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TO COMPARE THE EFFECTS OF ROPIVACAINE(1.8mg/kg) WITH FENTANYL (50µg) AND ROPIVACAINE (1.8mg/kg) WITH CLONIDINE (75µg) FOR INTRAVENOUS REGIONAL ANAESTHESIA (IVRA) FOR UPPER LIMB AND LOWER LIMB SURGERIES

Anaesthesiology

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ABSTRACT

Introduction: Intravenous Regional Anaesthesia (IVRA) is indicatedfor short surgical procedures of upper extremity(below elbow) and of lower extremity (below knee). The aim of this randomised double-blind controlled study was to investigate the effects of adding Injection Clonidine as adjuvant to Injection Ropivacaine and Injection Fentanyl as adjuvant to injection Ropivacaine for IVRA in patients undergoing upper limb (below elbow) and lower limb (below knee) surgeries. **Material and methods:**Sixty adult ASA I and II patients of either sex in the age range of 20 to 60 years were randomly divided equally into 2 groups of 30 each. Group A received Injection Ropivacaine(0.75%) 1.8 mg/kgwith Injection Clonidine75µg/kg and Group B received Injection Ropivacaine (0.75%) 1.8 mg/kg with Injection Fentanyl 50 µg/kg. **Results:** Sensory onset showed high statistically significant difference with Group A having earlier onset at 28.50 19.96 seconds as compared to Group B at 238 111.95 seconds (P<0.0001). Comparison of peak sensory showed high significant statistical difference with Group A having earlier onset at 194 223.21 seconds as compared to Group B at 720 217.19 seconds (P<0.0001). The sensory wearoff between both the groups were highly significant statistically showing Group A at 1150 ± 486.19 seconds as compared with Group B 184 ± 112.45 seconds (P<0.0001). The Visual Analogue Score in post operative ward just after completion of surgery show Group B having higher VAS score as compared with Group A.The time for rescue analgesia was prolonged in Group A as compared with Group B. **Conclusion:** Adding Clonidine to Ropivacaine improved the quality of anaesthesia and post-operative analgesia in Intravenous Regional Anaesthesia as compared to when Fentanyl was added to Ropivacaine.

KEYWORDS

Clonidine, Fentanyl Citrate, Intravenous Regional Anaesthesia (IVRA), Ropivacaine.

INTRODUCTION

Intravenous Regional Anaesthesia (IVRA) discovered by Bier is an easy and uncomplicated technique of producing both surgical and postoperative analgesia of the upper and lower extremities by applying local anaesthetics intravenously, while the circulation is occluded.[1]

Bier's block is mainly used for surgical procedures of short duration of approximately one to one and a half hours or less. Operative procedures or surgeries involving the upper extremities (below the elbow) and lower extremity (below the knee) are the only indications for IVRA.[2,3] In comparison to general anaesthesia, IVRA is a safer option, especially if the patient is elderly, has cardiovascular or respiratory disease and where we would like to avoid problems related to general anaesthesia.

Emergency surgeries for patients with accidents or trauma involving the extremities IVRA is ideal as the patients fasting profile may not be adequate.

IVRA is a Simple technique with very high success rates (>98%) ,Fast onset of action (5-10minutes) ,Good muscle relaxation and Fast return of sensation.[4]

Disadvantages of IVRA are limited operation time of 1-1½ hours and procedures above elbow or knee are not possible. Tourniquet pain during the procedure and Nerve damage due to the tourniquet cuff are other disadvantages.[4]

Contraindications to IVRA are Severe Raynaud's disease, Sickle cell ,Crush injury of the limb.[5]

IVRA is generally a safe technique,the most important complications to recognize is a leaking or accidentally deflated tourniquet cuff. This will result in a large volume of local anaesthetic being rapidly introduced into the circulation. The patient ,may develop dizziness, nausea, vomiting, tinnitus, perioral tingling, muscle twitching, loss of consciousness and convulsions. Avoidable death have occurred.[5]

The correct choice of local anaesthetic drug might be important to prevent severe systemic complications. Newer local anaesthetic agents such as ropivacaine, which is a pure S(-) enantiomer of propivacaine is associated with lower incidence of motor block than bupivacaine as well as reduced potential for CNS toxixity and cardiotoxicity.

