"A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY"

BY

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY

IN

ORTHOPAEDICS

Under the Guidance of

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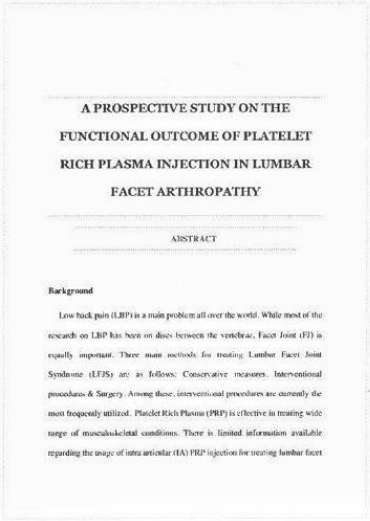

A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY

ABSTRACT

Background

Low back pain (LBP) is a main problem all over the world. While most of the research on LBP has been on discs between the vertebrae, Facet Joint (FJ) is equally important. There main methods for treating Lumbar Facet Joint Syndrome (LFJS) are as follows: Conservative measures, Interventional procedures & Surgery. Among these, interventional procedures are currently the most frequently utilized. Platelet Rich Plasma (PRP) is effective in treating wide range of musculoskeletal conditions. There is limited information available regarding the usage of intra articular (IA) PRP injection for treating lumbar facet

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A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY ABSTRACT Background Low back pain (LBP) is a main problem all over the world. While most of the research on LBP has been on discs between the vertebrae, Facet Joint (FJ) is equally important. Three main methods for treating Lumbar Facet Joint Syndrome (LFJS) are as follows: Conservative measures, Interventional procedures & Surgery. Among these, interventional procedures are currently the most frequently utilized. Platelet Rich Plasma (PRP) is effective in treating wide range of musculoskeletal conditions. There is limited information available regarding the usage of intra articular (IA) PRP injection for treating lumbar facet joint disease (LFJD). In this study, we utilized PRP as a novel substance for IA injections and assessed its viability and safety in managing LFJS. Aim & Objective To find out the functional outcome of injection of PRP in Lumbar Facet Arthropathy (LFA) using Visual Analog Score (VAS) & Oswestry Disability Index (ODI) score before & immediately after the procedure, at the end of 1 week, 1 month & 3 months. Methodology Participants in this research included Seventy One patients with the diagnosis of LFA who were brought to Emergency Medicine and Orthopaedics Department of the RL Jalappa Hospital in Kolar between September 2022 & December 2023. About 3ml of PRP was administered into each of the afflicted FJs. After the procedure, all patients were evaluated immediately and then at the end of one week, 1 month & 3 months. Each patient's functional outcome was assessed using the VAS and ODI, and the results were documented in the proforma. Results In this research, the average age of patients with LFA was 51.23 years. 46.5 percent of them were female, while the remaining 53.5 percent were male. 71.8 percent of the patients were found to have no comorbidities. The pain scale dropped dramatically immediately after PRP injection on the day of the procedure (6.7). Further, the pain score diminished even more by the end of one week (5.27), at the end of one month (2.96) and further decreased at the end of three months (1.07) after the PRP injection. Therefore, PRP injections continue to effectively reduce pain severity in patients with LFA even three months after administration. The disability score significantly lowered immediately after the PRP injection on the day of the procedure (52.9). Subsequently, the disability score experienced a further decrease at the end of one week (45.44), eventually a drop at the end of a month (33.69) and at the end of three months (22.55) after the PRP injection. PRP injections effectively decrease disability in individuals with LFA even three months after administration. Conclusion PRP injection significantly reduce pain and disability in persons with LFA for a duration of three months after being administered. Therefore, an autologous PRP is an optimal novel substance that can be injected directly into the joint to treat LFA. After 3 months follow-up, it was concluded that PRP was effective, easy to use and sufficiently safe for treating LFA. Keywords: Low Back Pain, Platelet Rich Plasma, Visual Analog Score, Oswestry Disability Index, Lumbar Zygapophysial Joint, Lumbar Facet Arthropathy INTRODUCTION In terms of epidemiology, society and the economy, low back pain (LBP) is a significant issue all over the globe. Among musculoskeletal disorders, it is among the most frequent worldwide and the main source of years of incapacity.1,2 Some of the spinal conditions that can lead to LBP include sacroiliac joint discomfort,

3/7/24

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DR. GILS THAMPI

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ABSTRACT

Background

Low back pain (LBP) is a major problem all over the globe. While most of the research on LBP has been on discs between the vertebrae, Facet Joint (FJ) is equally important. The three main methods for treating Lumbar Facet Joint Syndrome (LFJS) are as follows: Conservative measures, Interventional procedures and Surgery. Among these, interventional procedures are currently the most frequently utilized. Platelet Rich Plasma (PRP) is effective in treating wide range of musculoskeletal conditions. There is limited information available regarding the use of intra articular (IA) injection of PRP for treating lumbar facet joint disease (LFJD). In this study, we utilized PRP as a novel substance for IA injections and assessed its viability and safety in managing LFJS.

Aim and Objective

To assess the functional outcome of PRP injection in Lumbar Facet Arthropathy (LFA) using Visual Analog Score (VAS) and Oswestry Disability Index (ODI) score before and immediately after the procedure, at the end of 1 week, 1 month and 3 months.

Methodology

Participants in this research study included 71 patients diagnosed with LFA who were brought to the Emergency Medicine and Orthopaedics Department of the RL Jalappa Hospital in Kolar between September 2022 and December 2023. About 2ml of PRP was administered into each of the afflicted FJs. After the procedure, all patients were evaluated immediately and then at the end of 1 week, 1 month and 3 months. Each patient's functional

outcome was assessed using the VAS and ODI, and the results were documented in the proforma.

Results

In this research, the average age of the patients with LFA was 51.23 years. 46.5% of them were female, while the remaining 53.5% were male. 71.8% of the patients were found to have no comorbidities. The pain scale dropped dramatically immediately after PRP injection on the day of the procedure (6.7). Further, the pain score diminished even more at the end of one week (5.27), at the end of one month (2.96) and further decreased at the end of three months (1.07) after the PRP injection. Therefore, PRP injections continue to effectively reduce pain severity in patients with LFA even three months after administration. The disability score significantly lowered immediately after the PRP injection on the day of the procedure (52.9). Subsequently, the disability score experienced a further decrease at the end of one week (45.44), eventually a drop at the end of a month (33.69) and at the end of three months (22.55) after the PRP injection. PRP injections effectively decrease disability in individuals with LFA even three months after administration.

Conclusion

PRP injection significantly reduce pain and disability in persons with LFA for a duration of three months after being administered. Therefore, an autologous PRP is an optimal novel substance that can be injected directly into the joint to treat LFA. After 3 months follow-up, it was concluded that PRP was effective, easy to use and sufficiently safe for treating LFA.

Keywords: Low Back Pain, Platelet Rich Plasma, Visual Analog Score, Oswestry Disability Index, Lumbar Zygapophysial Joint, Lumbar Facet Arthropathy.

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ABBREVIATIONS

S. No	Abbreviation	Explanation
1	LBP	Low Back Pain
2	FJ	Facet Joint
3	LFJS	Lumbar Facet Joint Syndrome
4	OA	Osteo Arthritis
5	SJ	Synovial Joint
6	IA	Intra Articular
7	PRP	Platelet Rich Plasma
8	LFJD	Lumbar Facet Joint Disease
9	LFA	Lumbar Facet Arthropathy
10	VAS	Visual Analog Score
11	ODI	Oswestry Disability Index
12	IVD	Inter Vertebral Disc
13	LFJ	Lumbar Facet Joint
14	LZJ	Lumbar Zygapophysial Joint
15	FJA	Facet Joint Arthrosis
16	LFJOA	Lumbar Facet Joint Osteo Arthritis
17	FJOA	Facet Joint Osteo Arthritis
18	CT	Computed Tomography
19	BMI	Body Mass Index
20	FJP	Facet Joint Pain
21	MRI	Magnetic Resonance Imaging
22	FA	Facet Arthropathy
23	SPECT	Single Photon Emission Computed Tomography

24	FJS	Facet Joint Syndrome
25	RMQ	Roland-Morris Disability Questionnaire
26	RFA	Radiofrequency Ablation
27	SDUAHER	Sri Devaraj Urs Academy of Higher Education and Research
28	RCT	Randomized Controlled Trials
29	RPM	Revolutions Per Minute
30	CBC	Complete Blood Count
31	LDH	Lumbar Disc Herniation
32	USG	Ultrasonography
33	LFJP	Lumbar Facet Joint Pain
34	PRGF	Plasma Rich in Growth Factor
35	FS	Facet Syndrome
36	HA	Hyaluronic Acid
37	LFS	Lumbar Facet Syndrome
38	CS	Cortico Steroid

INTRODUCTION

INTRODUCTION

In terms of epidemiology, society and the economy, low back pain (LBP) is a significant issue all over the globe. Among musculoskeletal disorders, it is among the most frequent worldwide and the main source of years of incapacity.[1,2] Some of the spinal conditions that can lead to LBP include sacroiliac joint discomfort, facet joint dysfunction, spinal stenosis, intervertebral disc degeneration and myofascial pain.[3,4] While most of the research on LBP has been on discs between the vertebrae, Facet Joint (FJ) is equally important.

Spinal cord Lumbar Facet Joint Syndrome (LFJS) is characterized by lower back discomfort that may or may not radiate to the buttocks, groin or upper thigh.[5] According to reports, the incidence of LFJS among patients experiencing back pain ranges from 7.7 to 75 percent, based on individual diagnostic blocks.[6] Osteoarthritis (OA) of the FJs is by far the most widespread kind of facet disease.[7]

Although the precise causes of LFJS remain a mystery, many researchers attribute it to OA, in the same way as other peripheral Synovial Joints (SJ).[6,8,9] Chronic conditions of the FJs are associated with elevated levels of both pro- and anti-inflammatory cytokines, according to some research.[10,11] Bony

deformity, subchondral sclerosis, osteophytosis, joint OA and joint hypertrophy are all structural alterations that manifest in the latter stages of LFJS.[12]

There are three primary approaches in treating LFJS: conservative measures, interventional procedures and surgery. Among these, interventional procedures are currently the most frequently utilized.[13] The outcomes of intraarticular (IA) injections utilizing different medications are debatable, although numerous studies have demonstrated that a combination of steroids, local anaesthetics, normal saline, hyaluronic acid and phenols can effectively alleviate the pain of LFJS. Although steroids are frequently injected, only 18% to 63% of patients report long-term improvement from low back pain following IA steroid injection, according to prior uncontrolled research.[14] Therefore, it seems crucial to use a novel injectable drug and demonstrate both its safety and efficacy in the treatment of LFJS.

Plasma with an abundance of platelets is called platelet rich plasma (PRP). This type of plasma is generated utilizing the patient's own peripheral venous blood. Recent research has shown that PRP is a promising injectable material for the management of numerous musculoskeletal disorders including OA, lateral epicondylitis, rotator cuff diseases, achilles tendinitis, patella tendinopathy, hamstring injuries and chronic spine diseases.[15] Many cytokines and growth factors are responsible for PRP's beneficial effects. Crucial

functions for cell proliferation, matrix regeneration, angiogenesis and anti-inflammatory effects are performed by these components.[16]

Just a small number of studies have revealed that PRP is effective in treating a wide range of musculoskeletal conditions.[17,18] To the best of our knowledge, there is limited information available in relation to the use of IA injection of PRP for treating lumbar facet joint disease (LFJD). In this piece of work, we utilized PRP as a novel substance for IA injections and assessed its viability and safety in managing LFJS. The functional outcome of PRP injection in Lumbar Facet Arthropathy (LFA) was evaluated using Visual Analog Score (VAS) and Oswestry Disability Index (ODI) score before and immediately after the procedure, at the end of one week, one month and three months.

OBJECTIVES

OBJECTIVES

Aim

To evaluate the functional outcome of PRP injection in LFA using VAS and ODI score before and immediately after the procedure, at the end of 1 week, 1 month and 3 months.

Objectives

1. To assess the pain severity of LFJS patients (as measured by VAS scale) before and immediately after the PRP injection, at the end of 1 week, 1 month and 3 months.
2. To assess the functional outcome of LFJS patients (as measured by ODI scale) before and immediately after the PRP injection, at the end of 1 week, 1 month and 3 months.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Low Back Pain

The effects of LBP go beyond the person and into society as a whole; it affects 40–85% of the population at some time.[19] Although there is no simple answer to the question of where LBP originates, research has shown that the sacroiliac joints, FJs and intervertebral discs (IVD) are the major contributors.[20] Many believe that herniated discs in the back are the primary source of LBP. A new study found that lumbar disc degeneration is the underlying cause of LBP in roughly 45% of individuals.[21] As the sole synovial joints in the spine are FJs, they are susceptible to a wide range of pathologies such as arthropathy, infection, inflammation, trauma and tumors.[22]

Anatomy of Lumbar Facet Joint

The "three-joint complex" that is the lumbar spine segment is made up of the IVD and the posterior paired Lumbar Facet Joint (LFJ). When one joint has degeneration, it impacts the biomechanics of the other two joints and vice versa.[23] The LFJ originate from the articular processes of two nearby lumbar vertebrae, specifically the superior and inferior ones (Figure 1). The fibrous capsule that surrounds the articulating cartilage and the bone, is continuous with the periosteum and makes these joints synovial.[24]

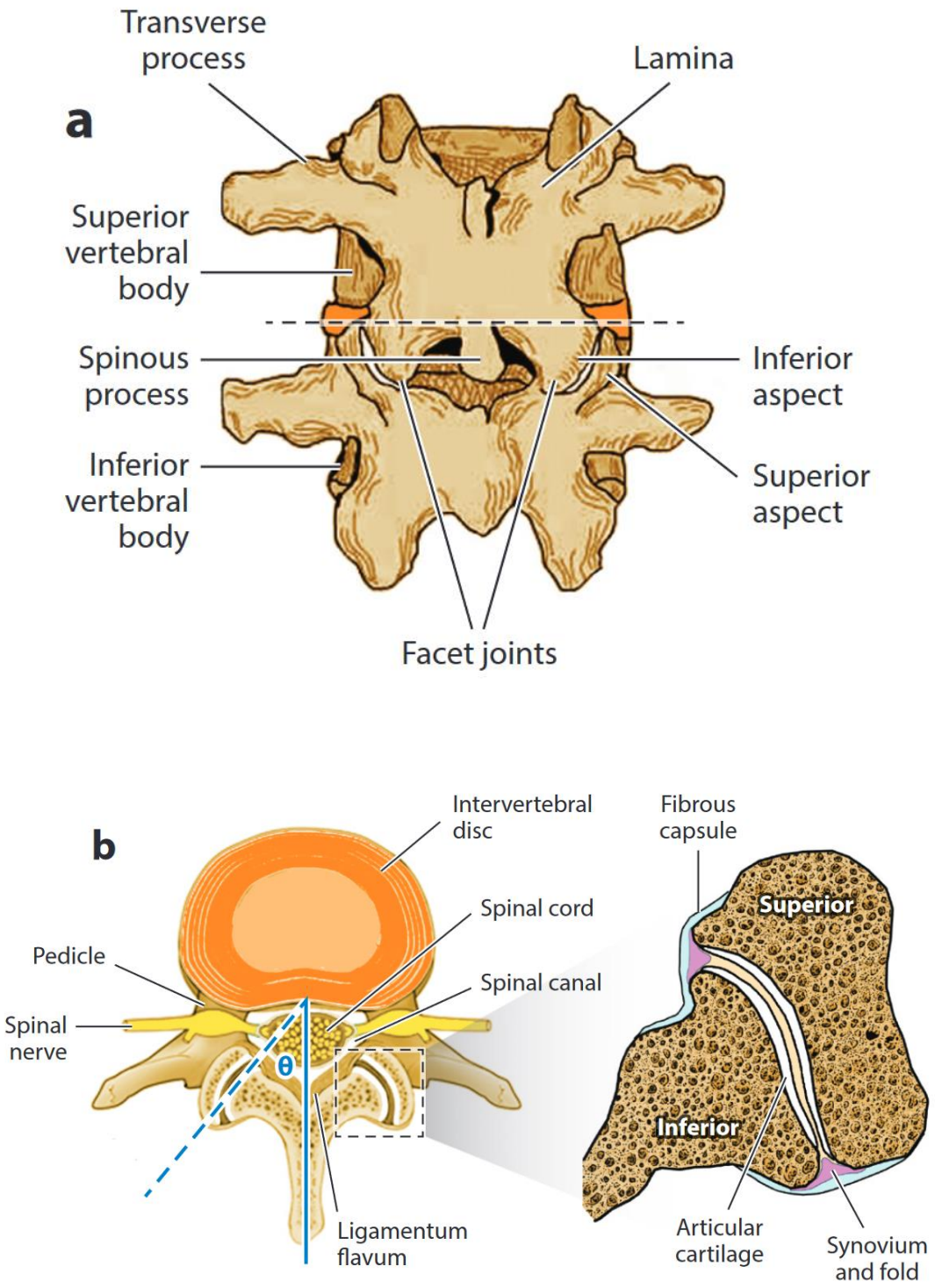


Figure 1: Facet joint anatomy. (a) Posterior view of the motion segment. (b) Axial view of the motion segment and a closer look (right)at the facet joint and its individual components.[25]

