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Comparison of fluoroscopy guided inter-laminar epidural platelet-rich plasma versus steroid injection in patients with lumbar radicular pain

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***Abstract*---**Background: Radicular back pain is one of the prevalent causes for low back pain. Objective: The aim of work is to compare the efficacies of fluoroscopic guided inter-laminar epidural injection of platelet-rich plasma (PRP) and epidural steroids in improving lumbar radicular pain. Settings and Design: This study was a prospective randomized controlled clinical trial. Methods: Forty-eight patients were enrolled in this study and divided into two groups. Steroid group (S); A 24 patient, that received fluoroscopic guided inter-laminar epidural injection of 1ml methylprednisolone (40mg/ml) + 4 ml normal saline and platelet rich Plasma group (p); A 24 patients, that received fluoroscopic guided inter-laminar epidural injection of 4.5 ml PRP + 0.5 ml PRP activator (calcium gluconate). Patients were followed up at one week, 4 weeks, and 3 months after the procedure. Results: No differences between study groups as regard pain scores at

pretreatment, after 1 and 4 weeks and 3 months of treatment and disability scores at pretreatment, after 4 weeks and 3 months of treatment. Steroid group had statistically significant lower mean values of cortisol after 1-week was 2.14 ± 0.95 versus 11.35 ± 6.21 where PRP group had statistically significant higher serotonin level after 4 weeks of treatment was 138.58 ± 30.82 vs. 121.85 ± 21.00. Conclusion: For the management of persistent radiculopathy, fluoroscopy guided inter-laminar epidural injection of platelet-rich plasma was comparable to steroid injection. However, inter-laminar epidural injection of platelet-rich plasma could be a safer option as it is associated with less complications and higher patient's satisfaction.

***Keywords*---**fluoroscopy, inter-laminar injection, platelet rich plasma, steroid, lumbar pain.

Introduction

Since LBP affects more than 80% of the global population, it has continuously been one of the most frequent reasons for functional impairment and absence from work. Lumbar radiculopathy, which has a prevalence of between 9.9% and 25%, is a prevalent diagnosis of LBP. Acute lumbosacral radiculopathy is a multi-root disease condition that causes motor dysfunction, loss of sensation, and pain of various intensities. Fluoroscopy-guided epidural steroid injection is a widely used treatment for persistent lumbar radiculopathy; nonetheless, it is associated with infrequent but serious consequences [1].

Platelet-rich plasma could be a different and possibly safer approach because it has been demonstrated recently to supply cytokines and growth factors which support healing and the anti-inflammatory process [2]. The aim of our work was to compare the efficacy of fluoroscopic guided interlaminar epidural injection of platelet-rich plasma (PRP) and epidural steroids in improving lumbar radicular pain.

Patients and Methods

This randomized controlled clinical trial was conducted at Anaesthesia and Surgical Intensive Care Department, Faculty of Medicine, Alexandria University Hospitals from October 2021 until October 2023.

During this study, 48 patients having complaints of lumbar radicular pain syndrome for more than 4 weeks duration with a positive Straight Leg Raising Test (SLRT) and not responding to the conventional treatment were enrolled, after consenting each of them and divided into two groups; steroid group (S) that included twenty-four patients received fluoroscopic guided inter-laminar epidural injection of 1ml methylprednisolone (40mg/ml) + 4 ml normal saline and platelet rich Plasma group that included twenty-four patients received fluoroscopic guided inter-laminar epidural injection of 4.5 ml PRP + 0.5 ml PRP activator (calcium gluconate). Patients were followed up at one week, 4 weeks, and 3 months after the procedure. Efficacy of fluoroscopic guided inter-laminar epidural injection of

platelet-rich plasma (PRP) and epidural steroids in improving lumbar radicular pain according to visual analogue score, modified Oswestry disability questionnaire, objective assessment of pain (serotonin level), patient's satisfaction and complications of intervention.

Outcomes

Primary

The efficacy of fluoroscopic guided interlaminar epidural injection of platelet-rich plasma (PRP) and epidural steroids in improving lumbar radicular pain according to visual analogue score and modified Oswestry disability questionnaire.

