# **ORIGINAL ARTICLE**



# A prospective randomized comparative study of gelfoam soaked nalbuphine vs. ketamine placed in epidural space during lumber spine surgery for postoperative analgesia

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# ABSTRACT

**Background:** Pain management is a major challenge after spine surgery. Parenteral opioids have been the mainstay of treatment for postoperative pain after lumbar spine surgeries. The biggest drawback of parenteral route is that drugs are given in large time gaps while ideal postoperative analgesia should provide continuous pain relief. Hence epidural route of analgesia has evolved as a critical component of pain management. We compared gelfoam soaked nalbuphine vs. ketamine placed in epidural space during lumber spine surgery for postoperative analgesia.

**Methodology:** A prospective randomized, double-blind study of 60 patients of either sex between the age group of 18-60 years belonging to American Society of Anesthesiologists (ASA) grade I or II, posted for elective one or two segment laminectomy were included in the study. Patients were randomly allocated into three groups (20 patients each). In Group K gelfoam soaked in 50 mg of preservative free ketamine diluted with 5 ml normal saline was used. Group N patients received gelfoam soaked in 10 mg nalbuphine diluted with 5 ml normal saline and in Group C gelfoam soaked in 5 ml normal saline was placed in the epidural space just before wound closure.

**Results:** The total rescue analgesic (inj. Diclofenac sodium 75 mg) consumption in Group K was  $90 \pm 86.37$  mg compared to  $150 \pm 91.04$  mg in Group N (p = 0.019) and time of 1<sup>st</sup> analgesic requested was also significantly delayed in Group K compared to Group N (p = 0.00048). Visual analogue scale (VAS) scores were also lower in Group K during a period of 48 hours.

**Conclusion:** Epidural application of gelfoam soaked ketamine and nalbuphine both are effective method for maintaining postoperative analgesia, but ketamine shows better response in terms of lower pain scores and lesser rescue analgesic consumption than nalbuphine with lesser adverse effects.

**Key words:** Ketamine; Gelfoam; Nalbuphine; Epidural Space; Spinal surgery; Postoperative analgesia

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# INTRODUCTION

Effective postoperative pain control is an essential

component of postoperative care, and inadequate pain control may result in increased morbidity or mortality.<sup>1,2</sup> Pain management can be a major

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Received: 9 Apr 2018 Reviewed: 14, 23 May 2018 Corrected & Accepted: 28 Dec 2018 challenge after spine surgeries. Spine surgeries are mostly elective in nature and commonly performed surgeries include laminectomies, discectomies, spinal fusions, instrumentations, scoliosis corrections, and spinal tumor excision. Pain from the back originates from different tissues such as vertebrae, intervertebral discs, ligaments, dura mater, nerve root sleeves, facet joint capsules, fascia, and muscles. The intensity of postoperative pain is directly proportional to the number of vertebrae involved in the surgery.<sup>3</sup> A variety of pain assessment tools can be utilized to quantify the pain in its different dimensions. The numerical rating scale and the visual analogue scale (VAS) are validated tools to quantify the intensity of pain.<sup>4</sup> Modalities available for postoperative pain management include central neuraxial blockade with local anesthetics, high-dose parenteral opioids, epidural local anesthetics and opioids with or without adjuvants like clonidine, and non-steroidal antiinflammatory agents.<sup>5</sup> Parenteral opioids have been the mainstay of treatment for postoperative pain after lumbar spine surgeries.6 The biggest drawback of parenteral opioids is that drugs are usually given with relatively large time lapses, so there are wide fluctuations in clinical effect. Ideal postoperative analgesia should provide continuous pain relief, in an alert patient who can be mobilized early.<sup>7</sup> Alternatively, we can use epidural administration of narcotics as a single dose at the time of the surgery, or via an epidural catheter post-operatively.8 Epidural catheters are difficult to manage and maintain after spine surgey.<sup>9</sup> In addition, there is always a concern of infection, restricting its widespread application.<sup>10</sup> To prolong the effect of epidural opioids, drugs can be given by soaking in gelfoam.<sup>11,12</sup> Gelfoam is a sterile compressed sponge, water-insoluble in nature. It is a hemostatic device capable of absorbing up to 45 times its weight of whole blood.<sup>3</sup> Ketamine is a non-competitive NMDA receptor antagonist. It inhibits central sensitization,<sup>14</sup> thus providing the analgesia for surgical pain. Nalbuphine, a derivative of 14-hydroxymorphine is a strong analgesic with mixed  $\kappa$  agonist and  $\mu$  antagonist properties.<sup>5</sup> It also exhibits ceiling effect on respiratory depression. We planned this study to evaluate and compare the effectiveness of drugs, e.g. nalbuphine and ketamine in the form of soaked gelfoam used in spinal surgery for postoperative analgesia.

