Original Article

Effectiveness of Platelet Rich Plasma and Methylprednisolone on lumbar facet joint hypertrophy: A Quasi-experimental study

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Abstract

Background: *Low back pain (LBP) is now regarded as the important cause of disability worldwide and a priority for future research on prevention and treatment. Facet joint hypertrophy is an important pathogenesis of Low back pain. The aim of this study was to assess the effectiveness of Platelet Rich Plasma and Methylprednisolone on Facet Joint Hypertrophy in Chronic Low Back Pain (LBP).*

Methods: *This Quasi-experimental study was carried out on adult patients with chronic low back pain due to lumbar facet joint hypertrophy attended the Pain Medicine Unit, OPD and KOSAKA Pain Clinic, BSMMU, during the period of October 2019 to September 2020. The patients were randomly assigned to one of the two groups; group A (patients treated with PRP); group B (patients treated by with Methylprednisolone). After providing the allocated treatment, all patients undergone follow-up examination 30 minutes after procedure, end of 1st week, end of 1st month and end of 3rd month for pain improvement by visual analogue scale (VAS) and for disability status by Roland Morris disability Questionnaire (RMDQ)score. Follow up of the patients were carried out while they visited in Pain Clinic at mentioned intervals or over phone. The significance of the difference of the VAS and RMDQ score at the end of 1st week, end of 1st month & end of 3rd month were tested by using unpaired t- test and chi-square test.*

Results: *It was observed that mean ± SD of age was 42.31 ± 7.6 years for Group A and 42.29 ± 8.0 years for Group B. Most of the participants in all Group A [14 (70.0%)] & in Group B [15 (75.0%)] were males. Male: Female ratio was about 2.6:1. Imaging findings shows that, Grade II degenerative changes were 13(65.0%) patients of group A & 12(60.0%) patients of group B. L3/4 level involvement was predominant, 15(75.0%) patients in Group A and 15(75.0%) in Group B. The difference was statistically non-significant (p>0.05) between groups. Mean VAS score at pretreatment & after 30 minutes of intervention were not statistically significant between groups. But end of 1st week, end of 1st month and end of 3rd month follow up, VAS score decreased in both groups, but significantly reduced in Group A. In case of disability improvement, RMDQ score more decreases in group A than group B.*

Conclusion: *Lumbar facet joint injection with platelet rich plasma (PRP) provides better pain relief and improvement of functional status than Methylprednisolone in chronic low back pain due to lumbar facet joint hypertrophy.*

Key words: *Chronic low back pain, Lumbar facet joint, Hypertrophy, Disability, Methylprednisolone, Platelet Rich Plasma*

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Background

Low back pain is a very common health problem worldwide and a major cause of disability - affecting performance at work and general well-being[1]. Between 70% and 85% of the population suffer from low back pain at some time in their lives [2]. Though several risk factors have been identified (including occupational posture, depressive moods, obesity, height and age) the causes of the onset of low back pain remain obscure and definitive diagnosis is difficult[1].

Facet joint (FJ) hypertrophy is important cause of LBP. Facet joint hypertrophy characterized by degeneration & modifications of the tissue material, biochemical, and structural morphology of joint [3]. The most prominent signs of FJ hypertrophy is degeneration, including cartilaginous loss, wear, tears, and necrosis, fibrillation, ulceration, sclerosis, exposure of subchondral bone, osteophytes, subchondral cysts, and capsular calcification [3,4,5].

Like in all synovial lined joints, osteoarthritis, loss of cartilage and bony overgrowth is common in facet joint hypertrophy. High-grade cartilage necrosis arises quite rapidly in facet joint hypertrophy. Inflammation generated by degeneration of FJs and surrounding tissues is believed to be a cause of local pain[6]. Some reports suggest that the radiographic features of facet joint hypertrophy are joint space narrowing, osteophytosis, joint hypertrophy, subchondral sclerosis, and bony deformity, which are similar to traditional peripheral osteoarthritis [7,8]. Other reports reveal that multiple inflammatory cytokines such as tumor necrosis factor-α (TNF α), interleukin-1ß (IL-1ß), and interleukin-6 (IL-6), as well as inflammatory mediators such as prostaglandins are enriched in the facet joint tissues in degenerative lumbar facet joints [9].

