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Effects of Perioperatively Administered Bupivacaine and Bupivacaine-Methylprednisolone on Pain after Lumbar Discectomy

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Study Design. A prospective, randomized, controlled trial that compared the efficacy of different protocols of local tissue infiltration with bupivacaine or bupivacaine-methylprednisolone at the surgical site for pain relief after lumbar discectomy.

Objective. To determine the efficacy of preemptive wound infiltration with bupivacaine and bupivacaine-methylprednisolone after lumbar discectomy.

Summary of Background Data. Patients usually have significant pain after lumbar discectomy. Wound infiltration with bupivacaine or bupivacaine-methylprednisolone is one method to address this.

Methods. Seventy-five patients were randomly allocated to 5 equal groups as follows: Group I (n = 15) had the musculus multifidi near the operated level infiltrated with 30 mL 0.25% bupivacaine and 40 mg methylprednisolone just before wound closure; Group II (n = 15) had the same region infiltrated with 30 mL 0.25% bupivacaine alone before closure; Group III (n = 15) had this region infiltrated with 30 mL 0.25% bupivacaine and 40 mg methylprednisolone before the incision was made; in Group IV (n = 15), this region infiltrated with 30 mL 0.25% bupivacaine alone before incision; and Group C (controls, n = 15) had this region infiltrated with 30 mL 0.9% NaCl just before wound closure. Demographics, vital signs, postoperative pain scores, and morphine usage were recorded.

Results. All 4 groups treated with bupivacaine or bupivacaine-methylprednisolone (by preemptive or preclosure wound infiltration) showed significantly better results than the control group for most parameters. The treated groups had lower parenteral opioid requirements after surgery, lower incidences of nausea, and shorter hospital stays. Further, the data indicate that, compared with infiltration of these drugs at wound closure, preemptive injection of bupivacaine or bupivacaine-methylprednisolone into muscle near the operative site provides more effective analgesia after lumbar discectomy.

Conclusion. In addition, our data suggest that preemptive infiltration of the wound site with bupivacaine alone provides similar pain control to preemptive infiltration of the wound site with bupivacaine and methylprednisolone combined.

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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Poor control of postoperative pain can lead to complications that delay discharge from hospital. Mild or severe pain after surgery can have negative effects on the pulmonary system (atelectasis, pulmonary edema, hypoxemia) and cardiovascular system (arrhythmias, increased systemic vascular resistance, hypertension, myocardial infarction).[1–3] It can also prevent early mobilization (thus increasing the risk of thromboembolism) and lead to reduced bladder and intestinal motility.[4–6] Effective postoperative analgesia is associated with lower rates of morbidity and mortality, and also results in shorter hospitalization, which reduces overall costs.[7]

Wound infiltration is one of the most simple and effective ways to manage acute pain after surgery, but this method is rarely used because of infection risk. Single-dose infiltration of a long-term local anesthetic around the wound can provide effective analgesia. The agent most widely used for this purpose is 0.25% bupivacaine. Injected corticosteroids also act against pain by inhibiting inflammation and therefore preventing the secretion of neuropeptides that stimulate thin nerve fibers. These drugs inhibit both the early inflammatory response (edema, fibrin formation, capillary dilatation, leukocyte aggregation) and the late effects of this process (proliferation of capillaries and fibroblasts, collagen formation, and scarring).[8,9]

Preemptive analgesia is the process of preventing pain by initiating pain-relief treatment before surgery or procedural trauma. This process involves administration of local anesthetics, opioids, and nonsteroidal anti-inflammatory drugs (NSAIDs) together or singularly *via* local, epidural, intrathecal, or systemic routes. Research has shown that this form of analgesia reduces pain, analgesic requirements, and morbidity and results in shorter hospitalization.[10,11]

Previous researchers have assessed levels of postoperative pain after intramuscular injection of various doses of anesthetics and/or corticosteroids during lumbar discectomy. However, no study has yet investigated the efficacy of preemptive analgesia with local anesthetic or corticosteroid in this patient group. The aim of this study was to assess how two different modes of local administration of two different treatments (bupivacaine alone or

bupivacaine plus methylprednisolone) affect pain levels after lumbar discectomy. Results were compared when each experimental treatment was locally administered in the muscle around the wound site before incision *versus* after skin closure.