AIMS AND OBJECTIVES

To study & compare the efficacy of Ropivacaine 0.75 % (1.8mg/kg) plus Fentanyl (50µg) and Ropivacaine 0.75 % (1.8mg/kg) plus Clonidine(75µg) for intravenous regional anaesthesia for upper limb and lower limb surgeries.

To observe any side effects of intravenous regional administration of local anaesthetic solution like Ropivacaine and adjuvants like Fentanyl and Clonidine.

MATERIAL AND METHODS

Sixty adult patients of either sex in the age group between 20 – 60 yrs in American society of anaesthesiologists (ASA) physical status I &II ,undergoing elective surgeries and emergency surgeries of moderate duration (< 2 hours) of upper extremity (below the elbow) and lower extremity (below the knee) were included in this Prospective, Double Blind ,Randomized controlled study after obtaining the institutional ethics committee approval prior to commencement of study.

Patients not willing for intravenous regional anaesthesia or Patients having previous history of allergy with either ropivacaine or fentanyl or clonidine.were excluded from the study.

Patients suffering from Raynaud's Disease, sickle cell anaemia or scleroderma which are contraindicated to IVRA were also excluded from the study.

Method of randomization - After obtaining informed and written consent all the patients were randomised via double blind method into two groups and were given drug according to statistical table of random number.

- Group A – Injection Ropivacaine 0.75 % (1.8mg/kg) plus Clonidine (75µg) was given for IVRA.

- Group B – Injection Ropivacaine 0.75 % (1.8mg/kg) plus Fentanyl (50µg) was given for IVRA.
- The total volume of the drug injected, keeping in mind the dose of the local anaesthetic drug, dose of fentanyl or clonidine and the diluting agent was kept 40 ml for the upper limb and 50 ml for the lower limb.

Prodecure
- An intravenous line was put up in the nonoperative arm and I/V fluid was started.
- An Intravenous cannula was placed into the operative extremity as distally as possible, with care taken to place it away from the site where surgical incision is to be made.
- Adequate padding with cotton pads was applied over the site where tourniquet was to be placed.
- Two tourniquets were applied over the proximal part of the operating limb, either above the knee or above the elbow, with a 1 cm distance between each tourniquet.
- Tourniquets werepreinflated and checked for leaks before beginning the procedure. The tourniquet pressure was kept adequate to ensure limb ischaemia.
- The limb was elevated for 3-5mins to allow venous drainage,and then an Esmarch bandage was applied as distally as possible and wrapped tightly upto the level of the tourniquet.
- The proximal tourniquet was then inflated 100 to 150 mm of Hg above the patient's systolic blood pressure, to act as an extension of the Esmarch bandage.
- Once the tourniquet was inflated, the Esmarch bandage was removed and the limb was checked for ischemic changes (like pale, white) before the injection of the local anaesthetic.
- After confirmation, the local anaesthetic solution was slowly injected over two minutes.
- Time was given till the onset of the sensory block.
- After the sensory block was achievedupto the lower border of the proximal tourniquet, distal tourniquet was inflated upto 100-150 mm of Hg above the patient's systolic blood pressure.
- Proximal tourniquet was then deflated and the intravenous cannula over the operating hand was removed and the puncture site of the cannula held tightly with a dry piece of cotton for 5 minutes or till the bleeding has stopped.
- After the end of the surgery, the tourniquet was deflated slowly. But the tourniquet had to be kept inflated for a minimum period of 45 minutes even if the surgery ended earlier.

Parameterslike Pulse Rate ,Systolic and Diastolic Blood Pressure & Oxygen Saturation were monitored intraoperatively –

The following parameters were noted down intraoperatively –
Sensory block was assessed by pin prick with 22 gauge short bevelled needle in an interval of 30 seconds.

Motor block was assessed by asking the patient to squeeze the finger of the assessor.

After the sensory and motor block was achieved, the operative tourniquet (distal cuff) was inflated to 100-150 mm of Hg above the systolic blood pressure while the proximal tourniquet was released and surgery was started. Parameters were monitored every 5 minutes by anaesthesiologist who did not know which drug was administered.

At the end of the surgery or after a minimum period of 45 minutes of cuff inflation, the cuff was deflated by the cyclic deflation technique.

