COMPARISON OF POST OPERATIVE ANALGESIA FOLLOWING EPIDURAL BUPIVACAINE WITH CLONIDINE AND EPIDURAL BUPIVACAINE IN ORTHOPAEDIC LOWER LIMB SURGERIES

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ABSTRACT :

Background Clonidine an alpha – 2 agonist drug, which was introduced into clinical practice as an anti-hypertensive medication, can be used as an additive to local anaesthetics in nerve blockade and central neuraxial blockade. This study was designed to evaluate the analgesic efficacy of bupivacaine and clonidine mixture given through lumbar epidural route in patients undergoing elective orthopaedic lower limb surgeries ,comparing the quality of analgesia with epidural plain bupivacaine and also to calculate the number of post-operative aanalgesic doses required.

Methods: The study population consist of ASA I & ASA II patients in the age group of 18 years to 65 years admitted to undergo elective orthopaedic lower limb surgeries at mookambika the period of January 2022 to June 2024. Inclusion criteria:Age Group 18 – 65 years,ASA I and ASA II,Elective orthopaedic lower limb surgeries,Duration of Surgery between 2:00 to 2:30 hours.Exclusion criteria:are Patient refusal,Age < 18 years and age > 65yearsPatient posted for emergency surgery,Ischemic heart disease/ rheumatic heart disease**.**

Results: In this study, we found that bupivacaine and clonidine administered epidurally, reduced the amount of analgesic that patients required postoperatively suggesting that clonidine may enhance the analgesic effect of bupivacaine. This study correlates with the meta-analysis done by Armand et al (2) which concluded that epidural clonidine clearly produced an analgesic effect and reduced the need for other analgesics.In this randomized control study, we have evaluated the analgesic efficacy of bupivacaine with clonidine mixture given through lumbar epidural route in patient undergoing elective orthopaedic lower limb surgeries.

Conclusion: Single dose administration of clonidine and bupivacaine mixture given through lumbar epidural route provides effective postoperative analgesia in patients undergoing elective orthopaedic lower limb surgeries, without any hemodynamic instability.

Keywords: Bupivacaine, Clonidine.

INTRODUCTION:

Recent advances in neurosciences have demonstrated that peripheral tissue injury may lead to long alterations in central processing with reduction in pain threshold, amplification of response to pain. Comparable alterations may also occur following surgical trauma, resulting in amplification and prolongation of postoperative pain.Postoperative pain treatment should be an integral component of the routine surgical and anaesthetic management not only for humanitarian reasons but also because it can help to reduce morbidity and complications as well as accelerate rehabilitation .Good perioperative analgesia is an important avenue to attenuate the surgical stress response
Post operative pain relief can be provided by pharmacological and non- pharmacological methods. Non pharmacological methods include hypnosis, cold or heat, relaxation therapy, splinting of wounds, Transcutaneous Electrical Nerve Stimulation and pre-operative explanation and education. The pharmacological methods include simple analgesics, Non- steroidal anti- inflammatory drugs, Opioids (oral, intramuscular, intravenous, Patient Controlled Analgesia, Epidural or intrathecal) and Local anaesthetic agents (wound infiltration, nerve blockade, epidural, intrathecal).

Epidural anaesthesia is a central neuraxial block technique with many applications. Epidural anaesthesia can be used as sole anaesthetic for procedures involving the lower limbs, pelvis, perineum and lower abdomen . The advantage of epidural over spinal anaesthesia is the ability to maintain continuous anaesthesia after placement of an epidural catheter, thus making it suitable for procedures of long duration. This feature also enables the use of this technique into the postoperative period for analgesia, using lower concentrations of local anaesthetic drugs or in combination with different agents.

Clonidine an alpha – 2 agonist drug, which was introduced into clinical practice as an anti-hypertensive medication, can be used as an additive to local anaesthetics in nerve blockade and central neuraxial blockade. Following local anaesthetics and opioids, clonidine is the most studied drug used for human neuraxial analgesia. Although the systemic administration of clonidine can provide analgesia, its primary site of antinociceptive action appears to be at the spinal level. Alpha - 2 receptors at the spinal cord level are thought to be responsible for the analgesic properties of α2-adrenergic agonists (10,11).
This study was designed to evaluate the analgesic efficacy of bupivacaine and clonidine mixture given through lumbar epidural route in patients undergoing elective orthopaedic lower limb surgeries ,comparing the quality of analgesia with epidural plain bupivacaine and also to calculate the number of post-operative aanalgesic doses required.

