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Epidural Steroid Facet Joint Injections Augment the Outcomes of Percutaneous Lumbar Spinal Fixation for Post-discectomy Failed Surgery through Local Immunomodulation

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ABSTRACT

Background: Surgical management of spinal disc disease is still questionable due to the high incidence of recurrence of pain and disability. **Aim of the study:** Evaluation of the outcomes of combined screw and rod spinal fixation with epidural steroid injection versus spinal fixation only.

Patients and Methods: Patients previously had back surgery, and presented with recurrent, persistent, or exaggerated back pain with increased disability and disturbed quality of life, drew preoperative blood samples for ELISA estimation of serum levels of tumor necrosis factor-α (TNF-α), and interleukins (IL) 1β, 6, and 10. These biomarkers were re-estimated at 6 months after surgery. Patients were divided into two groups: Group A received spinal fixation alone, and Group B received the combined procedure.

Results: At 6 months after surgical correction, the assessments of clinical scoring and serum inflammatory markers improved markedly, and the immune milieu disturbances were adjusted relative to the preoperative status. These changes were markedly evident in patients who received the combined procedures compared to those who received fixation only. Additionally, the extent of change in the estimated levels of serum biomarkers positively correlated with that reported in clinical scores.

Conclusion: The applied synchronous spinal fixation and epidural injection therapy ensured to be an effective procedure for the mitigation of the recurrent, persistent, or exacerbated manifestations of failed back surgery. This effect outperformed the effects of spinal fixation alone. The noticed better performance of the combined therapy might be attributed to the remodulation of the detected immune deregulation.

Keywords: Spinal fixation, Epidural injection therapy, Persistent manifestation after lumbar spinal surgery, Proinflammatory cytokines.

INTRODUCTION

Laminectomy is a commonly performed surgical procedure aimed at reducing back pain and disability through nerve decompression. Despite this target, surgery-induced excessive fibrosis in the epidural space induces recurrence or persistence of pain in a respectable number of patients; a condition termed as Failed Back Surgery Syndrome (FBSS) **(1)**.

The management of FBSS is debatable and must be selective for each patient, taking into account the deficient evidence for clinical outcomes **(2)**. Minimally invasive procedures for back surgery are advantageous through the minimization of operation-associated bleeding and the reduction of the need for postoperative analgesia and length of hospital stay. These advantages could predict better surgical outcomes with early resumption of daily activities and return to work **(3)**. Screws act as a rigid and stable anchor point that are bridged and connected with a rod as part of a construct for gripping the spinal segment to get spinal fusion **(4)**. Neuroimmune modulation through the suppression of pro-inflammatory and increased anti-inflammatory cytokines might mitigate epidural inflammation and fibrosis through MAPK-related signaling with subsequent modulation of the activity of microglia and astrocyte activity, to lessen epidural fibrosis [(5)]. The efficacy of facet joint injections of corticosteroid and local anesthetic relies on the pharmacological effects of the injected steroid that acts through modulation of the local immune milieu with subsequent resolution of the inflammatory edema that might relieve the nerve compression [(6)].

Objectives

Estimation of serum cytokine levels before and after epidural steroid injection for patients undergoing spinal fixation surgery for failed back surgery.

PATIENTS AND METHODS

Fifty patients with persistent pain and disability after lumbar discectomy were divided randomly into two groups. The control group included 25 patients who received spinal fixation only, and the study group included 25 patients who received epidural steroid and local anesthetic after spinal fixation.

Procedures

Surgical procedure was performed under general inhalational anesthesia, as previously described by **Mobbs *et al.* (7)**, using percutaneous insertion of screws and rods to stabilize the adjoining vertebrae. A 20-gauge Touhy needle was inserted approximately 2-3 cm into the interspinal ligament slowly into the epidural space, and 2 ml triamcinolone 40 mg/ml and 1500 IU hyaluronidase were injected [(8)].

Investigations

All patients drew two blood samples, preoperatively and at three months after surgery. The

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blood samples were collected, centrifuged and serum was collected and freeze at -80ºC till be ELISA assayed for estimation of serum levels of human tumor necrosis factor-α (TNF-α), interleukin (IL) 6, IL-1β, and IL-10 using Abcam ELISA kits (Cat. No. ab179886, ab46042, ab46052 and ab215089), Abcam Inc., at Cambridge, USA, by quantitative sandwich enzyme immunoassay technique.

