

# Comparative Analysis of Epidural Fentanyl and Conventional Analgesia in Single-Level Fenestration Lumbar Discectomy: A Randomized Controlled Study.

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## Abstract:

**Background:** Lumbar disc prolapse is a common cause of back pain, frequently requiring surgery. Post-operative pain following single-level fenestration lumbar discectomy can be moderate to severe, lasting up to 72 hours. This study aimed to evaluate the efficacy of intra-operative epidural fentanyl infiltration for post-surgical analgesia.

**Methods:** A randomized controlled trial was conducted between November 2017 and February 2018. Sixty patients undergoing single-level fenestration discectomy were randomly assigned to receive either intra-operative epidural fentanyl (1 mcg/kg, n=30) or placebo (n=30). Post-operative pain was assessed using the Visual Analog Scale (VAS) at specified intervals over 72 hours. Time to mobilization and rescue analgesia requirements (IV tramadol) were recorded.

**Results:** The fentanyl group demonstrated a statistically significant reduction in VAS scores at the first post-operative hour ( $p=0.02$ ). While the fentanyl group exhibited a numerically earlier time to mobilization (18.4 hours vs. 19.6 hours), this difference was not statistically significant ( $p>0.05$ ). No significant adverse effects were observed in either group.

**Conclusion:** Intra-operative epidural fentanyl significantly reduced early post-operative pain following single-level fenestration lumbar discectomy. Although time to mobilization was numerically shorter in the fentanyl group, it did not reach statistical significance. The procedure was well-tolerated with minimal side effects.

## Introduction:

Lumbar disc prolapse, a prevalent condition characterized by the herniation of the intervertebral disc nucleus pulposus, stands as a major contributor to back pain and radicular symptoms, significantly impacting patient quality of life. When conservative management fails to provide relief, surgical intervention, specifically lumbar discectomy, becomes a necessary recourse. Amongst the various surgical techniques, single-level fenestration lumbar discectomy, a minimally invasive approach, has gained traction due to its reduced tissue trauma, shorter hospital stay, and potentially faster recovery. However, despite its advantages, post-operative pain management remains a critical challenge. The immediate post-surgical period following lumbar discectomy is often marked by moderate to severe pain, primarily localized to the surgical site. This pain, typically peaking within the first 24-48 hours and persisting for up to 72 hours, can significantly impede patient mobilization, prolong hospital

stay, and increase the reliance on opioid analgesics, which are associated with a spectrum of adverse effects. Effective pain control is paramount not only for patient comfort but also for facilitating early ambulation, minimizing complications, and optimizing functional recovery. Traditional post-operative pain management strategies often rely on systemic opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and local anesthetics. While these approaches can provide some degree of pain relief, they are not without limitations. Systemic opioids, while potent analgesics, carry the risk of respiratory depression, nausea, vomiting, constipation, and potential for addiction. NSAIDs, on the other hand, can lead to gastrointestinal complications and renal impairment, particularly in elderly patients or those with pre-existing comorbidities. Local anesthetics, while effective for localized pain, may have limited duration and require repeated administration. In this context, the search for alternative and more effective pain management strategies has led to the exploration of epidural analgesia. Epidural administration of analgesics offers several advantages, including targeted drug delivery to the spinal cord, reduced systemic exposure, and the potential for prolonged pain relief. Fentanyl, a potent synthetic opioid with a rapid onset and short duration of action, has emerged as a promising candidate for epidural analgesia in the post-operative setting. The rationale behind using epidural fentanyl in single-level fenestration lumbar discectomy lies in its ability to provide localized analgesia at the level of the surgical site, minimizing systemic side effects. By administering fentanyl directly into the epidural space during surgery, it is hypothesized that the onset of post-operative pain can be attenuated, leading to improved patient comfort, earlier mobilization, and reduced reliance on rescue analgesia. Previous studies have explored the efficacy of epidural fentanyl in various surgical procedures, including abdominal and orthopedic surgeries. However, its specific role in single-level fenestration lumbar discectomy remains relatively underexplored. While some studies have suggested potential benefits, others have yielded conflicting results, highlighting the need for further investigation. The current study aims to address this knowledge gap by conducting a randomized controlled trial to evaluate the efficacy of intra-operative epidural fentanyl infiltration on post-surgical analgesia following single-level fenestration lumbar discectomy. By comparing the outcomes of patients receiving epidural fentanyl with those receiving placebo, this study seeks to provide evidence-based insights into the potential benefits and limitations of this approach. Specifically, this study will assess the primary outcome of post-operative pain intensity, as measured by the Visual Analog Scale (VAS), over a 72-hour period. Secondary outcomes will include time to mobilization, the requirement for rescue analgesia (IV tramadol), and the incidence of adverse events. By meticulously documenting these parameters, the study aims to provide a comprehensive evaluation of the safety and efficacy of epidural fentanyl in this specific surgical context. The findings of this study have the potential to significantly impact clinical practice by providing evidence-based guidance on the optimal management of post-operative pain following single-level fenestration lumbar discectomy. If epidural fentanyl proves to be effective, it could offer a valuable alternative to traditional pain management strategies, leading to improved patient outcomes and reduced healthcare costs. Moreover, this study will contribute to a deeper understanding of the mechanisms underlying post-operative pain and the role of epidural analgesia in modulating these processes. By elucidating the benefits and limitations of epidural fentanyl in this specific surgical setting, this study will pave the way for future research aimed at optimizing pain management strategies and improving the overall quality of care for patients undergoing lumbar discectomy.