# METHODOLOGY

This prospective randomized, double-blind study was conducted at Swaroop Rani Nehru Hospital associated with MLN Medical College, Allahabad (UP), India. After approval from ethical committee and obtaining written and informed consent from the patients, the study was done over a period of one year.

A total of 60 patients of either sex, in the age group of 18-60 years, belonging to American Society of Anesthesiologists (ASA) grade I or II, posted for elective one or two segment laminectomy were included in the study.

Exclusion criteria included patient refusal, patients with pre-existing neurological, psychological, cardiac or respiratory system disease, patients with history of substance abuse. Patients with BMI > 30, patients undergoing cervical or thoracic laminectomies and previous history of spine surgery were also excluded. Also excluded were patients who had accidental dural tear while undergoing laminectomy, or those unable to comprehend visual analogue scale (VAS).

We started our study with 66 patients who were posted for lumbar laminectomy, 6 patients were excluded before administration of study drugs due to various reasons. So, 60 patients were included and completed the study, 20 in each group (Figure 1). All patients were explained about visual analogue scale (VAS) the day before surgery and counseled.

A standardized protocol for general anesthesia was followed for all the patients. The study drugs were prepared by an anesthesia resident who did not participate in the study and handed over to the surgeon. Patients were randomly allocated into three groups (20 patients each) by computer generated sequence of random numbers.

Group K - received  $5 \times 1$  cm gelfoam soaked in 50 mg of preservative free ketamine diluted with 5 ml normal saline.

Group N- received  $5 \times 1$  cm gelfoam soaked in 10 mg nalbuphine diluted with 5 ml normal saline.

Group C- received  $5 \times 1$  cm gelfoam soaked in 5 ml normal saline placed in epidural space, just before closure.

Postoperative pulse rate, blood pressure and oxygen saturation were recorded and patient was shifted to post anesthesia care unit (PACU) where continuous monitoring was carried out. In PACU, all patients were supported with supplemental oxygen for first 2 h. After this time, oxygen was administered only if saturation dropped below 94%.

#### Following parameters were recorded:

1. Heart rate (HR)- rate of 50-100 bpm was taken as optimal range for this study, <50 bpm was considered as bradycardia, and inj. atropine 0.6 mg was given.

### Table 1: Demographic data

Parameter	Group N	Group K	Group C	P value
Age (years)	39.2 ± 9.865	41.8± 8.989	42.25±7.623	0.506
Weight (kg)	61.2 ± 4.927	62.45 ± 4.334	61.2±4.572	0.616
Sex (male:female)	10:10	11:9	12:8	0.818

(p < 0.05 was considered significant)

#### Table 2:- No. of segment involved in laminectomy

Laminectomy	Group N	Group K	Group C	P value	
One Segment	12	9	13	0.414	
Two Segment	8	11	7		

(p < 0.05 was considered significant)

