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Original Research Paper

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# RANDOMIZED CONTROL TRIAL COMPARING ORAL CLONIDINE AND ORAL PREGABALIN IN PATIENTS UNDERGOING UPPER LIMB SURGERIES UNDER SUPRACLAVICULAR BLOCK

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## ABSTRACT

**Background:** Preemptive analgesia may provide an effective approach for both pain control and decrease opioid consumption. A common approach for pain management after surgery is to relieve the pain that has already occurred. Aim: To compare pre-emptive oral pregabalin and clonidine in patients undergoing upper limb surgeries under supraclavicular block. **Methods:** The patients aged 18-60 years of either sex, American Society of Anaesthesiologists (ASA) physical status I-II and BMI 18.5-29.9 kg/m2 scheduled for scheduled for elective upper limb surgeries under supraclavicular block, were included over a period of 18 months in this study at Department of Anaesthesiology, Dr RPGMC Kangra at Tanda. Patients were randomly assigned to receive 200 μg of clonidine (group CL) or 150 mg pregabalin (group PR) one hour before surgery. **Results:** There was no significant difference in onset of sensory and motor block between both groups (P>0.05). However, duration of sensory and motor block was significantly higher in group PR in comparison to group CL (P<0.0001). Post-operative pain was significantly different between both groups at 1-hour, 4-hour, and 24 hours (P<0.01). None of the patients was not satisfied in any of the groups while 87% of the patients in group PR and 77% in group CL were very satisfied. **Conclusion:** Our findings shows superiority of pregabalin over clonidine in patients scheduled for upper limb surgeries under supraclavicular block.

**KEYWORDS :** Supraclavicular block, Pre-emptive, Pregabalin, Clonidine

## Introduction

A regional anaesthetic technique for Anaesthesiologists and patients with its advantages over general anaesthesia such as remaining conscious during surgery, avoiding polypharmacy, better haemodynamic stability and excellent post-operative analgesia.–1,2 The supraclavicular brachial plexus block is a popular technique for surgeries below the shoulder because of its quick onset and high success rate. However, the major disadvantages are higher incidence of complications such as inadvertent vascular injections, pneumothorax, phrenic nerve palsy and Horner's syndrome.

Pregabalin is a gamma-aminobutyric acid analog that reduces the depolarization-induced calcium influx at nerve terminals, with a consequent reduction in the release of several excitatory neurotransmitters, including glutamate, noradrenaline, substance P, and gastrin-releasing peptide. It has been found toprolong the duration of anesthesia.3 Clonidine is a partial α2-adrenoreceptor agonist increases the motor and sensory blockade.

The present study compared pre-emptive oral pregabalin and clonidine in patients undergoing upper limb surgeries under supraclavicular block.

## Methods

The patients aged 18-60 years of either sex, American Society of Anaesthesiologists (ASA) physical status I-II and BMI 18.5-29.9 kg/$m^2$ scheduled for scheduled for elective upper limb surgeries under supraclavicular block, were included over a period of 18 months. Exclusion criteria were patient's refusal for block, patients with known drug allergy to study drugs, patients who had taken analgesics 48 hrs before, use of anti-epilepticdrugs, hepatic and renal pathologies affecting drugclearance, history of long-term usage of NSAIDs and opioid analgesics, patient in whom the block effect was partial and required supplementary analgesic, diabetes mellitus and other neuropathic disorders, any contraindications for peripheral nerve blocks, coagulopathy disorders, psychiatric disorders, and/or addiction to anydrug.

The study was an open label randomized controlled study. It was commenced after obtaining approval of institutional ethics committee. Randomization was achieved using block randomization with block size of 30. Sequence was generated by a person not directly involved in execution of the study.

## Pre-anaesthetic Evaluation

During pre-operative visits, patient's detailed history, general physical examination and systemic examination was carried out. Basic demographic data like age, sex, height, weight, BMI was recorded.

Routine investigations like hemoglobin, urine sugar, bleeding time, clotting time, renal function tests, liver function tests, Chest X-ray, ECG were done in all patients. Patients were explained in detail about the anaesthesia procedure. Written and informed consent was taken from the patients

## Methodology

Sixty patients were enrolled in the study with orthopedic fractures of the upper extremity who underwent surgery under supraclavicular nerve block. They were randomly assigned to receive 200 μg of clonidine (group CL) or 150mg pregabalin (group PR) one hour before surgery. All patients were kept NPO eight hours before the surgery. They were pre-medicated in the form of tablet alprazolam 0.25 mg and tablet ranitidine 150mg at bed time and 6:00 am with sip of water on the day of surgery.

## Data analysis

Data were expressed as frequency, percentages, mean, and/or standard deviation. Categorical variables were compared using Chi square test. Student t-test was used to compare quantitative variables between 2 groups. P value <0.05 was considered significant. Statistical analysis was performed using SPSSv21.

## Results

General characteristics

Table 1 shows general characteristics of the study participants. The patients in both groups were comparable in terms of age, sex, weight, ASA physical status, and duration of surgery (P>0.05).

