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POSTOPERATIVE ANALGESIA WITH EPIDURALROPIVACAINEIN COMBINATION WITH 30 MICROGRAM AND 60 MICROGRAM CLONIDINE FOR LOWER LIMB ORTHOPAEDIC SURGERY: A COMPARATIVE,RANDOMISED DOUBLE BLIND STUDY



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ABSTRACT

Background And Aim: Clonidine is an adjuvant to ropivacaine for local anaesthesia. We aimed to investigate the effect of different doses of epidural clonidine in combination with a fixed dose of ropivacaine on post-op analgesia in lower limb orthopaedic surgeries: **Setting and Design:** Randomised double blind case control study among 48 healthy subjects aged 20 to 65 yrs undergoing elective orthopaedic surgery of lower limb. **Material and Method:** Intrathecal isobaric ropivacaine 18 mg (2.4 ml) was combined with 30 µg clonidine (Group A), and with 60 µg of clonidine (group B). All

solutions were diluted with saline to 2.6 ml. We compared post op analgesia between these groups using first demand of rescue analgesia and total analgesic (diclofenac) consumption in first 24 hours of post-operative period.

Conclusion: As compared to that of 30 µg clonidine, addition of 60 µg clonidine to ropivacaine by intrathecal route produced a significant



delay in time to first demand of analgesia, and a reduction in the total analgesic consumption, in post operative period.

KEYWORDS: microgram clonidine, Setting and Design, cardiotoxic and neurotoxic.

INTRODUCTION:

Bupivacaine has been extensively used in local anesthesia for lower limb surgeries. But lately,

Ropivacaine is gaining preference because of the latter's lesser cardiotoxic and neurotoxic adverse effects (1,2). Unfortunately, Ropivacaine has slightly lesser anaesthetic potency (3). Addition of adjuvants like clonidine or opioids increase the potency. This leads to reduced total anaesthetic dose as well as better post operative pain control (4,5,6). In this study, we tried to look into the post operative analgesic effect of two different doses of clonidine (30 µg, 60 µg) with Ropivacaine via spinal route. This is useful in as the trend of day care surgery and better patient experience is on a rise.

MATERIALS AND METHODS:

First, an approval was taken from the institution's ethics committee. Following this, written informed consent was taken from the patients and their attendants. 48 patients of American Society of Anaesthesiologists ASA grade 1 and 2 of either sex, aged between 18 and 60 years, height between 160 and 170 cm and BMI between 18.5 and 25 were selected. Patients with conditions like emergency surgery, poly-trauma, altered consciousness, allergy to the drugs being used were excluded from the study. Patients were randomly allocated in two groups of 24 each by using computer generated randomization table.

Group A received 18 mg (2.4 ml) of 0.75% isobaric ropivacaine with 30 µg (0.2 ml) of clonidine. Group B received 18 mg (2.4 ml) of 0.75% isobaric ropivacaine with 60 µg (0.2 ml) of clonidine. All patients had pre-anaesthetic check-up. Patients received standard orthopaedic splintage as per hospital protocols. Standard pre-op guidelines were followed. Tablet alprazolam 0.25 mg was given to all patients as a part of pre-op medication. The intra-op monitoring included electrocardiography, non-invasive blood pressure monitoring, and pulse-oxymetry. Baseline values were recorded. IV access was established with 18G cannula, and patients were pre-loaded with 15 ml/kg ringer lactate solution. Under sterile conditions, subarachnoid space of L4-L5 or L3-L4 inter-vertebral discs was accessed with 25G spinal needle, with patient in sitting posture by the on-duty anaesthesiologist. Drug syringes were prepared by another independent anaesthesiologist. Both the anaesthesiologists as well as the orthopaedic surgeons were blind to the drugs. After anaesthesia, patients were immediately shifted to supine position. Mean arterial pressure and heart rate were recorded at 3 minute interval for the first 30 minutes, and at 5 minutes interval for the next 30 minutes and then at 10 minutes interval for the rest of the surgery. Postoperatively, vitals were recorded for up to 3 hours after giving spinal. Any episode of significant bradycardia or hypotension was treated by IV bolus of atropine (600 µg) or phenylephrine (50-100 µg). Sensory block was assessed by pinprick along the mid-clavicular line, while motor block by Modified Bromage Scale. Surgery was allowed according to the standard hospital protocols.

