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COMPARATIVE CLINICAL STUDY OF ROPIVACAINE WITH FENTANYL AND ROPIVACAINE WITH CLONIDINE BY PERIPHERAL NERVE STIMULATOR GUIDED BRACHIAL PLEXUS BLOCK THROUGH AXILLARY APPROACH

Anaesthesiology

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ABSTRACT

AIM: "Comparative clinical study of Ropivacaine with Fentanyl and Ropivacaine with Clonidine by peripheral nerve stimulator guided brachial plexus block through axillary approach."

Material And Methods : A total number of 60 patients of either sex , age between 18- 60 years , ASA class I and II were randomly allocated in to two groups , thirty in each. Group RF received 0.5% ropivacaine (30ml) and 1µg/kg fentanyl. Group RC received 0.5% ropivacaine (30ml) and 2µg/kg clonidine. Patients were observed for onset and duration of sensory and motor block, duration of analgesia, hemodynamic variation, postoperative pain and side effects.

Result: Earliest onset of sensory and motor block was observed in Group RC in comparison to Group RF, which was highly significant ($p < 0.0001$). Significantly higher duration of sensory, motor blockade and duration of analgesia was observed in RC group in comparison to RF group ($p < 0.0001$). No significant hemodynamic changes were observed in both group and first analgesic demand in fentanyl group was earlier .

Conclusion: We concluded that addition of clonidine and fentanyl as adjuvant to ropivacaine for axillary brachial plexus block is safe and effective, however clonidine is better in terms of early onset, longer duration of analgesia and lesser hemodynamic changes.

KEYWORDS

Ropivacaine, Fentanyl, Clonidine.

INTRODUCTION

Regional anaesthesia has become the preferred option over general anaesthesia because of quicker patient rehabilitation and avoidance of possible complications from general anaesthesia . For the anesthesiologist and the surgeon , cardiovascular and respiratory stability , preservation of protective airway reflexes and rapid post-operative recovery are the most important advantages of regional anaesthesia.

Brachial plexus blocks have been widely used for upper limb surgeries. The axillary approach to the brachial plexus is the most popular because of its ease , reliability and safety.[1] Although blockade of musculocutaneous nerve is not always produced with this approach, it can be supplemented at the level of axilla or at the elbow. Axillary block is usually used for surgery to forearm and hand.

In general regional block avoid the unwanted effect of anaesthetic drug and improve the effect of post operative analgesia, reduce the post operative consumption of opioids, and avoids the general anaesthesia related adverse events, which make choice of anaesthesia procedure more flexible and can improve patient satisfaction .[2]

Ropivacaine, the S-enantiomer of S-1-propyl-2, 6-pipecoloxylidide is a long-acting amide local anaesthetic with chemical structure similar to that of Bupivacaine. Ropivacaine is less lipophilic, and less cardiotoxic when compared to Bupivacaine.[3]

Clonidine is a selective α2 adrenergic agonist, whose addition to local anaesthetic might improve peripheral nerve block by reducing the onset of time , improve efficacy of block and post op analgesia.

Clonidine enhances or amplifies the sodium channel blockade action of local anesthetics by opening up the potassium channels resulting in membrane hyperpolarization,a state in which cell is unresponsive to excitatory input. [4,5]

Fentanyl is a synthetic opioid and a phenylpiperidine derivative acting on the opioid receptors especially mu(µ) receptors. Its addition to local anaesthetic during peripheral nerve blocks provides stronger and long lasting analgesia without much systemic side effects .[6]

The following study aims to compare the efficacy, sensory and motor effect of Ropivacaine-fentanyl and Ropivacaine-clonidine in brachial plexus block through axillary approach for the surgery of forearm and hand .

MATERIALS AND METHODS:

After approval from ethical committee , the study was conducted at S.R.N Hospital (associated to M.L.N Medical College Prayagraj) over a period of one year from (July 2019 to June 2020). After obtaining informed written consent from all patients a total 60 patients belonging to ASA class I and II, aged 18 to 60 years, undergoing elective surgical operations being performed brachial plexus block through axillary approach were recruited for this study.

Study Design :

A randomized, controlled, double blinded, comparative study.

Group Allocation :

Patients were randomly allocated and divided into two groups (30 patients in each group) on the basis of computer generated random numbers by using Microsoft Excel, SPSS Version 24.0.