■ Materials and Methods

The design for this prospective, randomized, double-blind study was approved by our institutional ethics committee, and written consent was obtained from each participant. The research was conducted between September 2004 and March 2005. Patients were included if they met the following criteria: scheduled for surgery under general anesthesia for unilateral lumbar disc herniation; first lumbar disc surgery; age 17 to 70 years; Association of American Anesthesiologists (ASA) classification I or II; no benefit from a 4-week course of conservative treatment. The exclusion criteria were spinal stenosis, known allergy to local anesthetics and pregnancy. Patients using systemic steroids were also excluded. In total, 75 patients were enrolled.

Each individual was randomly assigned to one of five groups by envelopes that identified the treatment to be received. The groups were as follows: Group I (n = 15) had the musculus multifidi near the operated level infiltrated with 30 mL of 0.25% bupivacaine and 40 mg methylprednisolone just before wound closure; Group II (n = 15) had this region infiltrated with 30 mL of 0.25% bupivacaine alone just before closure; Group III (n = 15) had the musculus multifidi near the operated level infiltrated with 30 mL of 0.25% bupivacaine and 40 mg methylprednisolone just before the incision was made (preemptive analgesia with both drugs combined); Group IV (n = 15) had this region infiltrated with 30 mL of 0.25% bupivacaine alone just before incision (preemptive analgesia with bupivacaine only); and Group C (controls, n = 15) had the same region infiltrated with 30 mL of 0.9% NaCl just before wound closure.

In the operating theater, each patient was prepared for continuous noninvasive blood pressure monitoring, peripheral pulse oxymetry, and electrocardiography. Then a peripheral venous cannula was inserted and an intravenous (iv) infusion of crystalloid solution was started. Each individual was premedicated with midazolam 0.03 mg/kg iv 3 minutes before induction of anesthesia. A standard anesthetic protocol was used. Induction was achieved with 2 to 2.5 mg/kg propofol, 1 to 1.5 μg/kg fentanyl, 0.1 mg/kg vecuronium, and 1 to 1.5 mg/kg lidocaine. The maintenance anesthesia was 2% sevoflurane in a 40:60 mix of oxygen and nitrous oxide, with bolus doses of vecuronium and fentanyl given as required until 45 minutes before the end of surgery.

After surgery, each subject had access to patient-controlled analgesia (PCA). Two-milligram iv boluses of morphine were available for 24 hours, with the machine set for 10-minute lock-out time and a 4-hour dose limit of 0.4 mg/kg. Patients who developed postoperative nausea or vomiting received intramuscular injections of 10 mg metoclopramide.

Perioperative Data Recorded. Patient demographic characteristics and features of the operation: age, sex, weight, ASA classification, duration of operation, and amount of fentanyl used during the procedure. Vital signs: Systolic blood pressure, diastolic blood pressure and pulse rate (PR) at induction and at 5, 10, 15, 30, 60, and 90 minutes intraoperatively.

Postoperative Data Recorded. The parameters were recorded at 1, 4, 8, 16, 20, and 24 hours after surgery by a pain clinic nurse who visited each patient. Vital signs: Systolic blood pressure, diastolic blood pressure, PR.

Pain Visual Analogue Scale (VAS). An 11-point VAS was used to assess pain levels during movement (VAS_M) and at rest (VAS_R). A VAS score of 0 indicated no pain, whereas 10 indicated the most severe pain imaginable.

Pain Verbal Analogue Scale (VER). A 4-point VER was used to assess pain levels during movement (VER_M) and at rest (VER_R). A VER score of 0 indicated no pain, 1 indicated mild pain, 2 indicated moderate pain, and 3 indicated severe pain.

Ramsay Sedation Scale.[12] This 6-point scale was used to assess sedation levels, with 1 indicating agitated, anxious; 2, cooperative; 3, only responds to commands; 4, strong response to glabellar tapping or noisy stimulants; 5, weak response to glabellar tapping or noisy stimulants; 6, no response.

Postoperative PCA Parameters. Time of first analgesic demand, number of PCA demands, number of PCA boluses received, cumulative morphine dose for three separate periods (0–4, 4–12, and 12–24 hours), and total morphine dose at 24 hours.

Adverse Effects. Nausea, vomiting, and steroid-related adverse effects (gastrointestinal bleeding, gastritis, delayed wound healing, Cushing's syndrome).