Incidences of nausea, vomiting, headache, pruritus, shivering, respiratory depression and urinary retention requiring post-operative urinary catheterization were recorded. Post-op sedation scores were recorded at 3 hours and 6 hours after time zero. Patients were given rescue analgesia on demand only with initial dose of 75 mg of intramuscular diclofenac. This was followed by additional doses if pain wasn't adequately controlled. Time of the first demand, as well as the total analgesic consumption in first 24 hours of post-op period were recorded. Maximum allowed dose was 225 mg of diclofenac per 24 hours. Software SPSS version 16 was used for statistical calculations.

RESULTS:

Demographic profile and duration of surgery of both the groups were comparable. No patient had to be dropped out from the study due to any unexpected event.

| Characteristics | Group A (n=24) (mean + SD) | Group B (n=24) (mean + SD) | Test | dF | P value |
|------------------------------|----------------------------------|----------------------------------|--------------------|----|---------|
| Age (years) | 45.83(+/- 12.45) | 46.33(+/- 12.24) | Unpaired t test | 46 | .8890 |
| Height (cm) | 165.08 (+/- 2.99) | 164.96 (+/- 2.97) | Unpaired t test | 46 | .8851 |
| BMI | 21.175 (+/- 2.077) | 21.238 (+/- 2.099) | Unpaired t test | 46 | 0.9161 |
| Duration of Surgery (min) | 91.58 (+/- 24.010) | 90.17 (+/- 19.11) | Unpaired t test | 46 | 0.8221 |
| Male:Female Ratio | 14:10 | 13:11 | | | |
| ASA Score 1:2 | 13:11 | 12:12 | | | |

Table 1: Demographic profile, and duration of surgery.

| | Group A | Group B | Test used | t value | P value |
|--|-------------|-------------|--------------------|----------------|---------|
| Time to first demand of analgesic (min) | 390 (+/-75) | 531 (+/-92) | Unpaired t test | 5.81 (df =46) | <0.001 |
| Total Diclofenac consumed in first 24 hours (mg) | 101 (+/-32) | 74 (+/-25) | Unpaired t test | 3.2573 (df=46) | 0.0021 |

Table 2: Time of first analgesic demand, and total analgesic (diclofenac) consumption.

| Adverse Effect | Group A | Group B | Pvalue |
|----------------|---------|---------|--|
| PONV | 3 | 4 | 0.879 (df=2;X ² = 0.26) |
| Pruritis | 1 | 2 | |
| Shivering | 4 | 4 | |

Table 3: Adverse effects**DISCUSSION:**

Ropivacaine is a potent, long acting local anaesthetic. Its cardiotoxicity and neurotoxicity is fairly less in comparison to its congener bupivacaine (1,2). Clonidine is an α_2 adrenergic agonist and imidazoline receptor agonist. Apart from therapeutic uses in various disorders of neurology and psychiatry, clonidine has been studied as an adjuvant to many local anaesthetics like procaine, bupivacaine, ropivacaine etc. As an adjuvant, it enhances analgesia, motor block, and post-op pain control. However, it also causes certain side effects like hypotension, bradycardia, pruritis etc. (4,5,6,7,8).

In our study, we compared the effects of two different doses of clonidine (30 vs 60 micrograms) as an adjuvant to 18 mg ropivacaine by subarachnoid route on post-op pain control. Adults undergoing elective orthopaedic surgery of lower limb were the subjects. The "first sensation of pain" at incision site can be regarded as the end of anaesthesia which is mainly due to wearing off of local anaesthetic

effect. Delayed "request for further analgesic" seems to be due to wearing off effect of clonidine; and thus, can help us in judging the duration of post operative analgesia (9). We used first demand of rescue analgesia as end-point for analgesia. A second parameter for post-op pain control was total analgesic (diclofenac) consumption in the first 24 hours of post-operative period.

We found out that the demand of post-op analgesia was after 390 minutes in group A, and 531 minutes in group B (Table 2). The delay in demand between these two groups was statistically significant. Above findings are in line with our previous study (10), where we had seen that first demand analgesia was after 233 minutes with ropivacaine (same dose and route) alone, and after 405 minutes with ropivacaine (same dose and route) plus 30 µg clonidine.

Total consumption of analgesics for the first 24 post-op hours was 101 mg in group A, and 74 mg in group B (Table 2). The decrease in consumption in group B is statistically significant. These findings are in line with our previous study (10), where we had seen that the total analgesic consumption was 133 mg with ropivacaine (same dose and route) alone, and 106 mg with ropivacaine (same dose and route) plus 30 µg clonidine.