The LFJ's articular capsule is simple and is composed of two layers, similar to other Synovial Joints (SJ).[26] A thin synovial membrane resembling a sleeve constitutes the innermost layer of the capsule, which is composed of fiber and adipose tissue.[27] More specifically, the synovial membrane can improve joint equilibrium and force distribution by projecting from the joint capsule at the top and bottom of the joint and by entering between the articular surfaces to create fibro-adipose meniscoid. In addition, the joint's synovial fluid is contained within the inner membrane.[27]

Table 1: Structural and functional characteristics of the human facet joint.[25]

	Cervical	Thoracic	Lumbar
Surface area	0.80–1.07 cm^2	0.69–1.15 cm^2	0.97–2.12 cm^2
Sagittal orientation angle[a]	70–96°	93–110°	27–46°
Inclination angle[b]	31–59°	62–78°	71–86°
Range of motion per motion segment	Flexion/extension: 8–17° Lateral bending: 4–11° Axial rotation: 8–12°	Flexion/extension[c]: ~1–4° Lateral bending[d]: 6–9° Axial rotation[d]: 2–9°	Flexion/extension[c]: 12–20° Lateral bending: 3–8° Axial rotation: 2–5°
Contact forces on facet surfaces	Flexion/extension: 17–27 N Lateral bending: 17–40 N Axial rotation: 26–30 N	No data	Flexion/extension: 46–109 N Lateral bending: 10–75 N Axial rotation: 56–120 N

Innervation

Originating on the lumbar spine's dorsal ramus, the medial branch traverses the transverse process and continues beneath the collateral ligament. A pair of nerve branches, one going up to the LFJ and one going down, supply the joint with sensory information; these branches begin at the point where superior articular process and transverse process root converge.[28]

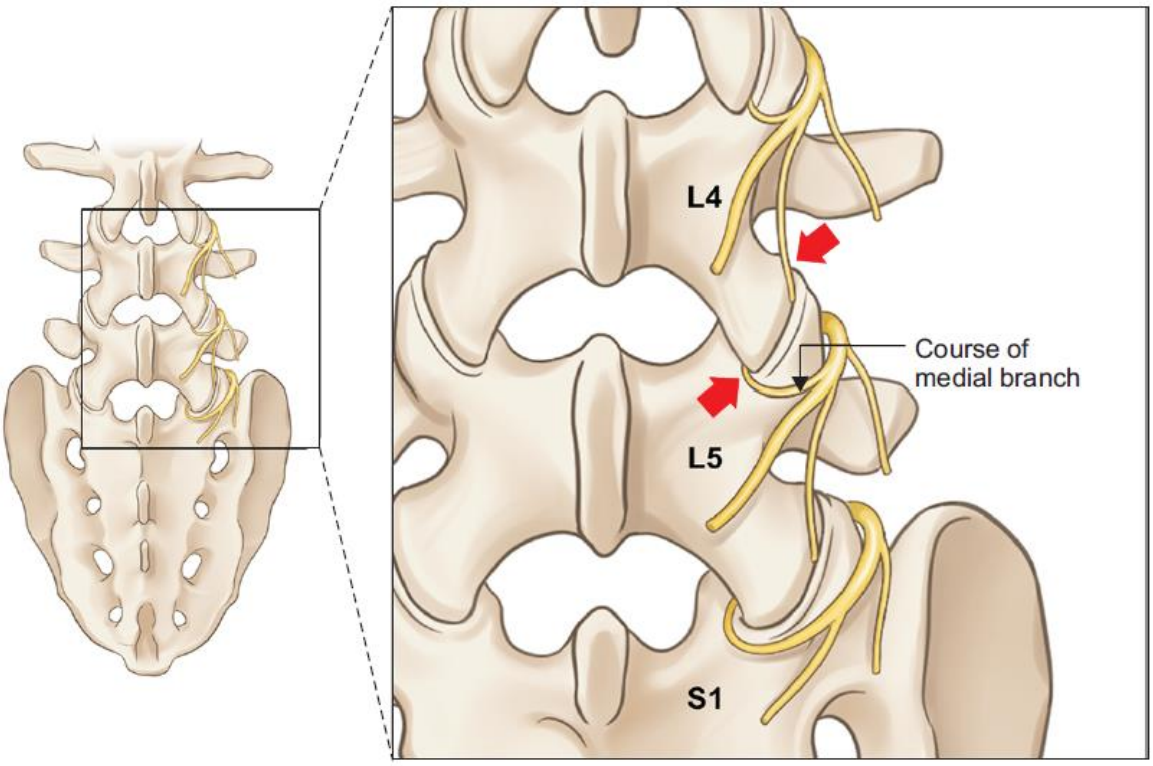


Figure 2: The path of the medial branch of dorsal ramus from the lumbar spinal nerve.[28]

The descending branch descends to the next lower LFJ capsule, while the ascending branch continues to the LFJ capsule at the same level. To review, every medial branch supply innervation to the LFJ at the same level as the following lower joint and every LFJ obtains innervation from a minimum of two segments of the medial branch, one from the comparable level adjacent to it and one from further up (Figure 2). Therefore, while treating facetogenic persistent LBP, the medial branch's trajectory is clinically important. Although they serve as the iliolumbar musculature and cutaneous innervation, the

intermediate and lateral branches of the dorsal ramus can also influence the development of LBP.[29]

Historic Review

Goldthwaite initially noticed in 1911 that the facet joints idiosyncrasies might cause back pain and fragility. Putti proposed sixteen years later, after dissecting seventy-five cadavers that sciatica may be caused by irritation of nerve roots due to local inflammation and degenerative changes in LFJs.[14]

The word "facet syndrome", first used by Ghormley in 1933, describes lumbosacral discomfort (with or without sciatica) that typically follows a rapid rotatory strain.[30] Mixter and Barr's seminal article suggesting rupture of the lumbar disc as the primary reason for leg and low back pain quickly put an end to speculation about the Lumbar Zygapophyseal Joints (LZJ) as possible origins of back pain.[31]

When Badgley proposed in the 1940s that as many as 80% of lumbar spine pain and sciatica cases are caused by referred pain from disease in the LZJs, rather than direct compression of nerve roots, the idea of these joints as pain generators was revived.[31]

The initial report of how injections into the LFJs could mimic back discomfort was published in 1963 by Hirsch et al. Percutaneous "facet rhizolysis" was popularized by Rees, who claimed to have a success rate of

99.8 percent in his seminal paper from the early 1970s. Subsequent research suggested that Rees's recommended method would not have been enough to accomplish rhizotomy in most individuals. In the mid-1970s, Shealy was the pioneer in using fluoroscopically guided radiofrequency denervation of the facet to treat LZJ discomfort, a procedure plagued by a high rate of haemorrhagic complications.[32]

Lumbar Facet Arthropathy

One typical source of low back discomfort is the LZJ, which is also called the FJ. The posterolateral articulation, which joins one vertebra's inferior articular process to superior articular process of the next vertebra below it, forms the FJ.[33]

Pathological breakdown of synovial facet joints is known as Facet Joint Arthrosis (FJA). A pathological degeneration process involving the cartilage, subchondral bone, synovium, joint capsule and periarticular soft tissues is unique to the LFJ anatomically compared to appendicular joints. The most common type of facetogenic LBP is Lumbar Facet Joint Osteoarthritis (LFJ OA), which affects a large percentage of people. In LFJ OA, there is an increase in subchondral bone resorption and turnover. The FJs sagittal position, elderly age and concurrent IVD degeneration are risk factors.[34]

Aetiology

The degenerative syndrome known as FJA usually develops as a result of microtrauma, weak body mechanics, obesity and repeated usage of the joints. A large body of research has established a connection between degeneration of intervertebral discs and degeneration of FJs, suggesting that the latter usually develops prior to the former.[33]

The breakdown of hyaline cartilage is the first stage of degenerative changes in the FJ. Subchondral bone sclerosis, constriction of the joint space and erosions occurs next. Research has revealed that when degenerative joint capsules progress, the posterior capsule swells, fibrocartilage multiplies and synovial cysts may occur. When fibrocartilage grows outside of the initial joint area, osteophytes most commonly form at the attachment points or entheses.[35]

Epidemiology

From less than 5% to more than 90% of patients describing back pain, estimates of the prevalence of lumbar facet-mediated pain have been reported in the literature. LFA is more common in older people. One study indicated that among persons aged less than 45, 36% had moderate to severe LFA, while the same problem affected 89% of persons aged 65 and older and 67% of adults aged between 45 and 64.[36]

Women over the age of 50 are more vulnerable of developing Facet Joint Osteoarthritis (FJOA) compared to males, according to another study that utilized lumbar computed tomography (CT) and plain radiography.[37] The prevalence of osteoarthritis of the FJ is higher in Caucasians compared to African Americans, according to the same study. Research shows that the risk increases with a greater body mass index (BMI), making it another independent risk factor. A BMI of 25–30 is linked with a threefold elevated risk of FJOA compared to normal range, while a BMI of 30–35 is related to a five-fold higher risk.[38]

Disc height narrowing, FJ sagittal orientation and weak spinal extensors are further recognized independent risk factors. When looking at the prevalence of LFJ OA, the levels most affected were L4-5 and L5-S1. L3-L4 levels are the most uncommon, followed by L1-2 and L2-3.[6]

Clinical Presentation

Typical symptoms of discomfort in the LFJs include persistent, non-specific low back ache. It is hard to make a diagnosis only according to the physical examination and the patient's history because the pain may show up in so many different ways. Localized pain throughout the back with a radiation pattern that is not dermatomal could be a sign of facetogenic pain. Lumbar spine referred pain almost seldom goes beyond the knee and usually affects the buttocks and thighs. Lower limb numbness or weakness is highly improbable.[39]

If the patient exhibits any neurological symptoms, such as incontinence or other bowel or bladder issues, the doctor should exclude the facet as a potential cause of discomfort. Tenderness to palpation across the lumbar paravertebral area over the transverse processes and paraspinal muscles may be found during a physical assessment of a person experiencing facet pain. Extending and rotating the spine could make this pain worse.[33]

In clinical settings, the pain referral patterns have become standard practice for the diagnosis of LBP associated to FJ discomfort. In terms of treatment, Kaplan et al. demonstrated that Facet Joint Pain (FJP) might be alleviated by injecting local anaesthetics into the joints.[40]

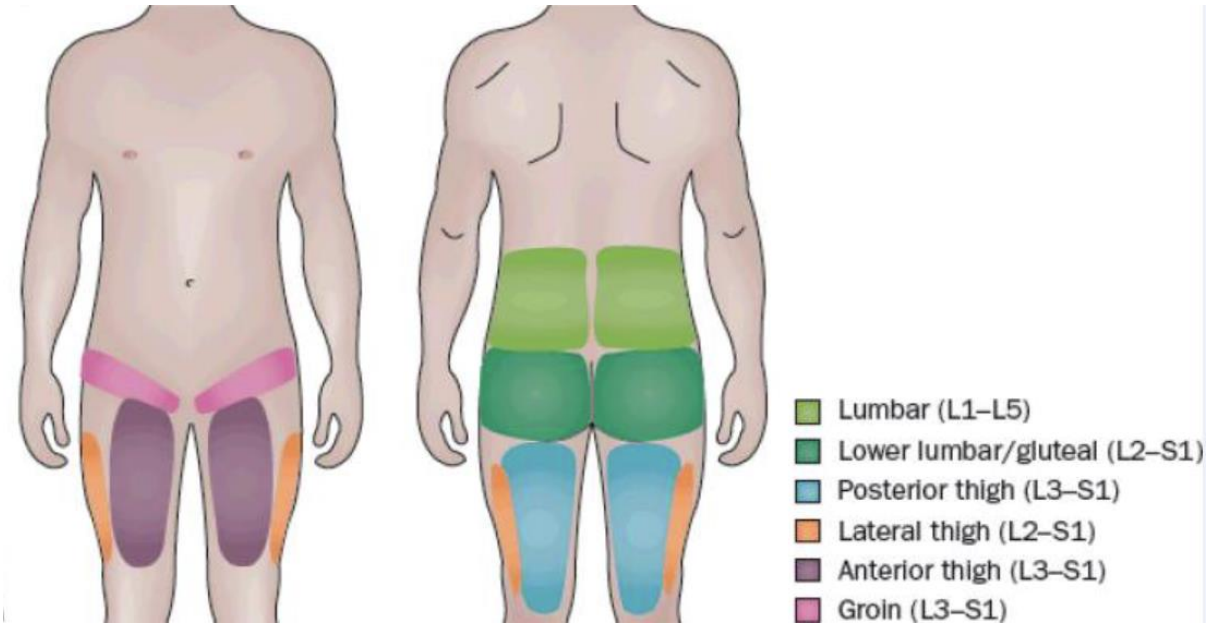


Figure 3: Pain distributions referred from the lumbar facet joints.[41]

Evaluation

In order to diagnose facet mediated pain, an anaesthetic block of the FJ is considered the benchmark of excellence. To rule out alternative reasons of suspected LBP, imaging is still a helpful technique.[42]

Because the FJs are positioned obliquely, standard lumbar radiographs (x-rays) are of limited utility and should include oblique images. Oblique x-ray, on the other hand, can only detect FJ illness with a sensitivity of 55% and a specificity of 69%.[6]

Contrary to claims made by certain researchers, Magnetic Resonance Imaging (MRI) is not just as delicate as CT when it comes to showing the bony cortical edge. On the other hand, MRI has been found to be more than 90% specific and sensitive when it comes to imaging facet degeneration.[43] Because of the lower cost and greater accuracy of CT in demonstrating bone features compared to MRI, it is still the recommended evaluation modality for imaging of Facet Arthropathy (FA). If non-facet mediated pain has to be ruled out, MRI remains an excellent diagnostic tool. Skeletal scintigraphy with Single Photon Emission Computed Tomography (SPECT) is one potentially helpful imaging tool for depicting bone regions with synovial alterations and degenerative remodelling.[33]

When it comes to identifying facet-mediated pain, the diagnostic block of the FJ is the gold standard. It has level I or level II evidence according to the US Preventive Services Task Force guidelines.[44]

There are benefits and downsides to both medial branch blocks and intra-articular injections into the facet joint. If the pain alleviation after injection is greater than or comparable to 80%, the diagnostic block is deemed effective.[33]

Management

Facet Joint Syndrome (FJS) treatment has come a long way in the last many years. In most cases, the first line of defence against OA of LFJ is anti-inflammatory and analgesic medication.[23]

When Physical therapy or pain medications do not alleviate facet-related discomfort, further conservative interventions are taken. If conservative approaches are unsuccessful, surgical care options include FJ excision, fusion, and replacement systems. IA injection of drugs can alleviate pain by analgesic or anti-inflammatory effects or by encouraging FJ healing.[23]

It is also possible to numb or cut off the nerves that go to the FJ in order to stop the pain signals from getting through. There are pros and cons to many treatment modalities and the debate over their effectiveness continues. Table 2 summarizes the characteristics of several treatment techniques.[23]

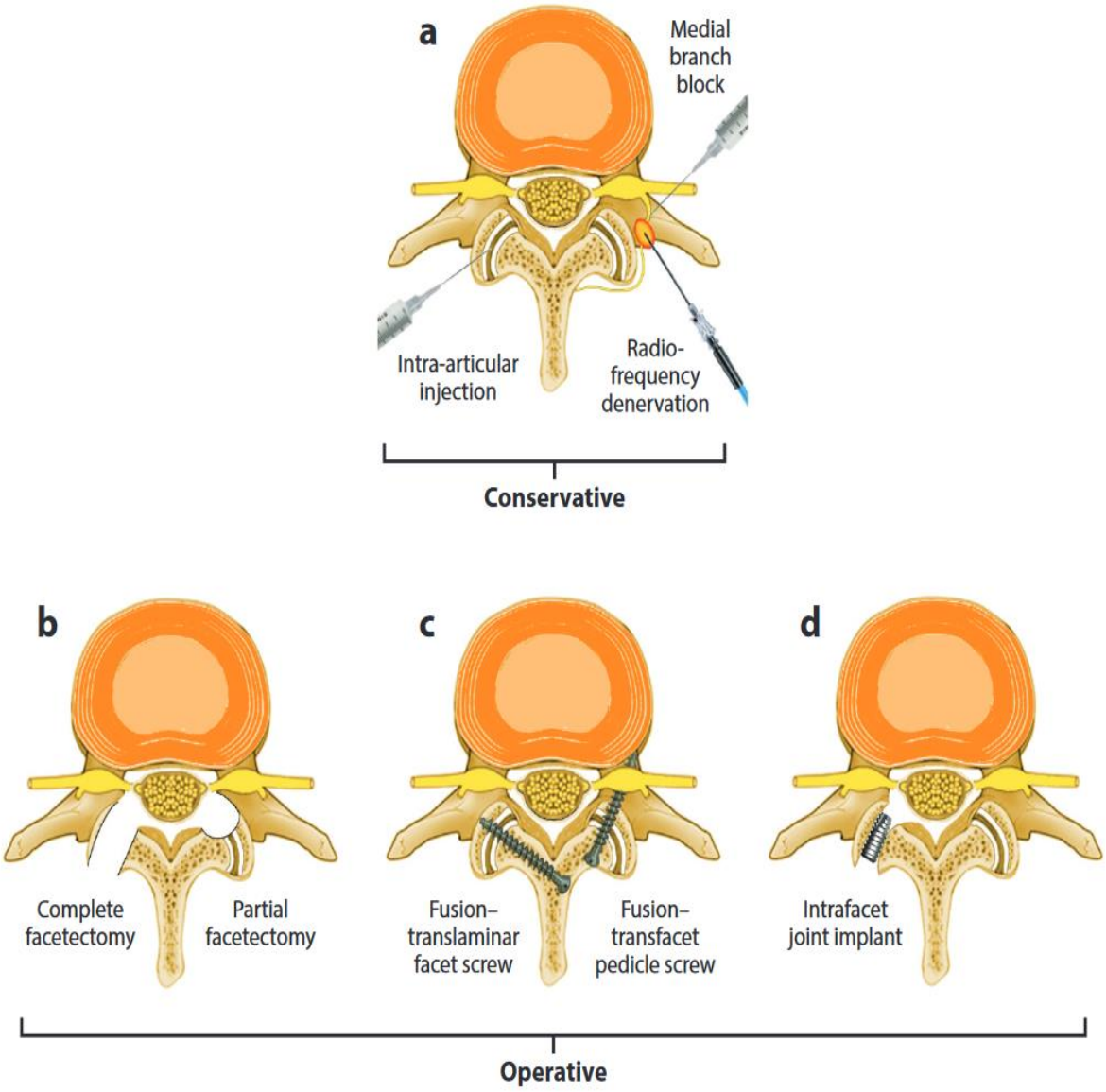


Figure 4: Strategies for the conservative and operative management in facet joint diseases, including (a) injections, (b) facetectomies, (c) fusion systems, and (d) implants.[25]