Group RF (n = 30) - Received 0.5% Ropivacaine 30 ml + 1mcg/kg Fentanyl

Group RC (n = 30) - Received 0.5% Ropivacaine 30 ml + 2mcg/kg Clonidine

Inclusion Criteria :

1: Patient giving valid informed and written consent.
2: Patient of either sex ,aged between 18 and 60
3: Patient under ASA grade I and II
4: Patient undergoing elbow, forearm and hand surgery.

Exclusion Criteria:

The following patients excluded from study:
1: Patient refusal
2: Patient under ASA grade 3 and above
3: Rheumatic heart disease and ischemic heart disease
4: Uncontrolled hypertension and diabetes.
5: Respiratory diseases like COPD and asthma
6: Hepatic and Renal disease
7: Bleeding disorder and Haemoglobinopathy

METHODOLOGY

Pre-anaesthetic evaluation was done on the evening before surgery. It includes General examination and systemic examination, routine investigation , Standard 12 lead ECG and X ray chest.

18 gauge intravenous cannula was inserted on the non operating hand

and an infusion of Ringer lactate was started . Monitor was connected to the patient to record all vitals parameter. Peripheral nerve stimulator (PAJUNK) and Insulated nerve stimulator needle of 5cm length with extension tubing along with all emergency equipments and all resuscitative drugs get ready.

A standard axillary perivascular block technique was applied in all cases (supine position with head turned to opposite side, arm abducted approximately 90° with the hand ,forearm flexed and externally rotated). Under aseptic precautions, skin wheal was raised with lidocaine 2% at the site of block prior to block placement . Neural blockade was performed by using a 22G insulated short beveled needle and peripheral nerve stimulator (PAJUNK). The positive electrode of (PAJUNK) nerve stimulator was connected to an ECG electrode placed on chest of patient and negative electrode is connected to insulated needle. The intensity of stimulating current was initially set to deliver 2mA with impulse duration of 0.1ms and frequency 2 Hz . All patients received a total 30ml of 0.5% Ropivacaine and 1µg/kg Fentanyl or 2µg/kg Clonidine.

The arterial pulse was palpated at the level of pectoralis major muscle, stimulating needle was inserted above the arterial pulse .Flexion of wrist and first three fingers was obtained (median nerve stimulation) with a current of 0.5 mA ,at this point 8 ml of solution was injected slowly with intermittent aspiration to avoid intravascular injection. Again needle was withdrawn subcutaneously and redirected obliquely, above and in to the coracobrachialis muscle. Appearance of maximum biceps contraction (musculocutaneous nerve stimulation) with a current of 0.5mA , at this point 5 ml of solution was injected slowly with intermittent aspiration.

The needle was withdrawn and inserted below the axillary artery .The fascia again penetrated, and first response, arm extension or thumb adduction, flexion of fourth and fifth fingers(ulnar nerve) with a current of 0.5 mA. These response was ignored ,needle was advanced deeper until wrist and finger extension was obtained (radial nerve), at this point remaining volume (16ml) solution was slowly injected with intermittent aspiration. For tourniquet discomfort supplemental 5ml of local solution was injected subcutaneously to block the intercostobrachial nerve.

Sensory and motor function was evaluated before the block and every 2 min for initial 30 min after the block, and then every 30 min till patient regained normal sensations after the block. Thumb abduction for the radial nerve, thumb adduction for the ulnar nerve, thumb opposition for the median nerve and flexion of elbow for the musculocutaneous nerve.

During the surgery Haemodynamic variables like Heart rate, mean arterial blood pressure, pulse oxygen saturation were monitored and recorded at fixed intervals. Post operative pain was assessed by using Visual Analog Scale and sedation score was assessed by using Ramsay sedation scale.
1 : To compare the onset of sensory and motor blockade .
2 : To compare the time taken for maximum sensory and motor blockade.
3 : To compare duration of sensory and motor blockade .
4 : To compare duration of analgesia .
5 : To compare the quality of overall block .

Sensory block was assessed by pin prick method. C7 to T1 dermatomes and graded according to. 0- Normal response to pin prick.1- Dull response to pin prick (onset)2- No response to pin prick (peak).

