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A COMPARATIVE CLINICAL STUDY OF POST OPERATIVE ANALGESIA WITH GELFOAM SOAKED WITH ROPIVACAINE OR LEVOBUPIVACAINE, PLACED IN EPIDURAL SPACE DURING SPINE SURGERY.

Anaesthesiology

Dr. Prem Shanker Malviya Professor Department of Anaesthesiology & Critical care, M.L.N. Medical college, Prayagraj, India

Dr. Vaibhav Singh Assistant Professor Department of Anaesthesiology & Critical care, M.L.N. Medical college, Prayagraj, India

Dr. Raghvendra Pratap Singh* Junior Resident Department of Anaesthesiology & Critical care, M.L.N. Medical college, Prayagraj, India*Corresponding Author

Dr. Amit Kumar Singh Assistant Professor in Neurosurgery Department of Surgery, M.L.N. Medical College, Prayagraj, India

ABSTRACT

A comparative , clinical , randomized study was undertaken to compare two local anaesthetic drugs - Levobupivacaine and Ropivacaine for postoperative analgesia during spine surgeries. A total of 90 patients were recruited who were divided into 30 each in control , Levo-bupivacaine and Ropivacaine groups. Observations for vital parameters , quality and duration of analgesia were made. Methods: Patients were randomized into three groups, group C (control) receiving 10 ml saline soaked gelfoam, group R receiving 10 ml 0.25% ropivacaine soaked gel-foam and group L receiving 10 ml 0.25% levobupivacaine soaked gelfoam. Postoperative 24 hours Heart rate (HR), Mean arterial pressure (MAP) and Visual analogue score (VAS) were rec-orded and time of 1st analgesic requirement (in hours) and total dose of analgesic requirement in the form of injection diclofenac sodium (75mg) i.v were recorded. Conclusions: Postoperative analgesia produced by two local anaesthetic drugs was significantly longer than seen in control group ($p < 0.05$) . Epidural application of gelfoam soaked Levobupivacaine showed better re-sponse in terms of lower pain scores and lesser rescue analgesic consumption than Ropivacaine ($p < 0.05$) . Hence, epidural gelfoam soaked Levobupivacaine or Ropivacaine can be effectively used for postoperative pain management in patients undergoing laminectomy , however Levobu-pivacaine stands better since it produced longer duration of analgesia. Future study – Same ex-periment can be extended in future with the help of indwelling catheter at the site of the wound and drugs being injected at the wound site as and when required.

KEYWORDS

Epidural gelfoam, Laminectomy, Levobupivacaine, Ropivacaine, Visual analogue score (VAS)

INTRODUCTION

Commonly performed spinal surgeries include laminectomy, discectomy, spinal fusion, scoliosis correction, and spinal tumor excision. Postoperative pain is severe and typically lasts for 3 days[1].Epidural local anaesthetics have been the mainstay of treatment for postoperative pain after spine surgeries[2]. Alternatively, we can use epidural administration of local anaesthetics as a single dose at the time of the surgery, or via an epidural catheter postoperatively[3]. Local anaesthetics administered directly over the duramater (dura) before closure have been used safely in a number of studies, but has limited application due to short duration of action. To prolong the effect of epidural local anaesthetics, drugs can be given by soaking in gelfoam.[4,5] Gelfoam is an inert com-pound which was originally used for the purpose of hemostasis in surgical wounds[6], but it has also been shown to soak a good volume of local anesthetic drug and release it gradually over a period of few hours. It was therefore decided to use gelfoam soaked local anesthetic as a slow release system for delivering postoperative analgesia in spine surgeries.

MATERIALS AND METHOD

The proposed study was conducted in S.R.N. Hospital associated with M.L.N. Medical college, Allahabad (Prayagraj) over a period of two years after approval from ethical committee and obtaining written and informed consent from the patient. Patients of either sex between the age group of 18-60 years belonging to American Society of Anesthesiologists (ASA) grade I or II were included in the study. Patients with ASA III or above, pre-existing neurological , psychological , cardiorespiratory or metabolic diseases , history of substance abuse, undergoing cervical level laminectomy, accidental dural tear, coagulation disorder were excluded from the4 study. After randomization and blinding patients were allocated into three groups (30 patients each)–

Group C- 5×1 cm gelfoam soaked in 10 ml saline placed in the epidural space.