Table 2: Characteristics of various therapies for Facet Joint Syndrome.[23]

Types of Treatment	Characteristics
MBB	Anesthetize the nerves innervating LFJ by local anesthetics to achieve short-term pain relief. It is often used in the diagnosis of facet joint syndrome.
Steroid Injections	Intra-articular injections are usually a mixture of steroid and local anesthetics. Pain relief is shorter than with radiofrequency ablation.
Medial Branch Radiofrequency Ablation	Medial branch radiofrequency ablation is a mainstream minimally invasive procedure for facet joint syndrome. However, some patients may have variation of medial branch anatomy, and a few patients have no pain relief after radiofrequency ablation.
Capsule Radiofrequency	Percutaneous radiofrequency to the LFJ capsule is easier than medial branch radiofrequency, and capsule radiofrequency leads to an extended period of pain relief compared to the medial branch radiofrequency.
Cryoneurolysis	Using a gas-cooled cryoprobe to freeze the nerve with an ice-cold temperature.
Chemical Neurolysis	Nerve damage with chemicals. Nerve regeneration is potentially dangerous to the formation of neuroma. It is rarely used.
Dorsal Root Neurotomy	Dorsal root neurotomy maintained significant relief of pain, longer than medial branch denervation. But there are few related studies.
Endoscopic Neurotomy	Endoscopic neurotomy can directly observe the nerve. Avoids the inconvenience of anatomical variation. Endoscopic neurotomy is more effective than percutaneous radiofrequency.

Platelet Rich Plasma (PRP)

PRP, is a plasma fraction obtained through centrifugation. It is hypothesized that PRP containing bioactive proteins at quantities above what is considered physiological might promote healing and regeneration in the targeted organs and tissues. Bone, cartilage, intervertebral discs, tendons, joints and neurological system tissues have all been treated with PRP in clinical settings for musculoskeletal system injuries.[45]

Autogenous PRP has been shown to alleviate pain and speed healing by way of several growth factors. PRP is a cocktail of growth factors and inflammatory mediators which stimulates tissue repair in injured tissues.[46]

Classification of PRP

To swiftly assess the PRP preparations utilized in various studies and clinical practice, DeLong et al. suggested a system for classifying them based on platelet concentration, activation or not, and leukocyte (White blood cell) concentration (PAW classification).[47]

Table 3: Classification of PRP Solutions.[48]

Classification	Description
Pure platelet-rich plasma (P-PRP)	Platelets only in a low-density fibrin network
Leukocyte and platelet-rich plasma (L-PRP)	Leukocytes and platelets in a low-density fibrin network
Leukocyte and platelet-rich fibrin (L-PRF)	Leukocytes and platelets in a high-density fibrin network
Pure platelet-rich fibrin (P-PRF)	Platelets only in a high-density fibrin network

The preparations were categorized more simply by Dohan et al. according to whether they were fibrin products or plasma and whether or not they contained WBCs.[49] Mishra et al. suggested classifying PRP preparations into eight groups according to platelet concentration (subtype), activation status and number of WBCs.[50]

Platelet Activation and Secretion

It is the exposure of circulating platelets to the arterial wall and soluble agonists that causes platelet activation and clot formation in the event of a vessel injury. Platelets include several secretory inclusions, such as lysosomes, dense granules and α-granules.. The majority of these particles are α-granules, which can be anywhere from 200 to 500 nm in size and numbering about 50 to 80 granules per platelet. The proteins found in α-granules are both attached to the membrane and are soluble.[51]

The activation of platelets results in the release of soluble proteins into the extracellular compartment as well as the expression of membrane-bound proteins on the surface of the platelets. In accordance with proteomic studies, activated α-granules are responsible for the release of over 300 different soluble proteins on their own.[52]

These multi-functional bioactive proteins that are produced by α-granules are involved in several processes such as haemostasis, inflammation,

angiogenesis, wound healing and antimicrobial host defence. The proteins in question are illustrated with concrete instances in Table 4.[51]

Table 4: Bioactive proteins released from α-granule.[51]

Factor	Examples
Adhesive proteins	Von Willebrand factor, fibrinogen, fibronectin, vitronectin, thrombospondin-1 and -2, laminin-8
Clotting factors and inhibitors	Factor V/Va, factor XI, multimerin, protein S, high-molecular-weight kininogen, protease nexin-1 and -2, tissue factor pathway inhibitor, protein C inhibitor
Fibrinolytic factors and inhibitors	Plasminogen, plasminogen activator inhibitor-1, urokinase-type plasminogen activator (u-PA), α2-antiplasmin, histidine-rich glycoprotein, thrombin-activatable fibrinolysis inhibitor (TAFI,) α2-macroglobulin
Proteases and antiproteases	Metalloproteinases (MMP)-1, -2, -4, -9, a disintegrin and metalloproteinase with thrombospondin motifs (ADAMTS) 10, -13, TIMPs 1–4, platelet inhibitor of FIX, C1 inhibitor, α1-antitrypsin
Growth and mitogenic factors	transforming Growth Factor (TGF)-β1, -β2, platelet-derived growth factor (PDGF) -A, -B, and -C, epithelial growth factor (EGF), insulin-like growth factor-1 (IGF-1), vascular endothelial growth factor (VEGF) -A, -C, basic fibroblast growth factor (bFGF)-2, hepatocyte growth factor (HGF), bone morphometric protein (BMP)-2, -4, -6, connective tissue growth factor (CTGF), signal peptide, CUB domain and EGF-like domain containing 1 (SCUBE1), insulin-like growth factor binding protein 3 (IGFBP3)
Chemokines, cytokines and others	Interleukin (IL)-1, RANTES (CCL5), IL-8 (CXCL8), macrophage inflammatory protein (MIP)-1α (CCL3), MIP-2 (CXCL2), LIX (CXCL6) GRO-α (CXCL1), ENA-78 (CXCL5), stromal cell-derived factor (SDF)-1α (CXCL12), MCP-1 (CCL2), MCP-3 (CCL7), platelet factor 4 (PF4) (CXCL4), pro-platelet basic protein (PBP), β-thromboglobulin (β-TG), neutrophil activating protein-2 (NAP-2), connective-tissue activating peptide III T(CXCL7), thymus and activation-regulated chemokine (TARC) (CCL17), angiopoietin-1, high mobility group box 1 (HMGB1), interleukin-6 soluble receptor (IL-6sR), bone sialoprotein, dickkopf-1, osteoprotegerin
Others	Chondroitin 4-sulfate, albumin, immunoglobulins G and M, amyloid β-protein precursor, disabled-2, complement factor H, bile salt-dependent lipase (BSDL), semaphorin 3A

Activated platelets and abundant growth factors make up activated PRP, which aids in tissue repair and regeneration. Activation, aggregation, and adhesion are three mechanisms by which platelets control hemostasis. In the wound-healing process, the growth factor release enhances revascularization and minimizes inflammation, which accelerates up epithelial regeneration.[53]

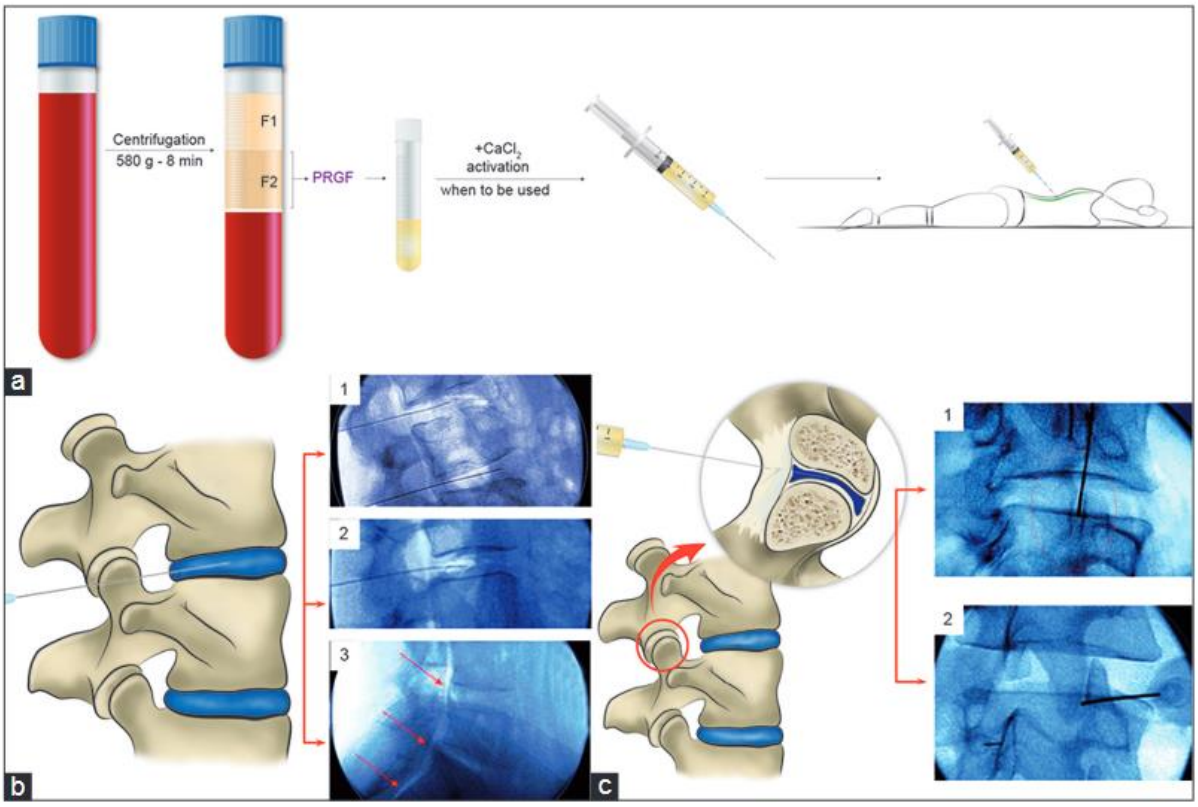


Figure 5: Platelet-rich plasma (PRP) preparation and infiltration of disc and lumbar facet joint.[54]

Limitations of PRP Injection

The usage of PRP to treat chronic LBP has been backed by certain clinical research. The effects of PRP may not endure indefinitely because of the short half-life of growth factors in it.[55]

There may not be enough residual viable cells for PRP to perform its functional role in individuals with advanced IVD and FJ degeneration. This suggests that PRP may not work as well for individuals with advanced illness, which is a major drawback. Further research is also essential to figure out the best time, dosage, and potential adverse effects of PRP injections.[56]

Relevant Articles describing the PRP's role in Facet Joint Disease

By 2016, **Wu et al.** had evaluated 19 Chinese patients with LFJ dysfunction prospectively in a clinic setting.[17] They underwent x-ray fluoroscopic control while receiving injections of autologous PRP. After one week of treatment, there was a substantial decrease in low back discomfort at rest and during flexion compared to before treatment. There were notable changes in lumbar functional capacity (greater than 10% improvement) based on Oswestry Disability Index (ODI) and Roland Morris Back Pain Questionnaire's (RMQ) scores showed statistical significance between the pre- and post-treatment

periods. Furthermore, throughout the injection procedure and subsequent follow-up, no serious significant problems were encountered.[17]

Using 46 patients diagnosed with LFJD in China between 2012 and 2016, **Wu et al.** compared the safety and effectiveness of PRP injection with IA steroid injection.[5] Injections of PRP and steroid were administered to about 23 individuals in Group A and 23 individuals in Group B, respectively. Both groups showed statistically significant betterment in pain VAS scores at rest or during flexion, the RMQ scores and the ODI scores compared to before therapy. Subjective satisfaction as measured by the modified MacNab criteria and the objective success rate for group B peaked at 80% and 85% after one month, respectively, but dropped to 50% and 20% after six months. The numbers, however, grew with time for group A. Injecting steroids or PRP into a patient suffering from LFJ condition was determined to be an uncomplicated, safe and effective therapy option. But when it came to therapy options with longer-lasting efficacy, they concluded PRP injection may be a more-efficient type of treatment.[5]

When it comes to treating chronic LBP caused by FJA, **Singh et al.** (2023) performed a prospective research in India with 45 patients to compare the efficacy and safety of intra-articular PRP and steroid along with radiofrequency ablation (RFA).[57] Following a 6-month follow-up, they found that PRP injections were just as safe as corticosteroid injections in treating

LFJD. But for longer-lasting effectiveness, autologous PRP may be a superior treatment option.[57]

To determine whether PRP is effective for LBP, **Xuan et al.** performed a meta-analysis and systematic review in 2020.[58] Three Randomized Controlled Trials (RCTs) with 131 patients were part of the meta-analysis. Overall, PRP administration was observed to considerably lower pain ratings, increase the fraction of patients experiencing pain reduction of at least 50% after three months, and provide quite acceptable patient satisfaction when compared to control intervention for LBP. Following PRP injection, there was no increase in reported adverse events.[58]

MATERIALS AND METHODS

STUDY DESIGN:

Patients diagnosed with LFA were enrolled in this prospective observational research.

STUDY AREA:

Those patients with LBP diagnosed as LFA who presented to the Emergency Medicine Department and the Orthopaedics Department of the R.L.Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, affiliated to Sri Devaraj Urs Academy of Higher Education and Research (SDUAHER) in Kolar were the ones who participated in the research study.

STUDY PERIOD AND DURATION:

One year and four months was the time frame in which the research was carried out, beginning in September 2022 and ending in December 2023.

STUDY POPULATION:

All patients with a diagnosis of LFA who meets all the inclusion criteria was admitted to the Orthopaedics ward from the Emergency Medicine and Orthopaedics Department of R.L.Jalappa Hospital and Research Centre, Kolar.

MATERIALS & METHODS

SAMPLE SIZE CALCULATION

Following IA injection with autologous PRP, 78.95% of patients with LFA had satisfactory or outstanding outcomes, according to a study by Juiping Wu et al.[17]

The Expected Proportion (p) is 79%, with a five percent alpha error (95% confidence limit).

The Absolute Precision (d) is 10%.

The Proportion of subjects with high to excellent functional outcomes was determined to be 64 subjects, which is the minimum required sample size.

The final sample size was exaggerated by 10% to account for a lost-to-follow-up rate of 10%, leading to the ultimate sample size of 71 subjects.

The sample size was derived from the following formula:

Sample size (n) = $(Z^2 (PxQ))/d^2$

Where Z represents the Confidence Interval, d represents the Absolute Precision, p represents the Expected Proportion and q is equal to 1-p.

INCLUSION CRITERIA:

- Patients having a clinico-radiological diagnosis of FJA who were above 40 years of age.
- A persistent or intermittent LBP that may or may not be accompanied by pain referred to the groin, buttocks or proximal thigh.
- Tenderness in the paraspinal region locally
- At rest, a pain score that is more than four on the VAS.
- Absent neurological impairment.
- The duration of LBP that is either continuous or intermittent for more than three months.

EXCLUSION CRITERIA:

- Those individuals who are suffering from cancer, mental disease and neurological disorders, as well as those who have co-morbid problems such as uncontrolled diabetes mellitus, uncontrolled hypertension.
- Individuals who have had spinal trauma, previous spine surgery, or lumbar facet joint intervention
- Those who suffer from spinal instability

- Disc herniation that is obvious or with radicular neurological complaints
- An allergy to anesthetics used locally
- An infection in the spine, systemically or locally
- Blood conditions such as thrombocytopenia, anemia and irreversible coagulopathy
- Pregnancy

SAMPLING METHOD:

All consecutive patients who were diagnosed with LFA between September 2022 and December 2023 and who were admitted to the Orthopaedics Department of the R.L.Jalappa Hospital in Kolar

DATA COLLECTION PROCEDURE

A comprehensive medical history, thorough physical examination and detailed analysis of radiographic images were documented according to the established protocol. Prior to the procedure, each individual underwent assessment utilizing the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI).

Once the site for injection was confirmed under fluoroscopic guidance, 2ml of PRP was administered into each of the afflicted FJs. After the procedure, all patients were evaluated immediately and then monitored at the end of 1 week, 1 month and 3 months. Each patient's functional outcome was evaluated using the ODI and VAS and the results were recorded in the proforma.

