **Esmaoglu et al**[7]observed that ingroup LD, except for basal values, heart rate remained significantly lower than that in group L.
- **Swami et al**[11]also observed a significantly lower heart rate at 60, 90 and 120 minutes in dexmedetomidine group as compared with clonidine group and was comparable at end of 180 minutes.
- **Dar et al**[12] also observed in their study that heart rate levels in group RD, except basal measurement, were significantly lower than those in group R.
- **Kaygusuz et al**[8] and **Aggarwal et al**[14] also observed that heart rate was significantly lower in dexmedetomidine group.
-

Systolic BP (Graph 2)

In the present study, mean (±SD) values of systolic BP (in mm Hg) recorded were statistically comparable at preoperative level [122.60 (±13.23) in LC group vs. 123.20 (±12.83) in LD group (p=0.859)]and up to 10 minutes after injection of drug but at 15 minutes, mean systolic BP became significantly lower in LD group as compared to LC group. Thereafter, mean values of systolic BP were again statistically comparable throughout till the conclusion of observations.

Diastolic BP (Graph 3)

In the present study, mean (±SD) values of diastolic BP (in mm Hg) recorded were statistically comparable at preoperative level [79.40 (±6.97) in group LC vs. 80.27 (±7.27) in group LD (p=0.639)] and up to 10 minutes after injection of drug but on 15 minutes, mean diastolic BP became significantly lower in LD group as compared to LC group similar to diastolic BP. Thereafter, mean values of diastolic BP were again statistically comparable throughout till the conclusion of observations.

Our results were in accordance with following studies:

- **Esmaoglu et al**[7]observed a significant fall in blood pressure (systolic and diastolic) indexmedetomidine group up to a period of 120 min ($p<0.05$) as compared to control group.
- **Swami et al**[11]found significant decrease in systolic and diastolic BP compared to baseline from 30 to 120 min in dexmedetomidine group as compared with clonidine group ($p <0.001$).

Our results were at variance with following studies:

- **Singh et al**[5]observed that preoperative and postoperative blood pressure was variable at each time interval and was also lower in the clonidine group in comparison with the control group, however the difference was not significant .

Respiratory Rate and Oxygen Saturation

The respiratory rate and oxygen saturation in the two groups was statistically comparable at preoperative level and throughout till the conclusion of observations.

VAS SCORE

(Graph 4) indicate a higher degree of analgesia in dexmedetomidine group as compared to clonidine group, especially in the late postoperative period when good control of pain is most important to ensure patient comfort.

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SEDATION SCORE

(Graph 5) This can be concluded that though dexmedetomidine causes a higher degree of sedation in patients compared to clonidine, short-lived and did not persist beyond 4 hours after the block. This sedation also contributes to better patient comfort and hemodynamic stability during surgery. **Esmaoglu et al[7],Swami et al[11], Ammar et al[10]** found more sedation in dexmedetomidine group as compared to clonidine group.

SIDE EFFECTS

(Table 3) In the present study, incidence of side effects was higher in group LC (n=5, 16.67%) as compared to group LD (n=3, 10%). All the side effects were self-limiting and did not need any specific treatment. No serious side effects pertaining to hemodynamic changes were noted in any group.

CONCLUSION

Dexmedetomidine when added to levobupivacaine as an adjuvant in supraclavicular brachial plexus block fastens the onset of motor and sensory blockade as compared to clonidine.Dexmedetomidine also prolongs the duration of sensory and motor blockade and have prolonged duration of analgesia with higher sedation. No significant added side effects and cardiovascular changes are observed with dexmedetomidine as compared to clonidine.

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