Patients who were discharged earlier than 24 hours after surgery were telephoned at home and their pain scores and sedation scores were recorded.

Statistical Analysis. Power analysis was done at the design stage of the study. The authors estimated there was 0.85 probability (in SD) that a patient who received a local injection of bupivacaine or bupivacaine-methylprednisolone would report lower pain intensity on VAS scoring than a patient who received a local injection of saline solution. Assuming that the pain scores would be compared using the Wilcoxon's rank sum test with two-sided 10% level of statistical significance and 90% power, the authors calculated that at least 70 patients (14 per group) were required. The Kruskal-Wallis, χ^2, and Mann-Whitney U tests were used to analyze the data. P values < 0.05 were considered statistically significant.

■ Results

There were no significant differences among the five study groups with respect to mean age, sex distribution, mean weight, proportions of ASA classifications, mean operating time, or mean amount of fentanyl used during the operation (Table 1). There were also no significant differences among the groups with respect to mean arterial pressure (MAP) or mean PR before induction, during the operation, or in the first 24 hours after surgery ($P > 0.05$ for all).

The results for the postoperative data are presented in Table 2. Groups I through IV all had significantly longer mean times to first analgesic (PCA) demand than the control group. Further, the mean time to first PCA demand in Group III (preemptive analgesia with bupiva-

Table 1. Demographic Characteristics of the Study Groups

	Group I (n = 15)	Group II (n = 15)	Group III (n = 15)	Group IV (n = 15)	Group C (n = 15)
Age (yr)	46.1 ± 11.1	45.4 ± 10.6	55.6 ± 9.5	48.8 ± 11.3	43.1 ± 13.2
Sex (M/F)	9/6	9/6	12/3	7/8	6/9
Height (cm)	170.8 ± 8.9	171 ± 6.8	170.8 ± 5.7	166.3 ± 7.8	165.6 ± 7
Weight (kg)	80.7 ± 18.2	76.2 ± 12.7	75.6 ± 9.3	69.8 ± 11.8	69.7 ± 16.3
ASA (I/II)	12/3	13/2	10/5	10/5	11/4
Operative time (min)	102.6 ± 29.1	109.6 ± 38.7	115.3 ± 30.7	102.6 ± 33.2	93 ± 30.1
Preoperative fentanyl usage (μg)	108.3 ± 41.9	98.3 ± 19.9	120 ± 36.8	110 ± 26.4	126.6 ± 37.1

Data are mean ± SD (or no.).

caine-methylprednisolone) was significantly longer than the corresponding times for Groups I, II, and C ($P < 0.05$, $P < 0.05$, and $P < 0.001$, respectively). However, there was no significant difference between Group III and Group IV (preemptive analgesia with bupivacaine alone) with respect to this parameter. There were no significant differences among the four medicated groups with respect to mean total numbers of PCA demands or mean numbers of PCA boluses delivered; however, Groups I through IV all had significantly lower values for PCA demands and PCA boluses delivered than Group C ($P < 0.001$ for all). Similarly, there were no significant differences among the four medicated groups with respect to mean values for cumulative morphine dose at 0 to 4, 4 to 12, and 12 to 24 hours, or total morphine received in the first 24 hours. However, the control group had significantly higher values for all these parameters than the treated groups ($P < 0.001$ for all). The medicated groups also had statistically similar mean hospitalization times, whereas the mean hospital stay for Group C was significantly longer ($P < 0.001$ for all).

The VAS and VER scores for the five groups are shown in Tables 3 and 4, respectively. For each of the five groups, the mean pain scores during movement (VAS_M and VER_M) at 1, 4, 8, and 16 hours postsurgery were all significantly higher than the corresponding pain scores at rest ($P < 0.05$ for all). The mean VAS_M scores at 1, 4, 8, and 16 hours in the two groups that received preemptive analgesia (Groups III and IV) were significantly lower than the corresponding means in the other three groups ($P < 0.05$ for all). Compared with the other three groups, the preemptive analgesia groups had significantly lower mean VER_M scores at 1, 4, 8, and 16 hours ($P < 0.05$ for all). The mean VAS_R scores for Group III at 1 and 4 hours were significantly lower than the corresponding means in Groups I, II, and C ($P < 0.05$ for all). Similarly, the mean VER_R scores for Group III at these 2 time points were significantly lower than the corresponding values for Groups I, II, and C ($P < 0.05$ for all).

