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Autologous Platelet Rich Plasma for Neck and Lower Back Pain Secondary to Spinal Disc Herniation: Midterm Results

Abstract

Background: Spinal disc herniation (HNP) can be a painful condition caused by a variety of traumatic events and degenerative conditions. It is one of the most common spine conditions in adults, occurring in both cervical and lumbar regions. Although these injuries are often associated with wear and tear (or degeneration), traumatic events such as automobile accidents or lifting injuries have been described as causes.

Methodology: We conducted a prospective, nonrandomized, single-center clinical study to evaluate the safety and midterm effectiveness of autologous platelet rich plasma injections (PRP) to treat neck and Low Back Pain (LBP) caused by spinal disc herniation (HNP). All patients had failed conservative treatment for 3 months to 6 months. The autologous PRP was performed using a table top centrifuge device and a standardized individual PRP preparation protocol method. Patients were followed annually for up to 8 years post-operatively. Pain status was documented using a visual analog scale self-reported measure, as well as the Oswestry disability score.

Results: Eighty-eight consecutive patients with spinal disc herniation (HNP) were enrolled; thirty-eight were treated for cervical disc herniation, thirty-eight for lumbar disc herniation, and twelve were treated for both cervical and lumber disc herniation. The duration of follow-up ranged from 4 months to 8 years (mean of 5 years). 87% of patients reported a successful outcome. Within the cervical group, the preoperative visual analog scale showed 81% improvement ($P \le 0.01$). For the lumbar patients, the preoperative visual analog scale improved by 77% ($P \le 0.01$). No complications were reported.

Conclusion: The results are durable with successful outcomes observed 8 years after procedure.

Keywords: Platelet rich plasma; Spinal injuries; Herniation; Lumbar; Cervical; Platelet Rich Plasma (PRP)

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Introduction

The literature is replete with evidence of an evolving view of the disease from a supernatural to a scientific basis [1]. The ancient Greeks and Egyptians began to take a more naturalistic view [2]. In the 20th century, German pathologist Christian Schmorl studied 10,000 spines and described his finding of disc protrusions as herniation. In 1932, Mixter and Barr are credited with the first operation of a ruptured disc diagnosis [3]. Later works, especially

by Weber and Hakelius, showed that many patients with (lumbar) disc herniation would improve without surgical intervention [3] another pivotal movement was the 2006 publication of the initial results of Spine Patient Outcomes Research Trial (SPORT) [4].

Herniated spinal disc is arguably the most common spinal disorder requiring surgical intervention [1]. Vulnerability of the lateral annulus in the flexed, compressed motion segment leads to disruption followed by circumferential tracking of nuclear material and results in either contained or uncontained extrusions

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in the posterior or posterolateral annulus. This highlights the complexity of the herniation process [5].

Conservative care for the treatment of spinal disc herniation has been well described and is often successful. Treatment consists of rest, ice, and activity modification acute phase. This can be followed with bracing, physical therapy, oral non-steroidal antiinflammatory drugs, topical applications, and injections of cortisone [1,3]. When conservative treatments fail, autologous PRP may be considered. The goals of PRP treatment of spinal disc herniation are pain resolution and a return to pre-injury function [6-9].

Platelet-rich plasma is an orthobiologic that has recently gained popularity as an adjuvant treatment for musculoskeletal injuries [10-18]. It is a volume of fractionated plasma from the patient's own blood that contains platelet concentrate. Autologous PRP injections were reportedly first used in 1987 in an open-heart surgery [19]. It was also used, over 20 years ago, in the dental field for promoting accelerated wound healing in cancer patients following jaw reconstruction. Physicians have used PRP to aid bone healing after spinal injury and soft tissue recovery following plastic surgery. PRP gained broad popularity in early 2009 when it was reported that two of the Pittsburg Steelers received PRP for their ankle injuries before their triumph at the Super Bowl [20,21].

PRP was a major initial step that led researchers to consider bone marrow aspirates and stem cells in the growing field of orthobiologics [10]. The role of PRP in the directed stimulation of musculoskeletal and mesenchymal stem cells is being widely investigated and shows promise as a short-term use agent that may assist in the simultaneous healing of several musculoskeletal tissues with trauma or elective surgery [6,14-16].

Based on the pioneering and long-term clinical experience of the oromaxillary field with PRP, and the thousands of patients being treated so far, the use of PRP is considered to be safe [22,23]. Since PRP is prepared from autologous blood, theoretically there are minimal risks for disease transmissions, immunogenic reactions or cancer [4]. In the musculoskeletal field, although no long-term outcome studies with PRP exist, a large number of patients have been treated worldwide [24-27]. In our review of the literature we did not come across RCT's that have comprehensively evaluated the safety of PRP treatment [10].

