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Original Research Article

Efficacy of Platelet Rich Plasma Versus Steroid Infiltration in Management of Low Back Pain: A Prospective Randomized Control Study

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Abstract:

Background: Pain and other neurological symptoms are frequently linked to spinal illnesses including lower back pain, which have a detrimental effect on patients' quality of life. An autologous source of many growth factors and cytokines, platelet-rich plasma (PRP) has the ability to stimulate tissue regeneration. Therefore, the focus of the study is to examine the efficacy of PRP against the steroid infiltration in the management of the lower back pain.

Methodology: For the time duration of 2 years, this prospective randomized control trial will include a total of 110 (55 in each group). After the allocation of the PRP or steroid injection of Methyl Prednisolone, the data will be collected for the VAS score, Oswestry Low Back Disability score, EuroQoL- 5D Questionnaire and the post follow up will be taken at 1week, 1 month, 2 months, 3 moths and finally at 6 months.

Expected outcome: A significant finding in the efficacy of PRP against steroid infiltration among the low back patient is expected.

Keywords: Protein rich plasma, Spinal diseases, Low back pain, Quality of life, Methyl Prednisolone.

Introduction

Low back pain (LBP) is one of the most common disorders and a major cause of morbidity and economical loss in society. It is the 2nd most frequent cause of disability in adults and a significant contributing factor to the lack of physical activity among individuals under the age of 45. As a result, it ranks among the most expensive musculoskeletal disorders and contributes significantly to the burden of sickness on society.[1]

There are three categories for non-specific low back pain: sub-acute (lasts six weeks to three months), acute (lasts less than six weeks), and chronic (lasts more than three months). Instability at a particular motion segment or aberrant motion of the vertebral bodies are common causes of pain. Radicular symptoms, which includes radiating pain in the leg, sensory deficiencies, and neurologic lower limb abnormalities, such as diminished reflexes and motor weakness, should all be considered when evaluating individuals with LBP. This pathological process has several components. These include congenitally small neural foramen, facet arthropathy, ligamentum flavum hypertrophy, ossification of the posterior longitudinal ligament, ligament laxity and subluxation, and disc degeneration leading to herniation.[2]

Given that aging contributes to these degenerative processes, it makes reasonable to assume that as life expectancies grow globally, low back pain prevalence will also rise.[3] Patients with LBP may usually be treated conservatively with a combination of pharmacological as well as non-pharmacological therapy, despite the need for invasive or surgical therapies.[4] Conservative treatment includes bed rest, opioids, muscle relaxants, oral or parenteral steroids, acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), and therapeutic exercises.[4,5] If these are ineffective, lumbar or caudal epidural glucocorticoid injections may be administered to relieve pain. Surgery is required when conservative

methods fail to reduce discomfort or when neurological problems manifest.

Zygapophysial joints, also known as Z-joints, are the paired structures located at the back each of the vertebra (spinal column bone) and are known as facet joints. The facet joints operate as a functional motion unit that offers movement between two vertebrae, just as other joints in the body. The "lumbar" area refers to the lower back. Similar to the knee or shoulder joints, the lumbar facet joints are enclosed in a capsule which lubricates the moving parts. Facet-mediated pain, or zygapophysial pain, is responsible for 15–45% of pain in the low back cases; in patients over 65, this prevalence can reach 52%. Additionally, spondylolisthesis—which contributes to discogenic pain—can be made possible by degenerated facets. The dorsal rami's medial branches innervate these facet joints. It has been demonstrated that the primary mediator of increased neuronal excitability as well as sensitization is prostaglandin E2 (PGE2).