Autologous PRP Synthesis

The PRP was made using the conventional two-step centrifugation technique. A blood bag was used to collect 50–75 mL of peripheral blood sample under sterile circumstances (based on the number of treatment tiers). Next, to obtain the entire serum supernatant and a tiny portion of the sub-natant erythrocyte, the sample was initially centrifuged using a light spin at 2630 Revolutions Per Minute (RPM) for 3 minutes at room temperature. A second centrifugation at 1500RPM for another 15 minutes was performed on the serum supernatant in order to scrape out a portion of the platelet-poor plasma.

Ultimately, 10–15 ml of autologous PRP was extracted and was prepared for injection. To confirm that the concentration of platelets in PRP was approximately four to five times more than that in native peripheral blood, tests were conducted on each enrolled patient's complete blood count (CBC) in

native peripheral blood prior to treatment and platelet concentration in PRP following standard centrifugations.

Lumbar Facet Joint Injection

Under fluoroscopy, a skilled spine surgeon injected the PRP to LFJ. In order to straighten the lumbar spine, the patients were positioned prone on the operating table with a C-arm surrounding them and a pillow under their abdomen. The C-arm was adjusted until its beam matched the joint's open angle and the targeted LFJ space was plainly visible. This point where the C-arm's beam and the skin meet was designated as the needle penetration location.

Following the completion of the normal antisepsis of the skin, 3ml of 2% lignocaine was administered. Under fluoroscopic guidance, a 22 gauge spinal needle was cautiously inserted into the FJ space. Approximately 2 milliliters of autologous PRP was injected into the targeted joint following a successful IA puncture. During the IA injection, slow and mild pressure was applied to avoid rupturing the joint capsule. Once it was determined that there was no visible bleeding, the LFJ injection was finished successfully.

Study Tools -

VAS - is a numerical pain rating scale that is subjective and ranges between 0 and 10, with 0 denoting no pain and 10 denoting the worst agony that a person has ever felt.

ODI - is currently regarded as the gold standard for determining a patient's degree of disability and quality of life in LBP patients. Ten elements make up the ODI and they all indicate how well the patient is able to manage their daily activities despite their discomfort. Every ODI item has six possibilities, each of which represented a score between 0 and 5. A percentage score showed: patient's total score / total score achievable x 100%. It has been determined that a 10% change is clinically significant. Five categories were identified by the results: mild (0%–20%), moderate (21%–40%), severe (41%–60%), disabled (61%–80%), bedridden or exhibiting exaggerated symptoms (81%–100%).

Follow up

All the interviews were conducted for patients before the procedure, immediately after the procedure, at the end of one week, one month and 3 months respectively.

STUDY VARIABLES

- Age
- Gender
- Co-morbidities

ETHICAL CONSIDERATION

The Institutional Ethics Committee granted its approval in terms of ethics. By only using the data gathered for the study's stated aims, the researchers ensured that throughout the whole study, each participant's confidentiality and privacy were protected.

DATA ANALYSIS

- The gathered data were imported into Microsoft Excel and then examined by IBM. software for statistics SPSS 23.0.
- For the purpose of characterizing the data using descriptive statistics for discrete variables, both frequency analysis and percentage analysis were utilized. The following statistical measures were utilized for continuous variables: mean, median, range, minimum, maximum and standard deviation.

- It was determined whether there were statistically significant alterations between the two groups by utilizing the Paired T test to analyse the modifications in VAS and ODI scores before and after the PRP injection at various intervals across both groups. To determine whether there was a statistically notable difference between the two groups at various intervals of evaluation, the Independent T test was utilized to analyse the differences in VAS and ODI scores.
- In each and every statistical method, the level of significance that was considered to be the most significant was the probability value of 0.05.

RESULTS

RESULTS

Table 5: Age distribution of enrolled patients

Age in years	
Mean	51.23
Median	50
Std. Deviation	8.034
Range	34
Minimum	41
Maximum	75

In this study, the average age of the patients who were diagnosed with LFA was 51.23 years, with a standard deviation of Eight years.

Figure 6: Age distribution of enrolled patients.

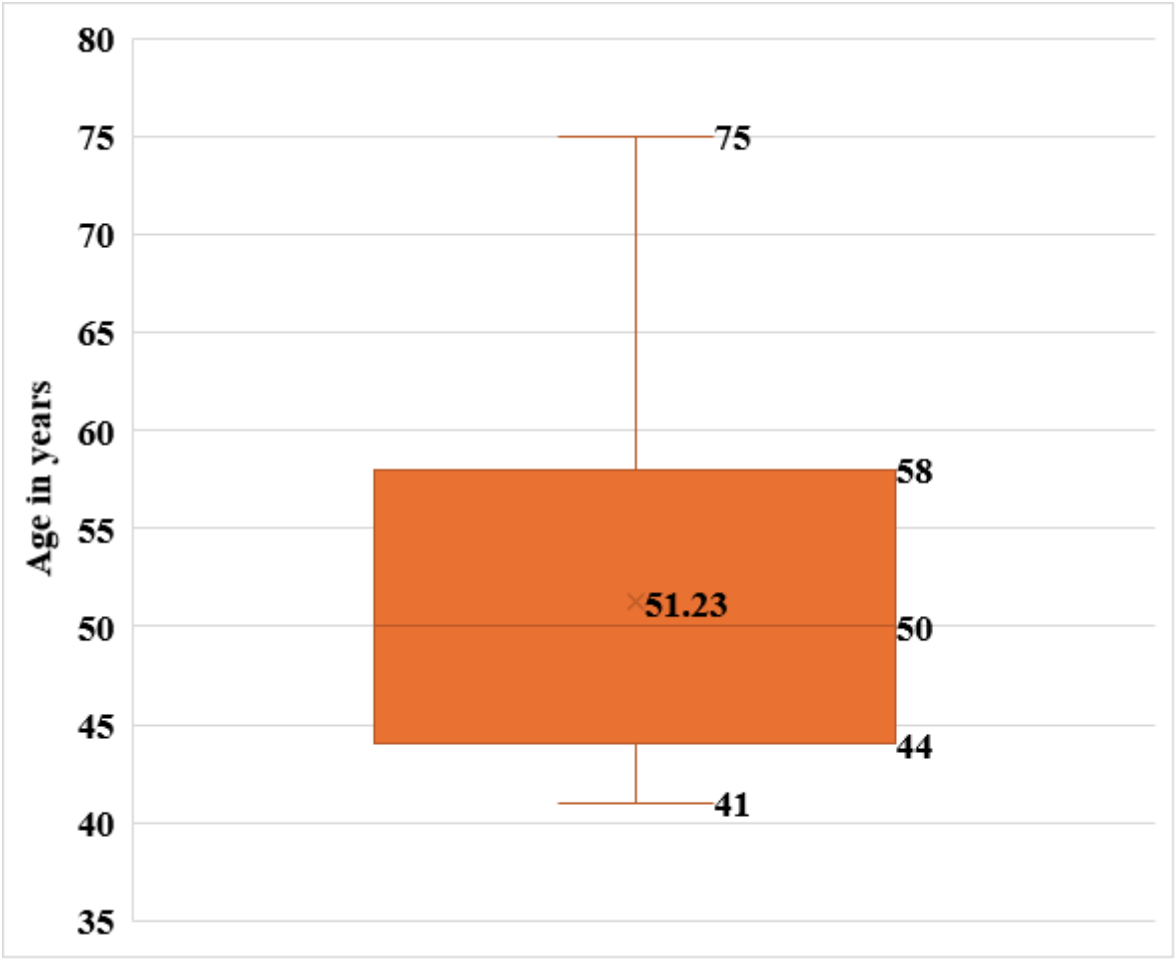


Table 6: Gender distribution of enrolled patients

Gender	Frequency	Percent
Female	33	46.5
Male	38	53.5
Total	71	100

Patients diagnosed with LFA were divided into two groups: 46.5% of them were female, while the remaining 53.5% were male.

Figure 7: Gender distribution of enrolled patients.

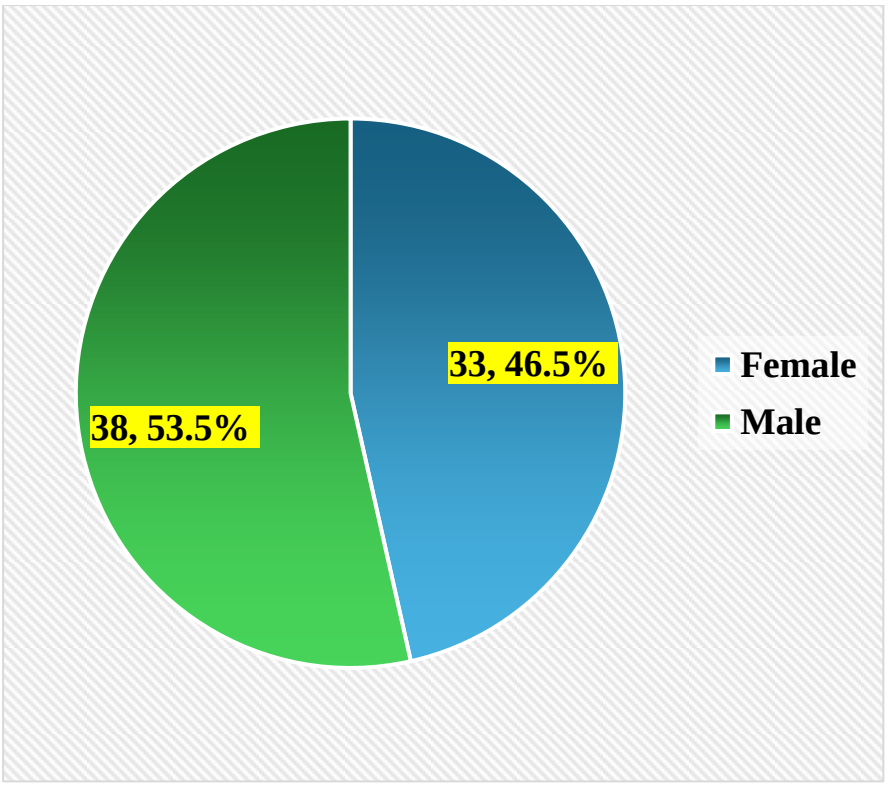


Table 7: Distribution of enrolled patients based on the occurrence of comorbidities.

Comorbidities	Frequency	Percent
Diabetes Mellitus	8	11.3
Hypertension	8	11.3
Diabetes Mellitus, Hypertension	4	5.6
Nil	51	71.8

- Patients diagnosed with LFA had a prevalence of hypertension and diabetes mellitus that was 11.3% when both conditions were considered separately, but the combined prevalence was only 5.6%.
- 71.8 % of the patients were found to have no comorbidities.

Figure 8: Distribution of enrolled patients based on the occurrence of comorbidities.

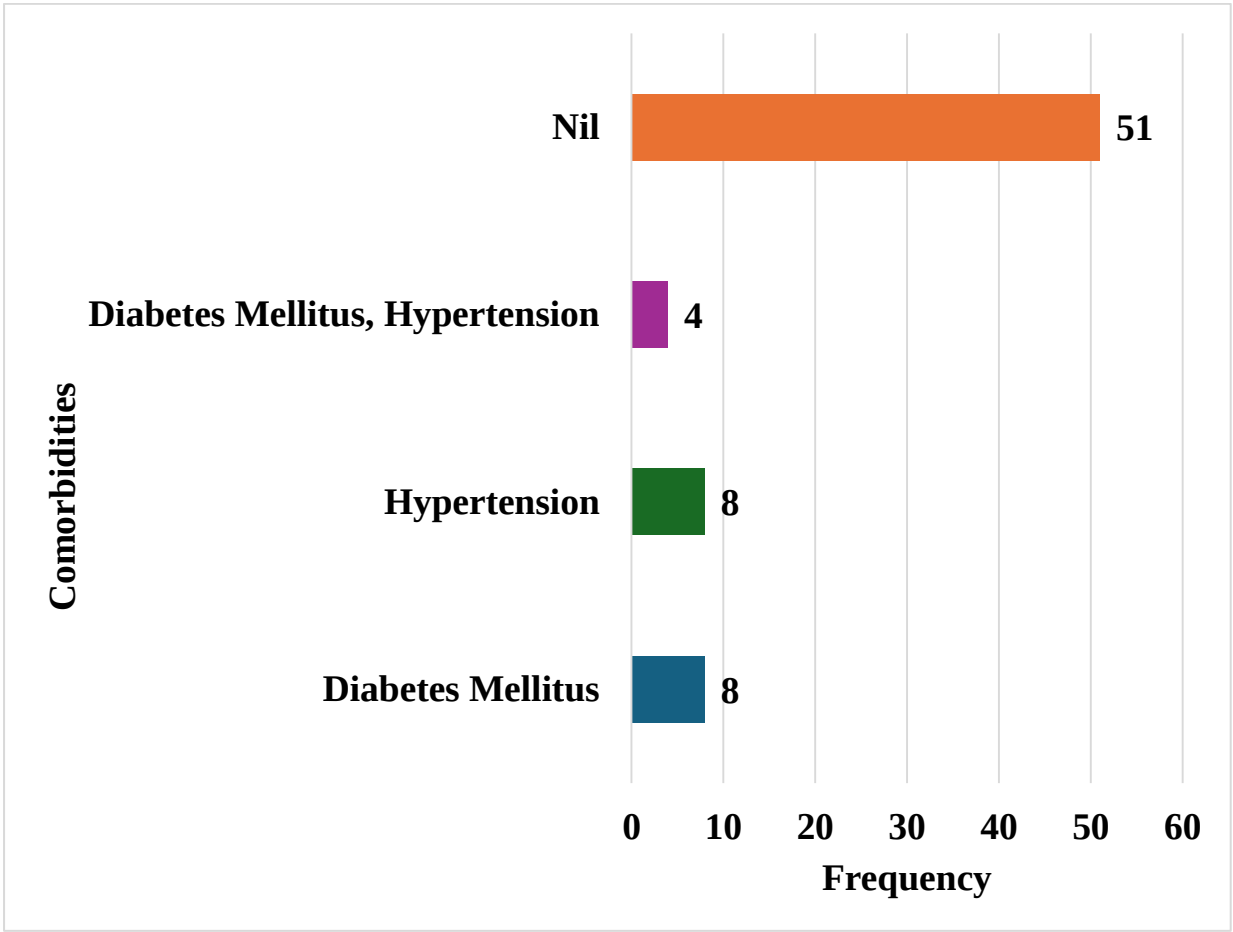


Table 8: Measures of VAS score before and after intervention

Measures of VAS score	Mean	Median	S. D	Range	Min.	Max.
Pre-procedure	7.66	8	0.755	3	6	9
Immediate post-procedure	6.7	7	0.725	3	5	8
1 week	5.27	5	0.755	3	4	7
1 months	2.96	3	0.745	3	2	5
3 months	1.07	1	0.617	2	0	2

- The table above presents the average VAS score evaluated at various time intervals before and after the PRP injection for the treatment of LFA. The pain score significantly decreased immediately after the PRP injection on the day of the procedure (6.7).
- Further, the pain score diminished even more at the end of one week (5.27) and one month (2.96) and further decreased at three months (1.07) after the PRP injection.
- There is a decreasing pattern in pain rating after PRP injection for the treatment of LFA.

Figure 9: Line diagram showing trends of mean VAS score before and after intervention.

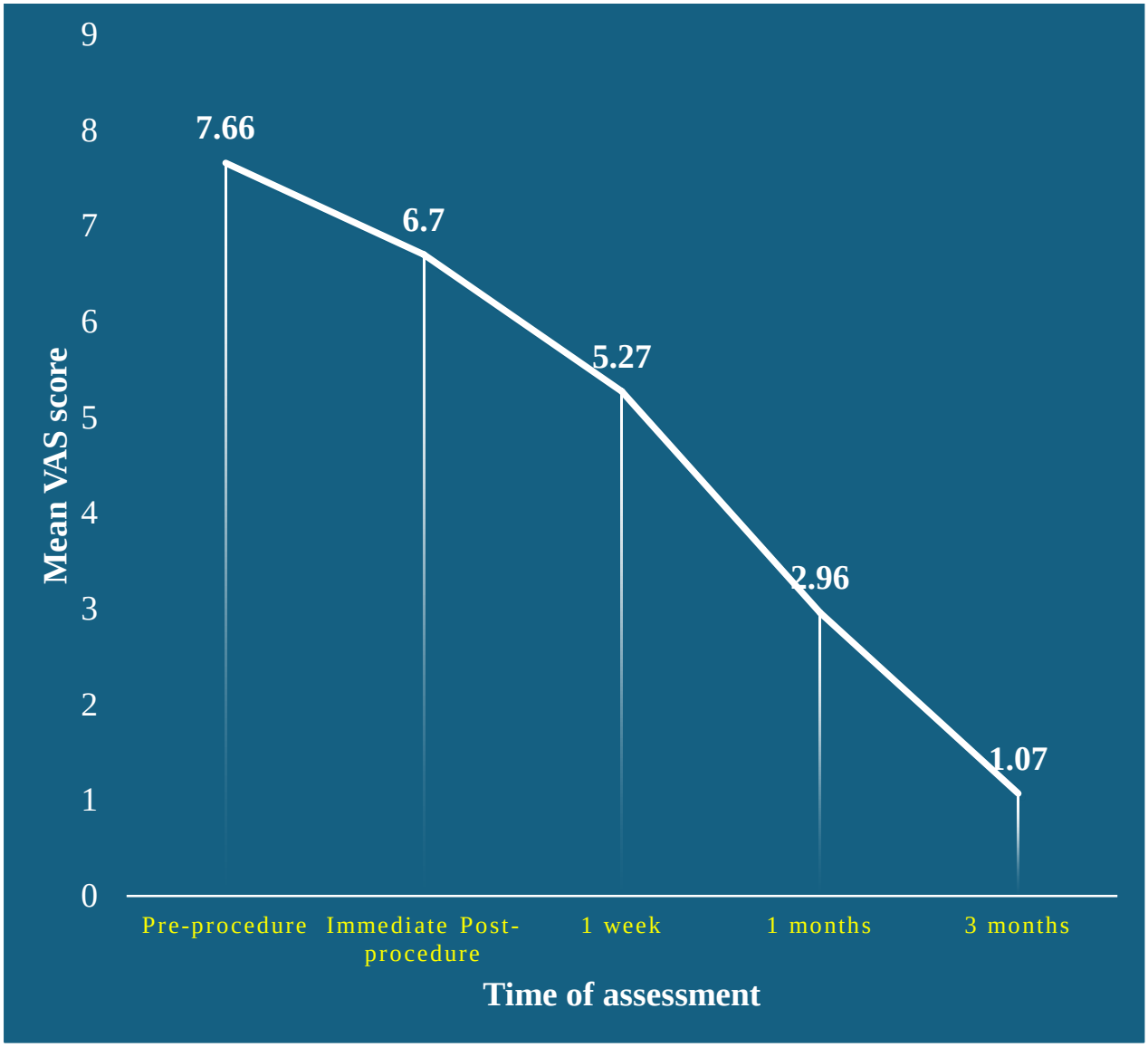


Table 9: Measures of ODI score before and after intervention.