## Materials and Methods:

**Study Design and Ethical Considerations:** This study was an open-label, randomized controlled trial conducted between November 2017 and October 2018. Approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. All participants provided written informed consent.

**Participants:** Patients presenting to the orthopedics outpatient department with a diagnosis of single-level intervertebral disc prolapse were considered for inclusion. Inclusion criteria included: age  $\geq 18$  years, clinical and radiological evidence of single-level lumbar disc herniation, and planned single-level fenestration lumbar discectomy. Exclusion criteria included: multilevel disc prolapse, pathological spine fractures, scoliosis, kyphosis, failed back surgery syndrome, procedures requiring instrumentation, and refusal to provide informed consent.

**Randomization and Blinding:** Eligible patients were randomly assigned to one of two groups using simple randomization: Group A (control) and Group B (fentanyl). While the study was open-label, the group allocation was concealed from the patients and the primary investigator responsible for post-operative assessments. The operating surgeon, however, was aware of the group allocation to administer the intervention.

**Surgical Procedure:** All surgical procedures were performed using a standardized single-level fenestration lumbar discectomy technique. The same incision and surgical approach were used for all patients.

### Intervention:

- **Group A (Control):** Patients received 2 ml of 0.9% normal saline (placebo) injected into the epidural space before wound closure.
- **Group B (Fentanyl):** Patients received an intra-operative epidural fentanyl bolus at a dose of 1 mcg/kg body weight, administered before wound closure.

All patients received 1 gram of intravenous paracetamol 30 minutes before the end of the procedure or before wound closure. This was followed by 1 gram of intravenous paracetamol every 8 hours for the first 24 hours post-operatively. Intra-operative analgesia was managed at the discretion of the anesthetist.

### Post-Operative Assessment:

- **Pain Assessment:** Post-operative pain was assessed using the Visual Analog Scale (VAS) at 4, 8, 12, 24, and 48 hours post-surgery.
- **Time to Mobilization:** The time taken for patients to mobilize after surgery was recorded.
- **Rescue Analgesia:** The requirement for rescue analgesia (50 mg intravenous tramadol) was recorded. Rescue analgesia was administered if the post-operative VAS score exceeded 5.
- **Adverse Effects:** The incidence of adverse effects, including respiratory depression, pruritus, and urinary retention, was monitored.

**Statistical Analysis:** Data was collected using structured proformas and VAS scoring charts, and entered into Microsoft Excel. Descriptive statistics were performed, with results presented as mean values and percentages. Continuous variables were analyzed using the unpaired t-test and the Mann-Whitney U test. Categorical variables were analyzed using the Fisher's exact test and the Chi-square test. A p-value of  $<0.05$  was considered statistically significant, representing a 95% confidence interval. Results were presented using appropriate tables and graphs.

## Results:

**Demographic Data:** The mean age of participants in the placebo group was 46.6 years (standard deviation: 8.6 years), while the mean age in the fentanyl group was 45.7 years (standard deviation: 8.1 years). The study included a total of 37 males and 23 females. In the placebo group, there were 19 males (63.3%) and 11 females (36.7%). In the fentanyl group, there were 18 males (60%) and 12 females (40%).

