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Comparative Study of Tramadol Vs Nalbuphine as an Additive With 0.125% Bupivacaine Plain for Post-Operative Epidural Analgesia in Total Knee Replacement and Total Hip Replacement Surgeries.

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ABSTRACT: *Lower limb arthroplasty particularly, total knee replacement (TKR) is an extremely painful surgical procedure. Post operative pain after total knee replacement (TKR) and total hip replacement (THR) interferes with early mobilization and recovery of the patients. Effective postoperative pain management can lead to better and earlier functional recovery. The use of epidural Bupivacaine in post-TKR patients gives effective analgesia, sometimes which can be associated with motor blockade, which can affect early functional recovery of the patients, but usually seen with higher concentration (>0.125%) of Bupivacaine. So, we compared analgesic efficacy and side effects of Tramadol vs. Nalbuphine as an additive with 0.125% Bupivacaine plain in postoperative patients undergoing TKR or THR through epidural catheter.*
KEY WORDS -: *BUPIVACAINE, EPIDURAL ANALGESIA, LOWER LIMB ARTHROPLASTY, NALBUPHINE, TRAMADOL, TKR, THR.*

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I. Aims And Objectives

1. To check the onset and duration of sensory block, degree of motor block and hemodynamic effects associated with epidural Bupivacaine 0.125 % with Tramadol during postoperative period.
2. To check the onset and duration of sensory block, degree of motor block and hemodynamic effects associated with epidural Bupivacaine 0.125 % with Nalbuphine during postoperative period.
3. To evaluate the impact of regional anesthesia on functional outcome of patients after TKR and THR surgery.

II. Introduction

The widely accepted definition of pain developed by a taxonomy task force of the International Association for the Study of Pain is, Pain is an unpleasant sensory and emotional experience that is associated with actual or potential tissue damage or described in such terms[(1)]. Pain is considered as a significant issue among human beings since the ancient period and many efforts were taken to understand and manage this problem since then.

Nowadays, one of the most existing problems in the society as well as among the healthcare professionals is pain and its effective management. Pain is well known issue after major orthopedic surgeries and it leads to difficulty in mobilization which increases hospital stay and expenses. Lower limb arthroplasties like Total Hip Replacement (THR) and particularly, Total Knee Replacement (TKR) are very painful surgical procedures with significant postoperative pain [(2)]. Effective postoperative pain management does more than just keep the patient comfortable, but also speed up the recovery time and prevents chronic pain[(3)]. Staying ahead of pain helps because it can ease stress, improve mobility and thus promote blood flow and finally lowers the incidence of complications.

The critical role of postoperative pain management within orthopedic surgical procedures is demonstrated by the fact that the effectiveness of a TKR or THR is often limited by the postoperative pain management itself. In fact, various modalities have been used in the management of pain among these patients such as epidural anesthetic agents, PNS blocks, IV opioid analgesics and oral analgesics. To reduce the occurrence of collateral effects, the analgesia protocol should be multimodal, which consists of the use of not less than two different drugs or modalities with various mechanisms or sites of action for synergistic effects on pain and should block pain at its origin[(3)].

Based on these assumptions, we found it ideal to conduct this study, to compare the benefits by using 0.125% Bupivacaine with Tramadol and 0.125% Bupivacaine with Nalbuphine.

III. Material And Methods

The study was conducted over a period of 6 months in our hospital after the approval of institutional ethical committee. Written informed consent was taken from the patients. 30 patients (ASA I-II) posted for elective TKR and THR surgeries under combined spinal epidural (CSE) anesthesia were included in the Study. The sample was randomly collected and divided equally into two groups with 15 patients in each group by using computerized randomization software.

Group BT (n = 15) Inj. Bupivacaine 0.125% + Tramadol 50 mg, Total drug volume of 8 ml.
Group BN (n = 15) Inj. Bupivacaine 0.125% + Nalbuphine 5mg, Total drug volume of 8 ml.