Measures of ODI scores	Mean	Median	S. D	Range	Min.	Max.
Pre-procedure	55.13	54	4.557	24	44	68
Immediate post-procedure	52.9	52	4.444	22	42	64
1 week	45.44	46	3.901	20	36	56
1 months	33.69	34	3.981	22	24	46
3 months	22.55	24	3.346	12	16	28

- The table above presents the average ODI score measured at various time intervals before and after the PRP injection for the treatment of LFA.
- The impairment score significantly lowered immediately after the PRP injection on the day of the procedure (52.9).
- Subsequently, the disability score experienced a further decrease at the end of one week (45.44), then a decrease at the end of a month (33.69) and at the end of three months (22.55) after the PRP injection.
- PRP injection has been observed to result in a decrease in disability score for patients with LFA.

Figure 10: Line diagram showing trends of mean ODI score before and after intervention.

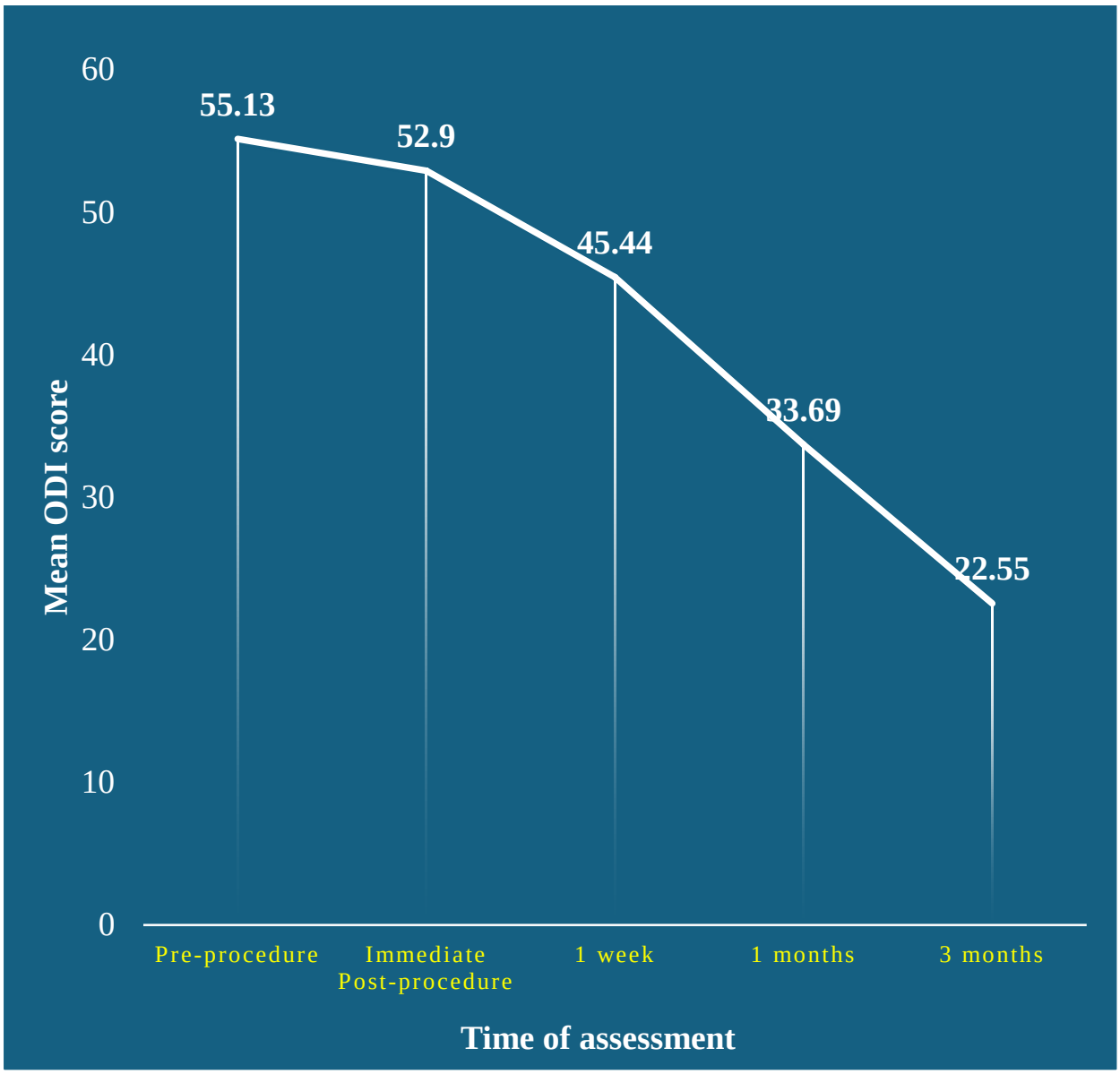


Table 10: Comparison of VAS score before and after intervention by Paired T test.

VAS scores before and after intervention		Mean	S. D	Mean diff.	P value
Pair 1	Pre-procedure	7.66	0.755	0.958	0.0001
	Immediate post-procedure	6.7	0.725		
Pair 2	Pre-procedure	7.66	0.755	2.394	0.0001
	1 week	5.27	0.755		
Pair 3	Pre-procedure	7.66	0.755	4.704	0.0001
	1 month	2.96	0.745		
Pair 4	Pre-procedure	7.66	0.755	6.592	0.0001
	3 months	1.07	0.617		
Pair 5	Immediate post-procedure	6.7	0.725	3.746	0.0001
	1 month	2.96	0.745		
Pair 6	Immediate post-procedure	6.7	0.725	5.634	0.0001
	3 months	1.07	0.617		

- The table above shows the comparison of VAS scores before and after intervention using Paired T test.
- The mean VAS score significantly decreased immediately after the procedure, at the end of 1 week, 1 month and 3 months after PRP injection for managing LFA, compared to the pre-procedure mean VAS score.
- Similarly, the mean VAS score significantly decreased at the end of 1 week, 1 month and 3 months after PRP injection, compared to the immediate post-procedure mean VAS score.
- This decrease in VAS score was statistically significant in each pair, with a P value of 0.0001.
- Therefore, PRP injections continue to effectively reduce pain severity in patients with LFA even three months after administration.

Figure 11: Comparison of VAS score before and after intervention by Paired T test.

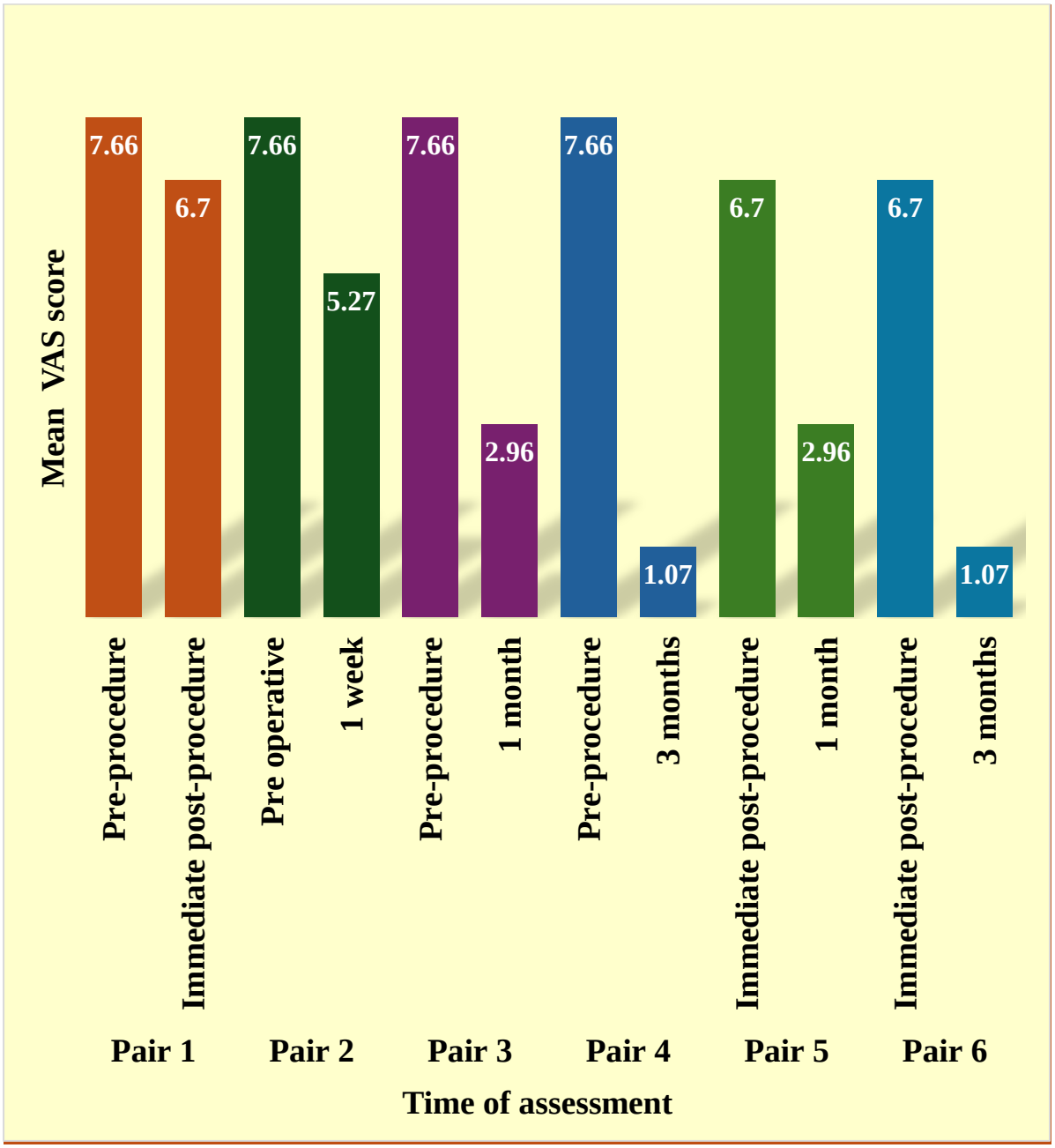
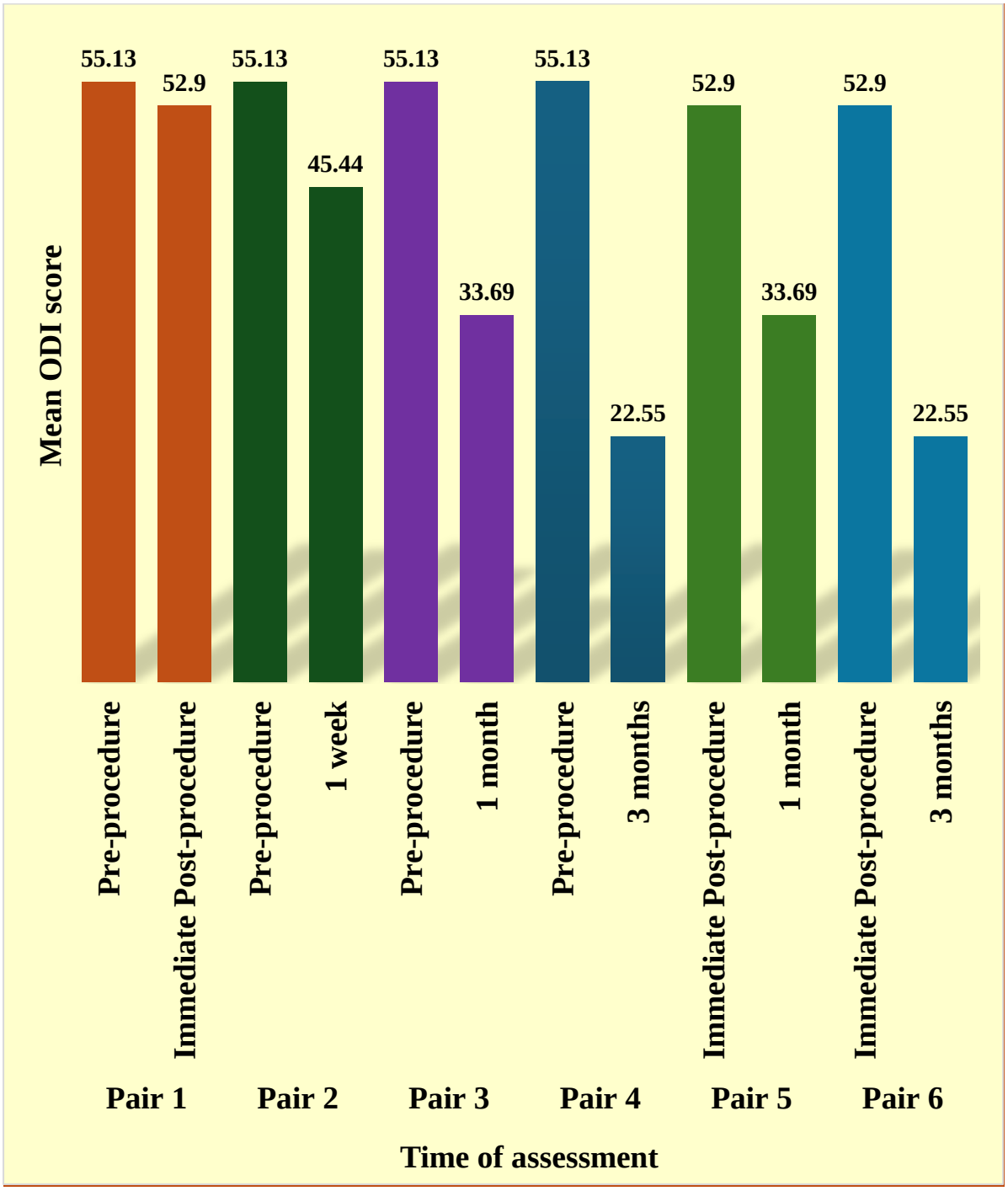


Table 11: Comparison of the ODI score prior to and following the intervention by Paired T test.

ODI scores before and after intervention		Mean	S. D	Mean difference	P value
Pair 1	Pre-procedure	55.13	4.557	2.225	0.0001
	Immediate post-procedure	52.9	4.444		
Pair 2	Pre-procedure	55.13	4.557	9.69	0.0001
	1 week	45.44	3.901		
Pair 3	Pre-procedure	55.13	4.557	21.437	0.0001
	1 month	33.69	3.981		
Pair 4	Pre-procedure	55.13	4.557	32.577	0.0001
	3 months	22.55	3.346		
Pair 5	Immediate post-procedure	52.9	4.444	19.211	0.0001
	1 month	33.69	3.981		
Pair 6	Immediate post-procedure	52.9	4.444	30.352	0.0001
	3 months	22.55	3.346		

- The table above displays the comparison of ODI scores before and after PRP injection using the Paired T test.
- The ODI score fell significantly immediately after the procedure, at the end of 1 week, 1 month and 3 months after the PRP injection for controlling LFA, compared to the ODI score before the treatment.
- Similarly, the average ODI score significantly decreased at the end of 1 week, 1 month and 3 months after PRP injection for treating LFA, compared to the ODI score immediately after the treatment.
- The drop in ODI score was shown to be statistically significant in each pair, as determined by a paired t-test (p-value of 0.0001).
- PRP injections effectively decrease disability in individuals with lumbar facet arthropathy for up to three months following administration.

Figure 12: Comparison of the ODI score prior to and following the intervention by Paired T test.



DISCUSSION

DISCUSSION

Although the majority of study on LBP has focused on the IVD, FJs are as significant. PRP has shown promise in the management of numerous musculoskeletal conditions. PRP is a plasma fraction with a high platelet content that is obtained through centrifugation. Numerous treatments in regenerative medicine have made use of biological and cellular therapy.[59]

PRP has been used in medicine to speed up tissue regeneration and the healing process.[60] In recent times, PRP has proven to be effective in healing affected tissues, particularly cartilage, ligaments and tendons, especially in the field of orthopaedics.[61,62] Recently, a number of studies have documented the use of PRP in the treatment of spinal disorders.[63] Nevertheless, the effectiveness of PRP utilized in therapeutic settings is occasionally disputed because of the insufficient high-quality clinical data.