**Post-Operative Pain (VAS Scores):** A statistically significant difference in post-operative Visual Analog Scale (VAS) scores was observed between the placebo and fentanyl groups at the first post-operative hour ( $p = 0.02$ ). The mean pre-operative VAS scores were 5.93 in the placebo group and 6.03 in the fentanyl group. No statistically significant differences in VAS scores were found between the groups at any other time points assessed.

**Rescue Analgesia:** Five patients (16.7%) in the placebo group required rescue analgesia, compared to seven patients (23.3%) in the fentanyl group. There was no statistically significant difference in the need for rescue analgesia between the two groups. The earliest time for rescue analgesia administration was six hours post-surgery for both groups.

**Urinary Retention:** Six patients (20%) in the placebo group and seven patients (23.3%) in the fentanyl group required catheterization due to urinary retention. There was no statistically significant difference in the incidence of urinary retention between the two groups ( $p > 0.05$ ).

**Time to Mobilization:** The mean time to mobilization was 19.6 hours in the placebo group and 18.4 hours in the fentanyl group. This difference was not statistically significant.

## Discussion:

This randomized controlled trial investigated the efficacy of intra-operative epidural fentanyl in single-level fenestration lumbar discectomy. Our findings revealed a statistically significant reduction in post-operative pain, as measured by VAS scores, at the first hour following surgery in the fentanyl group compared to the control group. However, this difference did not persist at later time points. Additionally, while the fentanyl group exhibited a numerically shorter time to mobilization, this difference did not reach statistical significance. The observed reduction in early post-operative pain in the fentanyl group aligns with the established mechanism of action of epidural fentanyl. As noted, epidurally administered local anesthetics and opioids exert their effects primarily at the ventral and dorsal spinal roots, resulting in selective sensory blockade.

The rapid onset of fentanyl's action, coupled with its short duration, likely explains the transient reduction in pain observed in the first hour post-surgery. This is consistent with previous reports highlighting the 1-3 hour duration of action of epidural fentanyl. Our finding of a statistically significant reduction in VAS scores at the first hour post-operatively, but not at later time points, is consistent with the short duration of action of fentanyl. This is also supported by Jason H.H. Chan et al. who showed significant reduction in pain at 2, 4 and 24 hours post operatively. However, our findings differ in the duration of effect. This difference can be attributed to the dosage of fentanyl and the timing of administration. The lack of statistically significant difference in rescue analgesia requirements between the two groups contrasts with some previous studies that reported a reduction in rescue analgesic use with intrathecal fentanyl or morphine. This discrepancy might be attributed to differences in study design, patient populations, and the specific analgesics used. For instance, studies using intrathecal morphine, which has a longer duration of action, have shown more pronounced reductions in rescue analgesia compared to epidural fentanyl. Furthermore, the variability in post-operative pain management protocols across studies could also contribute to these differences. The incidence of urinary retention was similar between the two groups, and no other significant adverse effects, such as respiratory depression or pruritus, were observed. This finding is consistent with previous studies that have reported a low incidence of side effects with epidural fentanyl. The absence of respiratory depression, even with fentanyl, may be related to the low dose used and the targeted delivery. The finding of no significant difference in urinary retention is consistent with Jason H et al. The numerically shorter time to mobilization in the fentanyl group, although not statistically significant, suggests a potential clinical benefit. Early mobilization is a crucial factor in post-operative recovery, and even small reductions in time to mobilization could contribute to improved patient outcomes. The lack of statistical significance might be due to the relatively small sample size or the influence of other factors, such as individual patient variability and post-operative rehabilitation protocols. Several limitations of this study should be acknowledged. First, the open-label design could have introduced bias, particularly in the assessment of subjective outcomes such as pain intensity. Second, the study focused on single-level discectomy, limiting the generalizability of the findings to multilevel procedures or those involving instrumentation. Third, the study did not evaluate the impact of pre-operative chronic pain or concurrent analgesic use on post-operative outcomes. Future studies should address these limitations by employing blinded designs, including patients undergoing multilevel procedures, and exploring the influence of pre-operative factors on post-operative pain management. In conclusion, intra-operative epidural fentanyl effectively reduced early post-operative pain following single-level fenestration lumbar discectomy. While the time to mobilization was numerically shorter in the fentanyl group, it did not reach statistical significance. The procedure was well-tolerated with minimal side effects. Further research is warranted to investigate the long-term effects of epidural fentanyl and to explore its efficacy in more complex surgical procedures.

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