Following Postoperative Parameters were noted –
Noninvasive Blood Pressure, Pulse Rate&Oxygen Saturation

Sensory Block Recovery was seen at 2, 5, 10 and 20 minutes postoperatively by pin prick with 22G needle.

Motor Block Recovery was seen at 2, 5, 10 and 20 minutes postoperatively by checking the grip strength of the patient by telling him to squeeze the finger of the assessor.

Visual Analogue Scale (VAS) was used to assess postoperative pain. It employs a 10 cm drawn line with left anchor point descriptor labelled "no pain" and right sided equivalent labelled "worst possible pain". It requires the patients to mark the severity of current pain on continuum. The VAS score is the measured distance from "no pain" to the pain estimate.

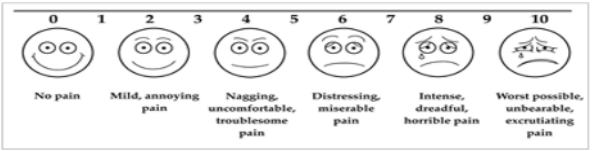


Figure 1 : Showing the Visual Analogue Scale

Where,
- 0 – No Pain
- 0 to 3 – Mild Pain
- 4 to 7 – Moderate Pain
- 8 to 9 – Severe Pain
- 10 – Maximum Pain

First rescue analgesic was given to patients with injection diclofenac sodium (75mg) I/M when VAS was more than 7.

READINGS

Following observations were made –
- T_0 – Time of injection of local anaesthetic
- T_1 – Time of onset of sensory block (the time interval between the intravenous regional anaesthesia injection and beginning of loss of pinprick sensation)
- T_2 – Time of onset of motor block (the time interval between the intravenous regional anaesthesia injection to the to the patients inability to squeeze the finger of the assessor tightly)
- T_3 – Time of peak sensory block (the time interval between the Intravenous Regional anaesthesia injection and complete loss of pinprick sensation)
- T_4 – Time of peak motor block (the time interval between the Intravenous Regional anaesthesia injection to the patient's complete inability to squeeze the finger of the assessor)
- T_5 – Time of duration of surgery
- T_6 – Time of sensory wear off (the time interval between the deflation of the tourniquet and regaining of pinprick sensation)
- T_7 – Time of motor wear off (time interval between the deflation of the tourniquet to the patient's ability to squeeze the finger of the assessor)
- T_8 – Time to rescue analgesia

Statistical analysis
At the end of study, results of both the groups were tabulated and subjected to statistical analysis by using "Microsoft office Excel" software and SPSS version 17.0 and the final interpretation was based on "Z" test (Standard Normal Variant) with 95% level of significance. P value less than 0.05 was considered as significant and P value less than 0.001 as highly significant.

OBSERVATION AND RESULT

This study was done to study & compare the efficacy of Ropivacaine(1.8mg/kg) plus Fentanyl (50µg) and Ropivacaine (1.8mg/kg) plus Clonidine(75µg) for intravenous regional anaesthesia for upper limb and lower limb surgeries and to observe any side effects of intravenous regional administration of local anaesthetic solution like Ropivacaine and adjuvants like Fentanyl and Clonidine.

Both the groups were comparable with respect to their demographic profiles like age ,sex, weight and ASA physical status with P value > 0.05, statistically not significant.

Comparison of sensory onset using "Z Test" in both the groups shows high statistically significant difference with Group A Ropivacaine + Clonidine having an earlier onset at 28.5 ± 19.96 seconds as compared to Group B Ropivacaine + Fentanyl at 238 ± 11.95 seconds.

Table - 1

Onset	Group A Mean ± SD (n=30)	Group B Mean ± SD (n=30)	Z Value	P Value
Sensory Onset (T1)	28.50 ± 19.96	238 ± 111.95	10.09	0.00001

Comparison of motor onset showed nostastistically significant difference between groups.

Comparison of peak sensory block using "Z Test" in both the groups show high statistically significant difference with Group A Ropivacaine + Clonidine having earlier peak sensory at 194 ± 223.21

seconds as compared to Group B Ropivacaine + Fentanyl at 720 ± 217.19 seconds.