Group R- 5×1 cm gelfoam soaked in 10 ml of 0.25% Ropivacaine placed in the epidural space. Group L- 5×1 cm gelfoam soaked in 10 ml of 0.25% Levobupivacaine placed in the epidural space.

Heart rate, mean arterial pressure (MAP), and, VAS recorded 2 hourly interval for the first 8 hours, and then at 4 hourly intervals till 24 hours.

Subjective pain measured by VAS on a scale of 0 to 10 with 0` representing no pain and 10 worst imaginable pain. All patients were acquainted with VAS preoperatively. Patients were ad-ministered supplemental analgesic with inj. Diclofenac 75 mg IV if they complain of pain or VAS ≥ 3, which could be repeated after 20 minutes if patient still complain of pain. Opioids and all other analgesic or anti-inflammatory agents will be prohibited for the first 24 hours after study dose. After 24 hours, alternate opioid therapies were permitted at the investigator's discre-tion. The duration of pain relief is defined as the time from the end of the operation until the pa-tient requested supplementation of analgesic. Time of first demand of analgesic and total analge-sic consumption in the initial 24 hours were recorded.5

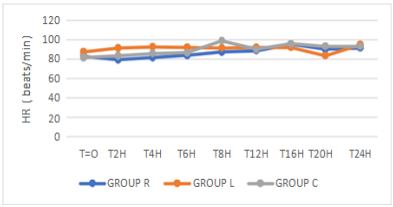
RESULTS

There is no significant difference ($p > 0.05$) regarding sex distribution and demographic profile of patients in all 3 groups, hence all the groups were comparable in context of sex, age and weight distribution.

Regarding changes in heart rate while comparing within the groups, group L baseline value was 87.25 ± 2.872 beats/min which significantly increases after 24 h, while in group R baseline value was 82.75 ± 2.062 beats/min which significantly increases after 12 h, and in group C baseline value was 81.50 ± 1.713 beats/min which significantly increases after 8 h. Between inter group comparison P1 (p value of comparison between group L and group R) was significantly high up to 6 h ($p<0.05$), after that mean values in group L group R were comparable from 8 h to 24 h postoperatively ($p<0.05$) ; P2 (p value of comparison between group R and group C) was comparable up to initial 6 h, after that mean values in group R were significantly reduced up to 20 h ($p<0.05$); P3 (p value of comparison between group L and group C) was significant through the study period ($p<0.05$), mean values in group L were significantly reduced after 6 h up to 20 h. Thus

heart rate in Ropivacaine group was significantly lower in initial study period but tends to increase by the end of study.

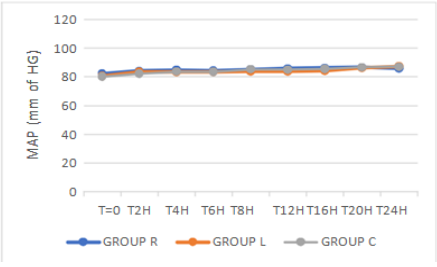
Fig.2 : Heart Rate



Regarding changes in MAP while comparing within the groups, group L baseline value was 80.67

± 3.215 which was comparable up to 16 h after that mean value significantly increases in rest of postoperative period ($p<0.05$) ; group R baseline value was 82.33 ± 1.528 which was comparable up to 12 h after that mean values significantly increases up to 24 h ($p<0.05$) ; group C baseline value was 80.33 ± 1.528 which was comparable up to 6 h after that mean values significantly increases throughout the postoperative period while inter-group comparison MAP values were comparable in all 3 groups in postoperative period. Thus statistically ($p >0.05$) there was no sig-nificant difference in mean arterial pressure in all the 3 groups.