Inclusion criteria:

1. Patient requiring TKR and THR under CSEA.
2. ASA I, II grade.
3. Age between 18 and 65 year.

Exclusion criteria:

1. Hematological disease
2. Bleeding and abnormal coagulation profile
3. Severe cardiac disease, RHD, IHD
4. Patient refusal
5. Patient with evidence of increased ICT
6. Local skin sepsis
7. Allergy to local anesthesia
8. Marked spinal deformity
9. Pre-existing neuropathy

Preoperative investigations:

Following preoperative investigations were done for all patients.

- Complete haemogram
- Bleeding/ clotting time
- Blood sugar levels
- Liver function, renal function test
- Serum electrolytes and ECG, if above 45 years.

C) Consent:

The patients fulfilling the selection criteria were explained meticulously in their vernacular language about surgery, anesthesia procedure and drugs to be used. A written informed consent was obtained in each case in their vernacular language.

D) Facilities & equipments:

1. Boyle's apparatus
2. Appropriate breathing circuits
3. Sphygmomanometer
4. Resuscitation equipments
5. ECG monitor
6. Pulse oximeter
7. Oxygen supply and cylinder

E) Drugs:

- Bupivacaine 0.5% w/v
- Tramadol 5% w/v
- Nalbuphine 1% w/v
- 0.9% NS for dilution

All emergency drugs and resuscitation equipment were made available in the operation theatre and ward.

F) Anesthetic technique:

Only after a thorough preanaesthetic evaluation, all the patients undergoing surgeries under combined spinal epidural anesthesia were selected randomly and consent obtained prior to the procedure. The patients were kept fasting overnight and tab. Alprazolam 0.5mg was administered orally to each patient the night before surgery. On the day of surgery, in preoperative ward, IV line was secured. Patients were then premeditated with inj. Ranitidine 50 mg and inj. ondasetron 4 mg IV. Preloading with Ringer Lactate 15ml/kg was started. After

that patients were transferred to operation theatre and baseline parameters including blood pressure & ECG were recorded using multipara monitors. Sedatives or opioids were avoided in the pre-medication and during intra operative period.

After transferring patients to Operation Theater, epidural catheter (18G) was inserted at the lumbar L3-4 vertebral level and the catheter was fixed at 9-10 cms. Following this, a subarachnoid block was performed with a 25G spinal needle and with 3ml of 0.5% heavy Bupivacaine, below the level of the epidural catheter insertion. After checking the level of the block, the surgeons were allowed to start surgery. The vitals of the patients were maintained throughout the procedure.

An epidural test dose with lignocaine + adrenaline (1:200000), 3ml was used to confirm the placement of the catheter. After the surgery, a bolus dose of 8ml of 0.125% of Bupivacaine with Nalbuphine 5mg or a bolus dose of 8ml of 0.125% of Bupivacaine with Tramadol 50mg was administered as per selected group, for the purpose of the postoperative analgesia, after patient attaining VAS score of ≥ 4.

All the patients were monitored post operatively for 24hrs and for adverse effects like bradycardia, hypotension, nausea, vomiting, shivering and pruritus. Any change in hemodynamic parameters was treated immediately. Emergency drugs and resuscitation equipment were kept ready.