Evaluation Tools

The measures were applied before surgery, immediately before hospital discharge, and every month for six months. These tools included:

1. Pain visual analogue scale to assess pain severity on 0-10 scale with zero indicated no pain.
2. Oswestry Low Back Pain Disability Questionnaire to evaluate the severity of pain-induced disability. This questionnaire examined ten activities; each was scored on a five-point scale, with five indicating severe disability for a total disability score of 50. The Oswestry Disability Index (ODI) is the result of multiplying the net patient's score by 100 and two to present the ODI severity as a percentage. The resultant ODI score indicated increasing severity with an increased score by twenties.
3. The analgesic requirements were graded according to the type of medication used, with no medication being graded by zero, using over-the-counter medication being graded by one, and by two for responding to non-opioid medications. Using opioid medications was graded by 3 or 4 according to the frequency of receiving and the type of opioid.
4. Surgical results were evaluated by the use of Odom's criteria. Excellent when the presenting manifestations disappeared, and Good if minimal residual complaints were detected. The outcome was fair when there was definite improvement of the presenting manifestations without detecting any improvement of other manifestations. Otherwise, it was defined as poor when no change or exacerbation of preoperative symptoms and signs was reported.
5. Satisfaction with outcomes was evaluated with a 10-point scale, with a higher score indicating higher satisfaction.

Ethical Considerations

This study was conducted after approval from the Research Ethics Committee of the Faculty of Medicine, Al-Azhar University, Egypt. All participants provided written informed consent prior to inclusion. The consent form clearly stated the study objectives, procedures, potential risks, and the right to withdraw at any time without affecting their medical care. It also included explicit consent for the use and publication of anonymized clinical and laboratory data while maintaining strict confidentiality and privacy. The research was performed in full accordance with the ethical principles of the Declaration of Helsinki and its subsequent amendments for studies involving human subjects.

RESULTS

Thirty-six males and fourteen females aged between 45 and 70 years were included in this study. Their mean age was 61.3±5.7 years. All patients were of average weight or obese grade I, with a mean BMI of 39.7±8.5; 26.3-33.5 kg/m^2. The duration elapsed between the primary surgery and presentation was in the range: 24-54 months. The duration lag before presentation after pain recurrence was 10±2.1 months. The majority of patients had 2-3 affected segments and mostly at the level of L4-S1.

The applied combined procedure improved outcomes of patients of the study group with marked differences compared to patients in the control group, with significantly higher percentage of improvement regarding pain and ODI scores. Interestingly, patients' distribution according to requesting pain medication changed marvelously, with a noticeably high percentage of patients who experienced decreased requirements and lower scores for requesting (Table 1).

Table 1: Outcome data of patients of both groups determined at the end of 6-m postoperative

Parameter		Group	Control	Study	P value
Pain score	Preoperative		6.76±0.78	6.92±1.04	0.541*
	6-m PO		2.28±0.46*	1.48±0.51*	<0.001*
Change in pain score at 6-m PO			51.72% [42.27-57.14]	66.7% [50-80]	0.00005*
ODI Score	Preoperative		33.2±6.2	30.92±5.52	0.176*
	6-m PO		16.52±2.86*	14.48±2.45*	0.0094*
Change in ODI score at 6-m PO			48.3% [37.3-57.4]	57.6% [44.3-64.3]	0.0045*
Pain medications	Requirement	Decreased	3 (12%)	12 (48%)	0.021†
		No change	15 (60%)	9 (36%)	
		Increased	7 (28%)	4 (16%)	
	Score at 6-m PO		1.52±0.85	1±0.57	0.014*

PO: Postoperative; P: indicates the significance of intergroup differences using the Unpaired t-test*, and Chi-square test†

Preoperative serum levels of the studied cytokines showed negligible intergroup differences. Serum levels of TNF-α, IL-1β, and IL-6 decreased noticeably at 6-m PO compared to preoperative levels in both groups. The intergroup differences regarding these biomarkers were significant. Concerning serum IL-10, its level in the withdrawn samples decreased significantly for the study group, but was insignificantly different for the control group with significant intergroup difference in favor of the study groups (Table 2).

