

**“COMPARATIVE EFFICACY IN THE OUTCOME OF GENICULAR  
NERVE BLOCK AND INTRA ARTICULAR INJECTION OF PLATELET  
RICH PLASMA VERSUS INTRA ARTICULAR INJECTION OF  
PLATELET RICH PLASMA IN THE TREATMENT OF PATIENTS  
WITH GRADE I AND II OSTEO ARTHRITIS OF KNEE –  
A RANDOMIZED CONTROL TRIAL”**

**Dissertation submitted to**

**The Tamil Nadu Dr. MGR Medical University**

**In partial fulfilment of the regulations for the award of the degree of**

**M.D. PHYSICAL MEDICINE AND REHABILITATION**

**UNIVERSITY EXAMINATIONS - MAY 2020**

**(REGISTRATION NO. 201729002)**



**GOVERNMENT INSTITUTE OF REHABILITATION MEDICINE**

**MADRAS MEDICAL COLLEGE**

**CHENNAI –600003**

**THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY**

**CHENNAI –600032**

**2017 - 2020**

## **CERTIFICATE**

This is to certify that the dissertation entitled “Comparative Efficacy in the outcome of Genicular Nerve block and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of Patients with Grade I and II Osteo Arthritis of Knee– A Randomized Control Trial” by the candidate DR.SATHISH K, Reg. No. 201729002 for M.D Physical Medicine and Rehabilitation is a bonafide record of the research done by him during the period of study (2017 –2020) in the Government Institute of Rehabilitation Medicine,  
Madras Medical College, Chennai –600003.

**DEAN**

Madras Medical College  
Chennai – 600003.

**DIRECTOR & HOD**

Government Institute of Rehabilitation  
Medicine, K.K. Nagar, Chennai.

## **CERTIFICATE**

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**Asso. Prof. Dr. A. RAJAKUMAR M.B.B.S.,DPMR.,**

(Guide)

Director & Head of the Department,

Government Institute of Rehabilitation Medicine,

Madras Medical College, Chennai.

## **DECLARATION**

I, **DR.SATHSH K**, declare that, this dissertation “Comparative Efficacy in the outcome of Genicular Nerve block and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of Patients with Grade I and II Osteo Arthritis of Knee – A Randomized Control Trial” is the original work done by me, **DR SATHISH K, Reg. No. 201729002** in the Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai under the direct guidance and supervision of Prof. Dr.C.Ramesh and Asso.Prof. Dr. A. Rajakumar, Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai as guide and is submitted to “The Tamil Nadu Dr. M.G.R.Medical University”, Chennai, in partial fulfilment of the board regulations for the award of the degree of M.D.(Physical Medicine and Rehabilitation).

**DR SATHISH K**

## **ABSTRACT:**

### **Introduction:**

Osteoarthritis (OA) particularly knee OA, is one of the most common delimiting disease affecting people in the world. Currently other than the pharmacologic and surgical modalities usage of Platelet Rich Plasma (PRP) is emerging as a novel technique in the treatment of OA.

### **Objectives:**

The study was aimed to assess the efficacy of Genicular nerve block using local anaesthetic and PRP versus only PRP among patients suffering from grade I and II knee OA.

### **Methodology:**

The study was an open double-blind randomised control trial among 100 subjects with grade I and II knee OA. They were divided based on computer generated random numbers into two groups. Group A: Genicular nerve (Superior medial genicular nerve, Superior lateral genicular nerve and Inferior medial genicular nerve) was blocked with 6ml of 0.5% Bupivacaine which is distributed equally to the targeted three injection sites under ultrasound guidance. Genicular nerve block (GNB) is followed by Intra articular injection of 2-4ml of autologous platelet rich plasma by inferolateral approach. This procedure was repeated at regular 4 weeks interval for three cycles. For Group B: 2-4ml of Intra articular autologous platelet rich plasma by inferolateral approach. This procedure was repeated at regular 4 weeks interval for three cycles.

Pain relief and functional outcome was analysed with VAS score, Numerical rating scale and Western Ontario and McMaster universities (WOMAC) Osteoarthritis Index before the intervention and on first post intervention day and at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 16 weeks and 24 weeks.

### **Results:**

The study was done among 100 subjects. The mean (SD) age of the GNB+PRP group and PRP group was 57.10(9.53) years and 57.90(8.89) years respectively. The minimum age of the population was 40 years and maximum age was 82 years. The mean (SD) age of the population was 57.34 (9.28) years. Both the group had most subjects in 50-59 years. [18(36%) in GNB+PRP vs 21(42%) in PRP group]. In the study majority 68(68%) of the study subjects were females and 32(32%) of the subjects were males.

Most 45(45%) of the population had their left knee affected. Next commonly affected was right knee 35(35%). 38(38%) of the subjects had an X ray grade I and 62(62%) of the subjects had an X ray grade II.

The mean (SD) of the VAS score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.31(0.72), 2.27(1.57),1.79(1.25),1.48(1.16), 1.06(0.84),0.87(0.77), 0.83(0.75) and 0.83(0.75) respectively. The mean (SD) of the NPRS score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks

and after 24 weeks were 8.32(0.72), 7.34(0.76),5.39(0.99),3.84(0.79), 3.11(0.92),2.61(0.72), 2.23(0.66) and 1.81(0.68) respectively. The mean (SD) of the WOMAC score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 68.97(13.25), 25.25(15.75), 21.21(14.19), 17.86(13.02), 12.67(10.41), 10.15(9.74), 9.87(9.41) and 9.87(9.41) respectively.

There is significant difference between the two groups across the time periods in terms of VAS score. Group A (GNB+PRP) showed better outcome in terms of decreased VAS score. There was significant difference between the two groups across the time periods in terms of WOMAC score. Group A (GNB+PRP) showed better outcome in terms of decreased WOMAC score. There was an association between NPRS score across different time periods between the groups. There is a significant difference between the two groups after 2 weeks, after 8 weeks and 16 weeks.

### **Conclusion:**

The study showed a better outcome among subjects receiving the GNB and PRP together across the time periods; also, significant reduction occurred in the group with PRP also less in comparison with the other group. The usage of PRP with adjuvants can be an emerging novel treatment in case of knee OA.

## **ACKNOWLEDGEMENTS**

I owe my special thanks to **Prof Dr. C. RAMESH** and **Prof Dr. T. JAYAKUMAR**, who were instrumental in conceptualization of this topic and has been my constant support and encouragement. They have been very kind and helped me academically. Their wisdom in solving problem has been inspirational. If not for them I would have not been able to complete this thesis work for which I am deeply indebted to them and I am proud to have them as my mentors. I also like to thank **Prof. Dr. R. JAYANTHI, MD., FRCP**, The Dean, Madras Medical college for her support.

I also extend my thanks to **Dr. B. JEYANTHI, Dr. K. PREMALATHA, Dr. K.UMA** for their help and constant support. I am grateful to all my seniors and colleagues for their everlasting support.

I am grateful to the Medical Records Department and Department of physiotherapy, Government Institute of Rehabilitation, Chennai for their support. I am indebted to all my patients who form an integral part of this study for their cooperation without whom this dissertation could have not been possible.

And I thank my parents, sister, brothers, in laws, my wife and my children for being a source of constant support and inspiration.

I dedicate this thesis to my sister Dr. K. Malarvizhi.

Dr. SATHISH K



## Urkund Analysis Result

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### Sources included in the report:

SOORAJ\_SSSMCRI\_A LONGITUDINAL INTERVENTIONAL STUDY TO EVALUATE THE FUNCTIONAL OUTCOME OF USING PLATELET RICH PLASMA IN KNEE OSTEOARTHRITIS.docx (D56767452)  
SOORAJ\_SSSMCRI\_A LONGITUDINAL INTERVENTIONAL STUDY TO EVALUATE THE FUNCTIONAL OUTCOME OF USING PLATELET RICH PLASMA IN KNEE OSTEOARTHRITIS.docx (D56285067)  
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## CERTIFICATE II

This is to certify that this dissertation work titled **“Comparative Efficacy in the outcome of Genicular Nerve block and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of Patients with Grade I and II Osteo Arthritis of Knee – A Randomized Control Trial”** of the candidate **Dr. SATHISH K**, with registration number **201729002** for the award of M.D in the branch of Physical Medicine and Rehabilitation. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **10 percentage** of plagiarism in the dissertation.

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## LIST OF ABBREVIATIONS

OA	Osteoarthritis
PRP	Platelet rich plasma
GNB	Genicular nerve block
VAS	Visual analogue scale
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
SD	Standard deviation
NPRS	Numeric pain rating scale
HcPRP	High concentrate Platelet Rich Plasma
IL	Interleukin
NO	Nitric oxide
NOS	Nitric oxide synthase
TNF	Tumour necrosis factor
MMP	Matrix metalloproteinase
PGE	Prostaglandin E
JSN	Joint space narrowing
NSAID	Non-steroidal anti-inflammatory drug
COX	Cyclooxygenase
IA	Intra articular
WHO	World health organization
MRI	Magnetic resonance imaging
FDA	Food and drug administration

CS	Corticosteroid
RNA	Ribonucleic acid
BSP	Betamethasone sodium phosphate
HA	Hyaluronic acid
P-PRP	Pure platelet rich-plasma
L-PRP	Leucocyte and platelet-rich plasma
GF	Growth factor
RF	Radiofrequency
PRGF	Plasma rich in growth factors
DASH	Disabilities of arm, shoulder and hand

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# *Introduction*



## 1) INTRODUCTION:

Arthritis is defined as swelling of a joint with features of pain, inflammation, and restriction of joint motions. Osteoarthritis (OA), the general frequent sort of arthritis, where as a joint whole affects and undergoes variations. Osteoarthritis (OA) is a continual degenerative illness of multi factor causes with features of loss of articular cartilage, hyper trophy of bone at the borders, sub chondral sclerosis, and range of biochemical and morphological changes of the synovial membrane and joint capsule.(1)

Osteo arthritis is the 2<sup>nd</sup> general common rheumatologic crisis and it is the generally frequent joint disease with an occurrence of 22% to 39% in India.(1,2) OA is common in women than men, but the incidence increases noticeably with age.(2,3) Almost, 45% of females more than 65 years age have characteristic of OA while radiological evidence is established in 70% of those > 65 years. OA of the knee is a main cause of mobility impairment, mainly amid females. OA was estimated to be the 10<sup>th</sup> foremost cause of nonfatal burden. (2,4,5)

OA of the Knee is a degenerative joint disease, distressing the articular cartilage. The cartilage wears down, becomes coarse and then it tears causing the over growth of the bone beneath. OA of the Knee is manifested with features of pain, stiffness, swelling and crepitus, due to the degeneration of cartilage matrix, derangement of the mechanical properties of the synovial fluid, development of bony osteophytes and inflammation.

At present, there are little treatment modalities for patients with mild to moderate arthritis. Most of the managements are palliative and are aiming to tackle the symptoms rather than influencing the biochemical aspect of the joint or the disease progression. Osteoarthritis particularly is a frequent disease which can be put under control by apt

weight reduction and muscle strengthening exercise. But these modalities are always Under the threat of poor adherence from the part of subject.

Present view is that the disease sequence results from a disparity between pro inflammatory cytokines (including interleukin [IL]-1a, IL-1, and tumor necrosis factor) and anti inflammatory cytokines (together with IL-4, IL-10, and IL-1ra). This cytokine difference is thought to trigger proteolytic enzymes, leading to the damage of cartilage. The bulk of newly planned remedial measures for OA has a base in attempting to tackle this cytokine disparity. In addition to cartilage damage, arthritis of the knee joint may harmfully influence sub chondral bone, synovium, ligaments, capsule, menisci, nearby musculature, and possibly the sensory nervous system.(6–9)

So the current trend is to advance the treatment in such a way to tackle interleukin mediated biochemical progression of the disease. Some of the experimental ortho biological treatments include platelet-rich plasma (PRP) injection graft therapy, high-concentrate PRP (HcPRP), autologous bone marrow aspirate concentration and adipose cells, IL-1 receptor antagonist, nerve growth factor inhibitor, and osteogenic protein-1.