AIM AND OBJECTIVES OF THE STUDY:

- To evaluate the analgesic efficacy of bupivacaine and clonidine mixture given through lumbar epidural route for postoperative analgesia in patients undergoing elective orthopaedic lower limb surgeries, by calculating the number of doses of postoperative analgesics required.

- To compare the quality and duration of analgesia of epidural bupivacaine - clonidine mixture with epidural plain bupivacaine intra and post- operatively.

- To evaluate the hemodynamic response of epidural clonidine intra and post-operatively.

MATERIALS AND METHODS:

The study population consist of ASA I & ASA II patients in the age group of 18 years to 65 years admitted to undergo elective orthopaedic lower limb surgeries at mookambika the period of January 2022 to June 2024. After getting approval by the institutional ethical committee and after obtaining written informed consent from each patient ,the study was conducted.
Inclusion criteria:Age Group 18 – 65 years,ASA I and ASA II,Elective orthopaedic lower limb surgeries,Duration of Surgery between 2:00 to 2:30 hours.

Exclusion criteria:are Patient refusal,Age < 18 years and age > 65years
Patient posted for emergency surgery,Ischemic heart disease/ rheumatic heart disease,Sinus bradycardia / heart blocks / conduction defects,Preoperative hypotension,Local infection at lumbar area,Pre-existing neurological disorder,Coagulation defects and patient on anticoagulants.

Patients were allocated randomly into two equal groups (20 in each group).Group P (placebo) received 1 ml of normal saline with the first dose of epidural 0.5% bupivacaine. Group C (clonidine) received 50µg of clonidine diluted with normal saline to 1 ml epidurally along with the first dose of bupivacaine.

No premedication was given. On arrival in the operating room, baseline cardiorespiratory parameters viz., Heart Rate(HR), Systolic blood pressure(SBP), Diastolic blood pressure(DBP),Mean arterial pressure(MAP) and Respiratory rate(RR) were recorded.
A good intravenous access was established using 18G IV cannula.
Preloading was done with crystalloids (10 ml/kg).

With the patient in sitting posture, after informing the procedure to the patient & under strict aseptic precautions, epidural space was identified at L3-L4 interspace using 17G Tuohy needle by loss of resistance technique. 19G epidural catheter was threaded in a cephalad direction & 4 cm catheter length was kept inside the epidural space. A test dose of 3 cc of 1.5 % lignocaine with adrenaline (5 µg/ml) was given.After confirming negative result for test dose, epidural catheter was fixed and secured with tapes. A standard anaesthetic technique was followed in all patients.
Epidural 1st dose -14 ml of 0.5% bupivacaine + 1ml of placebo or 50 µg of injection clonidine diluted with normal saline to 1 ml.
Epidural 2nd dose -6ml of 0.5% bupivacaine (90 mins after 1st dose)

Patients with duration of surgery between 2-2:30 hours requiring standard two doses of epidural local anaesthetics were only taken up for study. Unanticipated prolonged duration of surgery (requiring more than 2 doses) were excluded from the study.

Statistical analysis was done using the statistical package for social sciences (SPSS).Different statistical

methods were used as appropriate. Mean ± SD was determined for quantitative data and frequency for categorical variables. The independent t- test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p- value < 0.05 was considered significant.

RESULT:

According to Chi- square test, RSS was significant at 30 min (P-0.003), 60 min (P<0.001) and 90 min (P<0.001). RSS was not significant at 120 min and 150 min
respectively.

The post-operative pain score(verbal rating scale) was found to be significantly low at 4, 12, 18 and 24 hours in Group C when compared to Group P. Significantly low pain scores were observed at 4, 12, 18 and 24 hours intervals in patients belonging to Group C(P < 0.001 at 4 ,12 and 24 hours intervals and P -0.004 at 18 hours interval) than Group P as shown in figure-11. The study demonstrated that pain relief was significantly better (P < 0.05) in patients who received epidural bupivacaine with clonidine than the patients who received epidural bupivacaine with placebo.

DISCUSSION:

Our knowledge of acute pain mechanisms has advanced sufficiently over the past decade so that rational rather than empirically derived therapy can be used by aiming specifically at interrupting the mechanisms responsible for the generation of clinical pain. Breakthrough pain after surgical procedures is now beginning to be recognized as constituting suboptimal management. This is an active research area. A number of clinical trials have been conducted to prove the efficacy of anti- nociceptive effect of α2 agonists using different techniques and different types of
drugs with conflicting results. The use of epidural techniques also offer the advantage of effective prolonged postoperative analgesia as compared to nerve blocks and local infiltrations.