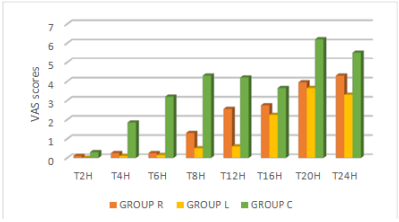
Fig. 3 : Mean Arterial Pressure



Regarding VAS scores, P1 (p value of comparison between group R and group L) was comparable up to 8 h after that mean VAS scores was significantly reduced ($p <0.05$)* in group L at most of the time intervals up to 20 h, which means patients experience had lesser pain compared to Ropi-vacaine. P2 (p value of comparison between group R and group C) was comparable in initial hours only and VAS score was significantly reduced ($p <0.05$)*in group R, which means patients in Ropivacaine had better pain control than control group. P3 (p value of comparison between group7

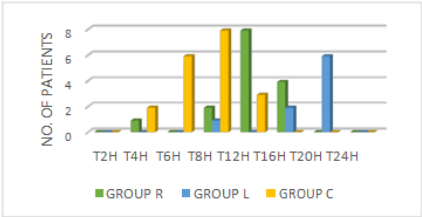
L and group C) was highly significant ($p <0.001$)** through the study period, implying that pa-tients of Levobupivacaine group had significantly reduced pain scores than control group. Thus we can conclude that patients in Levobupivacaine group were most pain free in comparison to Ropivacaine and control group, hence Levobupivacaine provides most effective analgesia among study drugs.

Fig. 4 : Visual Analogue Scale



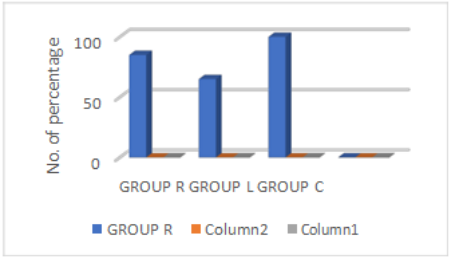
There was statistically highly significant difference ($p <0.01$)** on comparing all the three groups. Time of 1st analgesic requested was significantly prolonged ($p <0.05$)* in group R compared to group C, and in group L compared to both group R and group C. Analgesic requested by patients of group C was 13 hours and 5.4 hours earlier than group L and group R respectively, hence dura-tion of pain free period was longer in Levobupivacaine group compared to Ropivacaine and control group, implying that Levobupivacaine was effective for longer duration of postoperative period.

Fig. 5 : Time of 1st Analgesic Requested



Total analgesic consumption in group C was 3.6 times in group L and 2.24 times in group R which shows significantly reduced ($p <0.05$) consumption by patients of group L, thus proving Levobu-pivacaine to be most effective in postsurgical pain control.

Fig. 6 : % of Patients Requesting Rescue Analgesic



In our study 85% patients in group R and 65% in group L requested for rescue analgesic, while it was 100% in group C.9

DISCUSSION

Hernández-Palazón J et al. (2001)[7] conducted a prospective, randomized double blind study of 45 patients undergoing elective surgery for herniated lumbar disk repair under general anesthesia to find out superiority of one drug over another. Before the surgical wound was closed, the paraspinal musculature and subcutaneous tissue were infiltrated with 30 ml of 0.25% ropivacaine in group I (n = 15), 30 ml of 0.25% bupivacaine in group II (n = 15) or 30 ml of saline solution in group III (n = 15). He observed no significant difference in VAS scores among the groups, but the first request for analgesia was significantly longer in group II than in either groups I or III (164 +/-53 min versus 68 +/- 31 and 38 +/- 14 min, respectively). Significantly less ketorolac was used in groups I and II than in group III (58 +/- 20 and 59 +/- 21 mg versus 118 +/- 32 mg). This study was designed for 24 hours of postoperative phase per patient. The duration of analgesia in our study with 10 ml of 0.25% Ropivacaine soaked in gelfoam was 9.8 ± 6.28 hours and 17.4 ± 6.07 hours with 10 ml of 0.25% Levobupivacaine soaked in gelfoam . Hence both the drugs in our study provide analgesia for a longer duration than 30 ml of 0.25 % Ropivacaine and 30 ml of 0.25% Levobupivacaine infused in the paraspinal musculature and subcutaneous tissue signifying the importance of gelfoam being used as a vehicle for drug delivery.