Platelet plays a vital role in hemostasis which is a known factor. Platelets also have plentiful of development factors and cytokines which help in soft tissue curing and bone mineral formation.. Platelets on commencement exude a lot of bio active proteins accountable for attracting macrophages, mesenchymal stem cells, osteoblast. This bio active protein aid in removal of the necrotic tissue and also make possible tissue rejuvenation and healing. Autologous platelet rich plasma is a quantity of plasma having platelet amount over normal base line measures. (10–13)

Any concerns of immunogenic reactions or disease transfer are eliminated because PRP is geared up from autologous blood. No studies have recognized that PRP promotes hyperplasia, carcinogenesis, or tumor growth. Growth factors carry on cell membranes rather than on the cell nucleus and turn on regular gene expression.(14) Many studies are present which showed the effectiveness of PRP in the treatment of various bone etiologies.(15–17) The addition of local anaesthetics along with PRP can trigger some adverse or allergic reactions. There are limited studies in identifying effectiveness of the addition of local anaesthetics and PRP.

This study aimed at comparing the efficacy in the pain relief and functional outcome of ultrasound guided Genicular Nerve block with 0.5% Bupivacaine and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of PRP in the management of subjects with Grade I and II knee Osteo Arthritis.

# *Aim and Objectives*

## **2) AIM AND OBJECTIVES:**

To compare the efficacy in the pain relief and functional outcome of ultrasound guided Genicular Nerve block with 0.5% Bupivacaine and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of PRP in the treatment of patients with Grade I and II Osteo Arthritis of Knee.

# *Review of Literature*

### **3) REVIEW OF LITERATURE:**

Review of Literature of this study is discussed under the following heads:

- A. OA epidemiology and pathogenesis
- B. Knee OA features and grading
- C. Treatment of OA
- D. Newer modalities including Genicular Nerve Block (GNB) and PRP
- E. Studies about the application of PRP in OA knee.

#### **A. OA epidemiology and pathogenesis**

OA is a disease of the entire joint in which all articular structures are affected. The Osteoarthritis Research Society International (OARSI) defines osteoarthritis (OA) as “a disorder involving movable joints characterized by cell stress and extracellular matrix degradation initiated by micro and macro injury that activates maladaptive repair responses including pro-inflammatory pathways of innate immunity”. The disease manifests first as a molecular mal arrangement (abnormal joint tissue metabolism) followed by anatomic, and/or physiologic non adjustments (characterized by cartilage degradation, bone re modelling, osteo phyte formation, joint inflammation and failure of usual joint function), that can end in illness.(18)

Osteo arthritis is the second most general frequent rheumato logic problem and it is the generally frequent joint disease with an occurrence of 22% to 39% in India.(1,2) OA is common in females than males, but the occurrence boost obviously with age.(2,3) Almost, 45% of females more than 65 years age have characteristic of OA while

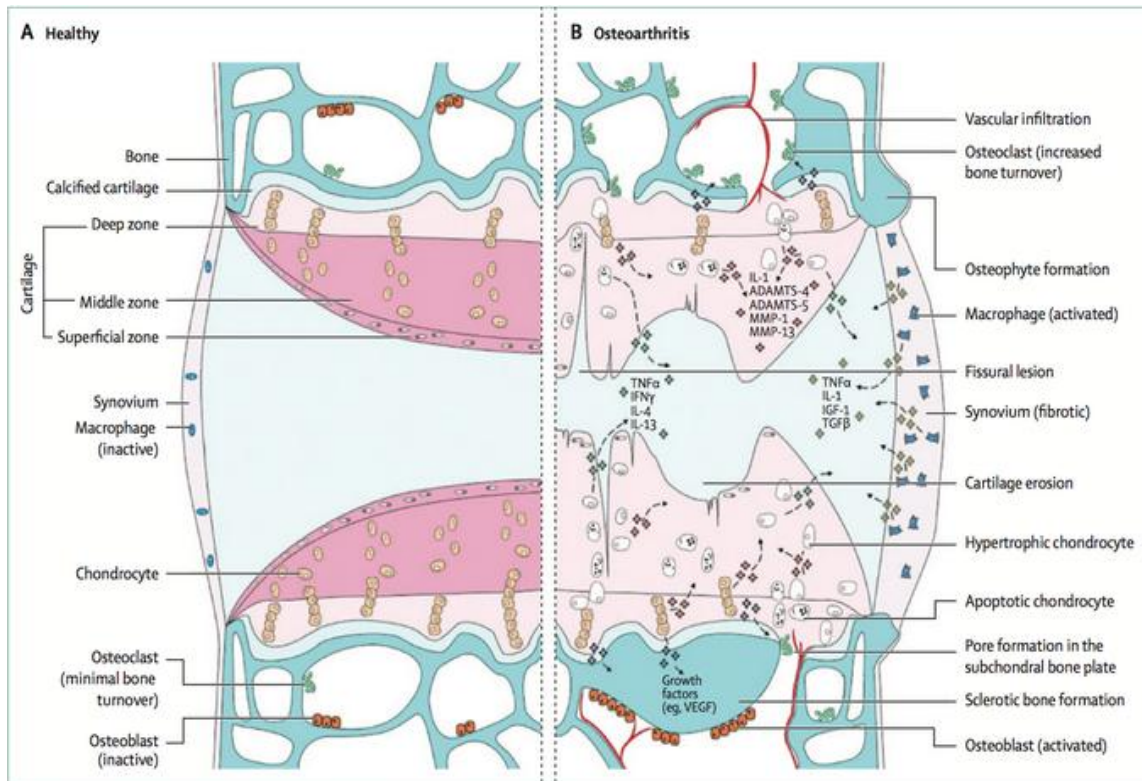
radiological evidence is established in 70% of those > 65 years. OA of the knee is a main cause of mobility impairment, mainly amid females. OA was estimated to be the 10<sup>th</sup> foremost cause of nonfatal burden. (2,4,5)

The occurrence of suggestive knee OA in the USA, is 12.1% 16.3% in participants aged 55–64 years.(19) Accordingly in a study the occurrence of knee OA in those aged 55 years and above was 15.6% in men and 30.5% in women, correspondingly. (20) A study made in Asian countries of India, Pakistan, and Bangladesh stated that a higher amount of OA knee in rural area was 13.7% as in comparison to 6.9% in urban area.(21) An information from a study completed in community demonstrated that in rural and urban regions of India shown the rate of OA to be in the series of 17%–60.6%.(22)

There is a obvious linkage amid OA and the ageing process and also mechanical injury. Firstly, there is a loss of glycos amino glycans from cartilage which reduces the osmotic pressure, making it softer and with reduced resistance to compressive forces. A repair reaction then leads to augmented creation of proteo glycans and collagen type II, and chondrocyte creation and clustering. However, amplified appearance of inflammatory cytokines and proteases denotes that catabolic activity is higher, and cartilage is degenerated; at first fibrillation occurs in the superficial zone, later deep fissures and full chondral loss occurs. Concerned cytokines include IL-6, IL-1 $\beta$ , TNF- $\alpha$ , IL-10, IL-13 and IL-4. They proceed through pro inflammatory and anti-inflammatory pathways, and are also involved in angio genesis and chemo taxis.(23–25)



**Figure: Patho physiology of OA(26)**



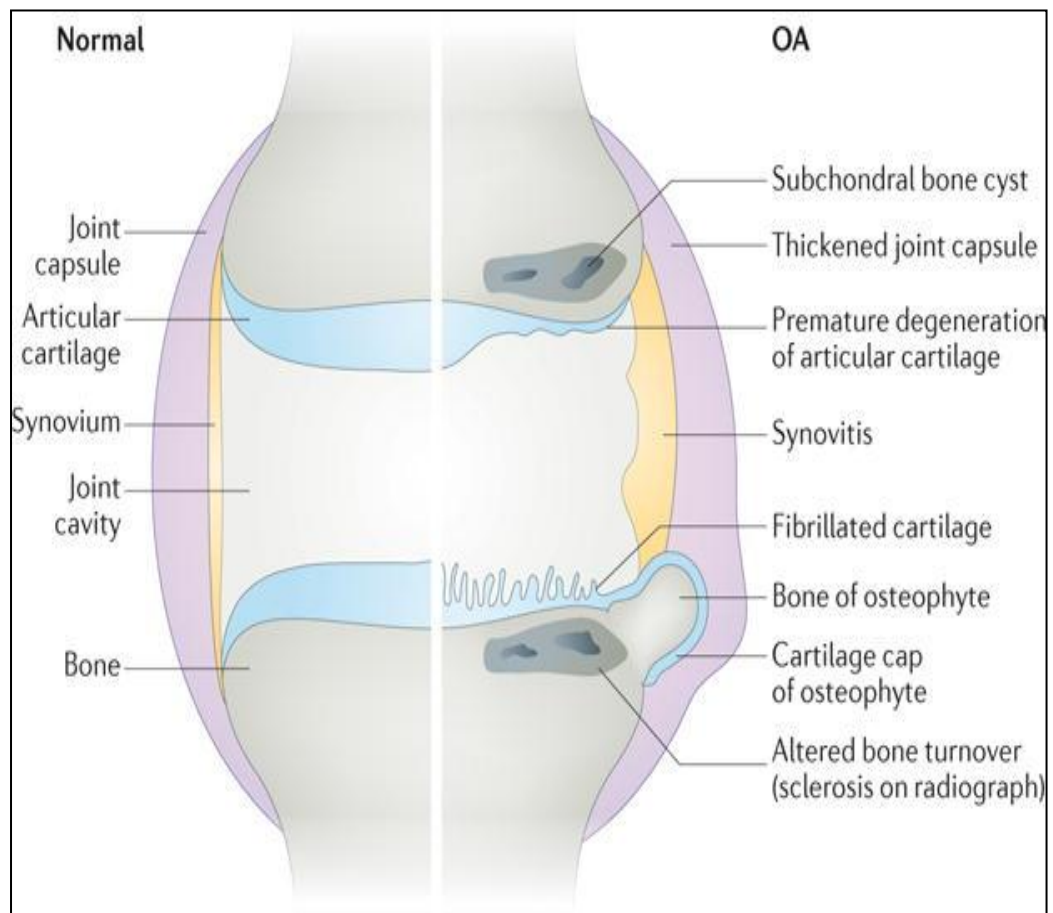
**Figure 3: Signalling pathways and structural changes in the development of osteoarthritis**  
 ADAMTS=a disintegrin and metalloproteinase with thrombospondin-like motifs. IL=interleukin. MMP=matrix metalloproteinase. TNF=tumour necrosis factor. IFN=interferon. IGF=insulin-like growth factor. TGF=transforming growth factor. VEGF=vascular endothelial growth factor.

OA leads to subchondral bone remodelling. The most common result of OA is sub chondral plate thickening. The visible changes in weight bearing bones occurs like erosions, excess occurrence of osteo chondrophytes (bone and cartilage). Articular cartilage also gets affected by OA frequently. Usually cartilage acts as a cushion to absorb shock in joints. In OA calcification and ossification occurs leading o degeneration of joints. Also increased production of alkaline phosphate and pyrophosphate levels leads to turnover of cartilage and erosion happens.(27–29)