**Table 1: Comparison of general characteristics**

| | Group PR (n=30) | Group CL (n=30) | P-value |
|---|---|---|---|
| Age (Years) | 34.93±9.47 | 33.40±8.86 | 0.521 |
| Sex, n<br>Male<br>Female | 20<br>10 | 20<br>10 | 1.000 |
| Weight (Kg) | 63.46±9.19 | 64.16±10.09 | 0.790 |
| ASA Grade, n<br>I<br>II | 25<br>5 | 26<br>4 | 0.718 |
| Duration of surgery (minutes) | 131.83±27.57 | 125.83±20.26 | 0.341 |

Data were expressed as mean±SD otherwise expressed

### Block characteristics

Onset of sensory block was defined asthe time interval between the end of injection and loss of sensation to pin prick or a score 1 on pin prick response while onset of motor block was defined asthe time interval between the end of injection and complete motor paralysis of the wrist and hand. There was no significant difference in onset of sensory and motor block between both groups (P>0.05). However, duration of sensory and motor block was significantly higher in group PR in comparison to group CL (P<0.0001) (Table 2).

**Table 2: Comparison of onset and duration of sensory and motor block**

| | Group PR (n=30) | Group CL (n=30) | P Value |
|---|---|---|---|
| Onset of sensory block (sec) | 3.77±0.82 | 3.83±0.83 | 0.779 |
| Onset of motor block (sec) | 7.70±1.21 | 7.37±1.10 | 0.274 |
| Duration of sensory block (min) | 269.50±11.09 | 226.73±9.36 | <0.0001 |
| Duration of motor block (min) | 231.33±12.45 | 211.16±12.74 | <0.0001 |

Data were expressed as mean±SD

### Post-operative pain score

In this study, pain post-operatively at 30-min was comparable between both groups. However, pain was significantly different between both groups at 1-hour, 4-hour, and 24 hours (P<0.01) (Table 3).

**Table 3: Comparison of post-operative pain score**

| | Group PR (n=30) | Group CL (n=30) | P Value |
|---|---|---|---|
| 30 min | 1.61±0.95 | 1.72±0.93 | 0.652 |
| 1-hour | 2.01±0.55 | 2.32±0.31 | 0.009 |
| 4-hour | 4.28±0.75 | 1.60±0.91 | 0.001 |
| 24-hour | 3.17±1.42 | 5.08±2.40 | 0.001 |

Data were expressed as mean±SD

### Requirement of rescue analgesia

Total boluses of injection diclofenac 1.5 mg/kg i/m used in each patient group in postoperative period at VAS > 4 were calculated. Total number of boluses used in group CL was significantly higherin comparison to group PR (P<0.01) (Figure 1).

### Patient satisfaction score

Patients were asked to rate on a 3-point scale (1- very satisfied, 2-satisfied, 3- not satisfied) their satisfaction in terms of pain relief in both groups. None of the patients was not satisfied in any of the groups while 87% of the patients in group PR and 77% in group CL were very satisfied (Figure 2).

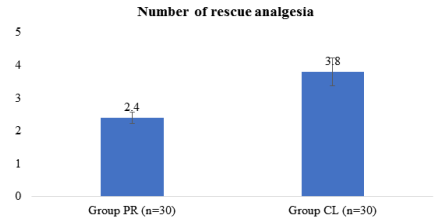


**Figure 1: Comparison of mean rescue analgesia**

### Patient satisfaction score

Patients were asked to rate on a 3-point scale (1- very satisfied, 2-satisfied, 3- not satisfied) their satisfaction in terms of pain relief in both groups. None of the patients was not satisfied in any of the groups while 87% of the patients in group PR and 77% in group CL were very satisfied (Figure 2).

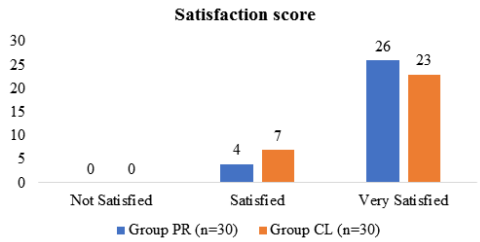


**Figure 2: Distribution of satisfaction score between both groups**

### Discussion

Pre-emptive analgesia prevents the central processing of afferent input responsible for postoperative pain and subsequently decreases the incidence of hyperalgesia and allodynia after surgery. This technique is highly desirable in surgeries associated with severe postoperative pain.[4]

Our findings showed the preemptive analgesia with pregabalin as an effective method for increased duration of sensory and motor block, reducing pain after surgery for longer period, lesser requirement of rescue analgesia, and higher patient satisfaction. Preemptive analgesia has certain clinical benefits, including reducing psychological distress, sleep disturbances, and the need for analgesics with the associated complications, as well as faster recovery and earlier and safer discharge.[5]

Peak effect of pregabalin orally is about 1 hour and its half-life is about 6 hours.8 Hence, in this study, duration of surgery in pregabalin group was 131.83±27.57 min, patients were very satisfied in pain relief management as compared to clonidine.

In a study conducted to evaluate the effect of oral pregabalin on the duration and quality of postoperative analgesia in spinal anesthesia, it was shown that oral pregabalin extended the duration of postoperative analgesia and reduced morphine intake.[6]

Mosaffa et al. used 40ml of 1.5% lignocaine with 200 μg clonidine, had onset of sensory block in 5.8mins and duration of sensory block was 176.5mins in clonidine group. In the present study, faster onset (3.83±0.83) and longer duration (226.73±9.36) could be due to higher concentration of lignocaine and addition of adrenaline(1:200000).7

### Conclusion

Pre-emptive use of pregabalin was superior over clonidine in terms of higher duration of sensory and motor block, higher

pain relief, lesser requirement of rescue analgesics, and higher patients satisfaction. However, further studies with a higher sample size are required to validate the findings.

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