

RESEARCH ARTICLE

Does Intra-Operative Posterior Facet Steroid Injection in Lumbar Laminectomy Decreases Post-Operative Low Back Pain? A randomized Clinical Trial

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Abstract

Objectives: The complexity of low back pain, involving factors like nerve compression and facet arthritis, prompts exploration of additional interventions, such as facet joint steroid infiltration during laminectomy, to potentially enhance post-operative pain relief in spinal stenosis patients.

Methods: This is a multicenter prospective randomized study. Patients were randomly allocated into two groups, one receiving a 2-ml injection of 80mg/2ml methylprednisolone acetate into the facets intraoperatively (n=25), the other receiving no injection (n=25). The Oswestry Disability Index (ODI) and Numeric Rating Scale (NRS) were collected at baseline, and at 1 week, 1 month, and 3 months post-operatively.

Results: Fifty patients were included, 25 in the control group and 25 in the infiltration group. The ODI significantly improved from baseline (32.6 ± 8.6) at 7 days (25.1 ± 7.4), 1 month (19.8 ± 9.9) and 3 months (17.0 ± 10.9) post-operatively in both the control and infiltration group. The NRS significantly improved from baseline at 7 days (2.7 ± 1.9), 1 month (1.7 ± 2.5) and 3 months (1.5 ± 2.5) post-operatively in both groups. No statistically significant difference was noted in ODI or NRS between the two groups at baseline or any of the follow-up timepoints.

Conclusion: Our research indicates that combining steroid infiltration of the facet joints with simple laminectomy does not provide significant advantages beyond possibly expediting recovery. Studies with larger sample sizes are needed to reach the best conclusions for patients with lumbar spinal stenosis.

Level of evidence: I

Keywords: Facet articulation, Laminectomy, Lumbar spinal stenosis, Steroid infiltration

Introduction

Low-back pain is the most common cause of activity limitation in people under 45, affecting 60% to 90% of adults at some point in their lives.^{1,2} This pain is divided into two main categories: acute low-back pain and chronic low-back pain. In fact, chronic low-back pain is the most significant contributor to long-term disability, significant healthcare expenditure and considerable societal costs.³ Lumbar stenosis is one of the most common entities leading to chronic low back pain, affecting around 11% of the elderly population in the USA. Research indicates that approximately 20% of people aged over 60 have evidence of spinal stenosis on imaging.⁴

Surgical management is often necessary for spinal stenosis. One must note that pain accompanying lumbar stenosis can be caused by nerve compression as well as other entities such as posterior facet osteoarthritis, highlighting the complexity of low back pain.^{5,6} The posterior facets was shown to have free and encapsulated nerve endings, as well as nerves containing P substance and calcitonin gene-related peptide (CGRP), both of which are nociceptive neurotransmitters.⁷

Studies have demonstrated a significant reduction in low-back pain of facet origin after corticosteroid injection, regardless of the severity of osteoarthritis.^{8,9} Since facet

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osteoarthritis may contribute to the low back pain seen in patients with lumbar stenosis, it might be beneficial to perform an intra-operative steroid injection in the apophyseal joint during laminectomies. Therefore, our study aims to explore the benefits of facet joint steroid infiltration during laminectomy, to determine whether it can improve post-operative pain for patients with spinal stenosis.

Materials and Methods

Study Design

This is a multicenter prospective randomized study that included patients operated on by simple lumbar laminectomy for spinal stenosis from July 2022 to January 2024. Patients were included if they 1) were aged from 18 to 80 years, 2) had a clinical and radiographic diagnosis of lumbar spinal stenosis, 3) and consented to comply with all aspects of study protocol, methods, and data provision during follow-up. Patients were excluded if they underwent posterior instrumentation, had a history of previous spinal surgery, have an active infection, had other causes of low-back pain (e.g. cancer, rheumatic disease, etc.), and if they were participating in any other ongoing studies.