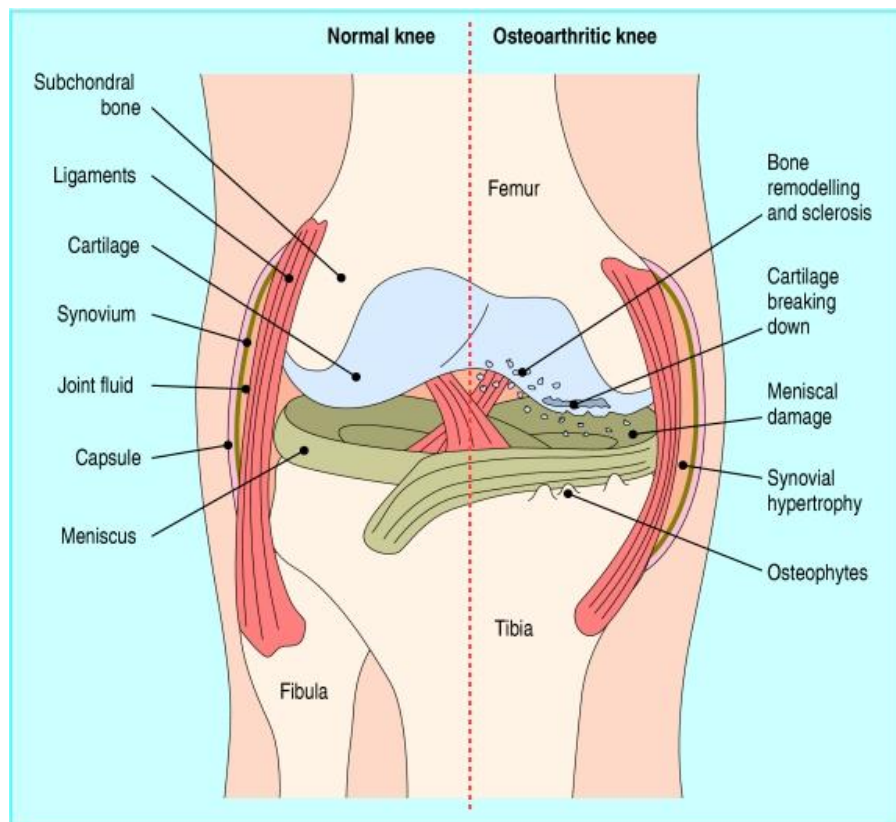
In patients with OA, the chondrocytes, as well as the synovial cells, generate augmented levels of inflammatory cytokines, as interleukin 1 $\beta$  (IL-1 $\beta$ ) and the alpha tumour necrosis factor (TNF- $\alpha$ ), that, consecutively, reduce the collagen production and augment catabolic mediators, such as metalloproteases (MMPs) and other inflammatory

substances as interleukin 8 (IL-8), interleukin 6 (IL-6), prostaglandin E2 (PGE2) and nitric oxide (NO). In addition together, mechanical stress, as by static compression, augments the manufacture of NO by chondrocytes, as well as the appearance of nitric oxide synthase (NOS). Oxidizing agents, amongst them NO, encourage apoptosis of chondrocytes, catabolic processes and deterioration of the matrix, therefore, leading to two significant pathogenic proceedings feature of the osteoarthritic chondrocytes - premature senescence and apoptosis. These proceedings assist to construct up the idea that OA is a illness of early aging of the articulation.(30–32)

**Figure: Pathology of OA (33)**



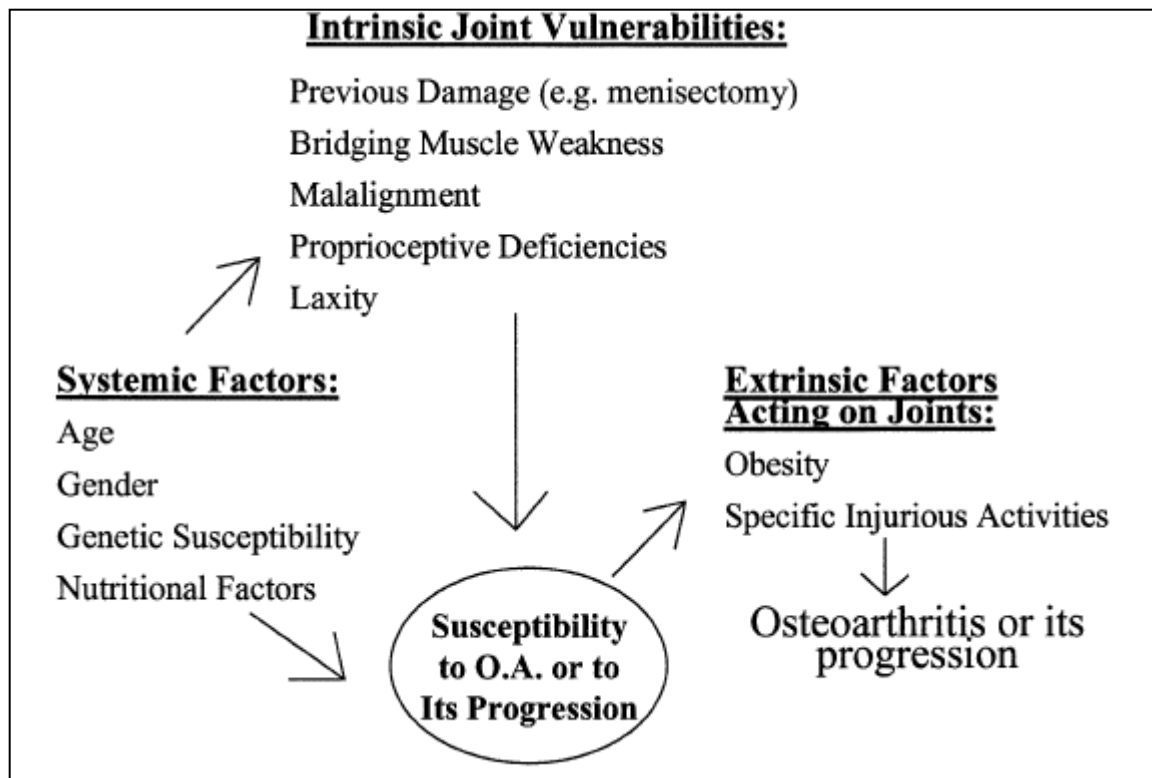
**Figure: Changes inside joint in OA(34)**



**The risk factors for OA**

- Inheritance or genetic(35)
- High bone density(36)
- Women (hormonal)and nutritional deficiencies(37)
- Developmental abnormalities which affects joint shape(38)
- Localised injury(39)
- Joint mal alignment
- Obesity(40)
- Particular occupations(41)

**Figure: Factors affecting OA(42)**



### **Primary and secondary OA**

**Primary:** Primary osteoarthritis is a chronic degenerative disorder associated to but not caused by aging. The pathophysiology of osteoarthritis involves a mixture of mechanical, cellular, and biochemical processes. The interface of these processes leads to changes in the composition and mechanical properties of the articular cartilage. (43)

**Secondary OA:** This type of OA is caused by other factors but the ensuing pathology is the same as for primary OA, (44)

- Congenital or developmental disorders of joints
- Mechanical: limb length discrepancy, malalignment, hyper-laxity, Ehlers-Danlos syndrome
- Inflammatory: rheumatologic diseases, i.e., rheumatoid arthritis, SLE, all chronic forms of arthritis

- Traumatic: injury to joints or ligaments, postsurgical
- Infective: septic arthritis, Lyme disease
- Metabolic: haemochromatosis and Wilson's disease, gout, calcium crystal deposition, alkaptonuria
- Endocrine: diabetes, acromegaly, hypothyroidism, obesity Neuropathic arthropathy
- Miscellaneous: haemophilia, osteonecrosis

## **B. Knee OA features and grading**

About 13% of females and 10% of males above the age of 60 have indicative knee OA. The amount of persons concerned with suggestive knee OA is supposed to elevate due to the increased age of the population and the pace of obesity or over weight in the common inhabitants.(45)

Features of knee OA are pain at commencement of the movement, afterwards on pain throughout movement and finally lasting pain. These patients will also have a loss of purpose like stiffness, decreased range of motion (ROM) and destruction in everyday activities. Other probable features of knee OA are bony swelling, crepitus, joint line tenderness and elevated sensitivity to cold or dampness.(46)

- Stage 0: This is the “normal” knee health, devoid of any pain in the joint functions.
- Stage 1: A being in this phase has very slight bone spur development and is not experiencing any pain or uneasiness.
- Stage 2: This is the phase where individuals will understand symptoms for the first time.

They will have pain after a lengthy day of walk and will sense a larger stiffness in the joint. X-rays will by now disclose bigger bone spur development. The cartilage will likely stay behind at a healthy size.

- Stage 3: Stage 3 is measured as a moderate osteoarthritis. People with this phase will understand a regular pain during movement. The joint rigidity will also be more in attendance, particularly after sitting for long periods and in the morning. The cartilage between the bones reveals clear damage, and the space between the bones is getting slighter.
- Stage 4: This is the most severe stage of osteoarthritis. The joint space between the bones will be dramatically reduced, the cartilage will almost be totally gone and the synovial fluid will be reduced. (47)

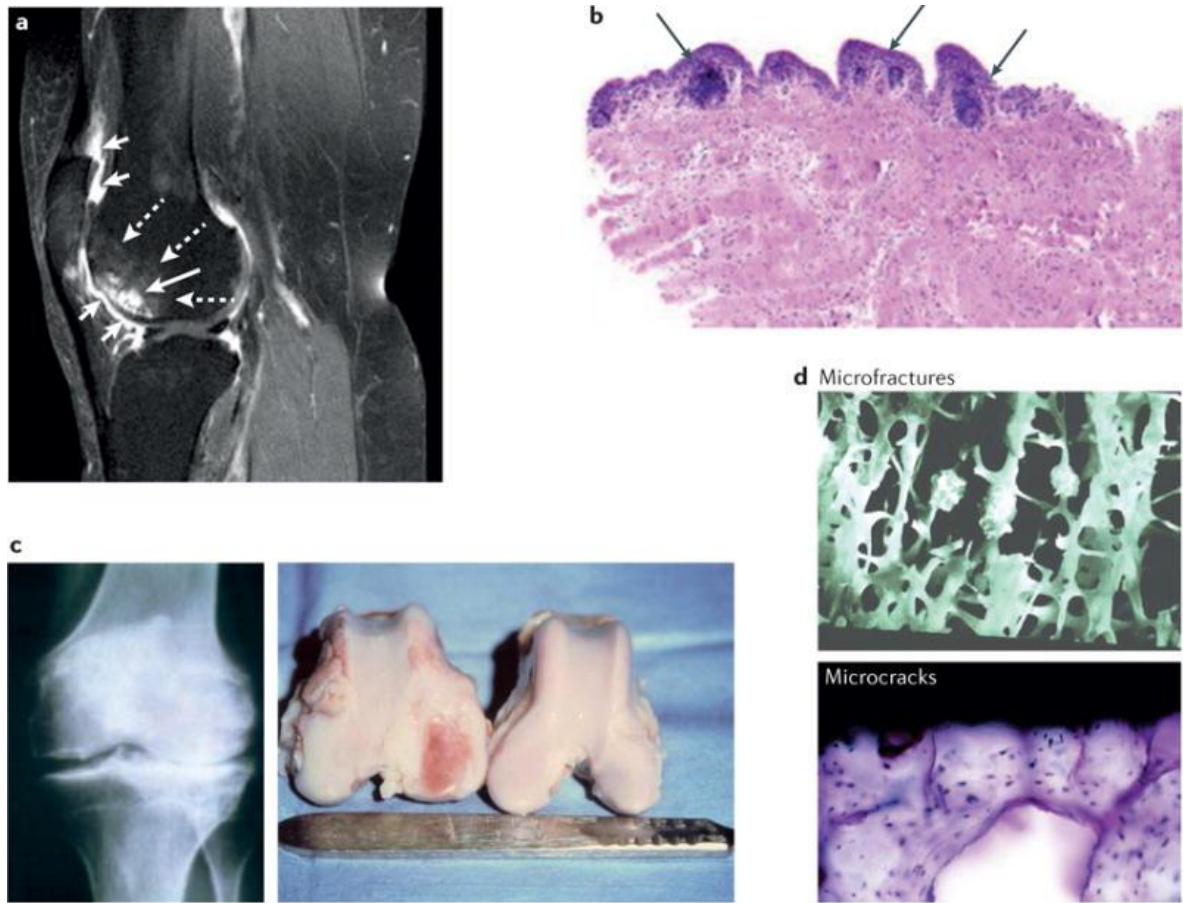
The features of knee OA are similar for most other joints:

- joint space narrowing
  - usually asymmetric, classically of the medial tibio femoral compartment, and/or patella femoral compartment
  - <3 mm on weight bearing knee radiographs is considered a finding of absolute joint space narrowing with a normal joint space >5 mm
  - weight bearing radiographs will demonstrate more joint space narrowing than non weight bearing radiographs
- subchondral sclerosis
- marginal osteophytes
- subchondral cysts (geodes)
- altered shape of the femoral structures

### **Classification of knee OA(48)**

- The Kellgren and Lawrence system is a frequent means of classifying the firmness of knee osteo arthritis (OA) using 5 grades This categorization was projected by Kellgren et al. in 1957 and later established by WHO in 1961.
  - **grade 0:** no radio graphic features of OA are present
  - **grade 1:** vague joint space lessening (JSN) and probable osteo phytic lipping
  - **grade 2:** exact osteophytes and possible JSN on antero posterior weight bearing radiograph
  - **grade 3:** plentiful osteo phytes, exact JSN, sclerosis, probable bone malformation
  - **grade 4:** big osteo phytes, obvious JSN, callous sclerosis and exact bone malformation
- This classification was proposed by Ahlback et al. in 1968. According to Ahlbäck system, knee joint osteoarthritis is classified as:
  - **grade 1:** joint space narrowing (less than 3 mm)
  - **grade 2:** joint space elimination
  - **grade 3:** slight bone abrasion (0-5 mm)
  - **grade 4:** reasonable bone abrasion (5-10 mm)
  - **grade 5:** harsh bone abrasion (> 10 mm)

**Figure: Radiographic and histologic findings in OA: evidence of inflammation and bone remodelling (42,49,50)**



a. Gadolinium improved MRI (sagittal view) scan of a knee with numerous characters characteristic of OA: Short white arrows point out obvious peripatellar synovitis, dashed white arrows indicate bone marrow lesions, and the long white arrow which point to bright white structures specifies bone cysts. **b** | A synovial biopsy specimen get hold of during meniscectomy from a subject with knee OA, presenting histological proof of inflammation. Arrows designate the occurrence of peri vascular mono nuclear cell gathering. **c** | Re modelling of the sub chondral bone in OA, as noticed by radio graphy of the knee of an person with OA (left), and by gross examination of distal femurs of a dog (right) that had under gone uni lateral anterior cruciate ligament transection. **d** | Micro fractures and micro cracks in sub chondral bone of a person with OA.