Materials and Methods

Patients

This was a prospective, nonrandomized, single-center clinical study. After receiving institutional review board approval, patients who were 18 years to 65 years of age with neck or back pain with or without radiation and a diagnosis of a confirmed spinal disc herniation with MRI imaging (Figures 1 and 2) were approached for enrollment. For inclusion, patients had to be symptomatic for at least 3 months to 6 months and had to have failed extensive conservative treatments. No operative treatment included activity modification, enrollment in a facility or home-based exercise program, bracing, oral non-steroidal anti-inflammatory medications, and cortisone injection. Candidates with confirmed or suspected pregnancy or with implanted instrumentation



Figure 1 Cervical disc herniation shown through MRI.



Figure 2 Lumbar disc herniation shown through MRI.

adjacent to the target were excluded. A single clinician performed a thorough medical history and clinical evaluation. The clinical follow-up and data collection were performed by an independent medical technician.

Clinical outcomes

Pain status was assessed by using a visual analog scale (VAS). Postoperative clinical assessment was conducted within the first 4 weeks to 6 weeks, at 6 months to 12 months, and up to 8 years postoperatively. The VAS scales were completed annually up to 8 years after the procedure.

The percent improvement of VAS score was calculated. This value represented the difference between the patient's preoperative and most recent VAS assessments. Failure of the procedure was defined as less than 50% improvement of the VAS score. **Tables 1-4** presents the VAS improvement for these patients after the autologous PRP. Pain status was also assessed by using the OSWESTRY disability scoring method for a total of thirty-six patients with a total of forty-two scores. The OSWESTRY scores were completed annually up to 8 years after the procedure.

The OSWESTRY disability score was calculated. This value represented the patient's total disability rating following the procedure. Failure of the procedure was defined at an OSWESTRY score over 35%.

Procedure

The senior author performed the procedures in this study. The patient was brought to the operating room and positioned prone. Standard sterile prep and drape were performed prior to

Table 1 Subjective improvement after autologous platelet-rich plasma injection.

VAS Score Improvement (Decrease)	Cervical	Lumbar
Excellent (≥ 88% decrease)	28	28
Good (75% to 87% decrease)	4	6
Fair (50% to 74% decrease)	13	8
Poor (≤ 50% decrease)	5	8

Table 2 The three-step process of PRP treatment.

Blood Collection \rightarrow PRP Prep \rightarrow Local Injection

Table 3 Subjective disability rating after autologous platelet -rich plasma injection.

OSWESTRY Disability Rating	Cervical	Lumbar
Excellent (0% to 10% Disability)	14	13
Good (11% to 25% Disability)	5	5
Fair (26% to 35% Disability)	2	1
Poor (≤ 35%)	1	1

Table 4 Summary of GF contained in PRP.

G-F	Fuction (among many others)
(TGF-β)	Stimulates undifferentiated mesenchymal cell (MSC) proliferation
(FGF)	Mitogenetic for MSC, chondrocytes, and osteoblasts
(PDGF)	Mitogeneteic for MSC and osteoblasts
(EFG) Epidermal	Stimulates endothelial chemotaxis or angiogenesis
(VEGF) Vascular endo.	Stimulates miotogenesis for endothelial cells
(CTGF) Connective tissue	Cartilage regeneration
(ILGF 1 and 2) Insulin- like	Chemotactic for fibroblasts and stimulates protein synthesis
(PF-4) Platelet factor	Chemo-attractant for fibroblast
(IL-8)	Pro-inflammatory mediator
(KGF) Keratinocyte	Promote endothelial cell growth, migration, adhesion, and survival

initiation of the procedure. We had previously, in the same setting, obtained sterile phlebotomy in order to perform an FDA approved centrifugation at high speed revolutions in order to obtain the autologous platelet rich plasma graft [28]. The patients then had fluoroscopic imaging to confirm the cervical or lumbar levels of the symptomatic area. The patients had the application of topical and local anesthetic injected only in the skin and subcutaneous tissue prior to the grafting. We used needle localization with fluoroscopic imaging to inject the area in a circumferential manner subfascially into the lateral masses, facet joints and lateral gutters and the inter and supraspinatus ligaments, Kambin's triangle, and spinous processes. The patients were awake throughout and were independently monitored by an anesthesiologist throughout. Aspiration technique was used to avoid any neurologic or vascular compromise or infiltration. Standard wound dressings were applied. In the immediate postop period, the patient was advised to use ice for 48 hours to 72 hours, avoid oral NSAID for 10 days to 14 days, and was advised to begin gentle active ROM exercises.