The two lumbar facet injection techniques used to treat lumbar facet pain are lumbar intra-articular injection and lumbar medial branch block. For the treatment of Lumbar Facet joint discomfort and lower back pain, new biological treatments are being researched. The use of platelet-rich plasma (PRP) is one such therapy. Platelets that have been concentrated and obtained from autologous blood are found in PRP. PRP proponents refer to it as a stopgap measure between conservative medicine and surgery. Growth factors and cytokines found in large quantities in platelets are thought to quicken the body's healing processes. Therefore, they could be helpful in treating the lumbar radiculopathy along with canal stenosis caused by irritated nerves. PRP is produced by sequestering platelets in the plasma fraction of autologous blood, which, when triggered by an external stimulation, releases a range of growth stimulants and mediators. Blood platelet counts typically vary from 150,000/μL to 350,000/μL. Conversely, platelet concentrations in PRP may reach up to 1,000,000/μL.[6] The practical definition of platelet-rich plasma is thought to be this concentration in five millilitres of autologous plasma.[7] However, in practical use, different amounts and concentrations are used. The advantages of platelet-rich plasma (PRP) are its autologous character, ease of preparation and acquisition, low invasiveness, and inexpressiveness. Therefore, PRP does not show any side effects that are usually associated with other widely used medications. This has thus inspired a number of medical professionals to use PRP in their clinics as a substitute for other more traditionally used intra-articular injectants such hyaluronic acids and corticosteroids (CS).[8] Because IFI raises the steroid concentration in the facet joint without causing the unfavourable side effects linked to systemic steroid injection, it has been employed as a therapy alternative. When there is evident paraspinal pain and a consistent compression pattern of coupled motion, the best current technique for diagnosing facet-related pain may have some merit. Traditionally, the best way to determine whether a patient has facet-related discomfort is to do a diagnostic injection using lidocaine.[9]

Biomechanism of Spine

There are three possible movements of the spine: flexion, extension, rotation, and lateral flexion. These movements incorporate translation and rotation in the sagittal, coronal, as well as horizontal planes of the motion. These movements apply compressive, tensile, shear, bending, and torsional forces to the sacrum and lumbar spine. During lumbar flexion, the front side of the disc experiences a compressive force while the posterior aspect experiences a distractive force. Lumbar extension produces opposing forces. The lumbar spine complex is a robust structure that can support weight. An external force delivered to the vertebral column stresses the relatively elastic disc and the stiff vertebral body, making the disc more prone to strain. There are very few studies that demonstrate the impact of steroid infiltration and platelet rich plasma on human tissues, much alone their therapeutic significance. Therefore, the aim of the study is to examine the effectiveness of PRP and steroid infiltration in treating the facet joint pains.

Methodology

This prospective randomized control study will be conducted among the patients who had a complaint of lower back pain in the Department of Orthopaedics, at Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Higher Education and Research, Wardha. A total of 110 patients (55 in each group, PRP and Steroid) will be examined during the time duration of 2 years. The following is the criteria for the selection of the patients:

Inclusion Criteria

- All Skeletally matured patients with either sex.
- Continuous or intermittent LBP for at least 3 months.

Exclusion Criteria

- Skeletally immature patients.
- Patient with infection, traumatic spine injuries, spinal tumours, spinal deformities, and congenital spinal anomalies.
- Pregnant women or women who are breast feeding.
- Operated cases of spinal fusion surgery.

Patients with lumbar spinal disc prolapse for nearly 3 months, who met the eligibility requirements were given detailed information about the treatment option and asked for their signed informed permission. Complete hemogram including ESR, coagulation profile, blood sugar, and X-ray spine (AP and lateral view) will be part of the diagnostic workup. Four hours prior to the surgery, patients shall be kept at zero per oral. The baseline Visual Analogue Scale (VAS) score, the Oswestry Low Back Disability score, the Neurological Examination of the Lower Limb before to the Procedure, and the EuroQoL-5D Questionnaire will all be documented. PRP was made using the patient's own blood in an aseptic environment. A little over 10 milliliters of the patient's blood will be drawn, centrifuged, and then 5 milliliters of platelet-rich plasma will be made at a blood bank. A single five millilitres injection of autologous PRP will be given in the epidural space using an 18G Tuohys needle in an interlaminar approach under close aseptic precautions, guided by fluoroscopic imaging. Following the surgery, all hemodynamic parameters shall be watched and recorded for the following thirty minutes, as well as for any potential issues, every five minutes. At all times, the results of the VAS, Oswestry Low Back Disability, and EuroQoL-5D questionnaires will be recorded. Additionally, a neurological evaluation of the lower limb will be performed, encompassing a motor assessment encompassing shape, tone, power, reflexes, as well as sensory examination.

An equal number of research participants will be divided into two groups, Group A and Group B, and will receive either steroid infiltration (Methyl Prednisolone injection 80 mg/ 2ML) or PRP infiltration. Methyl Prednisolone injection 80 mg/2ML will be administered as a steroid injection under arm supervision. The examiner alone will possess all the information on the filtering. The process will be done while the patients are blindfolded. Additionally, there will be post-follow-ups at one-week, one-month, two-month, three-month, and six-month intervals.