### C. Treatment of Knee OA


OA is a progressive and degenerative state, with doubtful regression and re-establishment of injured structures. Usual treatment modalities are designed to target symptom control if not the amount of severity needs any surgical intervention with joint replacement.

#### Non pharmacologic management:

Idleness and non-use of joints are damaging for the health of the knee joint, the be short of of mechanical stimulus begins further rapid cartilage deterioration owed to cartilage thinning, decreased of glycos amino glycan content, spoiled joint mechanics and flexibility. The addition of exercise to the treatment of OA not only provides benefits for the OA part but also for other non communicable diseases like diabetes mellitus, coronary diseases and also improves the mental health in terms reducing stress and stamina.

Exercise routines should be modified according to every person's necessities and also to the level of maximum tolerance. High level exercises should be restricted and plans have to make to make this consistent to increase the success rate.

**Table: showing different modalities of exercises for OA (51–53)**

<b>Aerobic/endurance</b>	<b>Resistance/strength training</b>	<b>Balance/proprioceptive</b>
Activities like walking, climbing stairs, and cycling. Decrease joint tenderness  Improve functional status and respiratory capacity.	Isometric, isotonic, isokinetic, and dynamic modalities Most of them targeting quadriceps, hip abductors, hamstrings, and calf muscles. improve strength, physical function, and pain levels,	Tai Chi, Yoga Slow and gentle movements to adopt different weight bearing postures + breathing techniques Stretching exercise

Water based exercises are also now gaining momentum which act as a more fun with effectiveness for the management of OA. (51)

Weight loss or managing it act as vital role in symptom management and it has been reported that the reduction of weight act as an addition factor to exercise. (52) Obesity can influence patients by both its molecular and mechanical effects. The adipose tissue itself is a foundation of inflammatory factors. The cytokines adipokine, IL6, TNF alpha, and C-reactive protein are prominent in the plasma of obese patients and have been linked with change of cartilage homeostasis and degeneration. Throughout movement, the knee joint has to bear 3–5 times the body weight, therefore little changes in weight symbolize the elevated difference of forces to the joint.(33,54) In spite of the used method (bariatric surgery vs lifestyles modifications), there is around 10% risk lessening of knee OA per kilogram of body-weight decreased (similar amount applies in the reverse direction for the increase in weight).(55) Total reduction in weight is not the only factor affecting also change in fat %, studies showed that each point decrease represent a 28% increase in function and a 9.4% enhancement in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.(56)

A latest systematic review showed that acupuncture that meet enough criterion was appreciably better in patients with chronic knee pain. This practice is rationally safe and well tolerated by most, although quite a few sessions are typically necessary.(57)

Some studies are suggesting the use of appropriate foot wear for the OA knee. The following sorts have been recommended for foot wear for people with OA: thick, soft, shock absorbing sole; negligible heel raise; wide fore foot to allow splaying of the toes during forefoot loading; and deep, soft uppers.(58)

## **Pharmacologic treatment**

### **Simple analgesia**

Both paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) are evidence-based drugs for symptom relief in OA. NSAIDs are effective agents for the treatment of OA. A meta-analysis concluded that NSAIDs, including COX-2 selective inhibitors, can reduce pain and functional disability in knee OA better than placebo. There occurs the side effect of gastrointestinal complications and cardiovascular risks.(59)

### **Topical therapy**

Short term use of topical NSAIDS is secure and successful in OA of the hand and knee according to a 2004 meta-analysis.(60)

### **Glucosamine sulphate**

These stimulate proteoglycan synthesis by chondrocytes, mild anti-inflammatory properties.

### **Chondroitin sulphate**

Stimulates RNA synthesis by chondrocytes, partially inhibits leukocyte elastase, overcomes dietary deficiency of Sulphur containing amino acids.(61)

### **Corticosteroids (CS)**

CS obtains their immune suppressive and anti-inflammatory effects by acting directly on nuclear receptors, interrupting the inflammatory cascade at multiple levels. They reduce the action and creation of IL-1, leuko trienes, prostaglandins, and metallo proteinases. At present, the accessible FDA approved Immediate Release (IR)

corticosteroids for IA usage are: Methyl prednisolone Acetate (MA), Triamcinolone Acetate (TA), Triamcinolone Hexacetonide (TH), Beta methasone Acetate (BA), Beta methasone Sodium Phosphate (BSP), and Dexamethasone.(62)

The clinical anti-inflammatory suggestion of CS are decline in erythema, swelling, heat, and gentleness of the inflamed joints and magnification in relative thickness with a boost up in hyaluronic acid (HA) quantity.

### **Visco supplementation with hyaluronic acid**

Hyaluronic acid (HA), is a usual glycosaminoglycan created by type B synovial cells, chondrocytes, and fibroblasts and provide into the synovial fluid. It provides viscous lubrication, has disgusting absorbing feature and in totaling to it a few probable anti-inflammatory and antioxidant purpose have been described.(62) Intra-articular HA injections are secure and might have usefulness and may give pain reduction in mild OA of knee up to 6 months. But the cost efficiency is a fundamental concern that patients must be learned earlier.

### **Opioid analgesia**

Many studies have shown a moderate pain reduction with opioids. The withdrawal rates were higher for stronger opioids (morphine, oxycodone) compared to weaker opioids (tramadol, codeine). There are also no extensive studies of opioids in OA. Yet, they have an important role, with concern, in the treatment of patients with chronic, obstinate pain for whom surgery is not an alternative and where other methods was unsuccessful.(63)

### **Other alternatives (64)**

Avocado/soybean unsaponifiable: Repress chondrocyte catabolic activities, inhibit inflammatory mediators

Strontium ranelate: Stimulate the synthesis of type II collagen and proteoglycans.

### **Surgery (65)**

Surgery is indicated for patients with pain and impairment of function obstinate to non-medical and medical therapy. Joint replacement surgery results in better pain and function, and is cost effective in its capacity to get better the quality of life

## **D. Newer modalities for treatment of OA**

### **PLATELET RICH PLASMA (PRP)**

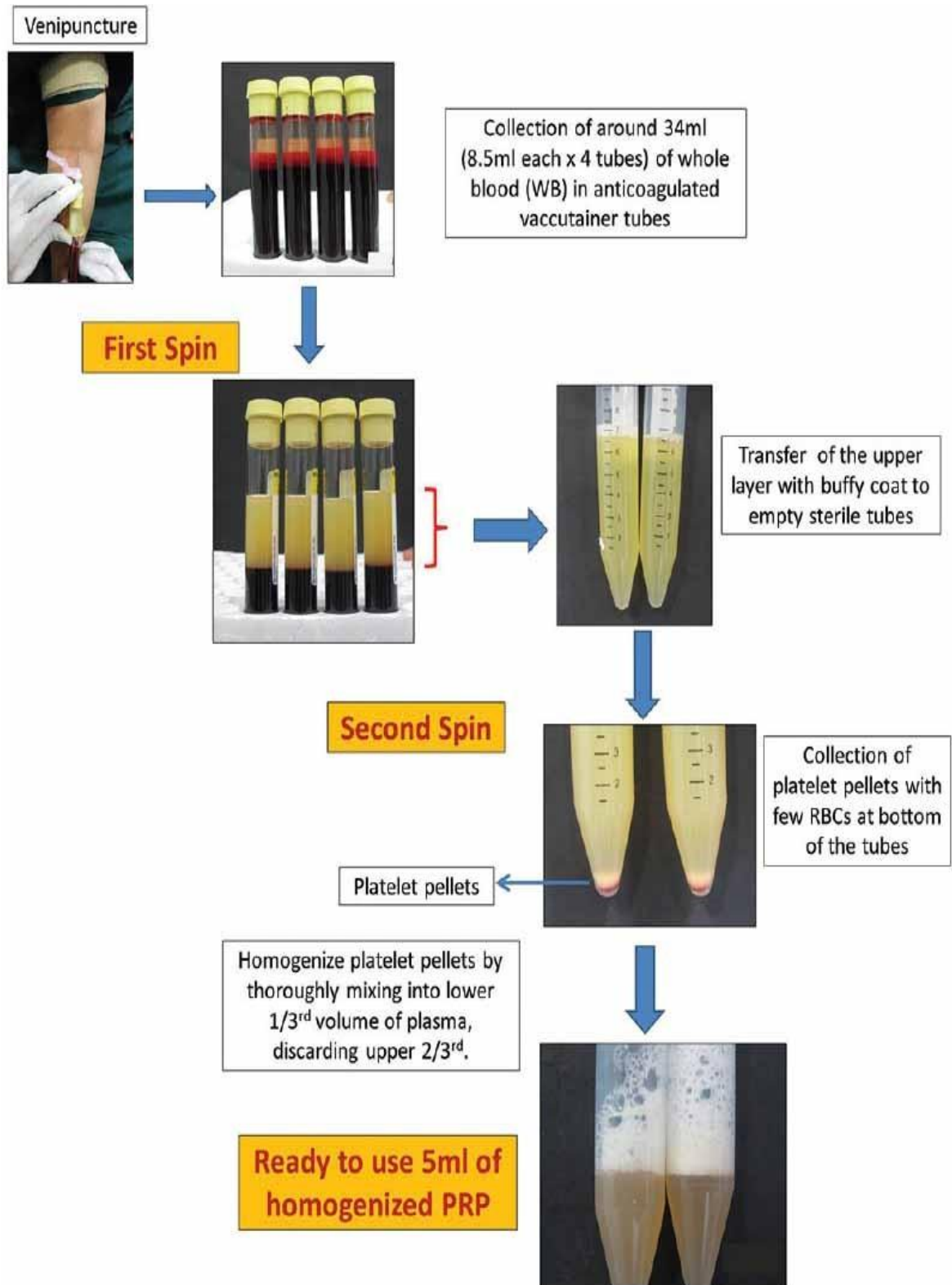
Platelet rich plasma (PRP) is set from autologous blood by centrifugation to obtain a very concentrated model of platelets, which is 4-5 times elevated than that of normal blood. The platelets bear degranulation to release growth factors (GFs). The plasma is the acellular part of combination including cytokines, thrombin, and other GFs.(66)

Fresh blood was taken from the patient and equipped directly before each injection of PRP. In order to check sterility, small volumes (2.8 ml) of ready PRP were sent for microbiology testing to ensure total sterility. The aim is to prepare PRP with a platelet count in excess of 300,000 platelets/mL.(67) The flow chart for preparation of PRP is given below.

According to the categorization projected by Ehrenfest et al. (2009), 4 main families of measures can be clear, depending on their cell contents and fibrin architecture.(68)

- Pure Platelet-Rich Plasma (P-PRP) or leucocyte poor PRP products are provision devoid of leucocytes and with a low-density fibrin network subsequent to formation.
- Leucocyte and PRP (L-PRP) products are procedures with leucocytes and with a low density fibrin network after foundation. In this family many trial are occurring.
- Pure platelet-rich fibrin (P-PRF) or leucocyte poor platelet rich fibrin measures are devoid of leucocytes and with a high density fibrin network. These products only in attendance in a power fully activated gel form, and cannot be injected or used like conventional fibrin glues.
- Leucocyte and platelet rich fibrin (L-PRF) or 2<sup>nd</sup> generation PRP products are provision with leucocytes and with a elevated density fibrin network.