When used as an adjuvant to intrathecal ropivacaine, post-op pain control was found significantly better with 60 µg clonidine, as compared to 30 µg clonidine. Our results are consistent with that of Bajwa et al (11), Koulet et al (12), and Forster et al (13), although these studies were performed with caudal epidural route.

There was no significant difference in adverse effect profile (table 3) of both the groups in post operative nausea and vomiting, respiratory depression, pruritis, shivering. Our results corroborate with the findings of Ghodki et al (14).

CONCLUSION:

Post op analgesia with intrathecal isobaric ropivacaine is significantly better and equally safe when used with 60 µg clonidine as compared to 30 µg clonidine.

Keywords: ropivacaine, clonidine, analgesia, adjuvant, epidural.

BIBLIOGRAPHY:

- 1). Kuthiala, Gaurav, and Geeta Chaudhary. "Ropivacaine: A review of its pharmacology and clinical use." *Indian journal of anaesthesia* 55.2 (2011): 104.
- 2). Takenami, Tamie, et al. "Intrathecaly administered ropivacaine is less neurotoxic than procaine, bupivacaine, and levobupivacaine in a rat spinal model." *Canadian Journal of Anesthesia/Journal canadien d'anesthésie* 59.5 (2012): 456-465.
- 3). Kulkarni, Kalpana R., et al. "A comparative evaluation of hyperbaric ropivacaine versus hyperbaric bupivacaine for elective surgery under spinal anesthesia." *Journal of anaesthesiology, clinical pharmacology* 30.2 (2014): 238.
- 4). Kakunje, Ravishankar et al. "Effects of Adding Low-Dose Clonidine to Intrathecal Hyperbaric Ropivacaine: A Randomized Double-Blind Clinical Trial." *Anesthesia, Essays and Researches* 10.1 (2016): 38-44. PMC. Web. 20 Sept. 2016.
- 5). Shelgaonkar, Vaishali C., et al. "Clinical evaluation of intrathecal 0.5% isobaric levobupivacaine with and without fentanyl or clonidine in elective lower abdominal and orthopaedic surgeries." (2015).
- 6). Aveline, Christophe, et al. "The effect of clonidine on the minimum local analgesic concentration of epidural ropivacaine during labor." *Anesthesia & Analgesia* 95.3 (2002): 735-740.
- 7). Dobrydnjov, Igor, et al. "Postoperative pain relief following intrathecal bupivacaine combined with intrathecal or oral clonidine." *Acta anaesthesiologica scandinavica* 46.7 (2002): 806-814.

- 8). Pöpping, Daniel M., et al. "Clonidine as an Adjuvant to Local Anesthetics for Peripheral Nerve and Plexus BlocksA Meta-analysis of Randomized Trials." *The Journal of the American Society of Anesthesiologists* 111.2 (2009): 406-415.
- 9.) Klimscha, W., et al. "Hemodynamic and analgesic effects of clonidine added repetitively to continuous epidural and spinal blocks." *Anesthesia & Analgesia* 80.2 (1995): 322-327.
- 10). Srivastava, Swati, et al. "A COMPARATIVE CLINICAL STUDY OF INTRATHECAL ROPIVACAINE AND ROPIVACAINE-CLONIDINE COMBINATION FOR LOWER LIMB ORTHOPAEDIC SURGERIES." *International Journal of Pharmaceutical Sciences and Research* 7.3 (2016): 1292
- 11). Bajwa, SukhminderJit Singh, et al. "Caudal ropivacaine-clonidine: A better post-operative analgesic approach." *Indian journal of anaesthesia* 54.3 (2010): 226.
- 12). Koul, Archana, Deepanjali Pant, and JayshreeSood. "Caudal clonidine in day-care paediatric surgery." *Indian journal of anaesthesia* 53.4 (2009): 450.
- 13). Förster, J. G., and Per H. Rosenberg. "Small dose of clonidine mixed with low-dose ropivacaine and fentanyl for epidural analgesia after total knee arthroplasty." *British journal of anaesthesia* 93.5 (2004): 670-677.
- 14). Ghodki, Poonam S., Shalini P. Sardesai, and Shalini K. Thombre. "Evaluation of the effect of intrathecal clonidine to decrease shoulder tip pain in laparoscopy under spinal anaesthesia." *Indian journal of anaesthesia* 54.3 (2010): 231.

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