Jonnavithula N et al. (2015)[8] also conducted a study including 32 ASA I and II patients scheduled for laminectomy were randomly allocated to receive either 20 ml of normal saline (group I) or 20 ml of 0.25% of bupivacaine (group II) injected directly into the wound like infiltration technique after securing hemostasis. After a dwell time of 60sec the wound was closed in layers without mopping or suctioning. After extubation, the pain scores were evaluated by visual analog scale at every 4 hrs. for 24hrs and also the time for first demand of analgesia, number of analgesic demands and the total amount of analgesia consumed were noted by an independent observer. The median10

duration of analgesia in group I was 8.8 [5-11] and in group II 13 [8.5-16] hrs. with a p = 0.04. The number of demands and the amount of analgesia consumed was also statistically significant. When compared to our study, duration of analgesia with 10 ml of 0.25% Levobupivacaine soaked in gelfoam was higher [17.4 ± 6.07 hours].

Panwar S et al. (2017)[9] conducted a prospective randomized double blind study on 60 patients of ASA physical status I, II and III who underwent unilateral total knee replacement surgery under combined spinal epidural anaesthesia. Patients were selected as per exclusion and

inclusion criteria and divided into two Groups A and B randomly. Postoperatively Group A received continuous epidural infusion of ropivacaine (2 mg/ml) and fentanyl (2 µg/ml) along with clonidine (2 µg/ml) in the range of 3-7 ml/hr while Group B received the epidural infusion of Ropivacaine (2 mg/ml) plus fentanyl (2 µg/ml) in range of 3-7 ml/hr . The postoperative VAS scores, haemodynamic parameters, motor block, sedation, nausea, vomiting and any other significant side effects were noted for 24 hours. Visual analog scale scores were lower in Group A (3.38) than in Group B (3.72). The average infusion rate was lower in Group A (4.7 ± 0.7 ml/hr) than in Group B (5.5 ± 0.7 ml/hr). Patients in Group A required less dosage of rescue pain medication Paracetamol (1g i.v.), diastolic pressure and heart rate were lower in Group A. When compared to our study, group L (Levobupivacaine) VAS score was 3.30 ± 1.720 at 24 hours postoperatively which was comparatively lower than group R (Ropivacaine) with VAS score of 4.30 ± 2.105 and group C (Control) with VAS score of 5.50 ± 2.705.

In our study, Levobupivacaine group was most pain free in comparison to Ropivacaine and Control groups. This was also proved by the study of Benhamon D et al. (2003)[10] who conducted a double blind study on healthy women with labor pain in which 47 patients received levobupivacaine, and 47 received ropivacaine. Minimum local analgesic concentrations for levobupivacaine (0.077%;11

95% CI, 0.058-0.096%) were lower than those for ropivacaine (0.092%; 95% CI, 0.082-0.102%). Drugs were administered as a 20-ml epidural bolus. The concentration of each started at 0.11% and increased or decreased at intervals of 0.01%, depending on the response of the previous patient, using the technique of up-down sequential allocation. He concluded that levobupivacaine was 19% more potent than ropivacaine and provided similar safety results.

CONCLUSION

We conclude that epidural application of gelfoam soaked Levobupivacaine and Ropivacaine both are effective method for maintaining postoperative analgesia, but Levobupivacaine shows better response in terms of lower pain scores and lesser rescue analgesic consumption than Ropivacaine. Also, gelfoam is a better vehicle for drug delivery than the local infiltration. Hence, epidural gel-foam soaked Levobupivacaine can be effectively used for postoperative pain management in pa-tients undergoing laminectomy.

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