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COMPARISON OF 0.5% ROPIVACAINE ALONE AND IN COMBINATION WITH ADJUVANTS CLONIDINE OR DEXAMETHASONE USED IN BRACHIAL PLEXUS BLOCK THROUGH SUPRACLAVICULAR APPROACH : A RANDOMISED CONTROLLED DOUBLE BLIND CLINICAL STUDY

Anaesthesiology

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ABSTRACT

Background and Aim : Background the present study was planned to evaluate the effect of 0.5% ropivacaine with adjuvants 0.15mg clonidine or 8 mg dexamethasone with consideration to the onset and duration of sensory-motor blockade, hemodynamic variables, postoperative analgesia and adverse effects.

Material and Methods The study was conducted in the department of Anaesthesiology, Darbhanga medical college and hospital from April 2018 to December 2019. 105 consenting patients were included scheduled for moderate duration of upper limb surgeries of orthopedics and general surgery.

Results: 124 patients were assessed for eligibility. Eleven patients did not give consent for participation and eight was not included due to not meeting inclusion criteria. 105 patients were enrolled and randomized to any of the three groups; 35 each in the intervention and the comparator groups. Finally, 35 patients in placebo and dexamethasone group each and 35 patients in clonidine group were analyzed, the rest being excluded due to failed block.

Conclusion: we conclude that dexamethasone as an adjuvant is a good choice to prolong the duration of postoperative analgesia without any serious adverse effect. However, prolonged motor block is a matter of concern and the search for an adjuvant that selectively prolongs analgesia without impairing motor function continues.

KEYWORDS

INTRODUCTION

Regional anaesthesia in the form of brachial plexus nerve block is a popular technique used for upper limb surgeries. It may be used as a primary anaesthesia or an adjunct to general anesthesia. Upper limb surgeries under brachial plexus block avoids the complication of general anesthesia, decreases the immediate postoperative pain, lessens financial implication and faster discharge from hospital. With appropriate selection and sedation, these techniques can be used in all age groups. Skillful application of peripheral nerve blockade broadens the anesthesiologist's range of options in providing optimal anesthesia care.

Among the various techniques of brachial plexus blocks, the supraclavicular and subclavian perivascular methods produce the most complete limb block.

Lignocaine and Bupivacaine are frequently used well established local anesthetia. Lignocaine has the disadvantage of having short duration of action and bupivacaine of having adverse effects like cardio toxicity when used in high concentration or accidentally administered intravascular. It compelled the researchers to develop a new drug that can have all the advantages of bupivacaine without its toxicity.

Ropivacaine is one of such drugs which is a long acting local/regional anesthetic structurally related to bupivacaine i.e. of amide group. It is an S-enantiomer unlike bupivacaine which is a racemic mixture. The favorable clinical profile has prompted many clinicians to switch from bupivacaine to Ropivacaine for all types of neural blockade. However with clinical use, it was discovered that latency of sensory analgesia for Ropivacaine was approximately two thirds that of Bupivacaine, therefore there was significant delay in achieving peak effect and in achieving prolonged post- operative analesia. So, the challenge resides with the anesthesiologist to prolong the duration of analgesia while minimizing the adverse effects.

If we limit the block to a single injection, the effect begins to wane after few hours and duration of sensory and motor block and duration of analgesia depends on the local anesthetic used. Methods to prolong analgesia beyond the actual duration of the local anesthetic used include either placement of perineural catheters to allow continuous infusion or co-administration of adjuvants.

For moderate prolongation various adjuvant drugs can be admixed with local anesthetic. Adjuvants include Epinephrine, Clonidine, Opioids, Ketamine, Midazolam and Glucocorticoids. But all have met with limited success.

Dexamethasone microspheres have been found to prolong the block duration in animal and human studies and adding methyl prednisolone to local anesthetic increases the duration of axillary brachial plexus block. Dexamethasone appears to be effective in prolonging the duration of analgesia from supraclavicular block using Ropivacaine or Bupivacaine. It produces analgesia by blocking transmission of nociceptive mylenlintated c-fiberes and suppressing ectopic neuronal discharge. It may be due to to alteration in the function of potassium channels in the excitable cells. Recent studies indicate that 8 mg dexamethasone added to perineural local anesthetic injections augment the duration of peripheral nerve block analgesia.