Figure: flow chart showing the preparation of PRP (69)



Mechanism of action: The platelet focus is activated by adding up of calcium chloride, and this leads in the creation of platelet gel and the release of growth factors and bio active molecules. Thus, platelets actively obtain part in remedial procedures by discharging a wide spectrum of GFs (insulin like growth factor, trans forming growth factor b-I, platelet derived growth factor, and many others) and other active molecules (e.g., cyto kines, chemokines, arachi donic acid meta bolites, extra cellular matrix proteins, nucleo tides, ascor bic acid) to the wounded site.

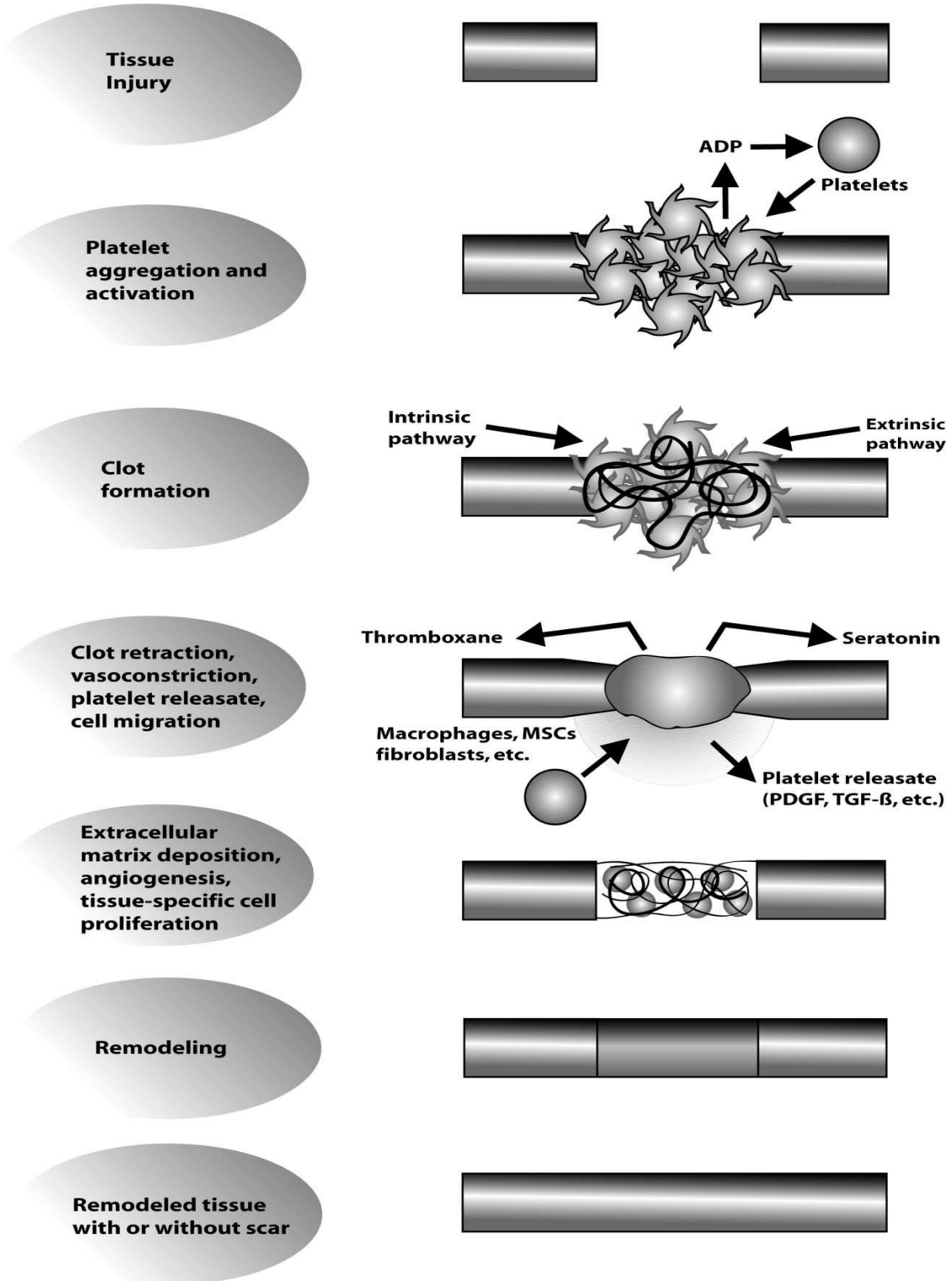
These factors in total add to fullfill roles of PRP, including chondro genesis, bone re modelling, propagation, angiogenesis, anti inflammation, coagulation and cell delineation.(12,67,70)

PRP is blood creations that permit in an simple, petite price, and minimally invasive method to get hold of an amount of a lot of growth factors and biologi cally active molecules and its use is correlated with reduced inflammation, pain aid, better function, and probable cartilage renewal.

The chief difficulty is methods original to this probable remedial effect of PRP remain as a legend till currently. Also, inter patient in consistency and the lack of bio chemical and imaging bio markers to advance diagnostic specificity of OA make the appliance of PRP hard.(71)



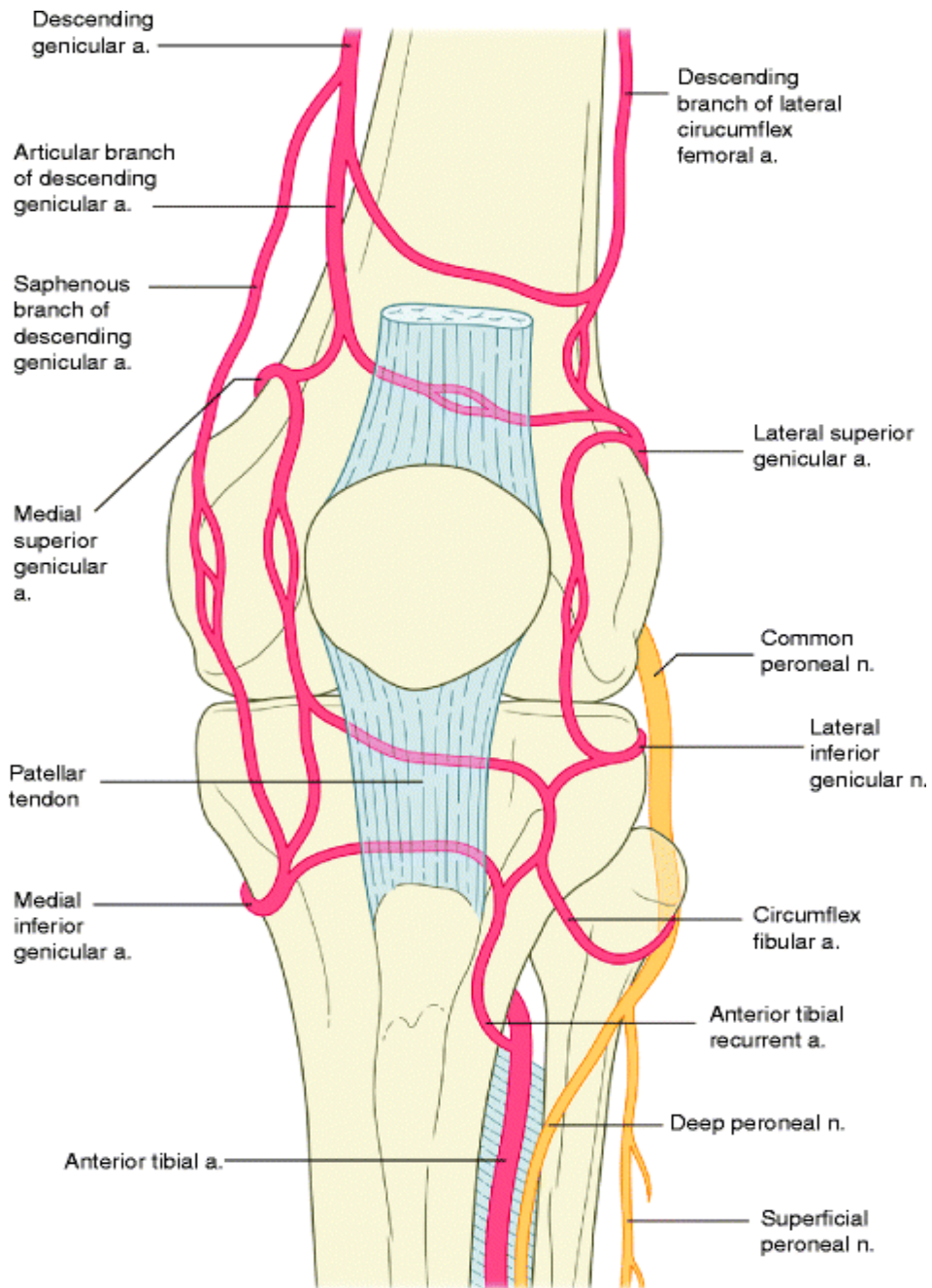
Figure: Role of platelets in wound healing (12)



## Genicular nerve block in Knee OA (72)

Patients with chronic knee pain that has unsuccessful to react to traditional care may be candidates for a genicular nerve block. This practice is based on a theory that blocking the nerve supply to a painful area may alleviate pain and restore function.

**Figure: Contiguity of genicular arteries and nerves**



A Genicular nerve block is a procedure where these nerves are anesthetized (“blocked”) with local anaesthetic injected through small needles. The procedure is performed under ultrasound guidance or fluoroscopic guidance. It generally takes 5 to 10 minutes for the procedure.

Usually, a diagnostic genicular nerve block (GNB) with local anaesthetic is performed before Radio Frequency (RF) genicular ablation, and a flourishing reaction to GNB is considered to indicate the call for RF genicular ablation. However, one study recommended that GNB, when injected jointly with corticosteroid, is as efficient as RF genicular ablation.(73)

Complications are uncommon, chiefly if injections are done using a precise needle positioning technique. Septic arthritis can be nullified with suitable aseptic safety measures. Severe allergic reactions to local anaesthetics are unusual. Post procedural pain flare up is not rare, and may be managed with pain killers. Neurological complications including paraesthesia and numbness have been reported but are enormously uncommon. Radio frequency treatment can cause irregular numbness of the above skin. Occurrence of infection is small as the method is done in stringent aseptic circumstances and the injections are extra articular i.e., outside the joint.(72)

#### **E. Studies done using PRP**

- Sánchez et al was initial one to report the Intra Articular injection of plasma rich in growth factors to handle an articular cartilage damage in a football player. Even with having a poorer future total articular cartilage curing was significantly

accelerated, and the final result was outstanding, allowing a fast carrying on of symptom free sporty activity.(74)

- Another study group reported initial results of an autologous arrangement rich in growth factors injection for knee OA, signifying the security and utility of this management advancement. They have done study by means of HA injections as a control. 30 subjects with OA selected and give 3 weekly injections. Medical result was calculated by means of the WOMAC questionnaires previous to the start and at 5 weeks after. The observed achievement rates by week 5 for the pain sub scale attained 33.4% for the PRP group and 10% for the HA group. The physical function and on the whole score according to WOMAC was better in PRP group.(75)
- Sampson et al done 3 sets of IA PRP injections at 4 weeks intervals for 14 patients concerned by knee OA and reported a constructive result in most of the patients at 12 months of follow-up. (76)
- Kon et al had done 3 sets of intra articular PRP injections at 3 week intervals to 115 osteoarthritic knees. Noteworthy improvements happened in all clinical scores from the basal evaluation to the end of the therapy and at 6- 12 months follow-up. The outcome was same from the end to 6 months, but starts worsening at 12 months follow up. The initial results point out that the management with PRP injections is secure and has the likelihood to reduce pain and get better knee purpose and worth.(77)
- Another study was done among 91 patients for 1 year follow up. All the patients were managed with 3 IA PRP injections. Every measured factor got deteriorated

at the 2 years follow up: these parameters were at significantly lesser levels with respect to the 12 month evaluation. The results demonstrated 9 months of median duration of the supportive effects and were better in young patients with lower degrees of OA.(78)

- A study by Peer booms et al was done among 100 with chronic lateral epi condylitis They were randomly allocated in the PRP group or cortico steroid group (n = 49).