Included patients were randomly allocated into two groups (en bloc randomization was performed with 4 patients being in each bloc), one receiving a 2-ml injection of 80mg/2ml methylprednisolone acetate into the facets intraoperatively, the other receiving no injection. The exposure of the facet joints is done routinely. Therefore, the injection can be done without any need for ultrasound guidance or fluoroscopy. The study was approved by the local ethics committee (CEHDF2059) and was completed in accordance with the Declaration of Helsinki.

Data Collection

The following information including age, gender, number of surgical levels, operative time and intraoperative bleeding volume were collected peri-operatively. In addition, the Oswestry Disability Index (ODI) and Numeric Rating Scale (NRS) were collected at baseline, and at 1 week, 1 month, and 3 months post-operatively.

Statistical Analysis

The data have been analyzed using the SPSS 26.0 software (SPSS Inc., Chicago, IL, USA). Continuous data was reported as mean and standard deviation. Categorical data was reported as numbers and percentages. A general linear model for repeated measures test was used to compare the same population at different post-operative times. The Student t-test with independent samples and the χ^2 test were used to compare the two intervention groups. A linear regression model was done to try and predict the ODI and NRS at 1 week, 3 months, and 6 months post-operatively by controlling for the injection and the numbers of decompressed levels. A p -value ≤ 0.05 was considered as the threshold for statistical significance.

Results

Demographics and surgical characteristics

Fifty patients were included, 25 in the control group and 25 in the infiltration group. The mean age of the cohort was 66.7 ± 13.3 years with 46% females and 54% males. No statistically significant difference was noted in age, or gender between the two groups. Furthermore, there was no statistically significant difference in the numbers of levels treated and estimated blood loss between the two groups. However, the intervention group had a shorter OR time (Control: 128.0 ± 45.7 , Infiltration: 84.4 ± 23.2 minutes, $p=0.003$) [Table 1]. There were no immediate complications in any of the groups.

Table 1. Baseline demographics and characteristics of the two groups.

Variable	Control (n=25)	Infiltration (n=25)	P-Value
Age (years) (mean \pm SD)	66.8 \pm 12.5	66.7 \pm 14.4	0.98
Gender (% females)	44 %	48 %	0.72
Number of levels treated (mean \pm SD)	2.1 \pm 1.0	1.9 \pm 0.9	0.60
	4% 4 levels (L1-L5)	24% 3 levels (L2-L5)	
	20% 3 levels (L2-L5)	36% 1 level (L4-L5, L5-S1)	
	20% 1 level (L4-L5, L5-S1)	40% 2 levels (L1-L3, L3-L5, L4-S1)	
	56% 2 levels (L1-L3, L3-L5, L4-S1)		
Estimated blood loss (ml) (mean \pm SD)	152.0 \pm 75.4	118 \pm 59.1	0.18
Operative room time (min) (mean \pm SD)	128 \pm 45.7	84.4 \pm 23.2	0.003

Patient-Reported Outcomes [Figure 1]:

Oswestry Disability Index

At baseline, mean ODI was 32.6 ± 8.6 . The ODI significantly improved from baseline (32.6 ± 8.6) at 7 days (25.1 ± 7.4), 1 month (19.8 ± 9.9) and 3 months (17.0 ± 10.9) post-operatively in both the control and infiltration group [Table 2]. In fact, in the control group, the generalized linear model showed that ODI improved significantly at 7 days ($p=0.021$) and decreased further at 3 months when compared to 1-month values ($p=0.05$). In the infiltration group, ODI

improved significantly at 7 days ($p=0.06$) and decreased further at 1 months when compared to 7-days values ($p=0.005$). However, the ODI values did not differ significantly between 1 and 3 months ($p=0.15$). Furthermore, when comparing the two cohorts, no statistically significant difference was noted in ODI at baseline or any of the follow-up timepoints [Table 3]. In addition, both the numbers of decompressed levels and the injection were not shown to be significant in the linear regression model trying to predict ODI at 1 week, 3 months,

and 6 months post-operatively.