#### Table 3 - Visual Analogue (VAS) Scores

Time Interval	Nalbuphine	Ketamine	Control	p value
T2H	0.1 ± 0.447	0	0.3 ± 0.470	P1 .161 P2 .088 P3 .003*
T4H	0.25 ± 0.910	0.1 ± 0.447	1.85 ± 1.565	P1 .256 P2 .00016** P3 .00012**
Т6Н	0.25± 0.5501	0.15 ± 0.6708	3.2 ± 1.852	P1 .304 P2 .00001** P3 .00001**
T10H	1.3 ± 1.75	0.5 ± 1.317	4.3 ± 1.78	P1 .055 P2 .00001** P3 .00001**
T14H	2.56 ± 2.64	0.6 ± 0.88	4.2 ± 2.015	P1 .00107* P2 .0218* P3 <.00001**
T18H	2.75 ± 2.07	1.65 ± 1.46	3.65 ± 1.66	P1 .029* P2 .069 P3 .00012*
T22H	2.9 ± 1.88	2.25 ± 1.802	5.3 ± 2.27	P1 .136 P2 .00041** P3 .000017**
T30H	4.25 ± 2.53	3.05 ± 1.66	5.75 ± 2.36	P1 .0423* P2 .030* P3 .00008**
T38H	3.95 ± 2.08	3.65 ± 1.53	6.2 ± 2.46	P1 .3037 P2 .0017* P3 .00017**
T48H	4.3 ± 2.105	3.3 ± 1.719	5.5 ± 2.704	P1 .054 P2 .0628 P3 .00197**

2. Mean arterial pressure (MAP) - if < 65 mmHg, inj. mephentermine 6 mg was given as a bolus.

3. Respiratory rate (RR) - 11-16 per minute was

taken as optimal range here, RR < 10 per min was considered as respiratory depression and supplemental oxygen was given if saturation fell below 92%.

4. VAS - patients were already famliarized with VAS preoperatively. In postoperative period they were asked about subjective pain. They were also asked about location of pain and its association with movement.

5. Rescue analgesic- patients were administered supplemental rescue analgesic with inj. diclofenac 75 mg IV bolus if VAS was > 3 which could be repeated after 20 min if required.

Opioids and all other analgesic or anti-inflammatory agents except inj. diclofenac were prohibited for the first 48 h after study dose. After 48 h, alternate opioid therapies were permitted at the investigator's discretion. Naloxone was permitted for opioid related side effects.

The duration of pain relief was defined as the time from the end of the operation until the patient request for supplementation of analgesic. Time of first demand of analgesic and total analgesic consumption in the initial 24 and 48 h were recorded.

6. Level of sedation was assessed by Ramsay Sedation Scale.<sup>16</sup>

7. Time of ambulation - patients were encouraged to ambulate 6 h after surgery if they felt comfortable. Time of ambulation was counted from the time to shift to PACU until the time patients could be ambulated, later patients were discharged from PACU to ward if modified Aldrete's score<sup>17</sup> was  $\geq$ 9, patient had voided urine and started accepting orally. Time of discharge was noted and pulse oximetry monitoring continued in ward for 48 h.

Different complications in all 3 groups were noted. All the parameters were recorded hourly for the first 6 h, after that at 2 hourly intervals till 12 h and at 4 hourly intervals till 48 h by the resident anesthesiologist, who was unaware of the group allocation.

Statistical analysis: Data were analyzed using statistical package of social sciences (SPSS, version

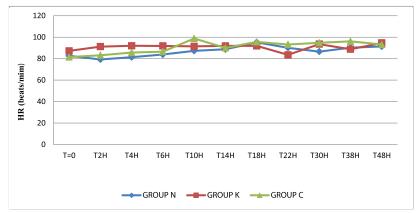


Figure 1: Comparative mean heart rate at different times

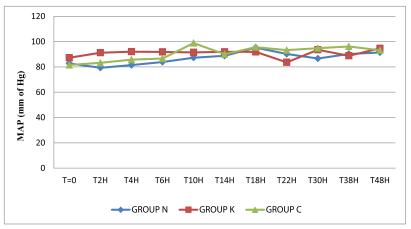


Figure 2: Comparative mean arterial pressure at different times

19) software and expressed as mean  $\pm$  standard deviation. Continuous data were analyzed using ANOVA test. Inter group and intra group comparison was done using paired *t*-test for numeric data. Control group was at power of 0.8, confidence interval of 95% was defined using software PS 3.1.2, p-value < 0.05 was considered as statistically significant.