Secondary

- Comparison according to objective assessment of pain (serotonin level).
- Assessment of patient's satisfaction.
- Recording any complications and dealing with them accordingly.

Sample size

Systematic random sampling and cases fulfilled the inclusion criteria were randomly assigned to either group. A total of 48 opaque envelopes were serially numbered, and the appropriate letter representing the assigned group was placed inside each envelope based on the randomization table. Next, each envelope was sealed and placed within a single box. Using MedCalc ® version 13, a computer-generated randomization sheet was used for the randomization process.

Statistical analysis

The statistical software for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA), was used to analyze the recorded data. When the distribution of the quantitative data was parametric (normal), it was shown as mean± standard deviation and ranges; for non-parametric (non-normally distributed) variables, it was shown as median with inter-quartile range (IQR). Quantitative variables were also shown as percentages and numbers. Using the Shapiro-Wilk and Kolmogorov-Smirnov tests, data were examined for normality.

Results

The patients' demographics data collected and show that there was no statistically significant difference between the study groups according to demographic data as, age "years," gender and medical history, with p-value ($p>0.05$).

Visual analogue score data collected and represented in table (I). This table shows that there was no statistically significant difference between study groups according to visual analogue score at pre, after 1wk, 4wks and 3 months, with p-value ($p>0.05$).

As regard modified Osewestry disability questionnaire; table (II) our study revealed that no differences between study groups as regard disability scores at pretreatment, after 4 weeks and 3 months of treatment. Cortisol level data collected and represented in table (III). This table shows statistically significant lower mean value of cortisol after 1wk. in S group was 2.14±0.95 comparing to PRP group 11.35±6.21, with p-value ($p<0.001$); while there was no statistically significant difference between study groups according to cortisol at pre cortisol and after 4wks., with p-value ($p>0.05$).

HgA1c level data collected and represented in table (IV). This table shows statistically significant higher mean value of HgA1c after 1wk and after 4 wks. in S group comparing to PRP group, with p-value ($p<0.05$); while there was no statistically significant difference between the study groups according to pre of HgA1c, with p-value ($p>0.05$).

Serotonin level data collected and represented in table (V). This table shows statistically significant higher mean value of serotonin level after 4wk. in PRP group was 138.58±30.82 comparing to S group was 121.85±21.00, with p-value ($p<0.05$); while there was no statistically significant difference between study groups according to serotonin level at pre and after 1wk., with p-value ($p>0.05$).

Short assessment of patient satisfaction data showed statistically significant higher frequency of very satisfied after 4wks. and after 3 months in PRP group compared to S group, with p-value ($p<0.05$); while there was no statistically significant difference between study group according to short assessment of patient satisfaction after 1wk., with p-value ($p>0.05$).

Complications data collected and represented in table (VI). There was a statistically significant higher frequency of complications in S group comparing was 6 patients (25%) comparing to S group was one patient (4.2%), with p-value ($p<0.05$)

Discussion

There is an insufficient of research on the use of orthobiologic treatments in LRP, despite the growing use of these therapies in orthopaedics, particularly for facet arthropathy, sacroiliac joint pain, and lower back pain caused by disc degeneration.

In agreement with our findings, Bise et al. (2020) observed that EPRPI is comparable to CT-guided epidural steroid injection (ESI) in treating chronic LRP and may even be a safer alternative. After six weeks, both groups showed a statistically significant improvement (mean NRS values of 5.7 (±2.36) after six weeks and 3.7 (±2.3) at D0). After six weeks, there was no discernible difference in the NRS score decline between the two groups. There were no significant issues found [3].