Table 2: Serum levels of studied cytokines estimated at the end of the study phases

Biomarker	Time Group	Control	Study	P value
TNF-α (pg/ml)	Preoperative	63.112±8.13	68.432±2.126	0.466
	6-m PO	44.184±9.6	29.58±7.59	0.008
	P1 value	0.008	<0.001	
	% of change	26.91±1.72	42±7.1	<0.001
IL-1β (pg/ml)	Preoperative	7.61±1.56	7.47±1.13	0.835
	6-m PO	5.63±1.49	4.75±1.18	0.025
	P1 value	0.0017	0.00007	
	% of change	18.6±4.4	28±1.8	0.0008
IL-6 (pg/ml)	Preoperative	5.168±1.63	5.354±1.74	0.698
	6-m PO	4.3±1.52	3.53±0.94	0.038
	P1 value	0.057	0.00003	
	% of change	9.9±2.25	25±5.6	<0.001
IL-10 (pg/ml)	Preoperative	13.12±3.81	13.57±3.23	0.694
	6-m PO	15.12±3.84	20.34±5.05	0.0005
	P1 value	0.111	<0.0001	
	% of change	7.38±1.56	22.38±5.8	<0.0001

TNF-α: Tumor necrosis factor-α; IL: Interleukin; r: Pearson's coefficient; P indicates the significance of the coefficient

The percentage of change in pain and ODI scores was positively correlated to the percentage of change of serum TNF-α, and IL-10 in both groups, but the correlation coefficient was more noticeable in patients of the study group than in the control group. Regarding the percentages of change in serum IL-6, it showed significant correlation with that in pain score in both groups, while was significant with change in ODI score in the study, and insignificant in control group. Additionally, the correlation between the percentage of change in serum levels of IL-1β and that of pain scores was insignificant in both groups. Also, the correlation of the change in serum IL-1β levels was significant with the extent of change in ODI scores in the study, not in the control group (Table 3).

Table 3: Correlation analysis of the percentage of change in pain and ODI scores and that of the estimated serum cytokines' levels at the end of 6-m follow-up

Dependent variables	Group Independent variables		Control		Study	
			r	p	r	p
Percentage of change in pain score	Percentage of change of serum levels of	TNF-α	0.578	0.002	0.537	0.006
		IL-1β	0.290	0.159	0.344	0.092
		IL-6	0.432	0.031	0.729	<0.001
		IL-10	0.438	0.029	0.425	0.034
Percentage of change in ODI score	Percentage of change of serum levels of	TNF-α	0.400	0.047	0.476	0.016
		IL-1β	0.300	0.145	0.415	0.039
		IL-6	0.189	0.365	0.419	0.037
		IL-10	0.411	0.041	0.544	0.005

ODI: Oswestry Low Back Pain Disability Questionnaire; TNF-α: Tumor necrosis factor-α; IL: Interleukin; r: Pearson's coefficient; P: indicates the significance of the calculated Pearson's coefficient

The distribution of patients among the outcome and satisfaction with the outcome grades showed a significantly higher difference between both groups in favor of the study group (Table 4).

Table 4: Patients' distribution according to Outcome and Satisfaction grading

Variables	Group	Control	Study	P value
Odom's criteria	Excellent	3 (12%)	9 (36%)	0.022
	Good	8 (32%)	12 (48%)	
	Fair	10 (40%)	3 (12%)	
	Poor	4 (16%)	1 (4%)	
Satisfaction scoring	Very satisfied	10 (40%)	18 (72%)	0.029
	Satisfied	8 (32%)	6 (24%)	
	Dissatisfied	7 (28%)	1 (4%)	
	Very dissatisfied	0	0	