While avoiding heavy lifting and strenuous physical activity. Each patient was evaluated at 4 weeks postoperatively. At 4 weeks, patients were permitted to increase the intensity of their activities. Return to sports or heavy lifting was allowed once the patient was asymptomatic and had achieved full strength and range of motion; this typically occurred at 6 weeks to 9 weeks postoperatively.

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Statistical analysis

Normally distributed data were described using standard parametric statistics (i.e., mean and standard deviation); nonnormally distributed date was characterized using nonparametric descriptors (i.e., median and quartiles). Statistical evaluation of improvement in pain status was performed by calculating 99% confidence intervals and using the Student T test for change between subsequent time points. Use of confidence intervals provides a descriptive analysis of the observed treatment effect, while permitting determination of statistical relevance. In all statistical testing, confidence bounds not including 0 were considered statistically significant. Probability of $P \le 0.01$ for committing type 1 experiment-wise error (rejecting a true null hypothesis) was selected for all statistical testing because of our lack of control group, small sample size, and evaluation of multiple postoperative time points.

Results

Eighty-eight consecutive patients with spinal disc herniation were included in this study. Thirty-eight patients were treated for cervical disc herniation, thirty-eight were treated for lumbar disc herniation, and twelve were treated for both cervical and lumbar disc herniation. The average age of the patients was 50 years. The duration of follow-up evaluation ranged from 4 months to 8 years (mean 5 years).

Within the cervical group, 90% (45/50) of the patient reported a successful outcome. The postoperative VAS improved by 81%. The average OSWESTRY disability rating for the cervical group was 9%. Among the lumbar group, 84% (42/50) reported improvement in symptoms. The postoperative VAS improved by 77%. The average OSWESTRY disability rating for the lumbar group was 8.7%.

Discussion

For the treatment of spinal disc herniation, autologous plateletrich plasma injections are successful in 87% of patients. Symptomatic improvement was observed up to 8 years postoperatively. During this study, no complications were recorded; 13 treatment failures occurred. When compared with other techniques, the results with autologous PRP are equivalent or better.

Regardless of surgical methods and their reported success rate, complications are associated with spinal disc herniation surgery. Post-operative problems may include restricted function, spinal instability, headaches, vasovagal reactions, dural puncture, increased and persistent neck and back pain. Unlike the proposed mechanism of an epidural steroid injection, the effects

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of PRP occur despite indirect delivery and irrespective of the suspected pain generator. The traditional non-surgical treatment of cortisone injections offers the potential for less morbidity and symptom improvement. However, disadvantages of the cortisone injections include recurrence of the symptoms and increased need for multiple treatments. There has been a reported 16.8% incidence of complication per injection with fluoroscopically guided interlinear cervical epidural injections [29].

Different proposed mechanisms of action have been described to explain the favorable effects of the PRP, such as induced healing by an angiogenic response, inflammatory regulation, cellular stimulation, proliferation and differentiation, as well as tissue regeneration. These factors have been shown to be associated with healing [30-32].

This midterm follow-up of patients with symptomatic spinal disc herniation has shown that autologous PRP can produce successful, durable results. PRP is a technically simple procedure to perform and is associated with a rapid and uncomplicated recovery. It is safe and can effectively eliminate or markedly reduce clinical symptoms.

Limitations

Spinal disc herniation has been described as a self-limited disease, with resolution of symptoms with conservative treatment. This

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perspective challenges the indication of any proposed surgical or invasive treatment for the condition. Although the results of this research demonstrated the benefits of autologous PRP, there are inherent limitations of the study design. The study lacks a control group, and randomization would improve the strength of the study. Additional outcome measures, such as PROM could complement pain scores to provide more data. Postoperative histologic analysis of treated human tissue would be ideal, but ethical considerations limit study to animal models. An additional limitation is potential examiner bias. Data collection was performed by an independent medical technician, a third-party blinded evaluation could have been performed, but this was not feasible in a clinical setting.

Finally, limitations regarding the lack of description for the PRP variant based on platelet concentration, fibrin concentration, and leukocyte presence and activation status. This omission disadvantages a comprehensive PRP graft assessment. Further analysis of cost effectiveness of PRP is also warranted.

Conclusion

Autologous platelet-rich plasma is a safe and effective procedure for neck and back pain caused by spinal disc herniation. The results are durable with successful outcomes observed 8 years after procedure.

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