Numerous clinical trials have showed the effectiveness of injection of platelet –rich plasma intradiscally to improve radiculopathy caused by disc degeneration [4-7]. These studies also found that the injections' anti-inflammatory and healing

properties were associated with type 1 MODIC alterations [8-9]. Just two studies have been published in the literature that examined PRP as a treatment for sacroiliac joint pain [10–11]. For sacroiliac joint pain, Singla et al. (2017) [10] evaluate PRP injections and steroid injections, with encouraging outcomes at three and six months. Surprisingly, they observed very minor short-term adverse effects in the PRP group and a higher percentage of VAS decrease (≥50%) in the steroid group at two weeks compared to the PRP group. Likewise, Wu et al.'s study [12] provided evidence in favour of PRP as a long-term therapy for pain associated with arthropathy of the facet joint; at 3 and 6 months, PRP shown a greater degree of recovery than the steroid group, even if the steroid group outperformed PRP during the initial follow-up month.

In the literature, there is only one pilot study that specifically examined PRP for LRP in a very small population (n = 10), evaluating epidural platelet-rich plasma in LRP [13] due to a chronically prolapsed intervertebral disc. Significant clinical improvement was shown in the trial, and this improvement was maintained without any consequences at three months (NRS ≤ 5; Modified Oswestry Disability Questionnaire < 30%; Straight Leg Raising Test improved to > 70). This improvement was confirmed after a brief follow-up period of three weeks. The effectiveness of PRP derivatives for epidural delivery in LRP has been assessed in several investigations. Our results are in line with a 2007 study by Becker et al [14], which in a group of thirty-two patients with LRP, found no appreciable difference in pain and disability between epidural autologous conditioned serum (ACS) injections under radiograph control and steroid injections (10 mg or 5 mg triamcinolone) at 6 weeks. Nevertheless, from 12 to 22 weeks, they saw a consistent pattern of the ACS group being better than both triamcinolone groups in terms of pain score; the difference between the ACS group and the 5 mg triamcinolone group only became statistically significant at 22 weeks. It provides evidence for a tenable long-term impact of ACS on LRP. Similar results over ACS and LRP with a substantial favourable effect on pain, disability, and general health after three weeks, three months, and six months were reported by another small series (n = 20) [15]. Similar to PRP, the accumulation of cytokines and growth factors in ACS solution (such as insulin-like growth factor 1 and interleukine-1 receptor antagonists) has an anti-inflammatory impact because it competitively inhibits pro-inflammatory interleukine-1 receptors [17]. However, the application of ACS is rare and complex, with comparatively few human trials, due to the preparation of this solution being expensive, challenging, and requiring special equipment (i.e., a laminar airflow system and a 24-hour incubation period)[18]. Another rationale for using PRP to treat disco-radicular impingement is to inject a high concentration of platelets (≥ three times the patient's baseline blood concentration) into the impingement site to start the inflammatory process and promote healing. PRP is easier to prepare—it can be injected 30 minutes after centrifugation is finished—and produces a platelet concentrate with 50–80 alpha granules that contain more than 30 active proteins and peptides, including growth factors and cytokines that reduce inflammation. Actually, the platelets at the site of impingement form and coagulate ten minutes after the exogenous PRP injection, and within an hour, nearly all of the alpha-granule load—roughly 95%—has been discharged. [13]. In our investigation, leukocyte-poor PRP was employed to lessen leucocyte-related inflammation and catabolism [19]. Another PRP component that has been researched in LRP, platelet lysates, supports our

findings [20]. Furthermore, a number of studies have shown that PRP has a beneficial impact not only on inflammation but also on the healing process following nerve damage [21–22] and the decrease of neuropathic pain [23–24].

It is also important to note that PRP is a relatively new therapy and is typically not covered by insurance, which is a drawback. Depending on the facility, patient costs can differ significantly. In Europe, PRP treatment costs around twice as much as corticosteroid treatment [25].

There were no significant clinical side effects noted during the procedure or the brief follow-up. In the literature, the interlaminar technique associated with very rare ischemic complications [26] since, the posterior epidural space lacks an artery, and the risk of embolic complication is minimal with both PRP and steroid injection [27]. Bleeding and infection are the main neurosurgical complications from interlaminar ESI technique [28-29], and because PRP, which is made from the patient's own blood and has antibacterial properties, might be a safer alternative, particularly in cases where the patient is in the pre-operative stage [30-31] [32]. Moreover, EPRPI permits avoiding systemic side effect of steroid and there is a decrease in the chance of allergic reaction [33].