Various methods have been applied to the treatment of lumbar facet joint hypertrophy, including open denervation, percutaneous endoscopic denervation, radiofrequency nerve ablation, kryodenervation, and local injection using local anaesthetic and steroid, among which, radiofrequency denervation and intra-articular injections are two of the most commonly used methods [10].

Hirsch et al (1963) [11] were the first to claim successful intra-articular injection of facet joints, since then, intraarticular injection has gradually become one of the vital therapeutic methods for lumbar facet joint hypertrophy. Intra-articular injection of a steroid and a local anaesthetic in the facet joint is performed mainly for therapeutic purposes for relief of pain. Intra-articular methylprednisolone are more effective if there is a clinical or radiological evidence of facet joint inflammation than if features of joint degeneration are present. Intra-articular injection is still being used although conclusions regarding effectiveness of intra-articular injections are inconsistent. Study by Jadon (2016) [10] regarding their effectiveness have concluded that facet joint Methylprednisolone injections have limited (level III) evidence of benefit it means either they are ineffective, or have no added benefit than other treatments.

Platelet rich plasma (PRP) consists of a high concentration of platelets derived from the patient's peripheral venous blood (Wu et al., 2016). PRP is an appropriate injectable material with great potential in treating many different musculoskeletal disorders such as osteoarthritis, lateral epicondylitis, rotator cuff disease, tendo achilles, patella tendinopathy, hamstring injuries, and degenerative spine disease [11]. Current studies indicate that the injection of PRP into facet joint hypertrophy is effective in restoring structural changes and improving the matrix integrity of degenerated facet hypertrophy as evaluated by magnetic resonance imaging (MRI) and histology. The results of this basic research have shown the great possibility that PRP has significant biological effects for tissue repair to counteract IVD degeneration [12].

Platelet-rich Plasma (PRP) has been widely used in different fields of medicine as autologous

therapeutic product. The main component that appears to be associated with the therapeutic effect is the presence of growth factors (GF) [13]. Platelet-rich Plasma acts by activation of collagen matrix. Activation will result in degranulation of platelets and release of α granules that contain growth factors. Activation also induces fibrinogen cleavage that promotes matrix formation[12]. A prospective study reported that PRP is effective and safe for patients with facet joint hypertrophy [1].

The purpose of the present study was to compare the effectiveness of PRP and methylprednisolone in the management of lumbar facet Joint hypertrophy.

Research design and methods

This study was conducted in the Department of Anaesthesia, Analgesia and Intensive Care Medicine, BSMMU to compare the effect of Platelet Rich Plasma and Methylprednisolone to reduce pain and disability in patients with chronic Low Back Pain (LBP) due to lumbar facet joint hypertrophy. Adult patients with chronic low back pain due to lumbar facet joint hypertrophy attending at the Pain Medicine Unit OPD and KOSAKA Pain Clinic were selected according to inclusion and exclusion criteria. The inclusion criteria were as follows: Age: 30 – 45 years of either sex, Patients with complaints of LBP more than 3months, VAS 3, SLR ≤ 45°, Absence of neurological deficit and MRI showing findings of lumbar facet joint hypertrophy (Grade I & II). Patients with traumatic, acute LBP, osteoporotic disc, having any complications like infection, malignancy or presence of bleeding disorder, uncontrolled diabetes, caries spine and pregnancy and prior surgery on the spine were excluded from the study.

Prior to the commencement of this study, the research protocol was approved by the Institutional Review Board (IRB). An informed written consent was taken from all the participants. Clinical, functional and radiological assessment of all patients were recorded by focused history taking, general examination and complete locomotor examination in a preformed questionnaire during first visit. The intensity of pain was assessed by VAS and disability status was assessed by RMDQ and treated facet joint hypertrophy level was mainly determined by clinical signs and lumbosacral imaging (X-ray lumbosacral spine and MRI of Lumbosacral spine).