The α-2 adrenoreceptor agonist agent clonidine, which has in-vitro local anaesthetic properties, has been added to local anesthetic solution to prolong their action. Adverse effects related to clonidine are dry mouth, hypotension and bradycardia.

The major goal in the management of postoperative pain is minimizing the dose of medication to lessen side effects while still providing adequate analgesia. Management of postoperative pain relieves leads early mobilization, shortened hospital stay, reduced hospital cost, and increased patient satisfaction. This technique of brachial plexus block seems to be a better alternative to general anaesthesia in today's era of day care surgeries.

AIMS AND OBJECTIVES

The present study comparing the effect of 0.5% ropivacaine alone and adjuvants Clonidine or Dexamethasone added to 0.5% ropivacaine in supraclavicular brachial plexus blocks in upper limb surgery. The study was undertaken with the following objectives:

Primary Objective

1. To assess the duration of analgesia

Secondary Objective:

2. To assess the onset of sensory and motor block
3. To assess the duration of sensory and motor block
4. To evaluate the incidence of hypotension, bradycardia or any other adverse effect.

MATERIAL AND METHODS

METHODS:

Study Design

This study was an interventional, prospective, double blind, randomized clinical study conducted on patients undergoing elective upper limb surgeries. A written informed consent was obtained from all the patients before the screening in the study.

Study Patients And Place

The study was conducted in the department of Anaesthesiology, Darbhanga medical college and hospital from April 2018 to December 2019.

Sample Size

A prospective sample size calculation indicated that 28 patients were required in each group to have an 80% power to detect a 25% difference at an alpha error of 0.05 for the duration of analgesia. Considering drop outs, 35 patients in each group recruited.

105 consenting patients were included scheduled for moderate duration of upper limb surgeries of orthopedics and general surgery. The sampling type was randomized cluster sampling.

ELIGIBILITY

Inclusion Criteria:

- Patients with ASA class I and II
- Patients aged between 18 to 65 years of either sex
- Scheduled for surgery on upper extremity under supraclavicular brachial plexus block

Exclusion Criteria:

After routine preoperative evaluation and investigation, the following patients were excluded from the study;

- Patient refusal
- Weight less than 45 kg
- Coagulation disorder
- Infection at the site of injection
- Allergy to local anesthetic and study drug
- Concomitant use of analgesic or sedatives
- Pre-exisiting central or peripheral neuropathy or any neurological deficit
- History of severe cardiopulmonary disease, hepatic or renal diseases, thyroid disorder, diabetes mellitus, psychiatric illness etc.
- Failed brachial plexus block

Study Groups

Eligible consenting patients were allocated to one of three groups by use of computer generated random numbers

Study Group I [GrPl] : Received 28 ml of 0.5% ropivaciane added with 2 ml normal saline to make 30 ml volume

Study Group II [GpCI]: Received 28 ml of 0.5% ropivacaine added with 0.15 mg clonidine diluted to 2ml in normal saline

Study GroupIII [GpDx] : Received 28 ml of 0.5% ropivacaine added with 8mg dexamethasone in 2ml

Statistical Analysis

The data was compiled and subjected to statistical analysis using Statistical Package for Social Sciences [SPSS Inc, Version 20.0]

Statistical Tests

One way ANOVA was employed to compare demographic and block parameters, haemodynamic variables. Bonferroni post hoc test was used to determine the difference between two groups. Data was presented as mean ± SD. P-Value <0.05 was considered to indicate statistical significance.

RESULTS

Demographic Characteristics

The demographic data of the patients comprising of age, sex, weight and ASA grading as follows :

Age

The patients assessed for the eligibility were in the age group of 18-60 yrs. The mean age in the Group I, Group II and Group III were 37.94±11.52, 40.22±11.64 and 41.18±13.08 years respectively. There was no significant difference among the groups in terms of age. (P-value =.809)

Weight

The mean weight of the patients in Group I was 68.60±10.02 in Group II was 65.84±8.67 and in Group III was 65.30±9.65 Kg. The weight distributions among the groups were not significant. (P-value=0.08)

Sex Distribution

All the three groups were found to be comparable in respects of male/female ratio as the p-value of sex ratio among the group was 0.804.