# RESULTS

Patients of all three groups were statistically comparable regarding mean age, weight, gender, ASA physical status and surgical characteristics (Table 1). Patients were also comparable in all three groups for number of segments involved for laminectomy (P=0.414) (Table 2).

Mean HR values were significantly lower in Group N up to 14 h, after that HR increased significantly in Group N compared to Group K. No incidence of bradycardia was observed during study. In Group C mean HR values significantly increased after 10 h and remained high throughout the study (Figure 1)

Regarding changes in MAP on inter-group comparison

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values were comparable in all 3 groups, statistically no significant difference was observed in postoperative period (Figure 2)

Regarding RR changes, mean values were significantly lower in Group N and Group K up to initial 14 h, after that mean RR in Group N was significantly increased. No incidence of respiratory depression was observed. Group C mean RR values remained high through the study.

VAS scores in Group K and Group N were significantly lower compared to Group C at most of the time interval, while Group K VAS scores were lower than Group N from 10 h to 30 h of study period (Table 3). Time of 1st analgesic requested was significantly prolonged in Group N compared to Group C, and in Group K compared to both other groups. Analgesic requested by patients of Group C was 26 h and 10.9 h earlier than Group K and Group N respectively. Total analgesic consumption in Group C was 3.6 times in Group K and 2.24 times in Group N which

shows significantly reduced (p < 0.05) consumption by patients of Group K, thus proving Ketamine to be most effective in postsurgical pain control (Table 4).

In our study 85% patients in Group N and 65% in Group K requested for rescue analgesic, while it was 100% in Group C.

Time of ambulation after surgery was significantly earlier in Group K and Group N compared to Group C, but it was earlier in Group K. Thus patients of ketamine group were able to ambulate earlier due to effective pain control. While no significant difference was observed in time to discharge among the groups (Table 4). Regarding side effects observed due to the use of study drugs nausea, vomiting, and sedation were comparable in all the groups with statistically no significant difference. No incidence of respiratory depression were observed among the groups; however, incidence of urinary retention and pruritus was significantly higher in nalbuphine group 8(40%) patients and 6(30%) patients respectively, while none observed in Group K and Group C (Table 5).

Parameters	Group N	Group K	Group C	p value
Time of 1 <sup>st</sup> analgesic requirement (hours)	19.7 ± 13.56	34.8 ± 13.14	8.8 ± 3.13	P1= 0.00048** P2 =0.0006** P3 < 0.00001**
Total analgesic consumption (mg) in form of inj. diclofenac sodium 75 mg i.v.	150 ± 91.04	90 ± 86.37	277.5 ± 60.09	P1=0.019* P2 < 0.00001** P3 < 0.00001**
Time of ambulation (hours)	6.05 ± 0.759	5.55 ± 0.759	7.5 ± 0.827	P1= 0.022* P2 < 0.00001** P3 < 0.00001**
Time of discharge (days)	2.9 ± 0.55	2.7 ± 0.47	2.95 ± 0.51	P1= 0.112 P2 =0.383 P3=0.057

 Table 4: Postoperative analgesic requirement, time of ambulation and discharge

#### **Table 5: Postoperative side effects**

Side Effect	Group N	Group K	Group C	p value (p <0.05)*
Nausea	9 (45%)	3 (20%)	6 (30%)	0.223
Vomiting	6 (30%)	1 (5%)	4 (20%)	0.177
Respiratory depression	0	0	0	-
Sedation	4 (20%)	7 (35%)	1 (5%)	0.12
Urinary retention	8 (40%)	0	0	0.0003**
Pruritus	6 (30%)	0	0	0.002*

# DISCUSSION

Ideally postoperative analgesia should be continuous,<sup>7</sup> which is not so easy in the case of parenteral route. Thus epidural analgesia has evolved as a critical component of multimodal approach and offers superior postoperative pain relief.