All patients were randomly divided into Group A (treated with Platelet rich plasma) and Group B (treated by Methylprednisolone) by computer generated randomization. All procedures were performed by single skilled physician in operating room.Lumbar facet joint injection was performed by fluoroscopy guidance. The patients were placed prone on the operating table surrounded by a C-arm, with a pillow under the abdomen to straighten the lumbar spine. After sterile dressing and draping the C-arm rotated until the targeted lumbar facet joint space be clearly seen, when the beam of the C-arm paralleled the open angle of the joint. The site for needle penetration will be marked at this intersection of the beam of the C-arm and the skin. After the standard antisepsis of the skin was prepared, local anesthesia with 0.5% lidocaine then administered. A 21-G spinal needle was gently inserted into the facet joint space under fluoroscopic control. To verify the intra-articular positioning of the needle, 0.1 – 0.2 mL of nonionic contrast medium was injected. The nonionic contrast medium was characterized by rapid metabolism, so there is little effect of the contrast medium injection on the PRP treatment. After successful intra-articular puncture, the targeted facet joint was injected with approximately 0.5mL pure PRP or 0.5ml (10 mg) of methylprednisolone. In unilateral administration, 0.5 ml was given at either right or left side of L3/4 or L4/5 level of Grade I or Grade II lumbar facet joint. In bilateral administration, 0.5 ml was given at both side of L3/4 or L4/5 level of Grade I or Grade II lumbar facet joint. The intra-articular injection was performed slowly with gentle pressure to avoid rupturing the joint capsule. After confirming that there is no obvious bleeding, the lumbar facet joint injection considers as successfully

completed. After the procedure, puncture-related complications observed for 4 hours. Also, gave advice to take rest and avoid bend at the waist for one week. No anti-inflammatory treatment advised for patients during the follow-up period. All patients were undergone follow-up examination after 30 minutes, 1st week, 1st month and 3rd month by clinical assessment. Follow up were carried out by personal visit of the patient in Pain Clinic at mentioned intervals or over the phone.

Roland-Morris Disability Questionnaire (RMDQ): The Roland-Morris Questionnaire (RMDQ) is a self-administered disability measure in which greater levels of disability are reflected by higher numbers on a 24-point scale. The RMDQ has been shown to yield reliable measurements, which are valid for inferring the level of disability, and to be sensitive to change over time for groups of patients with low back pain[14.] Roland and Morris did not provide descriptions of the varying degrees of disability (eg, 40%-60% is severe disability). Clinical improvement over time can be graded based on the analysis of serial questionnaire scores. If, for example, at the beginning of treatment, a patient's score was 12 and, at the conclusion of treatment, their score was 2 (10 points of improvement), we would calculate an 83% (10/12 x 100) improvement.

Statistical analysis

The sample size was calculated on the basis of means and SDs observed in different studies, the total number of patients included was 40. Statistical analyses were carried out by using the Statistical Package for Social Sciences version 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA). A descriptive analysis was performed for all data. The mean values were calculated for continuous variables. The qualitative observations were presented as frequencies and percentages over column total. Unpaired t-test was used to compare continuous variables between two groups. Chi-square test was used to compare categorical data like clinical signs and symptoms. A "p" value <0.05 was considered as significant.

Results

This Quasi-experimental study was conducted among the study population attended at Pain Medicine Unit OPD and KOSAKA Pain Clinic, Department of Anaesthesia, Analgesia and Intensive Care Medicine, BSMMU from October 2019 to September 2020. A total number of 40 adult patients with chronic low back pain due to lumbar facet joint hypertrophy were enrolled in the study. Results were analyzed in the light of comparison between the groups. Subjects were grouped as, Group A = patients treated with PRP; Group B = patients treated by with Methylprednisolone.