Numeric Rating Scale

At baseline, mean NRS was 6.4 ± 2.1 . The NRS significantly improved from baseline at 7 days (2.7 ± 1.9), 1 month (1.7 ± 2.5) and 3 months (1.5 ± 2.5) post-operatively in both the control and infiltration group [Table 2]. In fact, in both groups, the generalized linear model showed that NRS improved significantly at 7 days, but did not significantly

change at other time-points. Furthermore, when comparing the two cohorts, no statistically significant difference was noted in NRS at baseline or any of the follow-up timepoints [Table 3]. In addition, both the numbers of decompressed levels and the injection were not shown to be significant in the linear regression model trying to predict NRS at 1 week, 3 months, and 6 months post-operatively.

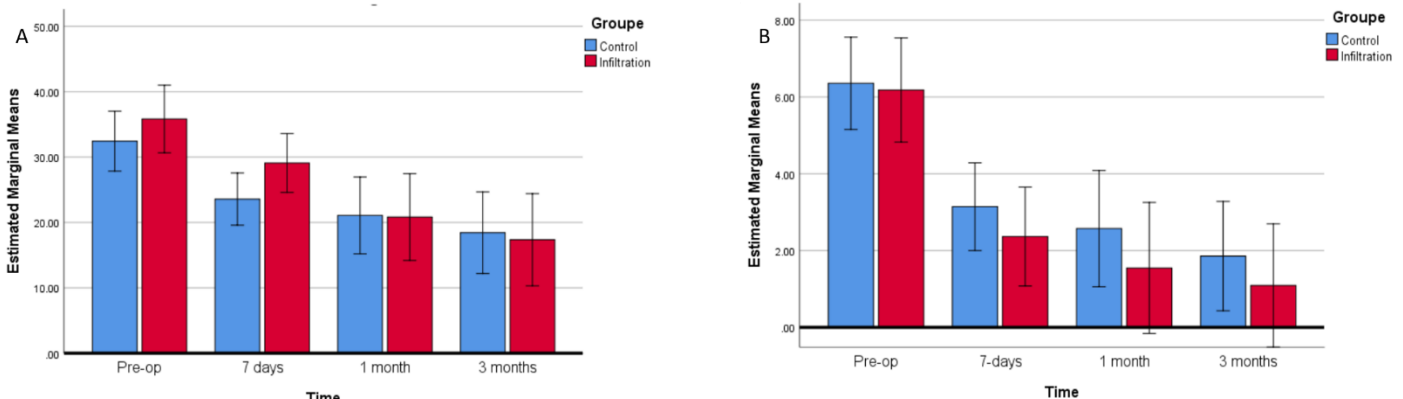


Figure 1. Mean values of ODI (A) and NRS (B) at different timepoints for both groups

Table 2. Improvement in patient-reported outcomes post-operatively

Variable	Timepoint	Control (n=25)	P-Value	Infiltration (n=25)	P-Value
Oswestry Disability Index (mean±SD)	Baseline	32.8 ± 9.1	-	32.4 ± 8.3	-
	7 days	23.6 ± 8.5	0.021	26.5 ± 6.1	0.06
	1 month	20.7 ± 11.8	0.005	18.9 ± 8.0	0.003
	3 months	17.7 ± 13.5	0.003	16.2 ± 7.3	0.001
Numeric Rating Scale (mean±SD)	Baseline	6.6 ± 2.1	-	6.3 ± 2.1	-
	7 days	3.1 ± 2.3	0.002	2.4 ± 1.3	0.002
	1 month	2.3 ± 3.0	0.015	1.1 ± 1.7	<.001
	3 months	1.9 ± 3.0	0.003	1.0 ± 1.8	<.001

Table 3. Comparative analysis of patient-reported outcomes between the two groups.

Variable	Timepoint	Control (n=25)	Infiltration (n=25)	P-Value
Oswestry Disability Index (mean±SD)	Baseline	32.8 ± 9.1	32.4 ± 8.3	0.89
	7 days	23.6 ± 8.5	26.5 ± 6.1	0.25
	1 month	20.7 ± 11.8	18.9 ± 8.0	0.61
	3 months	17.7 ± 13.5	16.2 ± 7.3	0.72
Numeric Rating Scale (mean±SD)	Baseline	6.6 ± 2.1	6.3 ± 2.1	0.64
	7 days	3.1 ± 2.3	2.4 ± 1.3	0.30
	1 month	2.3 ± 3.0	1.1 ± 1.7	0.15
	3 months	1.9 ± 3.0	1.0 ± 1.8	0.40