Motor Block Was Assessed By Modified LOVETT RATING SCALE:
Grade 6- Normal. Grade 5- Slightly reduced muscular force Grade 4- Pronounced reduction. Grade 3- Slightly impaired mobility. Grade 2- Pronounced mobility impairment. Grade 1- Almost complete paralysis. Grade 0- Complete paralysis.

Statistical Analysis:
The mean and standard deviation of the normally distributed quantitative variables were compared between the two groups using independent sample t-test. The median and inter quartile range (IQR) of the non- normally distributed quantitative variables were compared between the two groups, using Mann-Whitney U test. The qualitative variables were compared between the two methods using Chi-square test.

Efforts were made to control for the confounding by appropriate regression methods, for all the key outcome variables. P Value < 0.05 will be considered as statistically significant. Data were analysed by using Co-Guide software, V.1.0[77]

RESULTS AND OBSERVATIONS

A total 60 patients of ASA physical status I or II undergoing elective surgical operations being performed brachial plexus block through axillary approach were recruited for this study.

Table 1: Demographic Parameters Of The Two Groups RC And RF

Variable	Group RF	Group RC	P-value
Age(years)	35.8±9.625	39.8±10.545	0.1303
Sex (M/F)	19 (63.33%)/11(36.66%)	21(70%)/9(30%)	
Weight (kg)	62.4±7.491	61.67±5.561	0.6698
Height (cm)	161.966±5.346	163.4±5.66	0.3172

Demographic data and clinical characteristics were comparable between both the groups in respect of age, sex, weight, and height, and all vital parameters such as (non invasive blood pressure, heart rate spo2) in both groups were statistically insignificant (p-value > 0.05).

Table 2: Comparison Of Timing Of Anaesthesia Events Between Group RF And RC

Data were analysed by using Student,s t-Test and were presented as Mean±SD. Onset of sensory and motor block is significantly higher in group RF than group RC and duration of analgesia was significantly higher in group RC in comparison to group RF.

Timing anaesthesia	Group RF (n=30)	Group RC (n=30)	p-value
Onset of sensory block (min)	7.76±0.67	6.13±0.68	<0.0001
Mean of complete sensory block (min)	12.86±0.81	12.03±0.96	0.0006
Duration of sensory block	457.66±39.71	485.00±28.73	0.0034
Onset of motor block(min)	12.13±0.93	9.63±0.66	<0.0001
Mean of complete motor block (min)	17.80±0.99	16.93±0.78	0.0004
Duration of motor block (min)	377.66±27.75	438.33±36.30	<0.0001
Duration of analgesia (min)	704.66±25.28	760.00±48.56	<0.0001

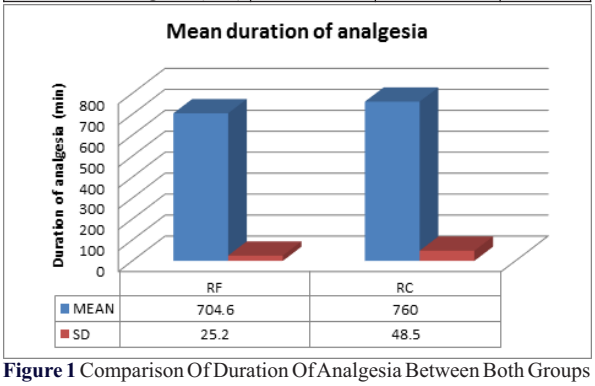

Figure 1 Comparison Of Duration Of Analgesia Between Both Groups

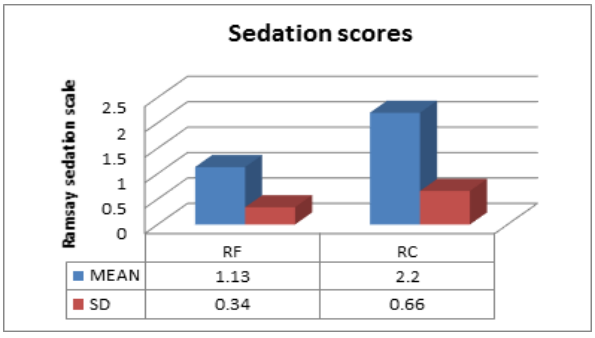

Figure 2

Sedation score was expressed as mean±SD and analyzed by unpaired student "t" test. Sedation score of patients in group RF 1.13±0.34 and in group RC was 2.2±0.66 p-value <0.0001. Which was statistically high significant.