Preparation of PRP

During this standard double spin process, the patient provides 20 milliliters of recently drawn autologous venous blood. Subsequently, 4 EDTA test tubes containing 5 mL of blood each are centrifuged for 15 minutes at 2000 rpm. After the RBCs are removed and the plasma has settled in the upper portion of the test tube, it is collected in a new test tube and centrifuged once more for ten minutes at 1200 rpm. The lowest 2-4 mL layer of plasma contains platelet rich plasma (PRP), whereas the top buffy coat contains platelet deficient plasma (PPP).

The centrifuge is a simple, uncooled kind. Since balancing tubes are present, the centrifuge process is standard. Room temperature, or 2224°C, is used for the operation.

Statistical Methods

Descriptive, subgroup, and multivariate analytic models will be used in the statistical analysis to identify the variables that predict negative outcomes.

Expected Outcomes

We expect significant results/outcomes in the of efficacy of the PRP vs Steroid infiltration in the patients admitted with lower back pain in the Department of Orthopaedics.

Discussion

According to the most current Global Burden of Disease Study, the main reason for years spent disabled was low back pain. If acute low back pain is not properly diagnosed and treated, the patient may develop chronic pain, which increases the likelihood of disability, reduces quality of life, and limits participation in daily activities. When symptoms worsen after a year, around 20% of those who have acute low back pain go on to acquire chronic low back pain.[10,11] In a study conducted by Marks RS et al, the steroid and local anaesthetic infiltration was administered in the aberrant lumbosacral articulations of individuals with persistent low back pain. The results showed that the eight patients experienced instant absolute relief from pain, while one patient experienced immediate partial relief which turned into complete relief after around seven days. After infiltration, three patients reported sufficient partial pain alleviation after intervals of seven to forty-one months, five patients reverted to their prior level of pain in durations ranging from one day to twelve weeks, and one patient remained pain-free for two years.[12]

In a different study where 103 patients received either an injection of placebo or local application of methylprednisolone to the affected nerve roots (with bupivacaine infiltrated into the wound) as part of their elective posterior lumbar discectomy and decompressive laminectomy procedures for degenerative spinal diseases. It was observed that the use of bupivacaine or methylprednisolone during surgery did not result in any problems. The study found the intravenous injection of methylprednisolone-bupivacaine had a positive impact without causing any complications immediately following posterior lumbosacral spine surgery for spinal fusion, decompression, and/or discectomy.[13] Akeda et al.'s clinical investigation revealed no statistically significant differences between the PRP-releasate and CS groups, however both groups saw a clinically significant

improvement in the amount of LBP assessed by a visual analog scale (VAS) at 8 weeks post-injection. However, during the 60-week follow-up, PRP-releasate injection treatment was found to be safe and to have sustained improvements in LBP, disability, and quality of life.[14] In a similar setting, a prospective, double-blinded, randomized controlled trial was carried out by Tuakli-Wosornu et al. to ascertain the effectiveness of PRP in symptomatic deteriorated IVDs. During the eight weeks following injection, those who received intradiscal PRP had substantially higher improvements in their functional rating index (FRI), numeric rating scale (NRS), and North American Spine Society (NASS) satisfaction levels than those who received a contrast agent.[15]

A single PRP or PRP-releasate injection significantly improved pain, disability, and quality of life (QOL) over the monitoring period (from 3 to 12 months), according to four prospective cohort studies.[14,16,17,18] Among these, Jain et al.'s study found a favourable correlation between increases in the platelet concentration of PRP and improvements in the NRS and Oswestry Disability Index (ODI) scores.[16]

In a different study conducted by Jiang et al. conducted a retrospective analysis to assess the impact of PRP injection combined with transforaminal endoscopic lumbar discectomy (TELD) on patients suffering from lumbar disc herniation. When compared to the control group (TELD without PRP therapy), they found that TELD with PRP treatment significantly reduced LBP and LBP-related disability, MRI findings, and the recurrence rate of LDH.[19]

Conclusion

The conclusion will be made after the completion of the study.

Consent

The author(s) has gathered and maintained the patients' written permission in accordance with international or university standards.

Ethical Approval

The author(s) has gathered and maintained documented ethical clearance in accordance with institution or international standards.

Competing Interest

The authors have stated that they have no conflicting interests.

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