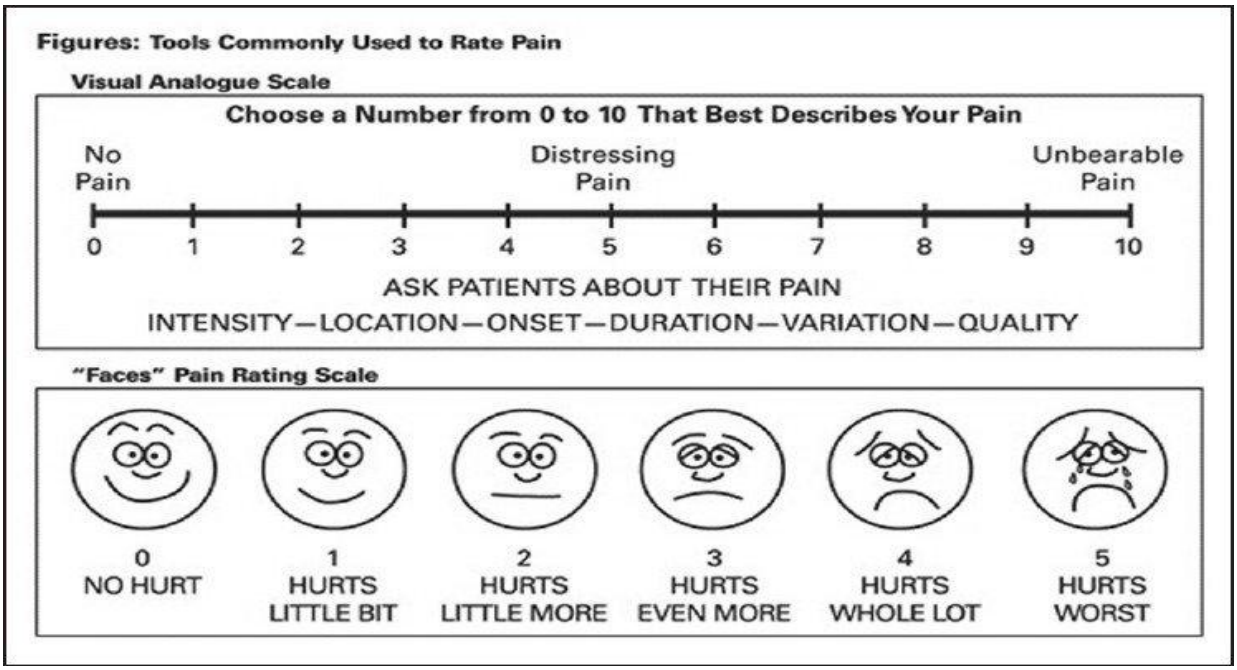

Figure-1

IV. Results

We conducted the study in a total of 30 patients undergoing TKR and THR surgeries under combined spinal epidural anesthesia. 15 patients (Group BN) received 0.125% Bupivacaine with Nalbuphine 5mg and remaining 15 patients (Group BT) received 0.125% Bupivacaine with Tramadol 50mg.

Analgesic effect was compared by using mean of VAS score recorded at 30min, 45min, 60min, 120min, 150min, 180min and 210min. The mean VAS score was between 3 and 4 after duration of 180 minutes, following which the epidural drug was repeated. The overall mean VAS score was significantly lesser in Group BN 2.46 as compared to Group BT 3.11.

Table - 1 MEAN VAS SCORE TREND

SR. No.	TIME INTERVAL (min)	BUPIVACAINE WITH NALBUPHINE (BN)	BUPIVACAINE WITH TRAMADOL (BT)
1	30	2.6	3.0
2	45	2.5	2.9
3	60	1.8	2.7
4	90	1.9	2.8
5	120	2.0	2.9
6	150	2.3	3.0
7	180	2.8	3.2
8	210	3.8	4.4
OVERALL MEAN VAS SCORE		2.46	3.11