There is limited information available regarding the use of IA injection of PRP for treating LFA. 71 patients who were diagnosed with LFA and who were brought to the Emergency Medicine Department and the Orthopaedics Department of R.L.Jalappa Hospital in Kolar were the ones who participated in the research study. After the procedure, all patients were evaluated immediately and then monitored at the end of 1 week, 1 month and 3 months.

The functional outcome of each patient was evaluated using the ODI and VAS, and the results were recorded in the proforma.

Comparison of basic characteristics of the enrolled patients with similar studies

In this research, the average age of the patients with LFA was 51.23 years. 46.5% of them were female, while the remaining 53.5% were male. The prevalence of hypertension and diabetes mellitus was 11.3% of the study samples. 71.8% percent of the patients were found to have no comorbidities.

In a clinical context, Wu et al. prospectively assessed 19 Chinese patients with LFJS by 2016.[17] The mean age of patients diagnosed with LFJS was 52.53 ± 6.79 years. Out of the total, there were 8 males and 11 females.

Zhen Xu et al. carried out a randomized controlled experiment where 124 patients with radicular pain from lumbar disc herniation (LDH) were randomly allocated to receive either steroid or PRP injections to ultrasonography (USG) guided transforaminal sites.[64] The patients had an average age of 56 years. Out of the total, 54.1% were female and 45.9% were male.

Comparison of effectiveness of PRP in reducing pain with similar studies

The average VAS score showed a significant decrease immediately after the procedure, at the end of 1 week, 1 month and 3 months following PRP

injection for the treatment of LFA, as compared to the average VAS score before the procedure.

Similarly, the average VAS score considerably decreased at the end of 1 week, 1 month and 3 months after PRP injection, in comparison to the average VAS score immediately after the surgery. Hence, PRP injections consistently diminish the intensity of pain in individuals with LFA even after a span of three months following the treatment.

Table 12: Comparison of VAS score with similar studies before and after the PRP injection.

Measures of VAS score	**Pre-procedure**	**Immediate post-procedure**	**1 months**	**3 months**
Present study	7.66	6.7	2.96	1.07
Singh et al[57]	7.2	3.2	2.07	0.47
Kirchner et al[54]	8.4	-	4	1.7
Kotb et al[65]	8	-	-	5.73
Eldin et al[66]	8.45	-	-	6.73
Ruiz-Lopez et al[67]	7.18	-	4.4	6.28

In this study, the pain score exhibited a considerable reduction immediately following the PRP injection on the same day of the procedure, with a score of 6.7. Additionally, the pain score further fell to 5.27 after a week, then to 2.96 at the end of one month and to 1.07 at the end of three months following the PRP injection. Similar observations were made in the study by Singh et al[57] as well as Kirchner et al[54] in which there was significant decrease in VAS score when followed up for 3 months after PRP injection. Whereas in the study by Kotb et al[65], Eldin et al[66] and Ruiz-Lopez et al[67] the decrease in VAS score was moderate 3 months after PRP injection.

Comparison of effectiveness of PRP in improving functional outcome with similar studies

The ODI score exhibited a substantial decrease immediately after the procedure, at the end of 1 week, 1 month and 3 months following PRP injection for the treatment of LFA, in comparison to the ODI score prior to the procedure.

Similarly, the mean ODI score showed a substantial decrease at the end of 1 week, 1 month and 3 months following PRP injection for the management of LFA, compared to the ODI score immediately after the procedure. PRP injections significantly reduce impairment in persons with LFA for a duration of three months after being administered.

Table 13: Comparison of ODI score with similar studies before and after the PRP injection.

Measures of VAS score	Pre-procedure	Immediate post-procedure	1 months	3 months
Present study	55.13	52.9	33.69	22.55
Singh et al[57]	72.33	32.27	23.2	14.47
Kotb et al[65]	58.13	-	-	47.6
Zhen Wu et al[64]	35	27	22	20
Jae Won et al[68]	32.7	-	24.3	18.7

The impairment score decreased significantly immediately following the PRP injection to FJs (52.9). Afterwards, the disability score underwent a subsequent decrease at the end of one week (45.44), eventually a drop at the end of one month (33.69) and at the end of three months (22.55) following the PRP injection.

Similar observations were made in the study by Singh et al[57] as well as Jae Won et al[68] in which there was significant decrease in ODI score when followed up for 3 months after PRP injection. Whereas in the study by Kotb et al[65] and Zhen Wu et al[64] the decrease in ODI score was moderate 3 months after PRP injection.

Overall, the administration of PRP as an injectable therapy for individuals suffering from lumbar facet joint pain (LFJP) is both harmless and efficient in easing pain and minimizing disability.

In a clinical context, Wu et al. prospectively assessed 19 Chinese patients with LFJS by 2016.[17] They underwent x-ray fluoroscopy while receiving autologous PRP injections. Following a week of treatment, There was a notable decrease in LBP both at rest and during flexion, as compared to the pre-treatment period. Significant increases in lumbar functional ability were seen and the RMQ scores demonstrated statistical significance when comparing the periods before and after PRP injection treatment.

By 2023, Singh et al carried out a study in which 60 cases of back pain were assessed in India. They concluded that autologous PRP was an ideal novel injectable preparation for the application of IA injection to treat LFJS. Both PRP injection and steroid injections were determined to be effective and safe for the treatment of LFJS after 6 months of follow-up. However, for a longer period of efficacy, autologous PRP might be an ideal option for treatment.[57]

Kirchner et al conducted a study among 80 patients with chronic LBP history and degenerative illness in Spain.[54] A substantial decrease in pain, as measured by VAS was observed in patients suffering from chronic LBP after undergoing a minimally invasive treatment that included Plasma Rich in

Growth Factors (PRGF) infiltrations of intradiscal and FJs. By the end of the sixth month follow-up, the percentage of pain reduction had gradually increased to 90%. This result agreed with what we found in our current investigation.[54]

In 2020, Xuan et al. carried out a meta-analysis and systematic review to assess the efficiency of PRP for LBP.[58] The meta-analysis included three RCTs involving 131 subjects. The results showed that compared to a control intervention for LBP, PRP injections decreased pain scores, enhanced the proportion of patients reporting 50% or more pain reduction at 3 months and generally provided good patient satisfaction. No worsening of symptoms occurred after PRP injection.[58]

After 18 months of treatment, 49 individuals with facet syndrome (FS) who had PRP reported much less discomfort and much better functionality. There were no reported side effects, further demonstrating that PRP is highly successful in controlling pain in FJs.[69]

One hundred forty-four individuals with FJ discomfort were enrolled in a RCT that compared PRP with hyaluronic acid (HA). The two group's outcomes were comparable after an average of 18 months of follow-up, however the PRP group demonstrated more significant improvements in clinical outcomes and had more satisfied patients.[70]

LFJS patients can benefit from PRP, a two-step centrifugation procedure. IA injections into the FJs were found to be a harmless and effective substitute to Corticosteroids (CS) and local anaesthetics, with no reported side effects. Success rates and levels of satisfaction were higher in the CS group at the outset, but they dropped after six months. Alternatively, the PRP group showed persistent improvement throughout the course of the study.[5]

In a study done in Egypt in 2022 by Kotb et al., 30 patients with LFJD were split into two groups of equal size and received PRP and CS injections.[65] At the 3 month follow-up, both groups showed an obvious enhancement in all the specified metrics. But PRP injections demonstrated better performance overall as compared to CS injection. Based on their findings, PRP may be a more successful treatment choice with a longer duration of effect.[65]

CONCLUSION

CONCLUSION

Based on study observations, it was concluded that even three months after administration, PRP injections were found to be still beneficial in alleviating pain severity and thereby improving the functional status of individuals with LFA.

Autologous PRP is a promising novel option for the treatment of patients with LFA. Our study demonstrates that this new treatment technique with autologous PRP injection is safe and effective for the patients with LFA and may have vast application going forward.

In a future study, a placebo-controlled trial with a larger sample size and tighter patient selection criteria may yield a more convincing result and could potentially confirm these findings.

LIMITATIONS

LIMITATION

- Due to the small number of participants and the fact that the research was conducted at a single location, it is possible that the findings cannot be extrapolated to the entire community.
- The limited duration of follow-up of 3 months emphasizes the necessity of a protracted, prolonged follow-up time of 6 months to comprehensively assess the enduring impact of the PRP injection.
- This study was carried out with a lack of a placebo-controlled group to compare with PRP group.
- The potential problems of LFJ injection may arise from the puncture procedure and the potential issues associated with the use of PRP were not considered.
- We did not conduct a prior diagnostic block to determine patient selection. Consequently, our confirmation of diagnosis and selecting patients were based only following a meticulous clinical assessment.
- The absence of quantification of physical activity levels prior to and following the intervention was observed.

SUMMARY

SUMMARY

Seventy one patients who were diagnosed with LFA and who were brought to Emergency Medicine Department and Orthopaedics Department of R.L.Jalappa Hospital in Kolar were the ones who participated in the study during the period between September 2022 and December 2023. About 3ml of PRP was administered into each of the afflicted FJs. After the procedure, all patients were evaluated immediately and then at the end of 1 week, 1 month and 3 months. Each patient's functional outcome was assessed using the VAS and ODI, and the results were documented in the proforma.

In this study, the average age of the patients with LFA was 51.23 years. 46.5 percent of them were female, while the remaining 53.5 percent were male. 71.8 percent of the patients were found to have no comorbidities. The pain score significantly decreased immediately after the PRP injection on the day of the procedure (6.7). Further, the pain score diminished even more at the end of one week (5.27), at the end of one month (2.96) and further decreased at the end of three months (1.07) after the PRP injection. Therefore, PRP injection continue to effectively reduce pain severity in patients with LFA even three months after administration. The disability score significantly lowered immediately after the PRP injection on the day of the procedure (52.9). Subsequently, the disability score experienced a further decrease at the end of one week (45.44), followed by a decline at the end of one month (33.69) and at

the end of three months (22.55) after the PRP injection. Therefore, PRP injection effectively decrease disability in individuals with LFA even three months after administration.

PRP injections significantly reduce pain and disability in persons with LFA for a duration of three months after being administered. Therefore, an autologous PRP is an optimal new medication that can be injected directly into the joint to treat LFA. After a 3-month follow-up, it was concluded that PRP was effective, easy to use and sufficiently safe for treating LFA.

Autologous PRP is a promising new option for the treatment of patients with LFA. Our study demonstrates that this novel treatment technique with autologous PRP injection is safe and effective for the patients with LFA and may have vast application going forward.

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ANNEXURE

ANNEXURE

ANNEXURE - I

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101

PATIENT INFORMATION SHEET

STUDY TITLE: "A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY"

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.**Details-** Patients presenting with low back ache and features suggestive of Lumbar Facet Arthropathy to the out-patient department of R.L Jalappa HOSPITAL AND RESEARCH CENTRE will be included in this study.

Routine blood samples (CBC, RBS, BT, CT, HIV, HCV & HBsAg) along with preoperative x-ray of Lumbosacral spine -anteroposterior and lateral view and preoperative MRI of Lumbosacral spine will be taken from these patients. Also around 50-75ml of blood will be taken, which will be processed to obtain 10-15ml of Platelet Rich Plasma (It is a platelet rich fluid made out from blood), following which around 2ml of Platelet Rich Plasma will injected to the affected joints. Intra articular Platelet Rich Plasma injection possess the following complications like infection, bleeding, allergy. All patients will be assessed before the procedure, immediately after the procedure, at 1 week, 1 month and 3 months. Each patient's functional outcome (disability and pain) will be assessed by using Oswestry Disability Index (ODI) and Visual Analog Scale (VAS)Please read the above information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will be collecting information (as per proforma) from you. Demographic details of the patient, presenting complaint, relevant past history and examination findings will be recorded. This information collected will be used only for dissertation and publication purpose. All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information or clarification please contact

Dr. GILS THAMPI (Post Graduate),

Department of ORTHOPAEDICS,

SDUMC, Kolar

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ANNEXURE – II

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: "ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ಮೇಲೆ ಪ್ಲೇಟ್ಲೆಟ್ ಸಮೃದ್ಧ ಪ್ಲಾಸ್ಮಾ ಇಂಜೆಕ್ಷನ್ ಸೊಂಟದ ಮುಖದ ಸಂಧಿವಾತದಲ್ಲಿ" ಒಂದು ನಿರೀಕ್ಷಿತ ಅಧ್ಯಯನ

ಸ್ಥಳ: ಆರ್ . ಎಲ್ . ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ, ಕೋಲಾರದಲ್ಲಿರುವ ಶ್ರೀ ದೇವರಾಜ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು.

ವಿವರಗಳು- ಕೋಲಾರದ ತಮಕದಲ್ಲಿರುವ ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನಲ್ಲಿ ಲಗತ್ತಿಸಲಾದ ಆರ್ ಎಲ್ ಜೆ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರದ ಹೊರರೋಗಿ ವಿಭಾಗಕ್ಕೆ ಸೊಂಟದ ಮುಖದ ಸಂಧಿವಾತವನ್ನು ಸೂಚಿಸುವ ಲಕ್ಷಣಗಳೊಂದಿಗೆ ಕಡಿಮೆ ಬೆನ್ನುನೋವಿನೊಂದಿಗೆ ಪ್ರಸ್ತುತಪಡಿಸುವ ರೋಗಿಗಳನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ.

ಲುಂಬೊಸ್ಯಾಕ್ರಲ್ ಬೆನ್ನುಮೂಳೆಯ ಪೂರ್ವಭಾವಿ ಕ್ಷ-ಕಿರಣದ ಜೊತೆಗೆ ಈ ರೋಗಿಗಳಿಂದ ದಿನನಿತ್ಯದ ರಕ್ತದ ಮಾದರಿಗಳನ್ನು (ಸಿಬಿಸಿ, ಆರ್‌ಬಿಎಸ್, ಬಿಟಿ, ಸಿಟಿ, ಎಚ್‌ಸಿವಿ ಮತ್ತು ಎಚ್‌ಬಿಎಸ್‌ಎಜಿ) ತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದೆ - ಆಂಟೆರೊಪೊಸ್ಟೀರಿಯರ್ ಮತ್ತು ಲ್ಯಾಟರಲ್ ವ್ಯೂ ಮತ್ತು ಲುಂಬೊಸ್ಯಾಕ್ರಲ್ ಬೆನ್ನುಮೂಳೆಯ ಪೂರ್ವಭಾವಿ ಎಂ ಆರ್ ಐ. ಅಲ್ಲದೆ ಸುಮಾರು 75-100ml ರಕ್ತವನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದೆ, ಇದು 30 ml ಪ್ಲೇಟ್ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾವನ್ನು ಪಡೆಯಲು ಸಂಸ್ಕರಿಸಲ್ಪಡುತ್ತದೆ (ಇದು ರಕ್ತದಿಂದ ತಯಾರಿಸಿದ ಪ್ಲೇಟ್ಲೆಟ್ ಸಮೃದ್ಧ ದ್ರವವಾಗಿದೆ), ನಂತರ ಸುಮಾರು 3ml ಪ್ಲೇಟ್ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾವನ್ನು ಪ್ರತಿಯೊಂದಕ್ಕೂ ಚುಚ್ಚಲಾಗುತ್ತದೆ. ಬಾಧಿತ ಮುಖದ ಕೀಲುಗಳು. ಇಂಟ್ರಾ ಆರ್ಟಿಕ್ಯುಲರ್ ಪ್ಲೇಟ್ಲೆಟ್ ರಿಚ್ ಪ್ಲಾಸ್ಮಾ ಇಂಜೆಕ್ಷನ್ ಸೋಂಕು, ರಕ್ತಸ್ರಾವ, ಅಲರ್ಜಿಯಂತಹ ಕೆಳಗಿನ ತೊಡಕುಗಳನ್ನು ಹೊಂದಿದೆ.

ಎಲ್ಲಾ ರೋಗಿಗಳನ್ನು ಕಾರ್ಯವಿಧಾನದ ಮೊದಲು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ, ಕಾರ್ಯವಿಧಾನದ ನಂತರ ತಕ್ಷಣವೇ, ನಂತರ 1 ವಾರ, 1 ತಿಂಗಳು ಮತ್ತು 3 ತಿಂಗಳುಗಳಲ್ಲಿ ಅನುಸರಿಸಲಾಗುತ್ತದೆ. ಓಸ್ವೆಸ್ಟ್ರಿ ಡಿಸಾಬಿಲಿಟಿ ಇಂಡೆಕ್ಸ್ (ODI) ಮತ್ತು ವಿಷುಯಲ್ ಅನಲಾಗ್ ಸ್ಕೇಲ್ (VAS) ಅನ್ನು ಬಳಸಿಕೊಂಡು ಪ್ರತಿ ರೋಗಿಯ ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶವನ್ನು (ಅಂಗವೈಕಲ್ಯ ಮತ್ತು ನೋವು) ನಿರ್ಣಯಿಸಲಾಗುತ್ತದೆ.