According to the visual analogue scores, 49% in the cortico steroid group and 73% in the PRP group were considerably diverse. Also, according to the DASH scores, 51% in the cortico steroid group and 73% in the PRP group were statistically diverse. The cortico steroid group was superior at first and then declined, where as the PRP group gradually more got better.(79)

- In a study by Patel et al amid 78 subjects with bilateral OA were separated randomly into 3 groups. Group A got a sole injection of PRP, group B received 2 injections of PRP 3 weeks apart, and group C be given a sole injection of normal saline. Result was assessed using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire before conduct and at 6 weeks, 3 months, and 6 months after management. Noteworthy improvement in all WOMAC parameters was noted in groups A and B within 2 to 3 weeks and lasting until the final follow-up at 6 months, with minor deterioration at the 6-month follow up. The average WOMAC scores for group A at base line was 49.86, respectively, and at final follow up was 27.18, respectively, showing significant improvement. Similar improvement was noted in group B with 53.20 at base line and average WOMAC scores at final follow up: 30.48. In group C,

the mean WOMAC scores deteriorated from base line from 45.54, to last follow up 53.09. (80)

- In a study by Li et al among 30 patients with knee articular cartilage degeneration were randomly divided into PRP group (n = 15) and Sodium Hyaluronate group (n = 15). Both treatments were governed in series of 3 IA injections at 3 weekly intervals. The patients of 2 groups were followed up 6 months. There were significant disparities in the scores between pre and post injection in 2 groups ( $P < 0.05$ ). There occurred no significant disparity across time periods in PRP group. The efficiency of test group was significantly better than that of control group at 6 months after application by means of score.(81)
- In a study by Wang et al among 261 patients, 109 women and 152 men, with an average age of 48.39. 3 IA injections of autologous PRGF were given at 2-week intervals in out patient surgery. Statistically noteworthy disparity ( $P < 0.0001$ ) amid pre-treatment and follow-up values were found for pain, stiffness and functional capability in the WOMAC Index.(82)

*Research Question or  
Hypothesis*

## **4) RESEARCH QUESTION OR HYPOTHESIS**

### **Research Question:**

Whether there is any difference in efficacy in the pain relief and functional outcome of ultrasound guided Genicular Nerve block with 0.5% Bupivacaine and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of patients with Grade I and II Osteo Arthritis of Knee?

### **Null Hypothesis:**

There is no difference in efficacy in the pain relief and functional outcome of ultrasound guided Genicular Nerve block with 0.5% Bupivacaine and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the management of subjects with Grade I and II knee OA.

### **Alternate Hypothesis:**

There is a difference in efficacy in the pain relief and functional outcome of ultrasound guided Genicular Nerve block with 0.5% Bupivacaine and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the management of subjects with Grade I and II knee OA.



# *Methodology*

## 5) METHODOLOGY

### 5.1. Study participants:

Patients who got referred to the Department of Physical Medicine and Rehabilitation at Government Institute of Rehabilitation Medicine, KK Nagar, Chennai

### 5.2. Study Design:

The study was an open, double blind randomized control trial.

### 5.3. Study setting:

Department of Physical Medicine and Rehabilitation at Government Institute of Rehabilitation Medicine, KK Nagar, Chennai

### 5.4. Sampling Procedure:

The study participants were randomized using computer generated random numbers. The total patients studied were 100 with 50 in each group.

- **Group A:** Will be treated with Genicular nerve block and Intra articular injection of platelet rich plasma
- **Group B:** Will be treated with Intra articular injection of platelet rich plasma.

Both Groups (A & B) had undergone the Scheduled Exercise Therapy.

### 5.5. Inclusion Criteria:

The patients with

- Age:>50 years
- Symptoms > 3 months
- Both sexes

- Grade I and II osteoarthritis knee by Kellgren- Lawrence grading
- Knee pain unresponsiveness to conservative treatment for 1 month
- Stiffness:<30mts
- Crepitus
- Bony tenderness
- Bony enlargement
- No palpable warmth

#### **5.6. Exclusion criteria:**

Excluded those

- Post Operative cases
- Cellulitis / Infections
- Polyarticular disease
- Steroid treatment in the last 3 months.
- Any implants inside.
- Associated with DVT calf muscles
- Non co-operative patient
- Low I.Q Patients /psychiatric patient
- Trauma
- Meniscal injury
- Anterior/Posterior cruciate ligament injury
- Medial/Lateral collateral ligament injury
- Bursitis
- Rheumatoid arthritis
- Pseudogout/ Hyperuricemia

- Other grades of osteo arthritis knee
- Informed consent not provided.
- Cancer/ Malignant lesions.

### **5.7. Sample Size:**

Total of 100 subjects were selected and was randomly divided into 2 groups.

### **5.8. Study procedure:**

Before the start of intervention detailed history taking, review of case file including investigations such as FBS, PPBS, X-RAY knee and assessed to for any underlying medical conditions. Sociodemographic details were collected and anthropometric measurements was done

After getting informed consent, subjects of Group A and Group B were given a test dose of 2% Lignocaine.

For both the group of patients :

34 ml (8.5ml X 4) of whole blood was collected in acid citrate dextrose tubes. First spin (soft spin) was done at 900g for 5 minutes. Supernatant plasma containing platelets was transferred into another sterile test tube (without anticoagulant). Second spin (Hard spin) was done at 1000g for 10 minutes. Upper 2/3rd (platelet poor plasma) was pipetted out and the lower 1/3<sup>rd</sup> (Platelet rich plasma) platelet pellets is suspended in minimum quantity of plasma (2-4ml) by gently shaking the tubes.

- After ensuring that there is no adverse reactions, subjects was taken to the operation theatre and parts (according to intervention) was cleaned with surgical spirit and Betadine followed by draping with sterile towel.

- Under strict aseptic precautions, the injection site is anaesthetized with 2% Lignocaine.
- For Group A: Genicular nerve (Superior medial genicular nerve, Superior lateral genicular nerve and Inferior medial genicular nerve) was blocked with 6ml of 0.5% Bupivacaine which is distributed equally to the targeted three injection sites under ultrasound guidance. Genicular nerve block was followed by Intra articular injection of 2-4ml of autologous platelet rich plasma by inferolateral approach. This procedure was repeated at regular 4 weeks interval for three cycles.
- For Group B: 2-4ml of Intra articular autologous platelet rich plasma by inferolateral approach. This procedure was repeated at regular 4 weeks interval for three cycles.
- After the procedure, the study participants were observed for 15 minutes for any adverse reactions.
- Study participants was asked to report immediately in case of adverse reactions like post injection flare (increased pain, swelling)/hypersensitivity reactions etc.
- Both Groups (A & B) had undergone the Scheduled Exercise Therapy.
- Pain relief and functional outcome was analysed with VAS score, Numerical rating scale and Western Ontario and McMaster universities (WOMAC) Osteoarthritis Index before the intervention and on first post intervention day and at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 16 weeks and 24 weeks.

### **5.9. Ethical Consideration:**

Institutional Ethical Committee approval was obtained before the start of the study. Informed written consent was obtained from each participant.

### **5.10. Statistical Methods:**

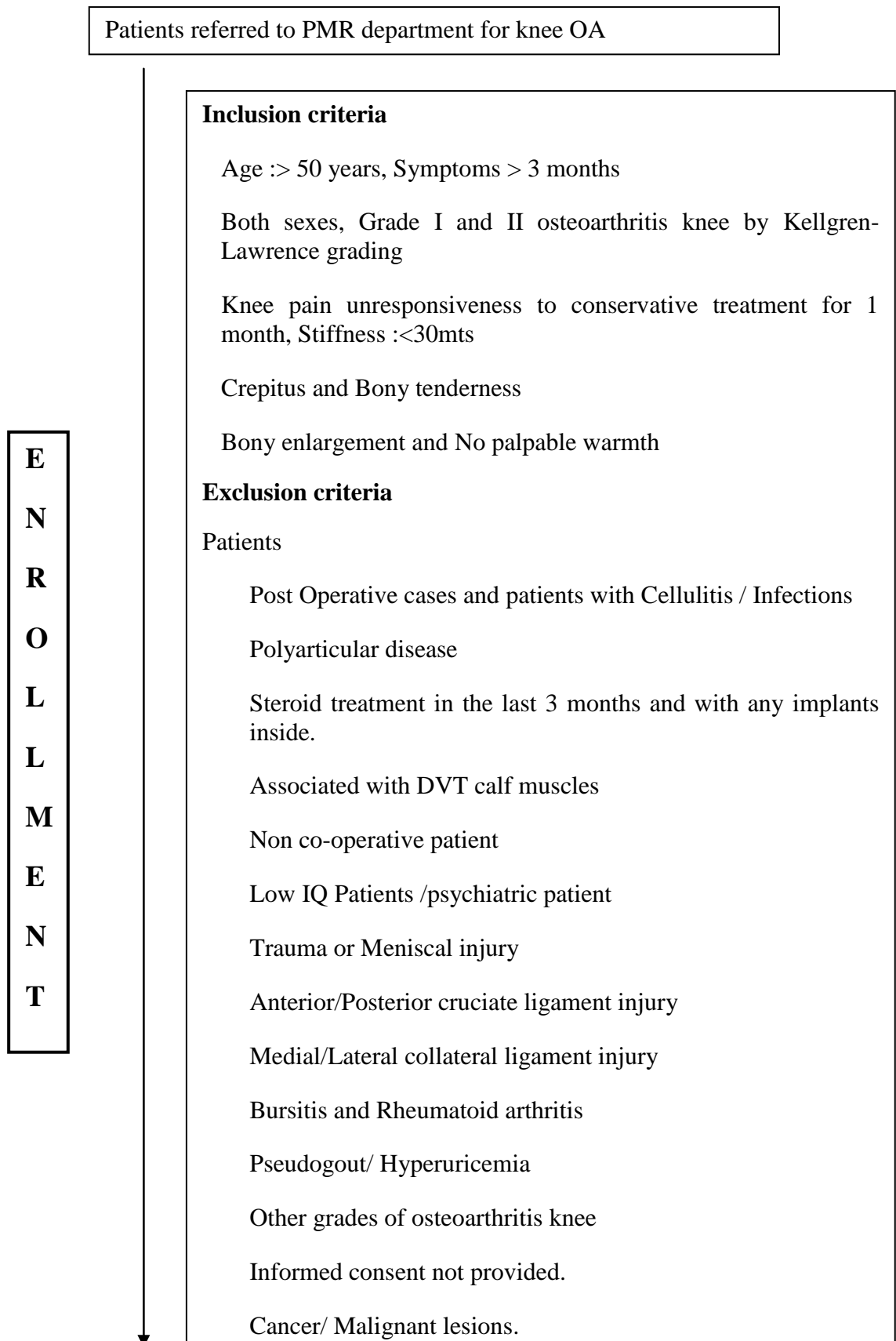
#### **Descriptive Statistics:**

1. Continuous variables are represented in mean, median, mode and standard deviation.
2. Categorical variables are represented in frequencies and percentages. Pie-charts and bar diagrams are used as appropriate.

#### **Inferential Statistics:**

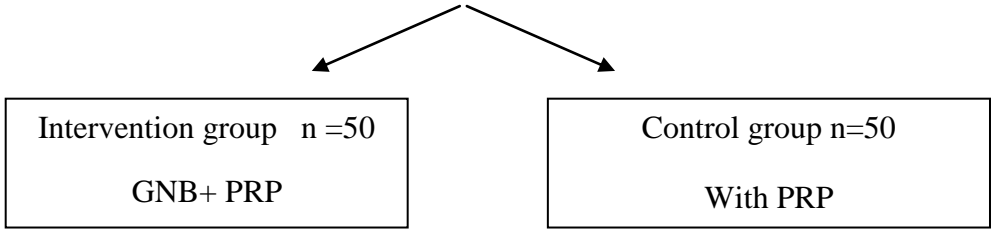
3. When a Categorical Variable is associated with a categorical variable, the variables are represented in both by tables and bar diagrams. For test of significance, chi-square test is used. Fisher's exact test is used when more than 20% of the cell values have expected cell value less than 5.
4. When a Continuous variable is associated with the categorical variables such as patient groups independent t test is used after checking for normality. Otherwise non parametric tests like Mann Whitney U test were used.
5. P-values less than 0.05 were considered statistically significant.
6. Data was entered in MS excel sheet and analysed using SPSS software version 16.

**Figure: Schema of the study**



**A  
L  
L  
O  
C  
A  
T  
I  
O  
N**

Randomized through computer generated randomization



Assessed by VAS score, Numerical rating scale and Western Ontario and McMaster universities (WOMAC) Osteoarthritis Index before the intervention and on first post intervention day and at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 16 weeks and 24 weeks.