Discussion

One of the main goals of spinal surgery is to alleviate postoperative pain and completely avoid the occurrence of failed back surgery syndrome.¹⁰ The surgeon's responsibility is to find the best means and tools for immediate optimal analgesia and long-term remission. Given the difficulty of this task, this study, the first of its kind, was done with the aim of

improving and developing analgesic techniques in lumbar spinal surgery. As mentioned, low back pain can result from several concomitant causes, making the determination of a single etiology complex. Thus, one hypothesis has been put forward: patients suffering from a lumbar spinal stenosis may also have a latent facet syndrome. Therefore, by treating

both lumbar spinal stenosis and facet syndrome simultaneously in these patients, we could expect both post-operative and long-term benefits.

No disparities were observed in bleeding and level of surgery between the two groups. However, it is important to note that operative time was significantly longer in the control group that did not receive infiltration (Control: 128.0 ± 45.7 , Infiltration: 84.4 ± 23.2 minutes, $p=0.003$). This could be explained by surgeon heterogeneity, given that the operative time for the same procedure depends on the surgeon.¹¹⁻¹⁴ Furthermore, the number of levels operated on showed no significant difference between the two groups, reinforcing our interpretation that this variability is surgeon-dependent.

In addition, we found that the Oswestry Disability Index (ODI) and Numerical Pain Scale (NRS) scores of both groups improved significantly post-operatively. This improvement was particularly noticeable after one week (7 days) post-op. This improvement is linked to the initial reference point, which is the patient's condition prior to surgery.¹⁵ Indeed, within the control group, the generalized linear model revealed a noteworthy improvement in ODI at the 7-day mark ($p=0.021$), followed by a further decrease at the 3-month assessment compared to values observed at 1 month ($p=0.05$). Conversely, in the infiltration group, there was a significant improvement in ODI at 7 days ($p=0.06$), with a subsequent decrease at 1 month compared to the 7-day measurement ($p=0.005$). Notably, within the infiltration group, there was a marked acceleration in ODI improvement. This leads us to consider that the infiltration may hasten the recovery process by resolving inflammation and completing the cicatrization process faster when compared to the control group.

Furthermore, the results of our study revealed no significant difference in either ODI or NRS between the infiltration group and the second group without infiltration. Several factors could explain these results. First, our sample of patients included in the study is relatively small. Second, not all patients have the same perception of pain. This perception is linked to many factors, including genetics.¹⁶ In addition, not all patients undergoing laminectomy have a facet syndrome that would benefit from infiltration. Moreover, even in the presence of osteoarthritis of the posterior facet joints, corticosteroid infiltration only has an effect if the patient is in the midst of an osteoarthritis crisis, as in the case of glenohumeral osteoarthritis or advanced gonarthrosis.^{17,18} Therefore, at this stage, we do not have a definitive recommendation for the use of this infiltration during laminectomy. Especially since corticosteroid infiltration can have a number of side-effects, such as increased risk of infection at the surgical site, accelerated bone loss at the site, para-spinal muscle damage and even increased radicular

pain.¹⁹⁻²¹ Note that a patient, in the infiltration group, developed a failed back syndrome 6 months after the procedure with synovial cysts in the infiltrated facet joints.

Strengths and limitations

This study has several strengths. It is the first study in the literature to explore this analgesic modality in the context of laminectomy. This pilot study has the potential to open up new perspectives and bring improvements to the design of postoperative analgesia for spine surgery. However, it should be noted that the limitations of the study lie in the number of participants, which did not exceed 25 patients in each group.

Conclusion

Our research suggests that utilizing steroid infiltration of the facet joints alongside simple laminectomy does not confer any clear benefit aside from speeding up recovery. Both groups, regardless of whether they received the infiltration or not, experienced improvement, particularly within the first week, with continued progress during subsequent check-ups. Therefore, based on our study findings, we recommend further investigation into this topic with larger patient populations to draw definitive conclusions regarding the efficacy of this infiltration method.

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