ದಯವಿಟ್ಟು ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ, ನಾವು ನಿಮ್ಮಿಂದ ಮಾಹಿತಿಯನ್ನು (ಪ್ರೊಫಾರ್ಮಾ ಪ್ರಕಾರ) ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಇತಿಹಾಸ ಮತ್ತು ಪರೀಕ್ಷೆಯನ್ನು ಮಾಡಲಾಗುತ್ತದೆ. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ನೀವು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಒತ್ತಾಯವಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ಕಾಳಜಿಯು ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸಿದರೆ ಮಾತ್ರ ನೀವು ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ.

ಗೌಪ್ಯತೆ

ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನ ವೈದ್ಯರು ಮತ್ತು ಸಿಬ್ಬಂದಿ ಗೌಪ್ಯವಾಗಿಡುತ್ತಾರೆ ಮತ್ತು ಸಾರ್ವಜನಿಕವಾಗಿ ಲಭ್ಯವಾಗುವಂತೆ ಮಾಡಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮೂಲ ದಾಖಲೆಗಳನ್ನು ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ಎಥಿಕ್ಸ್ ರಿವ್ಯೂ ಬೋರ್ಡ್ ಪರಿಶೀಲಿಸಬಹುದು. ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಅಥವಾ ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ದಯವಿಟ್ಟು ಸಂಪರ್ಕಿಸಿ

ಡಾ. ಗಿಲ್ಸ್ ತಂಪಿ,
ಮೂಳೆಚಿಕಿತ್ಸಾ ವಿಭಾಗ,
ಎಸ್‌ಡಿಯುಎಂಸಿ, ಕೋಲಾರ
ಸಂಪರ್ಕ ಸಂಖ್ಯೆ: 7795177611 ಇಮೇಲ್ ಐಡಿ: gilsthampi@gmail.com

ANNEXURE – III

Date:

INFORMED CONSENT FORM

I Mr./Mrs. _____ have been explained in my own understandable language, that I will be included in the study entitled, "A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY"

I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions

Researcher has explained to me,

-that my clinical findings, investigations, postoperative findings will be assessed and documented for study purpose.

-that my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.

-in my own understandable language about the interventions needed, possible benefits and adversities due to interventions,

-i have to answer the questionnaires related to study.

I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.

I give full consent to be added in the part of this study.

Signature (or Thumb impression) of the patient :_____

Patient's Name: _____

Date: _____/_____/_____

Signature of the Investigator: _____

Study Investigator's Name: _____

Date: _____/_____/_____

Signature or thumb impression of the Witness: _____

Name of the Witness: _____

Date: _____/_____/_____

ANNEXURE – IV

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ನಾನು ಶ್ರೀ/ಶ್ರೀಮತಿ. _____ ಅನ್ನು ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, "ಸೊಂಟದ ಮುಖ ಆಸ್ಟ್ಯೋಪತಿಯಲ್ಲಿ ಪ್ಲೇಟ್‌ಲೆಟ್ ಶ್ರೀಮಂತ ಪ್ಲಾಸ್ಮಾ ಚುಚ್ಚುಮದ್ದಿನ ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ಬಗ್ಗೆ ನಿರೀಕ್ಷಿತ ಅಧ್ಯಯನ" ಎಂಬ ಶೀರ್ಷಿಕೆಯ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು ಸೇರಿಸಲಾಗುವುದು.

ಮೇಲಿನ ಅಧ್ಯಯನದ ದಿನಾಂಕದ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶವನ್ನು ಹೊಂದಿದ್ದೇನೆ ಎಂದು ನಾನು ಖಚಿತಪಡಿಸುತ್ತೇನೆ

ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ

- ನನ್ನ ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನೆಗಳು, ತನಿಖೆಗಳು, ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ ಮತ್ತು ಅಧ್ಯಯನ ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ.
- ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಯ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.
- ಅಗತ್ಯವಿರುವ ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಬಗ್ಗೆ, ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ಮಧ್ಯಸ್ಥಿಕೆಗಳಿಂದ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲತೆಗಳು.
- ನಾನು ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಪ್ರಶ್ನಾವಳಿಗಳಿಗೆ ಉತ್ತರಿಸಬೇಕಾಗಿದೆ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಪತ್ತೆಯಾದ ನನ್ನ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗಿದೆ ಮತ್ತು ಸಂಶೋಧನೆಗಳನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ ಹಂಚಿಕೊಳ್ಳುವಾಗ, ನನ್ನ ವಿವರಗಳನ್ನು ಮರೆಮಾಚಲಾಗುತ್ತದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.
ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಉತ್ತಮ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.
ರೋಗಿಯ ಸಹಿ (ಅಥವಾ ಹೆಬ್ಬೆರಳಿನ ಗುರುತು):
ರೋಗಿಯ ಹೆಸರು: _____
ದಿನಾಂಕ: _____/_____/_____

ತನಿಖಾಧಿಕಾರಿಯ ಸಹಿ: _____
ಅಧ್ಯಯನ ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು: _____
ದಿನಾಂಕ: _____/_____/_____

ಸಾಕ್ಷಿಯ ಸಹಿ ಅಥವಾ ಹೆಬ್ಬೆರಳಿನ ಗುರುತು: _____
ಸಾಕ್ಷಿಯ ಹೆಸರು: _____
ದಿನಾಂಕ: _____/_____/_____

ANNEXURE – V

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.

PROFORMA

TITLE:
"A PROSPECTIVE STUDY ON THE FUNCTIONAL OUTCOME OF PLATELET RICH PLASMA INJECTION IN LUMBAR FACET ARTHROPATHY''

Case no : **Hospital no :**

1. BASIC DATA

Name : Age/Sex :

Address :

Mobile No :

Date of Procedure :

Date of Admission/OP :

Date of Discharge :

History:

General physical examination:

Vitals: Pulse - B.P -

RR - Temp -

Systemic Examination:

CVS - PA -

RS - CNS -

Co-morbidities :

Local examination:

Deformity : Present/Absent

Swelling : Present/Absent

Tenderness : Present/Absent

Right Left

SLRT

Power :

L2 (Hip Flexion)		
L3 (Knee Extension)		
L4 (Ankle Dorsiflexion)		
L5 (EHL)		
S1 (Ankle Plantarflexion)		

Deep tendon reflexes :

Distal sensation :

Peripheral pulsation : Palpable /Absent

Radiological Investigations:

X ray LS SPINE AP, Lateral – flexion / extension :

MRI LS Spine :

2. DIAGNOSIS:

3. HAEMATOLOGICAL INVESTIGATIONS:

CBC :

BT :

CT :

RBS :

HIV, HCV & HBsAg status :

4. TREATMENT:

Procedure :

Procedure date :

Type of anesthesia :

5. POST PROCEDURE

Drugs :

Complications:

Early :

Delayed :

Late :

OSWESTRY DISABILITY INDEX SCORE

SECTION 1 - PAIN INTENSITY
- ☐ I can tolerate the pain I have without having to use painkillers.
- ☐ The pain is bad but I manage without taking painkillers.
- ☐ Painkillers give complete relief from pain.
- ☐ Painkillers give moderate relief from pain.
- ☐ Painkillers give very little relief from pain.
- ☐ Painkillers have no effect on the pain and I do not use them.

SECTION 2 - PERSONAL CARE (washing, dressing etc.)
- ☐ I can look after myself normally, without causing extra pain.
- ☐ I can look after myself normally, but it causes extra pain.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help, but manage most of my personal care.
- ☐ I need help every day in most aspects of self-care.
- ☐ I do not get dressed, wash with difficulty and stay in bed.

SECTION 3 - LIFTING
- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights, but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned (e.g., on a table).
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

SECTION 4 - WALKING
- ☐ Pain does not prevent my walking any distance.
- ☐ Pain prevents me walking more than 1 mile.
- ☐ Pain prevents me walking more than ½ of mile.
- ☐ Pain prevents me walking more than ¼ mile.
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

SECTION 5 - SITTING
- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair as long as I like.
- ☐ Pain prevents me sitting more than 1 hour.
- ☐ Pain prevents me from sitting more than ½ an hour.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

SECTION 6 - STANDING
- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than 30 minutes.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

SECTION 7 - SLEEPING
- ☐ Pain does not prevent me from sleeping well.
- ☐ I can sleep well only by using tablets.
- ☐ Even when I take tablets, I have less than 6 hours sleep.
- ☐ Even when I take tablets, I have less than 4 hours sleep.
- ☐ Even when I take tablets, I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

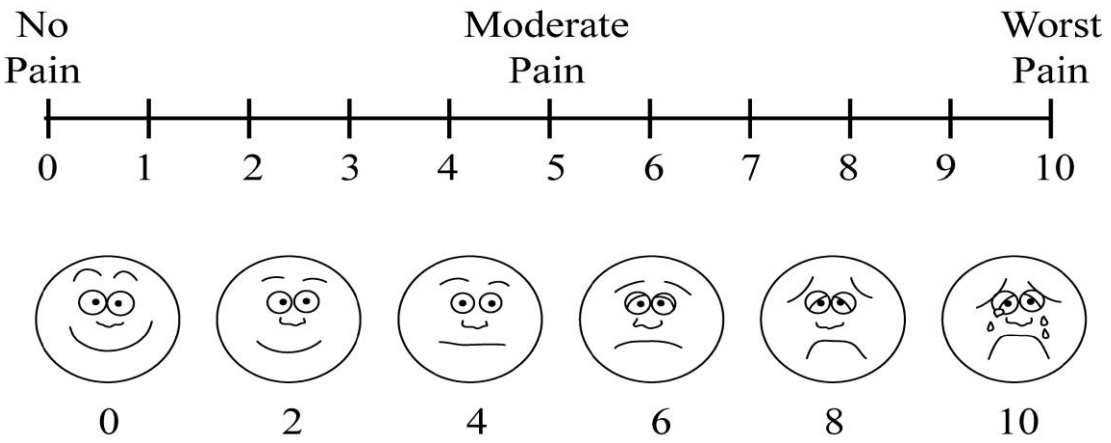
SECTION 8 - SEX LIFE (If applicable)
- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

SECTION 9 - SOCIAL LIFE
- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal, but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

SECTION 10 - TRAVELLING
- ☐ I can travel anywhere without extra pain.
- ☐ I can travel anywhere but it gives extra pain.
- ☐ Pain is bad but I manage journeys over 2 hours.
- ☐ Pain restricts me to journeys of less than 1 hour.
- ☐ Pain restricts me to short necessary journeys under 30 minutes.
- ☐ Pain prevents travel except to the doctor or hospital.

	IMMEDIATE PRE OP	IMMEDIATE POST OP	1 WEEK	1 MONTH	3 MONTHS
OSWESTRY DISABILITY INDEX SCORE (ODI)					

VISUAL ANALOG SCALE



	IMMEDIATE PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1 WEEK	1 MONTH	3 MONTHS
VISUAL ANALOG SCALE (VAS)					

IMAGES

ANNEXURE – VI

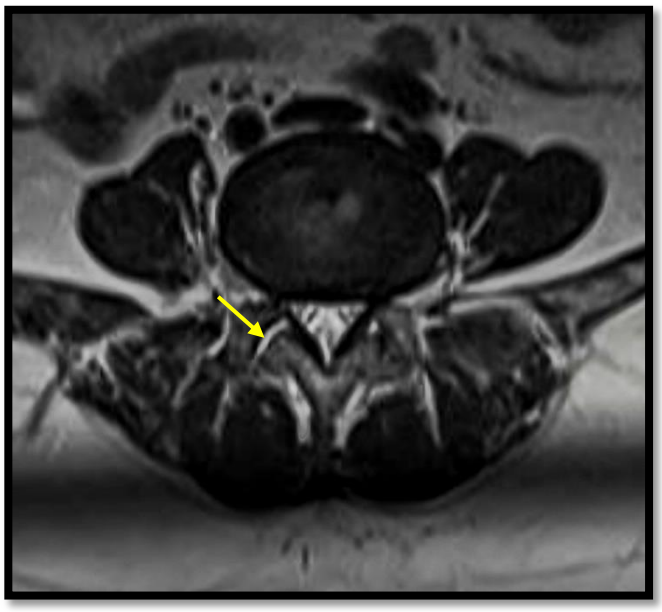


Figure 13 : MRI

MRI T_2 Axial section of Lumbar Spine at L3-L4 level with L3-L4 Right Lumbar Facet Arthropathy (yellow arrow)

Figure 14 : Centrifugation machine

Blood bag centrifugation machine, initially blood will be centrifuged using a light spin at 2630 RPM for 3 minutes and 1500 RPM for another 15 minutes to sediment the RBC's and WBC's