Table - 2

Peak	Group A Mean ± SD (n=30)	Group B Mean ± SD (n=30)	Z Value	P Value
Sensory Peak (T3)	194 ± 223.21	720 ± 217.19	9.25	0.00001

Comparison of peak motor showed no statistically significant difference between the groups.

Comparison of Sensory wear off was done in both the groups using "Z Test" show high statistically significant difference with Group B Ropivacaine + Fentanyl having earlier sensory wear off at 184 ± 112.45 seconds after deflation of tourniquet as compared to Group A Ropivacaine + Clonidine with sensory wear off at 1150 ± 486.19 seconds after deflation of tourniquet.

Table - 3

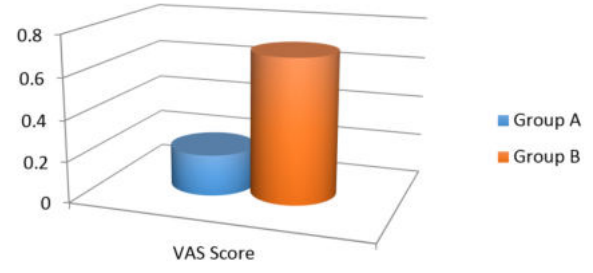
Wear off	Group A Mean ± SD (n=30)	Group B Mean ± SD (n=30)	Z Value	P Value
Sensory (T6)	1150 ± 486.19	184 ± 112.45	10.60	0.00001

Comparison of Motor wear off showed no statistically significant difference between groups.

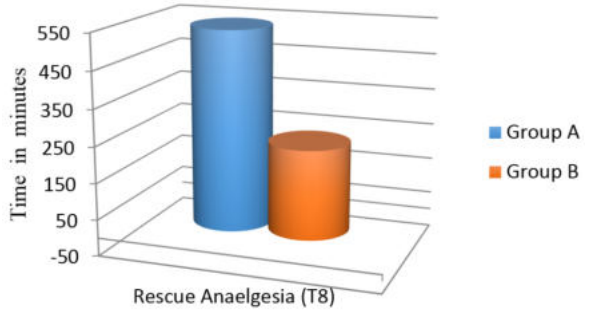
Comparison of Visual Analogue Score (in postoperative ward just after completion of surgery) showed high statistically significant difference with Group B Ropivacaine + Fentanyl having higher VAS score.

Table - 4

Parameter	Group A Mean ± SD (n=30)	Group B Mean ± SD (n=30)	Z Value	P Value
VAS Score	0.20 ± 0.41	0.70 ± 0.75	3.21	0.003



Comparison of Rescue Analgesia showed high statistically significant difference with Group A having higher rescue analgesia timeof 547.67 ± 121.73 minutes after surgery as compared to Group B with rescue analgesia time of 244 ± 70.11 minutes after surgery.



Comparison of SpO_2showed statistically significant difference at 20 minutes after IVRA ,which was not clinically significant. There was no statistically significant difference preoperatively, 5, 10 minsand on arrival to post operative ward.

Comparison of Pulse Rate, Systolic Blood Pressure and Diastolic Blood Pressureshowed no statistically significant difference .

DISCUSSION

Intravenous regional anaesthesia (IVRA) also known as Bier's block enjoys continuous popularity because of its simplicity, reliability and safety for a variety of peripheral procedures.

IVRA is mainly used for surgical procedures of short duration of approximately one to one and a half hours or less. Operative procedures or surgeries involving the upper extremities (below the elbow) and lower extremity (below the knee) are the only indications for IVRA.[1,2]

In our study conducted on 60 patients divided into two groups of 30 patients each for Ropivacaine with Fentanyl and Ropivacaine with Clonidine there were no statistically significant differences in patient's demographic profile. The duration of surgery in both the groups was also not statistically significant.

In our study we found that the sensory onset in both the groups show high statistically significant difference with Group A(Ropivacaine with Clonidine) having earlier onset as compared to Group B(Ropivacainewith Fentanyl).

Though many studies have been done with clonidine as adjuvant to local anaesthetics for regional anaesthesia, not much literature is available for its use in IVRA .