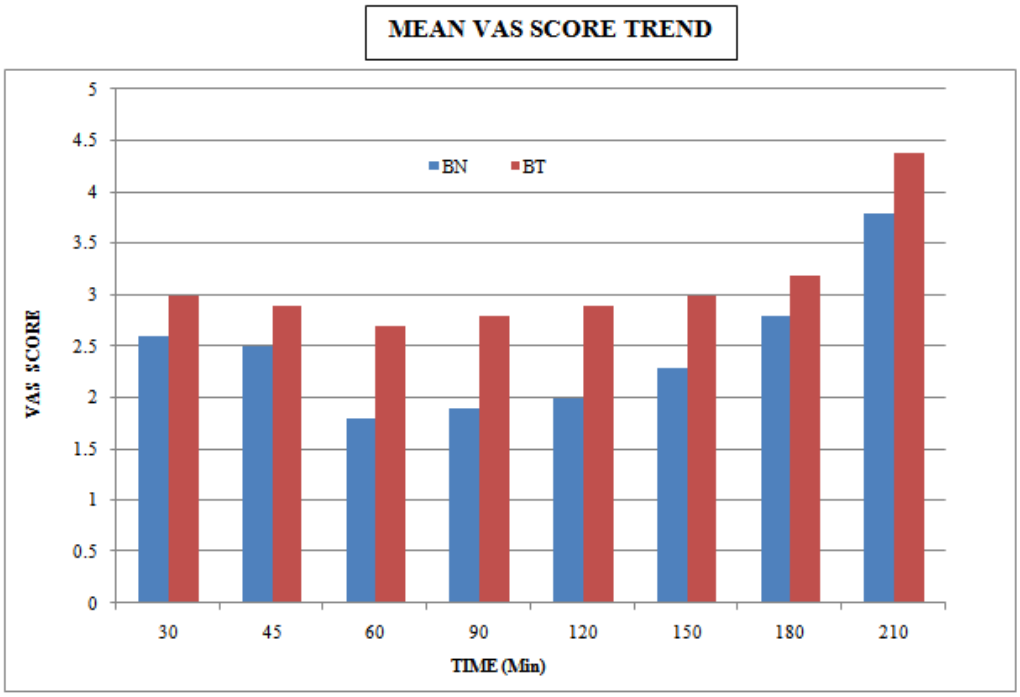

Figure-2

V. Discussion

The Italian Decree Law n. 38 adopted on March 15, 2010, known as the "Anti-pain Law", was one of the first decrees in Europe devoted to guaranteeing access to palliative care and pain therapies to patients, within the public health system.

In the present study, VAS score is used to check the degree of analgesia during recovery phase.

Pain following surgeries is an unavoidable event. Every patient suffers different degree of pain from mild to severe during his perioperative phase, which is a result of an intentional injury during surgery[(4)]. There is no study available showing comparison between the effect of Tramadol vs. Nalbuphine as an additive with 0.125% Bupivacaine plain for post-operative epidural analgesia in total knee replacement and total hip replacement surgeries.

Lower limb arthroplasties are widely done and widely accepted procedures now a days, specially TKR and THR. Both the procedures are associated with moderate to severe post operative pain and great attention has been paid to control postoperative pain, particularly in postoperative TKR patients [(5)]. It helps in fast recovery of patients significantly, which is necessary to achieve "FAST TRACK" protocols. The patients who undergo TKR or THR are not included in standard "fast track" protocols, however, perioperative and postoperative pain control, particularly during the recovery phase, is currently mandatory. Also, it is beneficial to reduce the metabolic oxygen demand during stress, better cardiovascular and respiratory outcome, offers the advantages of early ambulation to prevent joint stiffness, muscle weakness, life threatening complications like DVT, pulmonary embolism and also reduces the chance of post operative risk of myocardial infarction[(6)]. When we use opioids as additive to local anesthetic agents, it shows synergistic effect which reduces the requirement of individual drug and also the side effects associated with them [(7)].

Regional techniques offer additional advantages over general anesthesia like reduced response to surgery and analgesia which extend into the post operative period. Epidural analgesia provides a new dimension in managing post operative pain and is effective, safe and acceptable to patients and surgeons too, as it is feasible and has limited side effects. It also provides better continuous intra operative and immediate post operative assessment of patients than in general anesthesia. Also, pain and surgical stress cause a pro-inflammatory response followed by down-regulation of the immune response, which increase the incidence of postoperative complications, such as infections, prolonged wound healing and this is reduced and benefits in post operative analgesia[(8)]. Regional technique is also beneficial in reducing post operative cognitive dysfunction (POCD) in patients over general anesthesia after hip and knee surgeries [(9)].

VI. Conclusion

We conclude that, when we use inj. Nalbuphine 5mg as an additive with 0.125% Bupivacaine, it provides a faster onset and longer duration of sensory blockade and better pain relief with lower VAS score, with no degree of motor blockade, with stable hemodynamic parameters and lower incidence of side effects like hypotension, bradycardia, nausea, pruritus, as compared to when we use inj. Tramadol 50mg as an additive with 0.125% Bupivacaine, as a postoperative analgesic agent through epidural catheter after TKR and THR surgeries.

The present study reports a good pain control during recovery phase in pain control protocols used after primary uncomplicated TKR and THR patients.

Further studies need to be conducted on larger sample size of population.

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