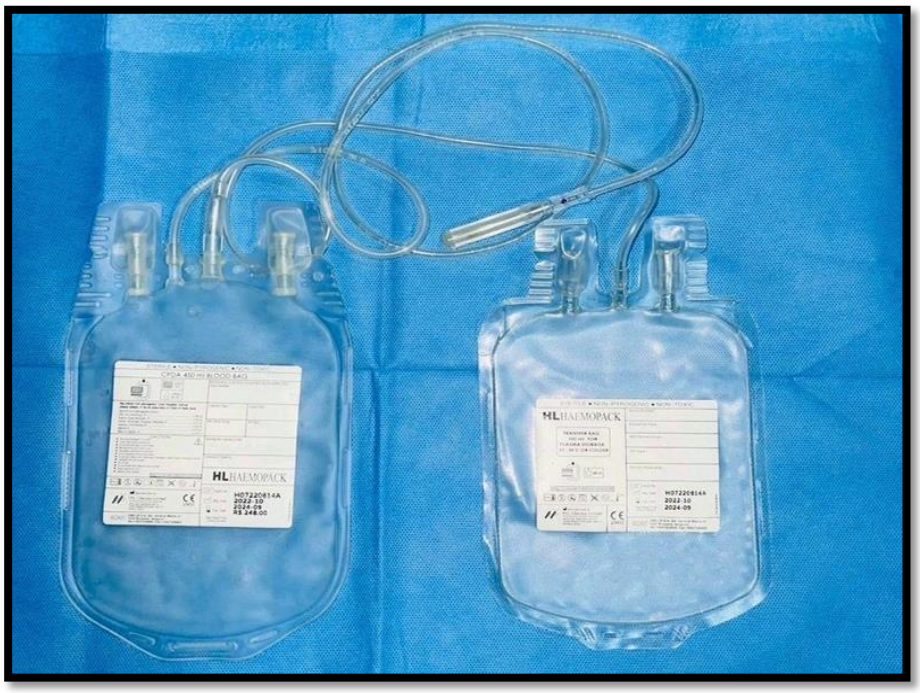


Figure 15 : Double blood bag used for PRP collection

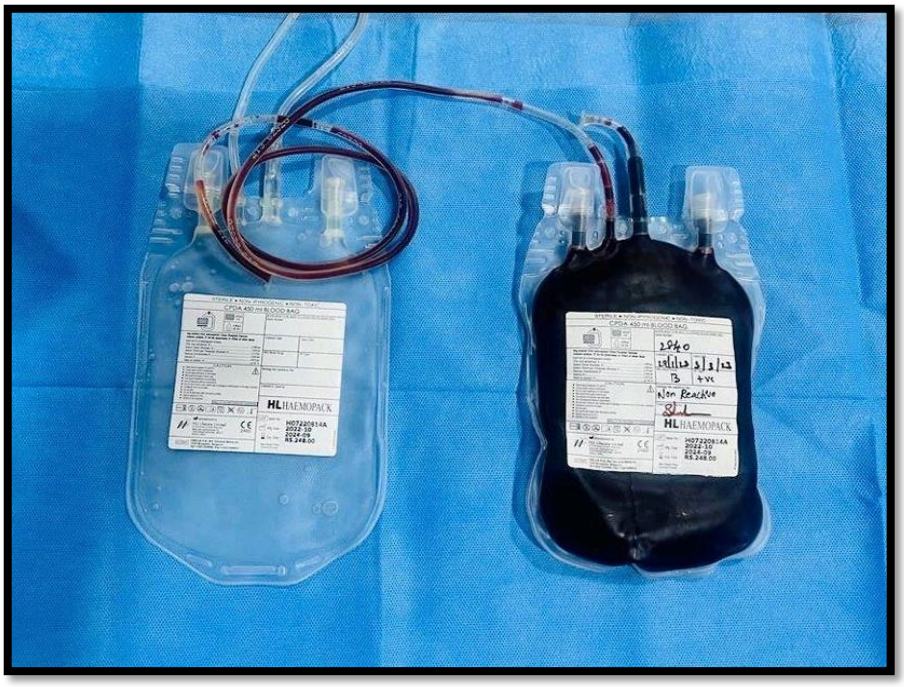


Figure 16 : Blood separation

Figure 17 : PRP separated in blood bag

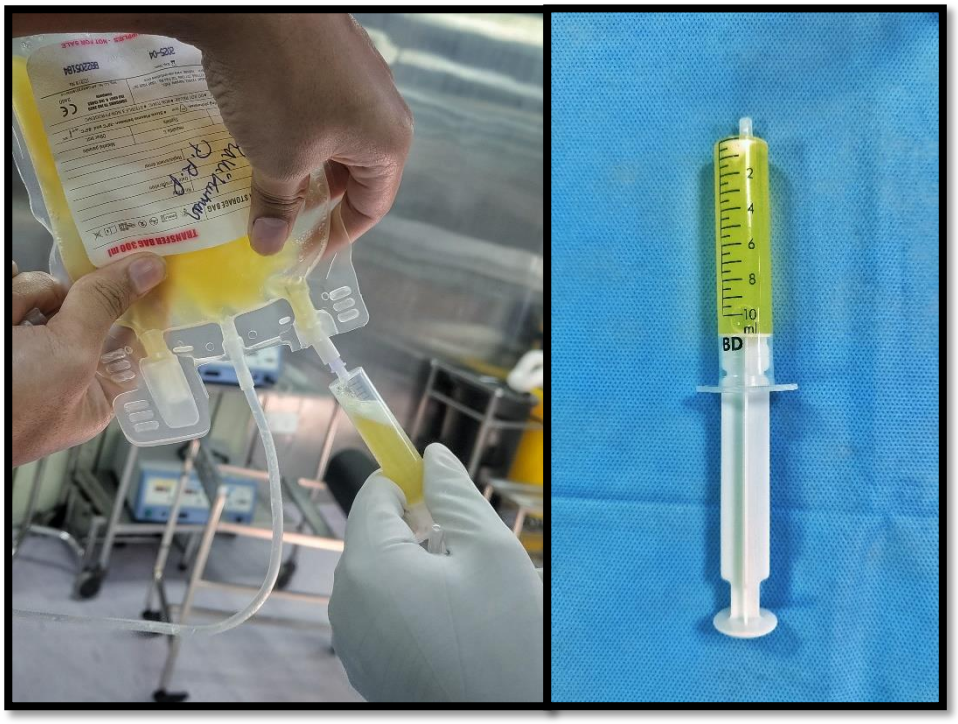


Figure 18 : PRP aspirated in 10 cc syringe

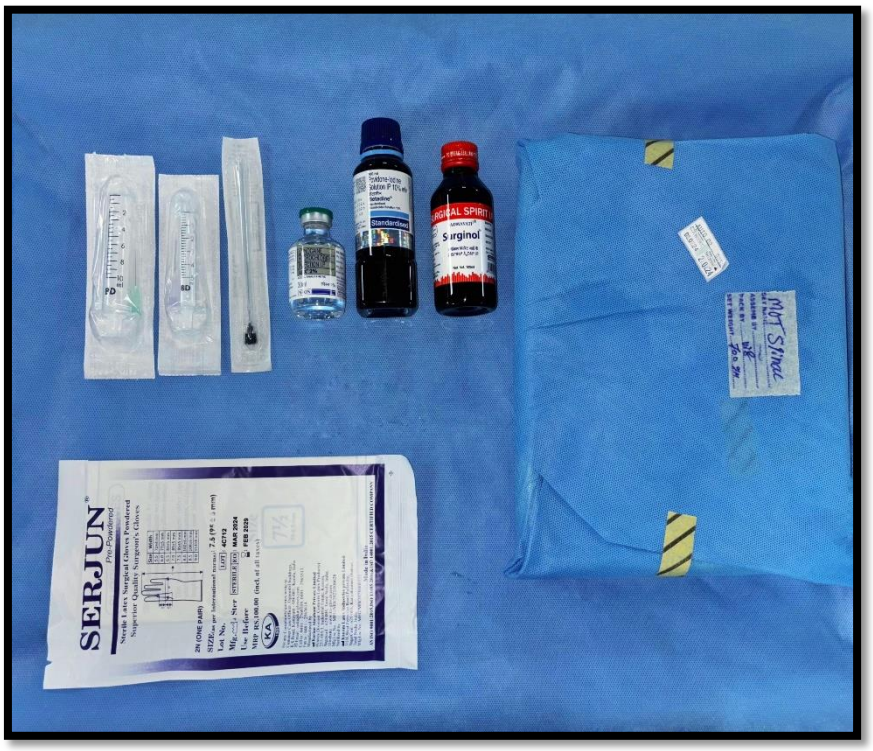


Figure 19 : Sterile kit for intra articular PRP injection

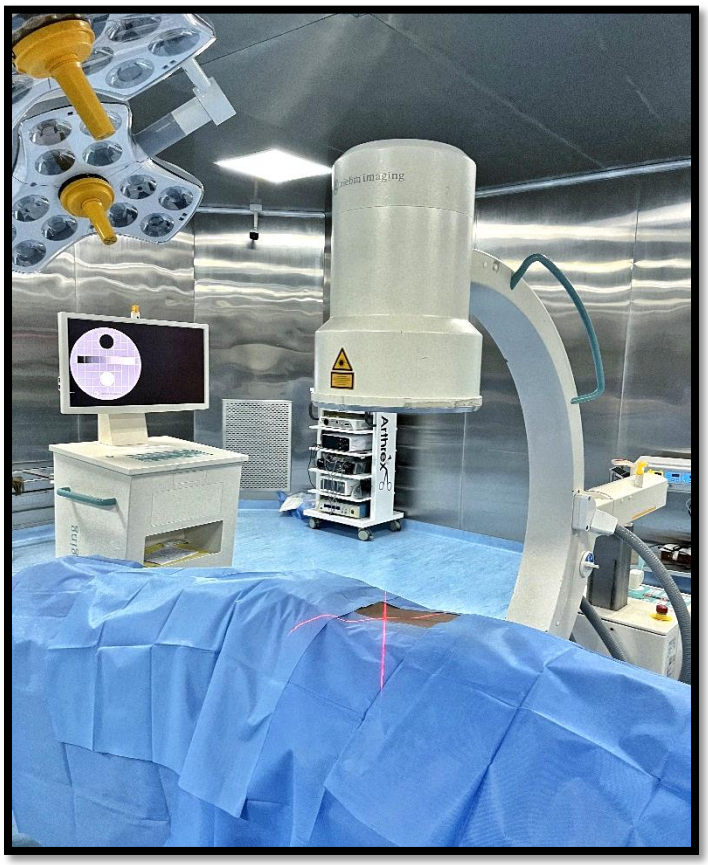


Figure 20 : Positioning and Draping

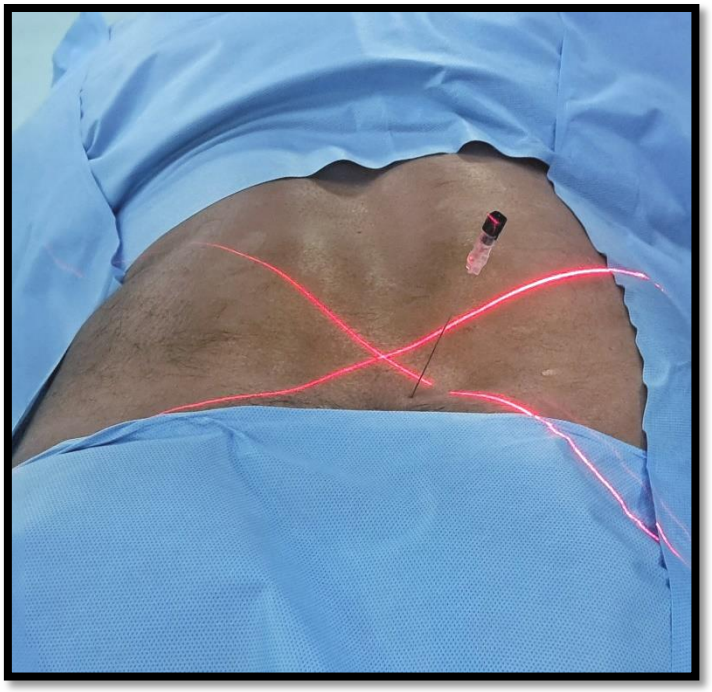


Figure 21 : Insertion of 22 G spinal needle to Facet Joint under C-arm guidance

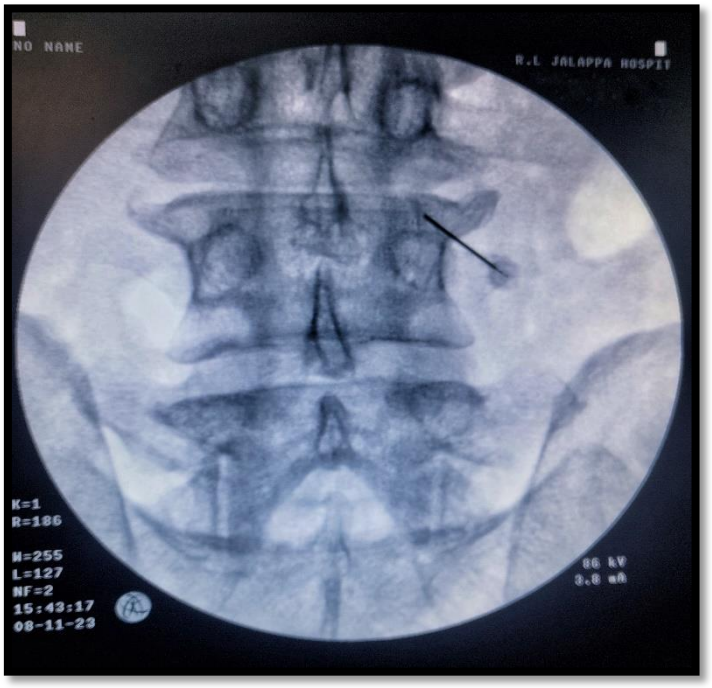


Figure 22 : C-arm image showing placement of needle in Right L3-L4 Facet Joint

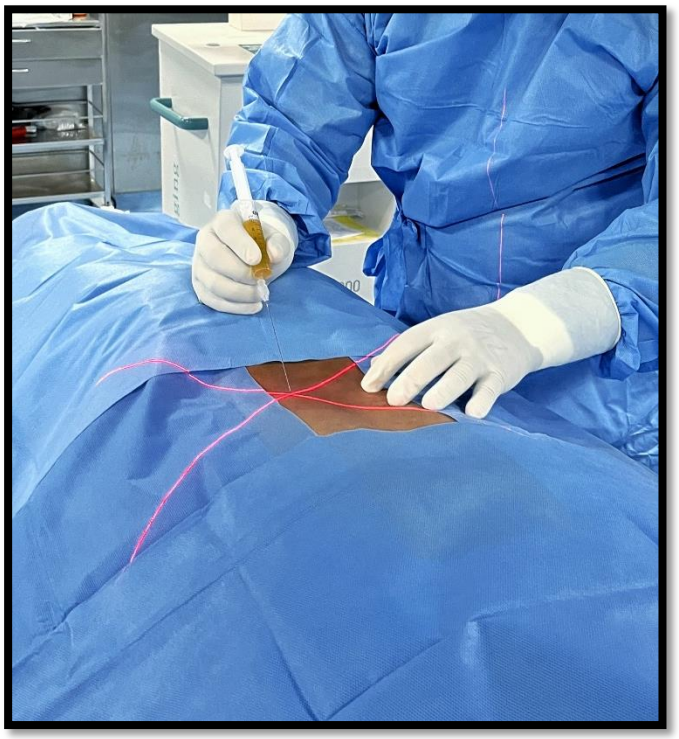


Figure 23 : Under aseptic precautions, 2ml PRP being injected to Facet Joint

MASTER CHART

ANNEXURE – VII

KEY TO MASTER CHART

M	MALE
F	FEMALE
UHID	UNIQUE HOSPITAL IDENTIFICATION
S.NO	SERIAL NUMBER
VAS	VISUAL ANALOG SCALE
ODI	OSWESTRY DISABILITY INDEX
HTN	HYPERTENSION
DM	DIABETES MELLITUS

S.NO	UHID	AGE	SEX	CO-MORBIDITIES	VISUAL ANALOGUE SCALE (VAS)					OSWESTRY DISABILITY INDEX (%)				
					PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH	PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH
1	215513	42	M	NO	7	6	5	3	1	44	42	36	28	18
2	156084	45	M	NO	7	6	5	2	0	52	48	42	32	24
3	116456	62	M	DM	8	7	6	2	1	64	60	52	40	28
4	165365	49	F	HTN	7	6	5	4	1	54	52	48	32	23
5	165379	45	F	NO	8	7	6	2	0	48	46	40	32	26
6	163749	43	F	DM	8	7	5	3	1	56	54	48	36	28
7	163727	53	M	NO	8	7	5	2	0	52	48	42	32	24
8	170390	43	M	DM	7	6	4	2	0	56	54	46	32	18
9	170387	43	M	NO	9	8	6	2	0	58	54	46	34	24
10	175427	45	M	NO	8	7	6	5	2	52	50	44	36	24
11	173642	46	M	NO	8	7	6	4	1	52	50	44	36	26
12	172016	42	M	NO	7	6	5	4	1	52	50	44	34	26
13	170407	52	F	DM	8	7	6	4	1	48	46	40	28	20
14	173659	43	F	NO	9	8	5	2	0	48	44	38	30	24
15	187093	52	M	NO	8	7	4	2	1	54	52	46	34	24
16	219581	47	F	NO	9	8	7	3	2	58	54	46	36	22
17	205341	60	M	NO	8	7	5	4	2	54	52	46	32	22
18	287097	53	M	HTN	7	6	4	2	0	52	50	48	40	24
19	265089	43	M	NO	8	7	5	3	1	56	56	44	30	22
20	273351	70	F	NO	7	6	5	2	1	56	54	46	30	24
21	142756	59	F	DM, HTN	7	6	5	3	1	52	50	44	34	22
22	239821	60	F	HTN	8	7	5	3	2	54	52	46	36	26
23	239270	60	M	NO	7	6	5	2	1	52	50	44	34	24
24	397754	48	F	NO	8	7	5	3	1	54	52	46	32	20
25	239029	58	M	HTN/DM	8	7	5	3	1	52	50	44	34	26
26	264663	55	M	NO	8	7	5	3	1	54	52	46	36	28
27	280715	75	M	DM	8	7	4	2	1	62	60	52	34	24
28	267652	59	M	NO	9	8	6	3	1	54	52	46	32	18
29	285682	65	M	NO	7	6	5	3	0	54	52	46	36	22
30	266123	42	M	NO	7	6	5	3	1	52	50	44	34	26
31	287096	53	M	NO	7	6	5	4	1	54	52	46	36	28

S.NO	UHID	AGE	SEX	CO-MORBIDITIES	VISUAL ANALOGUE SCALE (VAS)					OSWESTRY DISABILITY INDEX (%)				
					PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH	PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH
32	287094	48	F	HTN	6	6	4	3	1	54	52	46	34	22
33	287093	53	M	NO	7	6	5	3	1	52	50	44	32	26
34	287103	53	F	HTN,DM	7	6	4	3	1	54	52	46	34	22
35	252669	41	M	NO	7	6	5	2	1	52	48	44	34	26
36	256023	54	F	DM	7	6	5	4	2	54	52	46	34	26
37	243847	55	F	NO	7	6	5	3	2	50	48	42	28	16
38	258761	69	M	NO	6	5	4	2	0	52	50	42	32	26
39	257595	45	F	NO	7	6	4	3	1	52	52	44	34	18
40	291215	42	M	NO	7	6	5	3	1	52	50	42	32	16
41	279303	60	M	NO	6	5	4	2	0	52	52	44	36	22
42	176319	50	M	NO	7	6	5	3	1	56	54	46	34	16
43	167464	52	F	NO	8	7	6	4	2	58	54	48	34	24
44	133092	43	M	HTN	8	7	6	3	1	62	60	56	42	26
45	299009	43	M	NO	8	7	6	4	1	64	62	52	44	26
46	324288	42	F	DM	8	8	6	5	2	58	58	48	38	18
47	312532	53	F	NO	8	7	5	2	0	62	60	46	32	22
48	396572	44	M	NO	7	6	5	3	1	48	46	36	28	20
49	396568	58	F	DM/HTN	8	7	5	3	1	64	60	52	32	18
50	316976	41	F	NO	7	7	5	2	1	58	56	48	38	18
51	285994	42	F	NO	9	7	6	3	2	68	64	54	32	24
52	333274	62	F	NO	8	7	6	3	2	58	56	42	34	26
53	306982	48	M	NO	8	7	5	3	1	52	50	42	24	18
54	316411	50	F	NO	9	8	6	3	1	56	54	46	32	24
55	312820	45	M	NO	7	7	4	2	1	52	50	42	28	18
56	312826	53	M	NO	8	7	6	3	1	64	62	48	32	22
57	312821	58	F	HTN	9	8	7	3	2	54	52	42	32	22
58	366454	61	F	NO	9	8	6	3	1	58	56	44	32	24
59	316889	45	F	NO	7	6	5	3	2	52	50	44	32	18
60	322078	58	M	NO	8	7	6	3	1	56	54	48	32	24
61	358891	56	F	HTN	9	8	7	4	2	56	56	48	38	26
62	369162	46	F	NO	8	7	6	4	2	56	54	48	36	20
63	396573	46	M	NO	8	7	6	3	1	62	58	42	32	22

S.NO	UHID	AGE	SEX	CO-MORBIDITIES	VISUAL ANALOGUE SCALE (VAS)					OSWESTRY DISABILITY INDEX (%)				
					PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH	PRE PROCEDURE	IMMEDIATE POST PROCEDURE	1ST WEEK	1ST MONTH	3RD MONTH
64	384363	42	F	DM	8	7	6	3	1	52	50	42	36	24
65	385994	43	F	NO	8	7	5	4	2	58	54	52	46	22
66	302794	48	M	NO	7	6	5	3	1	62	60	54	38	24
67	302802	55	M	NO	8	7	5	3	2	64	62	52	44	26
68	312826	53	M	NO	7	6	6	3	1	54	52	46	30	18
69	245847	65	F	HTN	8	7	6	3	1	52	50	42	26	16
70	364827	58	F	NO	7	6	5	2	1	56	52	42	28	18
71	180524	45	F	NO	8	7	6	3	1	58	56	44	34	22