Several studies done by different authors like Kulkarni et al[6] in 2012 &Bajwa et al[7] in 2013 usingRopivacaine with clonidine as adjuvant in epidural anaesthesia and brachial plexus block respectivelyshowed that clonidine makes the onset of ropivacaine faster, which was similar to our study.

It can be concluded that in our study, sensory onset in Group A was earlier than compared to Group B. The difference was highly statistically significant. Though the motor onset of both the groups were not significant statistically.

In our study peak sensory block in Group A was earlier as compared to Group B with a high statistical significance. However the peak motor block in both the groups were comparable and was not statistically significant.

Our observations were found to be in accordance with the following previous studiesconducted by Kulkarni et al in 2012using clonidine(75µg) with bupivacaine in orthopaedic patients scheduled for upper extremity procedures under brachial plexus block.[6]

Bajwa et al in 2013usedropivacaine with clonidine in epidural for elective caesarean section and had similar observations.[7]

In our study we found that Sensory wear off in both the groups show high statistically significant difference with Group B having earlier Sensory wear off after deflation of tourniquet as compared to Group A . The above observations were found to be in accordance with previous studies conducted by Saied A et al [8] in 2000and Öztin C et al[9] in 2006using Ropivacaine with Clonidine .

However the motor wear off in both the groups were comparable and was not statistically significant.

In our study the VAS score was lower and the Rescue Analgesia time was longer in Group A when compared with Group B. Rescue Analgesia was given to the patients when VAS was more than 7.

Ropivacaine with Clonidine provided a higher degree of postoperative analgesia and reduced dose of rescue analgesia as compared to Ropivacaine with Fentanyl.

Haemodynamic parameters remained stable in both the groups and was within physiological limits at all time intervals.

In present study, we monitored for the following side effects like Nausea, Vomiting, Excessive sedation, Shivering, Bradycardia, Hypotension, Seizures, Respiratory depression.

We did not observe any of the side effects in both the groups.

Limitations of IVRA

1. There is a practical time limit on its use (1-1½ hours) due to the tourniquet restricting blood flows to the extremity.
2. In case of extended crush injury to the limb, application of Esmarch bandage is not possible.
3. Caution should be employed in the patients who have sustained

crush injuries of the relevant limb as potentially viable tissue will be subjected to a further period of hypoxia which may provoke further tissue damage secondary to hypoxia.

CONCLUSION

As per our study we conclude that addition of Clonidine to Ropivacaine for upper and lower limb surgeries under IVRA improved the surgical anaesthesia as well as the postoperative analgesia.

It also decreased the requirement and dose of rescue analgesia for the patients postoperatively.

There were no side effects in both the groups.

REFERENCES

1. Wildsmith J A W. Intravenous regional analgesia: Essential safeguards.Anaesthesia 1982;37:959.
2. Rodola F, Vagnoni S, Ingletti S, et al. An update on intravenous regional anaesthesia of the arm. EurRevMedPharmacolSci2003; 7: 131-38.
3. Metwalli R A, Mowafi A. A modification of the inter-cuff technique of IVRA for use in knee arthroscopy. Can J Anesth 2002; 49: 687–689.
4. Jankovic D. Intravenous Regional Anaesthesia. In : Regional Nerve Blocks and Infiltration Therapy Textbook and Color Atlas. 3rd ed. Blackwell Publishing 2004. p. 162
5. Clark N, Devon R. Intravenous Regional Anaesthesia – Bier's Block. Update in Anaesthesia 2002;15
6. Kulkarni A, Tarkase A S, Chaudhari S A. Effects of addition of clonidine to bupivacaine in brachial plexus block. Pravara Med Rev 2012;4(4):15-9.
7. Bajwa S, Bajwa S,Kaur J. Comparison of epidural ropivacaine and ropivacaine clonidine combination for elective cesarean sections. Saudi J Anaesth 2010;4(2):47-54.
8. Saied A, Steyn M P, Ansermino J M. Clonidine prolongs the effect of ropivacaine for axillary brachial plexus blockade. Can J Anaesth 2000;47(10):962–67.
9. Öztin C, Kirgiz E, Duman A, *et al*. The Comparison Of Intrathecal Isobaric Ropivacaine And Isobaric Ropivacaine-Clonidine For Caesarean Delivery. The Internet Journal of Anesthesiology 2006;15(1).