For all five groups, the mean Ramsay sedation score at each postoperative time point evaluated was 2 (cooperative).

The numbers of patients who developed postoperative nausea in Groups I, II, III, IV, and C were 5, 6, 1, 5, and 9, respectively. The control group had a significantly higher frequency of nausea than all other groups ($P < 0.05$ for all). The group incidence rates for postoperative vomiting were statistically similar.

■ Discussion

In our study, all four groups of lumbar discectomy patients who were treated with bupivacaine or bupivacaine-methylprednisolone (by preemptive or preclosure wound infiltration) showed significantly better results than the control group for most parameters. The treated groups had lower parenteral opioid requirements after surgery, lower incidences of nausea, and shorter hospital stays. Further, the data indicate that, compared with infiltration at wound closure, preemptive injection of bupivacaine or bupivacaine-methylprednisolone into muscle near the operative site provides more effective analgesia after lumbar discectomy.

Table 2. Results for Time to First Analgesic Demand, No. of PCA Demands, No. of Boluses Delivered, Morphine Consumption, and Length of Hospital Stay in the 5 Study Groups

	Group I (n = 15)	Group II (n = 15)	Group III (n = 15)	Group IV (n = 15)	Group C (n = 15)
First analgesic requirement (min)	48.3 ± 22.4*	44.6 ± 21.2*	68.3 ± 22.5†‡	57.3 ± 13.7*	32.3 ± 16.7
PCA demands (n)	13.5 ± 9.2†	14 ± 10.8†	10.2 ± 7.2†	10.6 ± 6.3†	33.1 ± 22.7
PCA boluses (n)	6.1 ± 2.5*	6.4 ± 3.2*	5.2 ± 2.8*	6.7 ± 3.1*	13.2 ± 6.4
Mean cumulative morphine at 0–4 hr (mg)	2.1 ± 1.9†	2.4 ± 1.4†	1.6 ± 1.5†	2.2 ± 1.6†	5.6 ± 2.1
Mean cumulative morphine at 4–12 hr (mg)	4.3 ± 1.8†	4.6 ± 1.7†	3.5 ± 2.1†	3.9 ± 1.9†	7.5 ± 1.4
Mean cumulative morphine at 12–24 hr (mg)	6.5 ± 2.7†	7.2 ± 2.7†	6.2 ± 1.8†	6.8 ± 3.2†	12.2 ± 3.6
Total morphine consumption at 24 hr (mg)	12.8 ± 3.1†	13.4 ± 2.3†	11.2 ± 3.1†	13.2 ± 4.1†	26.4 ± 4.1
Hospital stay (hr)	18.6 ± 2.3*	19.1 ± 1.7*	18.1 ± 2.2*	18.2 ± 1.6*	22.8 ± 1.3

Data are mean ± SD. PCA = patient-controlled analgesia.
*$P < 0.05$, compared with Group C.
†$P < 0.001$, compared with Group C.
‡$P < 0.01$, compared with Groups I and II.

Table 3. The VAS_M and VAS_R Scores in the First 24 Hours After Surgery

	Group I (n = 15)	Group II (n = 15)	Group III (n = 15)	Group IV (n = 15)	Group C (n = 15)
VAS_M 1 hr	3.4 ± 1.9	3.6 ± 2.2	2.7 ± 2.3*	2.4 ± 2.3*	4.6 ± 2.8
VAS_M 4 hr	2.8 ± 2.1	2.6 ± 1.9	0.8 ± 1.3*	1.4 ± 1.8*	2.6 ± 2.8
VAS_M 8 hr	2.4 ± 1.7	1.8 ± 1.7	0.2 ± 0.7*	0.5 ± 0.9*	1.3 ± 1.2
VAS_M 16 hr	0.9 ± 1.7	0.9 ± 1.2	0*	0*	0.6 ± 0.9
VAS_M 20 hr	0.2 ± 0.6	0.3 ± 0.8	0	0	0.1 ± 0.5
VAS_M 24 hr	0.1 ± 0.7	0.2 ± 0.7	0	0	0
VAS_R 1 hr	2.2 ± 0.5	1.3 ± 1.3	0.4 ± 1.0†	0.8 ± 1.7	2.6 ± 2.1
VAS_R 4 hr	0.6 ± 0.9	0.8 ± 1.3	0†	0.2 ± 1.1	0.8 ± 1.5
VAS_R 8 hr	0.3 ± 0.7	0.4 ± 0.9	0	0	0
VAS_R 16 hr	0.1 ± 0.5	0.2 ± 0.2	0	0	0
VAS_R 20 hr	0	0	0	0	0
VAS_R 24 hr	0	0	0	0	0