Sociodemographic profiles are presented in table I. It was observed that Mean ± SD of age was calculated to be, (42.31 ± 7.6) for Group A and (42.29 ± 8.0) for Group B. The mean age difference was not statistically significant (p= 0.914) among two groups. Most of the participants in all Group A [14 (70.0%)] & in Group B [15 (75.0%)] were males. Male: Female ratio was about 2.6:1. The sex difference was statistically not significant (p=0.525) among two groups (Table I).

Table I: *Demography of patients in two studied groups*

Variable	Group-A (n=20)	Group-B (n=20)	p-value
Age			
30-34	5 (25%)	4 (20%)	
35 - 39	6 (30%)	7 (35%)	
40 - 45	9 (45%)	9 (45%)	
Mean ± SD	42.31± 7.6	42.29 ± 8.0	0.914
Sex			
Male	14 (70%)	15 (75%)	
Female	6 (30%)	5 (25%)	0.525

Imaging findings shows that, Grade I degenerative changes were 7(35.0%) patients of Group A & 8(40.0%) patients of Group B. Grade II degenerative changes were 13(65.0%) patients of group A & 12(60.0%) patients of group B. L3–L4 level involvement was predominant, 15(75.0%) patients in Group A and 15(75.0%) in Group B. The difference was statistically not significant (p>0.05) between groups (Table II).

Table II: *Distribution of the cases according to imaging findings*

Variables	Group-A (n=20)	Group-B (n=20)	p value
MRI grade of degeneration			
Grade I	7 (35%)	8 (405)	0.862
Grade II	13 (655)	12 (60%)	
Location & level			
L3–L4	15 (75%)	15 (755)	1.000
L4–L5	5 (25%)	5 (25%)	
Sides of pain			
Bilateral	8 (40%)	6 (30%)	0.493

Data presented as frequencies, within parenthesis percentages over column total

Mean VAS score at pretreatment & after 30 minutes of intervention were not statistically significant between groups. But end of 1st week, end of 1st month and end of 3rd month follow up period, VAS score decreased in both groups, but significantly reduced in Group A(Table III).

Table III: *Demography of patients in two studied groups*

VAS score	Group A (n=20)	Group B (n=20)	p value
Pre-treatment	8.65±0.8	8.01±0.6	0.146
After 30 minutes	8.03±0.7	7.84±0.6	0.092
End of 1st week	6.04±0.3	7.29±0.5	0.001
End of 1st month	4.56±0.4	5.87±0.4	0.001
End of 3rd month	3.32±0.5	4.12±0.5	0.001

Values are presented as Mean ± SD

Similarly, RMDQ score more decreases in Group A than Group B. The difference was not statistically significant ($p<0.05$) among two groups (Table IV).

Table IV: *Distribution of the study patients by RMDQ score*

RMDQ	Group A (n=20)	Group B (n=20)	P value
Pre-treatment	10.8±0.3	11.9± 0.6	0.124
After 30 minutes	7.7±0.6	8.1±0.6	0.122
End of 1st week	7.4±0.7	7.6±0.5	0.001
End of 1st month	6.3±0.5	6.8±0.7	0.014
End of3rd month	6.2±0.5	6.9±0.7	0.023

Values are presented as Mean ± SD

Discussion

In this present study mean age was found 42.31 ± 7.6 years in group A and 42.29 ± 8.0 years in group B. The mean age was almost alike among the groups, the difference was not statistically significant (p=0.914). Male: Female ratio was about 2.6:1. Similar study reported that age ranged 38 to 59 years with male predominant [1]. Age standardized prevalence of LBP was higher in females than males. LBP prevalence increased with age, and peaked around the ages of 80 to 89 years, and then decreased slightly [1.]

Present study shows that mean VAS score at pretreatment & after 30 minutes of intervention were not statistically significant between groups. But at end of 1st week, end of 1st month and end of 3rd month follow up period, VAS score decreased in both groups, but significantly reduced in group A. Similarly, RMDQ score more decreases or disability outcome was better in Group A patients than Group B.