ASA grading

There was no statically significant difference between the groups with respects to ASA physical status. (Chi-square:0.404, p-value=0.816)

HAEMODYNAMIC PARAMETERS

Heart rate and Mean arterial pressure were observed intraoperatively. Baseline values were noted and thereafter at every 10min interval till the surgery lasted.

Heart Rate (beats/minute)

There was no significant difference in heat rate among the groups at baseline, 10 min, 20 min, 30 min, 40 min, 50 min and 70. Data shows significant difference at 80 min. only few cases in each group were of more than 80 min of duration and due to this significant initial in HR in the groups and remained almost stable.

Mean Arterial Pressure (MAP)

Along with the heart rate MAP were recorded, baseline and thereafter at every 10 min interval till the surgery lasted. There was no significant difference in MAP among the groups at any time during the surgery.

BLOCK CHARACTERISTICS

Time Of Onset Of Sensory Block

Onset of sensory block was comparable among the groups. Mean time of onset of sensory block for group I, group II and group III was 5.24±1.09, 5.22±1.13 and 4.91±1.28 respectively. Mean onset time for dexamethasone group was lower than clonidine and saline group this was statistically insignificant. P-value was 0.44. (Table 1)

Time Of Onset Of Motor Block

Onset time of motor block was statistically insignificant among the groups. P-value was 0.08. mean time of onset of motor block was 10.33±1.67, 9.94±1.48 and 9.48±1.42 for group I, group II and group III respectively. Mean onset time for dexamethasone group was lesser than other group. (Table 2)

Table 1: Onset Of Sensory Block

PARAMETER	GROUPS						REMARKS
Onset of sensory block (minutes)	Group I [GrP]		Gropup II [GpCI]		Group III [GpDx]		P-value=0.44 Not significant
	Mean	SD	Mean	SD	Mean	SD	
	5.24	1.09	5.22	1.13	4.91	1.28	

Table 2: Onset Of Motor Block

PARAMETER	GROUPS						REMARKS
Onset of motor block (minutes)	Group I [GrP]		Group II [GpCI]		Group III [GpDx]		P-value=0.08 Not significant
	Mean	SD	Mean	SD	Mean	SD	
	10.33	1.67	9.94	1.48	9.48	1.42	

DURATION OF MOTOR BLOCK

Regression of block was assessed at every thirty minutes. The mean duration of motor block in dexamethasone group was near double and in clonidine group was prolonged for about hundred minutes in respect of plain ropivacaine group. This was statistically highly significant ($p<0.001$). The mean duration of motor block was 443.64±24.72, 541.88±22.78 and 910.91±44.89 for group I, group II and group III respectively. [TABLE 3]

DURATION OF SENSORY BLOCK

The mean duration of sensory block was 539.09±28.54, 665.63±30.89 and 1031.82±45.58 for group I, group II and group III respectively. The p value was <0.001, indicating that the difference was highly significant. Duration was increases for more than hundred minutes in clonidine group and almost double in dexamethasone group in respect of plain ropivacaine group. [TABLE 4]

Table 3: Duration Of Motor Block

Parameter	Groups						Remarks
Duration of motor block (minutes)	Group I [GrP]		GropuP II [GpCI]		Group III [GpDx]		P-value <0.001 highly significant
	Mean	SD	Mean	SD	Mean	SD	
	443.64	25.72	541.88	22.78	910.91	44.89	

Table 4: Duration Of Sensory Block

Parameter	Groups						Remarks
Duration of sensory block (minutes)	Group I [GrP]		GroupII [GpCI]		Group III [GpDx]		P<0.001 highly significant
	Mean	SD	Mean	SD	Mean	SD	
	539.09	28.54	665.63	30.89	1031.82	45.58	

DURATION OF ANALGESIA

Duration of analgesia was defined as time from drug delivery to rescue analgesia for pain at surgical site. It lasts about one hour more than duration of sensory block and it was highly significant. (P<0.001)

Table 5: Duration Of Analgesia

Parameter	Groups						Remarks
Duration of analgesia (minutes)	Group I [GrP]		Group II [GpCI]		Group III [GpDx]		P<0.001 highly significant
	Mean	SD	Mean	SD	Mean	SD	
	593.64	34.17	720.00	27.47	1097.27	53.58	

DISCUSSION

This study was carried out to compare the effect adjuvants clonidine and dexamethasone admixed with local anaesthetic ropivacaine in respect of duration of analgesia and other block parameters.