Table 3: Time Required For Rescue Analgesia(min) (Mean±SD).

	Group RF	Group RC	t-Value	P-Value
Time required for rescue analgesia	503.33±49.3	569.66±47.9	5.285	<0.0001

Time required for rescue analgesia as first analgesic request (Inj Diclofenac) in group RF was503.33±49.33min and in group RC was 569.66min p-value <0.0001. Which was longer in group RC than RF group and highly significant.

DISCUSSION

All the groups were comparable with respect to demographic profile. There was statistically no significant difference **(p-value>0.05)** Hemodynamic parameters like heart rate, systolic BP. diastolic BP mean arterial pressure and oxygen saturation were within normal limits during preoperative , intraoperative and postoperative period in both groups and were statistically insignificant **(p-value > 0.05)**.

Mundhada D, Thatte J, et al. [7] Compare the effect of Fentanyl and Clonidine added to Bupivacaine in supraclavicular brachial plexus block. Patients were randomly divided into two equal groups of 35 each. Group C received 25ml 0.5% Bupivacaine + 1 µg /kg Clonidine whereas Group F received 25ml 0.5% Bupivacaine + 1 µg /kg Fentanyl. Mean onset of sensory in Group C was 6.14±50min, and in Group F was 7.40±44min p-value <0.001 and mean complete onset of sensory block in Group C was 13.12±15min,and in Group F was 13.53±50min p-value<0.004. Mean onset of motor block in group F was 11.10±52min and in group C was 9.53±1.5min p-value <0.001 and time taken for complete motor block in group F was 18.4±50min, group C was 17.10±55min, p-value<0.001 which was highly significant in both and significantly higher in Group F as compared to Group C. Post-op analgesia in group C was 13.13hrs±52min and in group F was 11.37hrs±45min.Which was higher in group C. This result is consistent with our study.

Lee, Ki- Young , et al. [8] Studied the addition of Clonidine 2µg/kg or Fentanyl1µg/kg to 1.5% lidocaine for brachial plexus block.. They found that Clonidine causes a rapid onset of analgesia and prolonged duration of sensory blockade in comparison to the addition of epinephrine or fentanyl to 1.5% lidocaine. Hemodynamic changes were not significantly different in all groups. This result is consistent with our study.

Ratre BK , Mangal V, et al.[9] Assessed the effects of Fentanyl and Clonidine added to 20ml of 0.25% Bupivacaine in supraclavicular brachial plexus block. Group I received 10 ml of 1.2% lidocaine, group II received 1.2% lignocaine with Fentanyl (50 µg) and group III received 1.2% lignocaine with Clonidine (75µgm). The mean onset of sensory blockade was highly significant in both fentanyl and clonidine (p<0.001). The mean duration of analgesia in clonidine was higher .This result obtained is similar to our study.

Nehra P, Oza V, Parmar V, et al.[10] Compared the effect of Fentanyl 25 µg and Clonidine25 µg as adjuvant added to 3 ml of 0.5% Bupivacaine and 5ml of 2% lignocaine in peribulbar blocks .. It were observed that mean onset of globe and lid akinesia was significantly faster in group F and group C compared to group S, The duration of analgesia was longer in Clonidine as compare to Fentanyl and group S. This study showed that, even lower volume of local anaesthetic agent with low dose of adjuvant added, obtained similar result. This is also consistent with our study.

Kumar, K. [11] Compared the addition of Fentanyl and Clonidine as adjuvant with local anaesthetic in supraclavicular brachial plexus block. The result obtained as earlier onset of sensory and motor blockade as well as longer duration of analgesia when Clonidine 150 µg was used as a perineural adjuvant to Ropivacaine was consistent with our study.

Limitation Of The Study:

In our study we did not use ultrasound guidance for the axillary brachial plexus block. Ultrasound guided block would be more precise and requires smaller volumes of local anesthetics.

CONCLUSION

From our study we concluded that the addition of Clonidine and Fentanyl as adjuvant to Ropivacaine for axillary brachial plexus block, is safe and effective. However Clonidine is preferred over Fentanyl in terms of early onset of sensory and motor blockade, longer duration of analgesia and lesser haemodynamic changes.

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