Loss to follow up=0  
Discontinued intervention=0

Loss to follow up=0  
Discontinued intervention=0

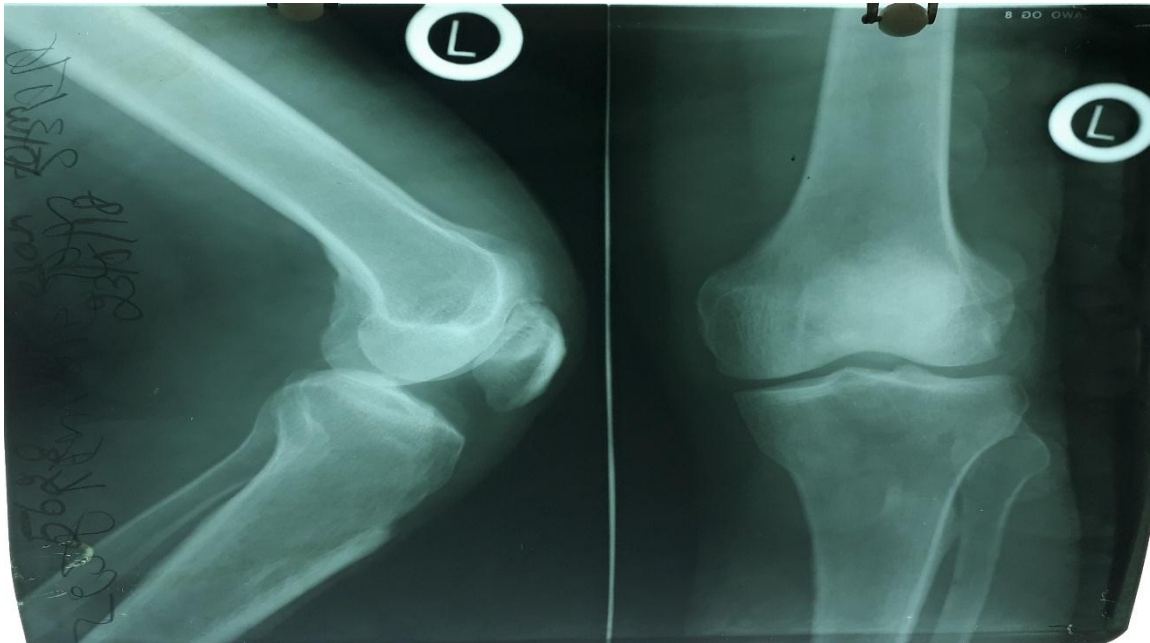
**Analysis  
&  
Follow  
up**

Analysis done n=50  
Excluded , n=0

Analysis done n=50  
Excluded, n=0

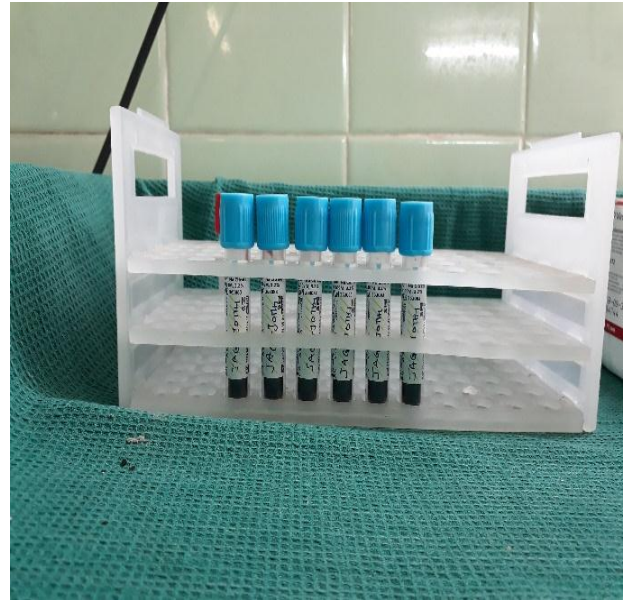


**TEMPLATE-1**  
**INVESTIGATION**



## TEMPLATE-2

## INTERVENTION



## TEMPLATE – 3

### SCHEDULED EXERCISE THERAPY



# *Results*

## 6) RESULTS

Results of this study are described under the following headings:

a. Descriptive statistics:

- i. Age
- ii. Gender
- iii. Side affected
- iv. Grade of OA
- v. Systolic and diastolic BP
- vi. FBS and PPBS
- vii. Baseline and other time period scores of VAS, WOMAC and NPRS scores

b. Inferential Statistics:

- i. Baseline comparison of both groups
- ii. Comparison of VAS score between two groups
- iii. Comparison of WOMAC score between two groups
- iv. Comparison of NPRS score between groups

The study was done with 100 subjects 50 each in groups.

50 in Genicular nerve block (GNB) and Intra articular injection of platelet rich plasma (PRP) and 50 in Intra articular injection of platelet rich plasma (PRP) group.

**Table: Age distribution among the population**

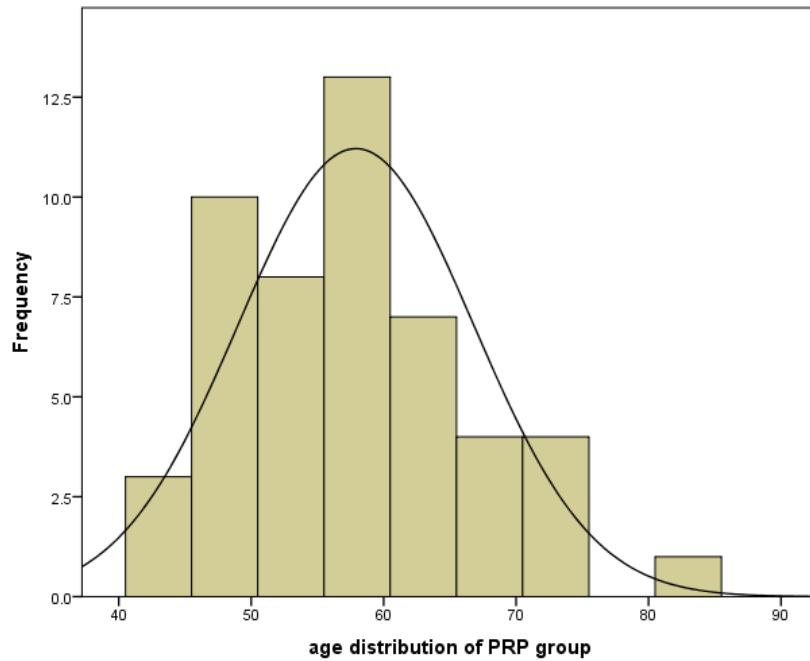
<b>Characteristics</b>	<b>GNB + PRP (in years)</b>	<b>PRP (in years)</b>
Mean	56.78	57.90
Standard deviation (SD)	9.70	8.89
Mode	60	48
Median	56.50	57.50
Minimum	40	43
Maximum	80	82

The table shows that the mean (SD) age of the GNB+PRP group and PRP group was 57.10(9.53) years and 57.90(8.89) years respectively. The minimum age of the population was 40 years and maximum age was 82 years.

The mean (SD) age of the population was 57.34 (9.28) years, with a median of 57 years and mode of 60 years.



**Figure: Age distribution of the population as two groups**



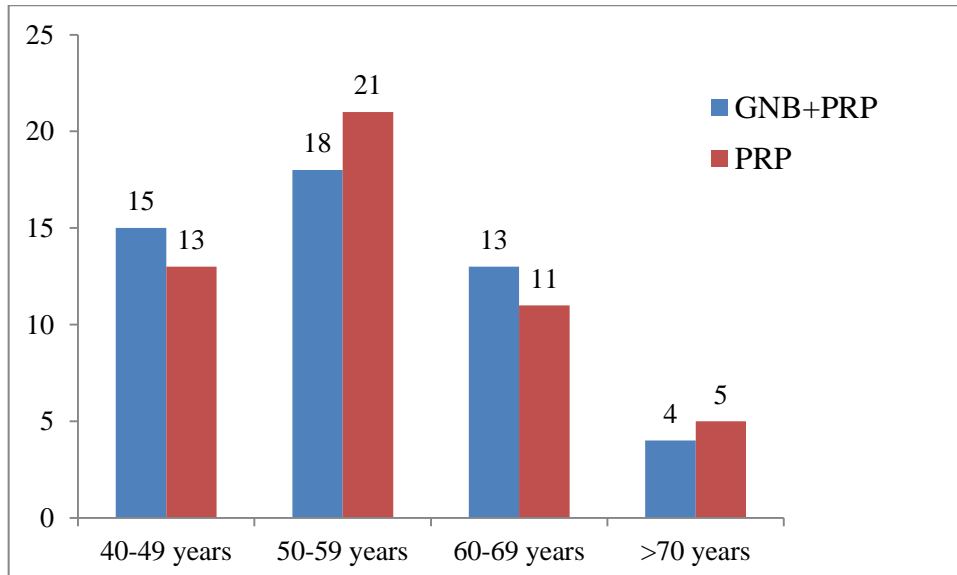
The figure shows that the mean (SD) age of the GNB+PRP group and PRP group was 57.10(9.53) years and 57.90(8.89) years respectively. The minimum age of the population was 40 years and maximum age was 82 years.

**Table: Age categories distribution among the population**

Age categories	GNB+PRP	PRP	Total
40-49 years	15(30%)	13(26%)	28(28%)
50-59 years	18(36%)	21(42%)	39(39%)
60-69 years	13(26%)	11(22%)	24(24%)
70 years and above	4(8%)	5(10%)	9(9%)

The table shows that in both the group had most participants in 50-59 years. [18(36%) in GNB+PRP vs 21(42%) in PRP group]. Next maximum is in the age group of 40-49 years [15(30%) in GNB+PRP group vs 13(26%) in PRP group].

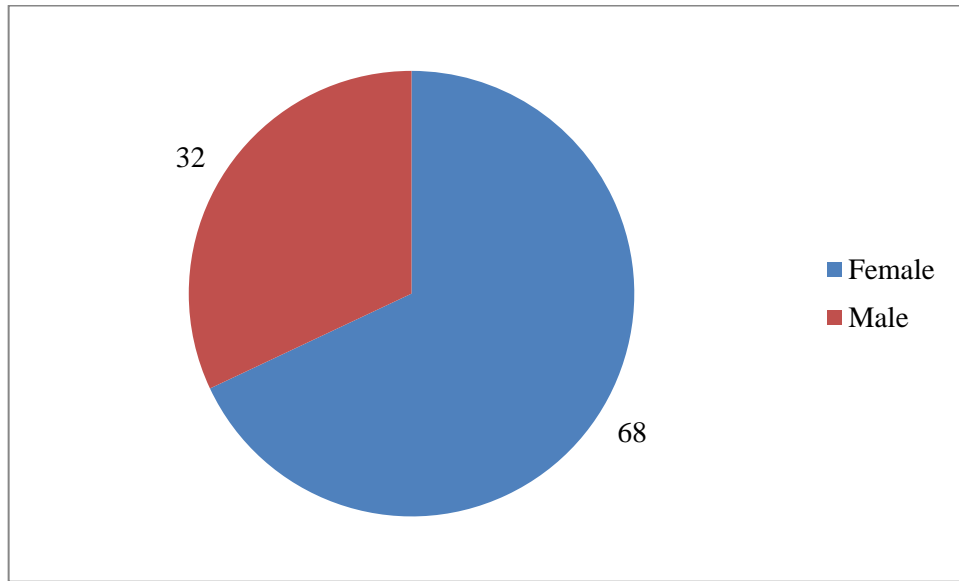
**Figure: Age categories distribution among the population**



The figure shows that in both the group had most subjects in 50-59 years. [18(36%) in GNB+PRP vs 21(42%) in PRP group]. Next maximum is in the age group of 40-49 years [15(30%) in GNB+PRP group vs 13(26%) in PRP group].