Thus routine use of surgical gelfoam in the epidural space at the completion of surgery encouraged many studies to use it as extended release drug delivery system to prolong the effect of epidural analgesics. Gibbons KJ et al.<sup>18</sup> conducted a study with 45 patients posted for lumbar discectomy, using 40-80 mg methylprednisolone acetate soaked gelfoam injected with 2 to 4 mg of preservative-free morphine. He observed that only 60% patients on the day of surgery and 51% on 1st postoperative day requested for supplemental analgesia. Similar study done by Movasaghi R et al.<sup>19</sup> with 100 patients found that supplemental analgesic (morphine) consumption was 10.75 mg in study group and 21.4 mg among control group patients (p < 0.0001). He also found that patients of study group (steroid + morphine) patients ambulate at 2 days and discharged on 4.7 days while control group (steroid) patients ambulate at 2.6 days and discharged on 6 days (p < 0.0001). In our study 25% patients in ketamine group while 65% patients in nalbuphine group requested for rescue analgesic in

1st 24 h, while patients were discharged earlier at 2-3 days.

Mishra LD et al.<sup>20</sup> used 0.3 mg buprenorphine soaked gelfoam in 30 patients and observed duration of analgesia of 14.8  $\pm$  0.77 h which is less than in duration for (19.7  $\pm$  13.56 h with 10 mg gelfoam soaked Nalbuphine and 34.8  $\pm$  13.14 hours with 50 mg gelfoam soaked ketamine) drugs used in our study.

al.23 Kundra S et observed a significantly prolonged duration of analgesia of 30.03 ± 6.796 h; in our study a longer duration of 34.8  $\pm$  13.14 h was observed with use of gelfoam soaked ketamine. Rescue analgesic (inj. diclofenac sodium) consumed in our study in nalbuphine group

was 1.7 times more than ketamine group, while in their study 3.5 times more and 20 h earlier in control group compared to morphine study group. VAS scores were lower in Group K of our study concluding that patients in ketamine group were most pain free in comparison to nalbuphine and control group, hence ketamine provides most effective analgesia among study drugs.

Another researcher<sup>21</sup> used absorbable gelatin sponge soaked in 0.1 ml of preservative free morphine (1 mg) diluted in 3 ml of normal saline followed by placement of another layer of gelfoam to prevent aspiration of the morphine in the drains, but no significant difference regarding VAS scores was observed when compared to PCA system of 5 mg/ml of morphine used in other group. So we can say that VAS scores were not significantly affected with the use of gelfoam, However, further studies are required in this context. A similar recent study using gelfoam soaked morphine was conducted by Hassanein A et al.<sup>24</sup> with 75 patients. He found that using colloid (6% HES) as a diluent significantly prolongs the duration of analgesia up to  $43.04 \pm 2.13$  h compared to  $38.04 \pm 2.05$  h with the use of crystalloid. The dose of Nalbuphine used in our study corresponds to the dose used in earlier studies.<sup>25,26</sup>

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Regarding side effects nausea/vomiting was higher in nalbuphine group while sedation was higher in ketamine group, but the difference was not statistically significant (p > 0.05). However, itching and urinary retention was significantly high in nalbuphine group with (p = 0.002) and (p = 0.0003) respectively.

# CONCLUSION

Epidural application of gelfoam soaked ketamine and nalbuphine both are effective for maintaining postoperative analgesia, but ketamine shows better response in terms of lower pain scores and lesser rescue analgesic consumption than nalbuphine with lesser adverse effects. Hence, epidural gelfoam soaked ketamine can be effectively used for postoperative pain management in patients undergoing lumbar laminectomy.

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Conflict of Interest: None declared

#### Authors' contribution:

MKG: Conduction of study work and literature research

VS: Design of study and manuscript editing

PP: Study analysis and literature research

LSM: Conduction of study work and statistical analysis

NNG: Design of study and literature research

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