Eight out of one hundred five patients were not evaluated due to failed block. Lack of ultrasound guidance can be attributed to this large number of procedural failure.

In this study of patients studied were comparable in respect of demographic characteristics age, sex,weight and ASA status. These parameters were matched among the groups to avoid any change that affects intraoperative and postoperative outcome of the patients.

This study demonstrates that both dexamethasone and clonidine significantly prolongs the analgesic effects of plain ropivacaine used as a single-injection supraclavicular brachial plexus block, and that this effect differs between the two local anesthetic groups. This finding is consistent with previous studies, but direct comparisons are difficult because of the different techniques of block, variety of local anesthetic mixtures used, different blocks studied, and different methods of evaluating block duration.

The time of onset and haemodynamic parameters were comparable among the groups.

ONSET OF SENSORY AND MOTOR BLOCKADE

In our study both the onset of sensory and motor block was comparable among the groups. Mean time of onset of sensory block for group I, group II and group III was 5.24±1.09, 5.22±1.13 and 4.91±1.28 respectively. Mean onset time for dexamethasone group was lower than clonidine and saline group but this was statistically insignificant. Mean time of onset of motor block was 10.33±1.67, 9.94±1.48 and 9.48±1.42 for group I, group II and group III respectively. Bonferroni multiple comparisons showed that there was no significant difference in between the two groups for onset time of sensory and motor blockade.

DURATION OF SENSORY AND MOTOR BLOCKADE AND DURATION OF ANALGESIA

In our study, the mean duration of motor block in dexamethasone group was near double and in clonidine group was prolonged for about hundred minutes in respect of plain ropivacaine group. This was statistically highly significant (p<.001). the mean duration of motor block was 443.64±25.72, 541.88±22.78 and 910.91±44.89 for group I, group II and group III respectively. The mean duration of sensory block was 539.09±28.54, 665.63±30.89 and 1031.82±45.58 for group I, group II and group III respectively. The P value was <0.001, indicating that the difference was highly significant. Duration of analgesia was defined as time from drug delivery to rescue analgesia for pain at surgical site. It did last about one hour more than duration of sensory block and it was also highly significant (P<0.001). Post hoc Bonferroni test for inter group comparision showed that statistically highly significant difference exists in between groups in terms of duration of motor and sensory block and duration of analgesia.

HAEMODYNAMIC PARAMETERS AND SIDE EFFECTS

Bradycardia was observed in one patient in clonidine group that was treated with injection atropine. No other side effects were seen.

There was no significant difference in heart rate and MAP among the groups at baseline, 10 min, 20 min, 30 min, 40 min, 50 min, 60 min and 70. Data shows significant difference in heart rate at 80 min. only few surgeries in each group were of more than 80 and more than eighty min of duration and due to this significant difference is an inadequate interpretation.

CONCLUSION

Based on the findings of our study, we can arrive at the conclusion that both clonidine and dexamethasone as an adjuvant to ropivacaine in supraclavicular brachial plexus block prolong the duration of sensory and motor blockade. They also prolong duration of analgesia significantly. In comparison to clonidine, dexamethasone increases duration of sensory and motor blockade and duration of analgesia significantly.

Clonidine and dexamethasone both do not affect the onset time of sensory and motor blockade as compared to ropivacaine alone.

Haemodynamic parameters, heart rate and mean arterial pressure are not affected by clonidine or dexamethasone when injected perineurally in supraclavicular brachial plexus block.

Hence, we conclude that dexamethasone as an adjuvant is a good choice to prolong the duration of postoperative analgesia without any serious adverse effect. However, prolonged motor block is a matter of concern and the search for an adjuvant that selectively prolongs analgesia without impairing motor function continues.

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