The dose-dependent antinociceptive effects of clonidine were demonstrated in 1981 (1). These effects are partly mediated by spinal cord muscarinic and nicotinic receptors and the release of acetylcholine and by the activation of inhibitory noradrenergic pathways (10). In experimental studies, animal models and clinical trials, subarachnoid opioids, local anesthetics and α2 adrenergic agonists show synergistic or additive interactions (10,11). Intrathecal or epidural clonidine is not neurotoxic.

In this study, we found that bupivacaine and clonidine administered epidurally, reduced the amount of analgesic that patients required postoperatively suggesting that clonidine may enhance the analgesic effect of bupivacaine. This study correlates with the meta-analysis done by Armand et al (2) which concluded that epidural clonidine clearly produced an analgesic effect and reduced the need for other analgesics.
In this randomized control study, we have evaluated the analgesic efficacy of bupivacaine with clonidine mixture given through lumbar epidural route in patient undergoing elective orthopaedic lower limb surgeries.

The level of sedation intraoperatively was monitored using Ramsay Sedation Scale. The patients in group C were well sedated and comfortable than in group P. This study correlates with the study conducted by Antonio Mauro et al(3) in which they concluded that the association of clonidine and local anaesthetic (ropivacaine) had produced longer analgesia and sedation.
Pain intensity was assessed using the verbal rating scale (VRS) post-operatively. Significant lower VRS scores after 2,4,6,8,12,18,24,26,48 hours has in group C demonstrated the clinical advantage of administering mixture of bupivacaine and clonidine through lumbar epidural route for effective postoperative analgesia.
Duration of analgesia was significantly more in group C patients receiving bupivacaine and clonidine mixture (6.05±0.64 hrs) as compared to group P (3.26±0.53 hrs). The demand for supplementary epidural top-ups over 48 hours postoperatively was significantly low in group C than group P. This correlates with the study of Armand et al(2).
Two patients of placebo group (10% of group P) and two patients of clonidine group (10% of group C) had episodes of hypotension with a MAP< 70 mm Hg during intraoperative period who were managed with a single dose of ephedrine 6 mg iv and crystalloids , and this may be as a result of epidural bupivacaine as such. In the studies conducted by Paech et al (17) and Senard et al(21), they have concluded that epidural administration of clonidine caused a dose dependent reduction in haemodynamic parameters such as blood pressure and heart rate.
Postoperatively none of the patients had episode of hypotension. No incidence of any bradycardia was noted in both the group during intraoperative and postoperative period.
his randomized control study was designed to evaluate the analgesic efficacy of bupivacaine with clonidine mixture given through lumbar epidural route for postoperative analgesia in patients undergoing elective orthopaedic lower limb surgeries and the quality of analgesia was compared with epidural plain bupivacaine.

Forty ASA I & II patients undergoing elective orthopaedic lower limb surgical procedure under epidural anaesthesia were randomly allocated into one of the two groups. Group P received 1 ml of normal saline along with first dose of 14ml 0.5% bupivacaine. Group C received 50 µg of clonidine diluted with normal saline to 1 ml along with the first dose of 14 ml 0.5% bupivacaine. Further top-up dose was given using 6 ml of 0.5 % bupivacaine, 90 min after the first dose. There was no complication encountered in technical skills in all forty patients.

Pain in the post-operative period was assessed using a verbal rating scale (VRS). Time of first rescue analgesic(TFA) and the supplementary analgesic doses required for 48 hours were noted for the two groups. Pain score were significantly less in Group C at 2,4,6,8,12,24,48 hours ($P < 0.05$) than in group P. Overall pain score over 48 hours period also revealed better pain relief in group C ($P<0.05$) as compared to Group P.

Time of first rescue analgesic (TFA) in group C was significantly prolonged compared with group P . The postoperative analgesic consumption was also significantly less in group C than in group P. The incidence of hypotension did not differ significantly between the two groups & there was no bradycardia in both the groups.

So this study demonstrates that addition of clonidine to bupivacaine definitely improves the quality of analgesia by reducing the overall pain score, prolonging the duration of the time of first rescue analgesia and causing reduction of total analgesic consumption in the postoperative period without any hemodynamic

instability.

CONCLUSION:

Single dose administration of clonidine and bupivacaine mixture given through lumbar epidural route provides effective postoperative analgesia in patients undergoing elective orthopaedic lower limb surgeries, without any hemodynamic instability. Epidural clonidine significantly reduces the postoperative analgesic consumption.

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