Data are mean ± SD. VAS_M = visual analogue score during movement; VAS_R = visual analogue score at rest.
*$P < 0.05$, Groups III and IV compared with Groups I, II, and C.
†$P < 0.01$, Group III compared with Groups I, II, and C.

In line with our results, Mullen and Cook[13] found that preemptive administration of bupivacaine to the incision site in patients who underwent lumbar laminectomy significantly reduced postoperative lumbar pain. Considering this effect, they concluded that this treatment can diminish the negative psychological impact of lumbar surgery.

Glasser *et al*[14] studied 32 test subjects who underwent lumbar microdiscectomy. Group 1 (12 patients) received 160 mg intramuscular Depo-Medrol (methylprednisolone acetate) and 250 mg intravenous Solu-Medrol (methylprednisolone sodium succinate) at the start of the operation. A macerated fat graft soaked in 80-mg Depo-Medrol was placed over the affected nerve root following discectomy. In addition, 30 mL of 0.25% bupivacaine was injected into the paraspinal musculature at the time of incision and also during closure. Group 2 (10 patients) received the same systemic steroid injections and had the paraspinal musculature infiltrated with 30 mL of 0.25% bupivacaine at both time points as well. However, in this group, a saline-soaked fat graft was placed over the affected nerve root. Group 3 (10 patients) acted as a control group and underwent lumbar microdiscectomy without corticosteroids or bupivacaine. The authors assessed postoperative pain scores at 24 hours, 1 week, and 1 month after surgery. At 24 hours, 44% of the patients in Group 1 exhibited total pain palliation, 14% of those in Group 2 showed this response, and none of the controls showed total palliation. Comparisons of pain scores at 1 month revealed no significant differences among the three groups; however, levels of patient satisfaction were higher in Group 1. In our study, we found that pain after lumbar discectomy was best controlled in the group that received preemptive local intramuscular injection of 40 mg steroid in addition to bupivacaine. It is significant that this effect was achieved without systemic steroid administration, as this means that the potential problems with systemic steroid can be avoided while achieving good analgesia.

Another study by Mirzai *et al*[15] investigated 44 lumbar discectomy patients. Group 1 (22 patients) had 20 mL 0.9% saline injected into the paravertebral muscles and subcutaneous tissues, and Group 2 (22 patients) received 20 mL 0.25% bupivacaine at these sites. All treatments were received preclosure. In Group 2, a piece of autologous fat was taken from the wound site, soaked in 40 mg of methylprednisolone for 10 minutes, and then placed over the exposed nerve root. The steroid that re-

Table 4. VER_M and VER_R Scores in the First 24 Hours After Surgery

	Group I (n = 15)	Group II (n = 15)	Group III (n = 15)	Group IV (n = 15)	Group C (n = 15)
VER_M 1 hr	1.4 ± 0.6	1.3 ± 0.7	1.1 ± 0.8*	0.8 ± 0.6*	1.7 ± 0.8
VER_M 4 hr	1 ± 0.6	1 ± 0.5	0.3 ± 0.4*	0.6 ± 0.6*	1 ± 1.1
VER_M 8 hr	0.9 ± 0.5	0.8 ± 0.5	0.2 ± 0.2*	0.2 ± 0.4*	0.6 ± 0.4
VER_M 16 hr	0.4 ± 0.6	0.4 ± 0.5	0*	0*	0.3 ± 0.4
VER_M 20 hr	0.2 ± 0.3	0.1 ± 0.3	0	0	0.2 ± 0.2
VER_M 24 hr	0.1 ± 0.3	0.1 ± 0.2	0	0	0
VER_R 1 hr	1 ± 0.7	0.6 ± 0.5	0.2 ± 0.4†	0.4 ± 0.6	0.8 ± 0.7
VER_R 4 hr	0.5 ± 0.7	0.4 ± 0.5	0†	0.2 ± 0.2	0.4 ± 0.6
VER_R 8 hr	0.2 ± 0.4	0.2 ± 0.4	0	0	0
VER_R 16 hr	0.2 ± 0.2	0.2 ± 0.2	0	0	0
VER_R 20 hr	0	0	0	0	0
VER_R 24 hr	0	0	0	0	0