Conclusion

Fluoroscopy guided inter-laminar epidural injection of platelet-rich plasma was comparable to corticosteroid injection for treatment of persistent lumbar radiculopathy as regard degree of pain relief and disability measured by visual analogue score and modified Osewestry disability questionnaire respectively. However, inter-laminar epidural injection of platelet rich plasma could be a safer option as it is associated with less complications and higher patient's satisfaction.

Limitations

There were a limited number of cases with relatively smaller sample size relative to study outcomes.

Abbreviations

PRP: platelets rich plasma LRP: lumbar radicular pain ACS: autologous conditioned serum

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Table I: Comparison between S Group and PRP Group according to Visual analogue score

Visual analogue Score	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
Pre					
Median (IQR)	8 (7-9)	8 (7-9)	-0.496	0.622	NS
Range	6-10	6-10			
After1wk.					
Median (IQR)	2 (1-2)	3 (2-4)	-1.801	0.071	NS
Range	1-4	2-5			
After 4wks.					
Median (IQR)	2 (1-3)	2 (2-2)	0.161	0.873	NS
Range	1-4	1-4			
After 3 Months					
Median (IQR)	2 (2-3)	2 (1-3)	1.213	0.231	NS
Range	1-4	1-4			

Table II: Comparison between S Group and PRP Group according to Modified osewestry disability questionnaire

Modified osewestry disability questionnaire	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
Pre					
Mean±SD	49.33±7.68	49.00±5.21	0.176	0.861	NS
Range	40-68	40-56			
After 4 wks.					
Mean±SD	5.67±1.49	5.79±1.86	-0.256	0.799	NS
Range	4-8	1-8			
After 3months					
Mean±SD	5.58±1.64	5.92±1.61	-0.710	0.481	NS
Range	2-8	4-8			

Table III: Comparison between S Group and PRP Group according to Cortisol

Cortisol	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
Pre					
Mean±SD	14.08±4.06	11.46±8.24	1.397	0.169	NS
Range	7.4-21.2	2.81-39.4			
After 1wk.					
Mean±SD	2.14±0.95	11.35±6.21	-7.187	0.000	HS
Range	0.6-4.23	3.8-28.7			
After 4wks.					
Mean±SD	13.13±3.76	12.34±4.78	0.636	0.528	NS
Range	6.1-18.9	6.4-25.16			

Table IV: Comparison between S Group and PRP Group according to HgA1c

HgA1c	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
Pre					
Mean±SD	5.87±1.46	5.85±1.35	0.062	0.951	NS
Range	4.1-8.6	4.2-8.5			
After 1wk.					
Mean±SD	6.54±1.95	5.97±1.30	2.095	0.048	S
Range	4.3-9.9	4.2-8.6			
After 4wks.					
Mean±SD	7.08±2.50	5.92±1.06	2.748	0.021	S
Range	4.4-10.9	4.4-8.1			

Table V: Comparison between S Group and PRP Group according to Serotonin level

Serotonin level	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
Pre					
Mean±SD	82.65±15.83	88.30±19.28	-1.109	0.273	NS
Range	55.6-113.2	59.4-140.6			
After 1wk.					
Mean±SD	109.81±22.81	114.03±57.22	-0.336	0.739	NS
Range	77.9-170.1	70.6-370.1			
After 4 wks.					
Mean±SD	121.85±21.00	138.58±30.82	-2.196	0.033	S
Range	96.4-180.7	99.1-240.6			

Table VI: Comparison between S Group and PRP Group according to Complications

Complications	S Group (n=24)	PRP Group (n=24)	Test value	P-value	Sig
No	18 (75.0%)	23 (95.8%)	4.077	0.044*	S
Yes	6 (25.0%)	1 (4.2%)			
DM	*1 (4.2%)*	*0 (0.0%)*	1.008	0.315	NS
HTN	*2 (8.3%)*	*0 (0.0%)*	*2.035*	*0.154*	NS
Uncontrolled	*5 (20.8%)*	*1 (4.2%)*	*2.960*	*0.085*	NS