Outcomes after treatment showed that the low back pain was relieved in patients treated with PRP intra-articular injections. The mean VAS scores at rest were 7.05 before treatment, 6.68, 4.89, 3.21, 3.37, and 2.63 immediately, at one week, one month, 2 months, and 3 months after treatment. The scores were 8.42, 8.05, 6.05, 4.21, 3.89, and 2.95 during flexion, respectively. RMDQ scores were significantly reduced after lumbar facet joint injections. The mean scores of RMDQ were reduced gradually in a time-dependent manner after treatment (Wu et al., 2016). Systemic review reported that PRP is a safe, effective and feasible treatment modality for the treatment of facet joint hypertrophy [15.]

At present, different studies have described multiple therapeutic techniques to manage lumbar facet joint hypertrophy, and intra-articular injection is one of the most important methods. Injection therapy is common for lumbar facet joint hypertrophy and has been modified with multiple drugs. However, a previous study suggests that the outcomes of intra-articular injection with different drugs are controversial and may result in different levels of drug-related complications [16]. Therefore, it is critical to seek new injectable materials to be used for intra-articular facet joint injection for the treatment of lumbar facet joint syndrome. But in this study no complications or adverse effect was observed. In this regards, PRP therapy as a safe, nonsurgical, biological treatment for osteoarthritis and musculoskeletal repair has gained a lot of attention. Since PRP is prepared from autologous blood, theoretically there are minimal risks for toxicity and side effects [17]. Due to these features, PRP becomes a very appropriate material for intra-articular injection.

PRP therapy is a new technique for the treatment of lumbar facet joint syndrome. Akeda et al (2019) [12] indicated that reparative efficacy with PRP can be expected with 4 – 5 times of normal blood level, whereas no further enhancement is observed for PRP with much higher platelet concentrations.

The results of our study demonstrated that facet joint injection using autologous PRP was an effective therapeutic method. Compared pain levels before treatment, the level of low back pain after treatment was significantly decreased. In regard to lumbar disability, the results of RMDQ showed that the degree of lumbar disability was obviously reduced and the quality of life had an anticipated improvement.

Mooney and Robertson et al (1976) [18] first declared that intra-articular facet joint injection with steroids and local anesthetics got a satisfying outcome with 32% of patients experiencing "complete relief" in a 6-month follow-up. Since then, injection therapy of facet joints has become a routine treatment option for lumbar facet joint syndrome, and steroids combined with local anesthetics have become the most used injectable materials. A systematic review has concluded that the low back pain relief after intra-articular methylprednisolone injection ranges from 18% to 63% [19]. Schulte et al (2006)[16] found that, about 41% of patients with lumbar facet joint hypertrophy gained better outcomes after intra-articular injections using a standardized protocol (Methylprednisolone, lidocaine 1%, phenol 5%). Our data showed that, based on the VAS score, 78.95% of the patients were assessed to have excellent or good outcomes end of 3 months after PRP injections, which suggested that application of PRP might be more effective than the standardized protocol. Nonetheless, in many systematic reviews, investigators take a skeptical attitude about the efficacy of steroid facet joint injections.

In a randomized and controlled study, Carette et al (1991)[20] reported that injecting steroid into the facet joints showed little effect on the treatment of patients with chronic low back pain. The mean pain VAS score for patients with steroid injection at one month was 4.7, which was similar with that at 3 months. According to our clinical experience, intra-articular facet joint injections with methylprednisolone may show pain relief in the short-term, but the long-term therapeutic effects are uncertain. All these findings suggested that PRP injection showed more effect on low back pain than injection with methyprednisolone, especially in a longer-term period.

Lumbar facet joint injection with platelet rich plasma (PRP) provides better pain relief and improvement of functional status than Methylprednisolone in chronic low back pain due to lumbar facet joint hypertrophy.

This study showed that intra-articular injection of platelet rich plasma can decrease joint pain and improve functional status of the patients up to three months.

Further studies are required to fully comprehend the 6 months clinical significance of MRI changes seen after platelet-rich plasma therapy for lumbar facet joint hypertrophy and how this varies to conservatively managed pain.

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Competing interests

No potential conflicts of interest relevant to this study were reported.

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