DISCUSSION

The study outcomes indicated the efficacy of using spinal fixation, as a solo procedure or with epidural injection, as an appropriate therapeutic strategy for patients who had post-surgical recurrence of back and/or leg pain. These outcomes provide evidence for those of earlier studies that dealt with similar patients [9-13]. In addition to the previous findings, the results of spinal fixation combined with epidural injection were significantly better than those of spinal fixation alone as a treatment for patients with recurring, persistent, or worsened back pain and disability after previous spinal surgeries. The increased effectiveness of the combined epidural injection and spinal fixation reflects the synergistic effect of local steroid injection alongside spinal fixation. These findings support earlier research that documented the benefits of using the epidural injectate for managing chronic back pain in patients with prior spinal surgeries [14]. Additionally, **Rapčan *et al.*** [15] and **Ceylan *et al.*** [16] reported marked resolution of pain in legs and back for a duration of 12 months after the epiduroscopic injection of a combination of hyaluronidase and steroid as adjuvant therapy to the mechanical lysis of epidural adhesions and fibrosis. The detected improvements with the epidural injection therapy were explained according to the published findings reported that the enzymatic activity of hyaluronidase allows medications to spread within the extracellular matrix through the breakdown of polysaccharides in the interstitial space [17].

The reported effectiveness aligns with **Arsanious *et al.*** [18], who found the combination therapy of pulsed radiofrequency followed by thermal radiofrequency improved the outcome of patients who had persistent chronic back pain. Also, **Do *et al.*** [19] in a comparative study, documented better analgesia with the intra-articular radio-frequency than by epidural injection of steroid for chronic back pain. **Chen *et al.*** [20] reported significant improvement in disability and pain scores and quality of life with subsequent improvements in patients' daily activities.

Additionally, previous studies documented that the sustained relieving effect of nerve ablation for a duration of 1-2 years after RF. Thereafter, **Ibrahim *et al.*** [21] found ablation of the sensory nerve branches along S1-3 lateral foramina and L4-S1 medial branches is a minimally invasive procedure that significantly relieved lumbar back pain for 24 months. Recently, **Speldewinde** [22] reported a sustained success rate of 69% in reducing sacroiliac ligament/joint complex pain, with improvements in physical and psychological function, for 12 months after thermal ablation using radio-frequency. Further, previous studies supported the safety of the applied procedures without complications or motor weakness [23,24].

The assessment of the obtained outcome was graded as excellent to good by the majority of patients, with considerable intergroup differences. Similarly, **Woiciechowsky and Richter** [25] reported that radio-frequency neuro-ablation for chronic back pain provided acceptable outcomes in 68% of patients with about fifty percent decrease of pain sensation and weakness of the walking ability with increased average walking distance of about eight meters. **Arıcı and Kılıç** [26] also documented that thermal radio-frequency is a safe and effective strategy and provided better than good results for about seventy percent of patients for a duration of about one year.

Failed spinal surgery is associated with higher immune deregulation than levels estimated in samples of healthy volunteers. The reported markedly elevated metrics of inflammatory cytokines, with highly decreased serum levels of anti-inflammatory cytokine, and increased IL-10, supported the previous assumption of considering recurrence of back pains. Additionally, in support of this suggestion, the detected preoperative immune deregulation was remodulated at the end of follow-up with decreased levels of the proinflammatory cytokines with increased levels of the anti-inflammatory cytokines. Moreover, the demonstrable differences between serum levels of these cytokines in patients who received the epidural injection synchronously with the spinal fixation than in patients who received only spinal fixation, illustrated the anti-inflammatory effects of epidural steroid injection

The reported modulation of the inflammatory milieu indicates a possible role of dysregulation in the inflammatory milieu in the initiation and maintenance of the primary disc disease. Furthermore, these outcomes suggest the possibility that disturbed levels of cytokines are a pathogenic mechanism inducing surgical failure. Furthermore, the reported significant correlations between the extent of change in serum cytokines and in pain and disability scores support the

provided explanations. Moreover, the findings of multiple preclinical studies provided support for the obtained results and the provided attribution.

CONCLUSION

The applied synchronous spinal fixation and epidural injection therapy provided evidence for its safety and effectiveness to improve patients who had recurrent, persistent, or exacerbation of back pain after spinal surgery. This effect outperformed the effects of spinal fixation alone. The noticed better performance of the combined therapy might be attributed to the remodulation of the detected immune deregulation.

RECOMMENDATIONS

The marvelous outcome of the combined therapy allowed recommending it as a safe and effective treatment for the primary spinal disorders.

LIMITATION

The short duration of follow-up is a study limitation.

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