Data are mean ± SD. VER_M = verbal pain score during movement; VER_R = verbal pain score at rest.
*$P < 0.05$, Groups III and IV compared with Groups I, II, and C.
†$P < 0.01$, Group III compared with Groups I, II, and C.

mained after the soaking process was also flushed into the wound. Visual analog scale pain scores were recorded for the first 12 hours after surgery, and Group 2 showed trends toward lower mean scores than Group 1 at all time points. This somewhat lower pain might have been related to the methylprednisolone-soaked fat pieces that were applied in Group 2. However, in our study, throughout the first 16 hours after surgery, both groups that received preemptive treatment (either bupivacaine alone or bupivacaine-methylprednisolone) had significantly lower VAS and VER scores during movement than the other three groups. As well, there were no significant differences between the two preemptively treated groups with respect to VAS and VER scores (at rest or at movement) during the first 24 hours after surgery. This suggests that the added methylprednisolone infiltration had minimal impact on postoperative pain.

One of the main factors that determines efficacy of analgesia is the time to first requirement for supplemental analgesia. Hernandez-Palazon *et al*[16] assessed the efficacy of three different injections into paraspinal musculature and subcutaneous tissue at wound closure after lumbar discectomy. Group I (15 patients) received 30 mL of 0.25% ropivacaine, Group II (15 patients) received 30 mL of 0.25% bupivacaine, and Group III (15 patients) received 30 mL of saline solution. Supplementary postoperative analgesia with intramuscular ketorolac (an NSAID) was made available. The authors found that the mean time to first request for supplemental analgesia was significantly longer in Group II (bupivacaine) than in Group I or Group III (164 ± 53 minutes, 68 ± 31 minutes, and 38 ± 14 minutes, respectively). In line with these results, we observed that the mean times to first PCA demand in our groups that received bupivacaine or bupivacaine-steroid (either preemptively or at wound closure) were significantly longer than the corresponding result for the control group.

Numerous studies[14,17,18] have demonstrated that wound infiltration with local anesthetics and/or different forms of cortisone for lumbar discectomy can reduce requirements for rescue analgesics in the postoperative period. However, our results specifically indicate that administering local anesthetics (alone or combined with steroid?) to paravertebral and cutaneous-subcutaneous tissues at the time of incision (preemptively) offers the best pain relief after this operation.

None of our patients developed side effects typically associated with corticosteroid usage, such as gastrointestinal hemorrhage, gastritis, delayed wound healing, or Cushing's syndrome. As Glasser *et al*[14] indicated, the likelihood of such adverse effects occurring in this setting is low because only a small steroid dose is administered.

■ Conclusion

Preemptive administration of bupivacaine or bupivacaine-methylprednisolone to the paravertebral muscles in patients who undergo lumbar discectomy provides effective analgesia, starting immediately after the operation. These individuals experience significantly less pain in the early postoperative period compared with patients who receive no local anesthetic or steroid. Preemptive infiltration with bupivacaine or bupivacaine-methylprednisolone offers no advantage over preclosure, administration with respect to hospitalization time, or supplemental opioid requirements. In addition, our data suggest that preemptive infiltration of the wound site with bupivacaine alone provides similar pain control to preemptive infiltration of the wound site with bupivacaine and methylprednisolone combined.

■ Key Points

- A prospective, randomized, controlled study was conducted to assess the efficacy of certain methods of pain control after lumbar discectomy. The main focus was preemptive wound infiltration with bupivacaine or bupivacaine-methylprednisolone.
- All 4 treatment groups (preemptive or preclosure wound infiltration with bupivacaine or bupivacaine-methylprednisolone) had significantly lower pain scores and significantly lower total morphine consumption than the control group (saline infiltration only).
- Preemptive analgesia with bupivacaine or bupivacaine-methylprednisolone effectively reduces pain after lumbar discectomy.

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