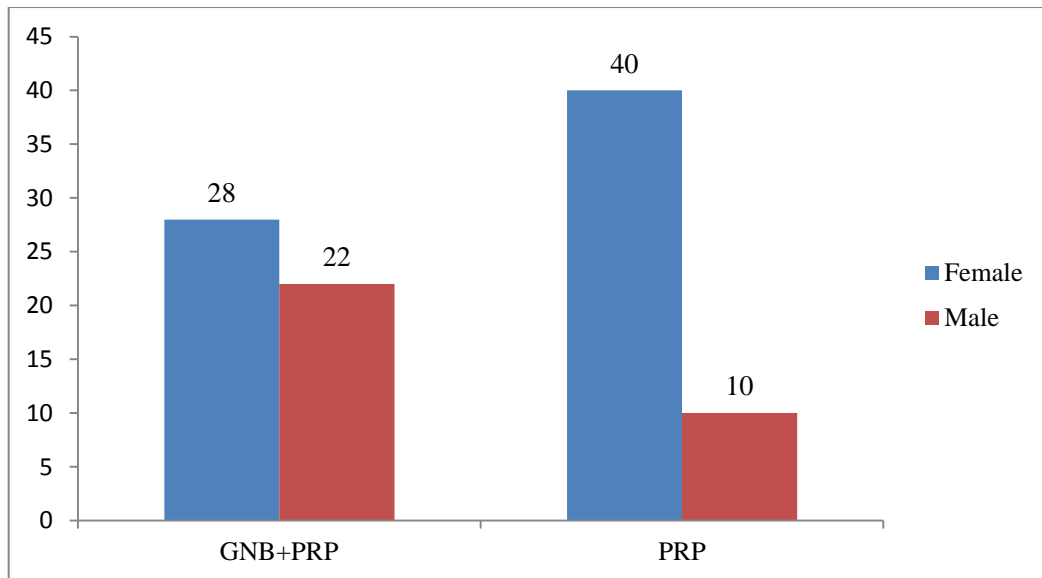


**Figure: Gender distribution in the study population**



The figure shows that majority 68(68%) of the study subjects were females and 32(32%) of the subjects were males.

**Figure: Gender distribution among the groups**



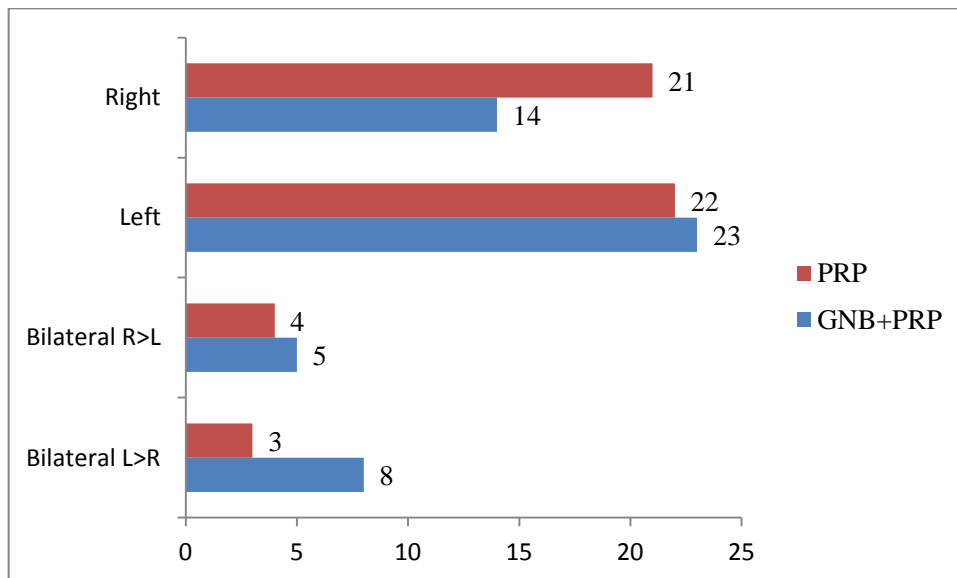
The figure shows that 28 (56%) and 40 (80%) among the GNB + PRP and PRP groups were females

**Table: Distribution of side affected among the population**

Side affected	GNB+PRP	PRP
Bilateral L>R	8(16%)	3(6%)
Bilateral R>L	5(10%)	4(8%)
Left	23(46%)	22(44%)
Right	14(28%)	21(42%)

The table shows that most 45(45%) of the population had their left knee affected. Next commonly affected was right knee 35(35%). The bilateral involvement is there in 19(19%) with left more than right in 11(11%).

**Figure: Distribution of side affected among the population**



The figure shows that most 45(45%) of the population had their left knee affected. Next commonly affected was right knee 35(35%). The bilateral involvement is there in 19(19%) with left more than right in 11(11%).

**Table: Grading of OA among the population among the groups**

<b>Grading of OA</b>	<b>GNB+PRP</b>	<b>PRP</b>
Grade I	19(38%)	19(38%)
Grade II	31(62%)	31(62%)

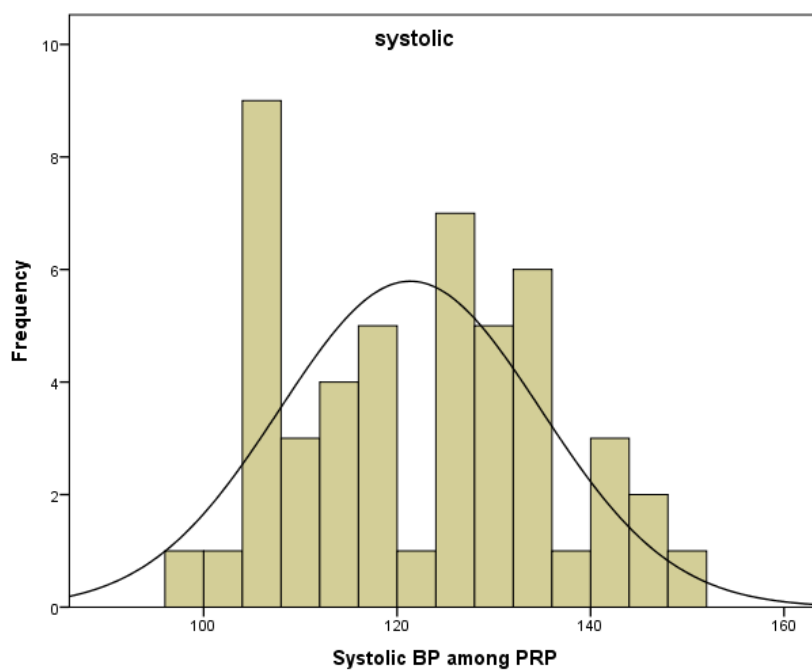
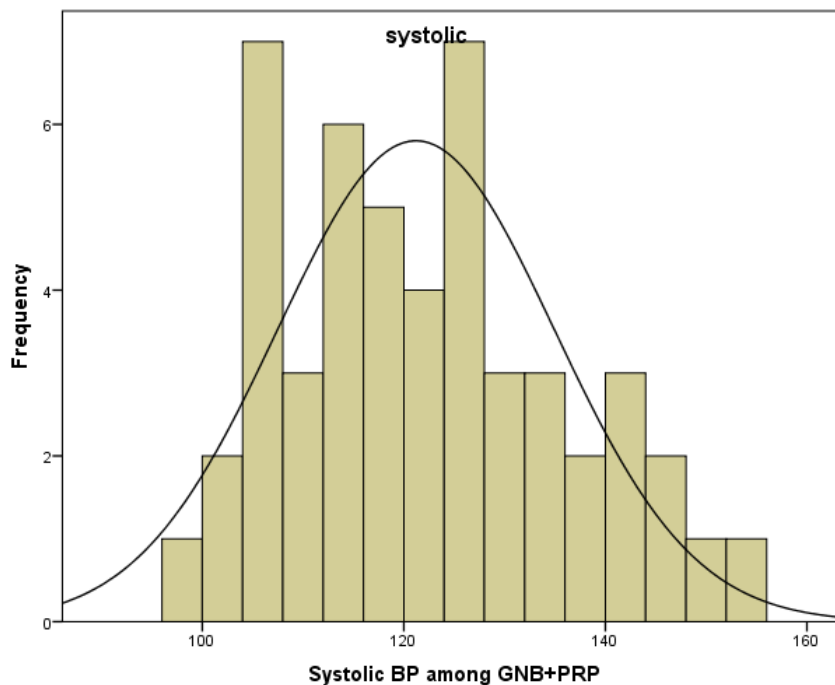
The table shows that 38(38%) of the subjects had an X ray grade I and 62(62%) of the subjects had an X ray grade II.

**Table: Systolic BP distribution among the population**

<b>Characteristics</b>	<b>GNB + PRP (in mm Hg)</b>	<b>PRP (in mm Hg)</b>
Mean	121.20	121.04
Standard deviation (SD)	13.75	13.54
Mode	124	126
Median	122	123
Minimum	98	98
Maximum	152	150

The table shows that mean (SD) of the systolic BP was 121.20(13.75) mm Hg for the GNB+PRP and 121.04(13.54) mm Hg for the PRP. The minimum systolic BP was 98 mm Hg and Maximum was 152 mm Hg.

**Figure: Systolic BP distribution among the population**



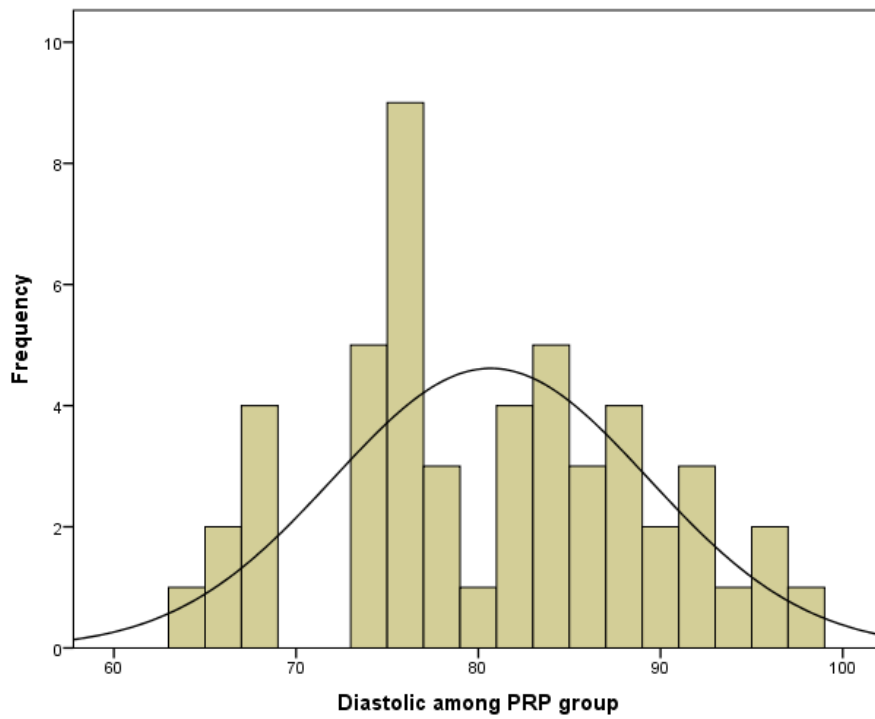
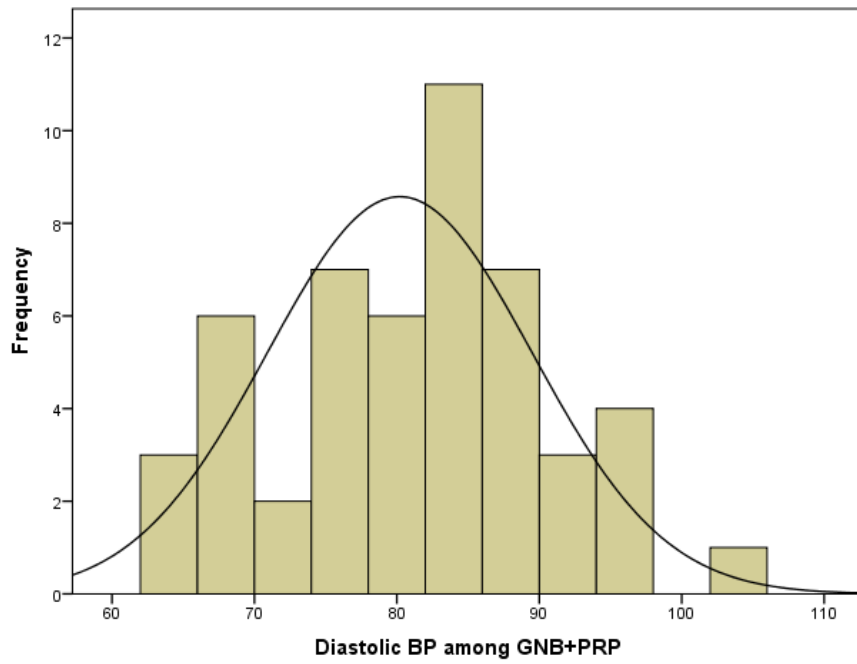
The figure shows that mean (SD) of the systolic BP was 121.20(13.75) mm Hg for the GNB+PRP and 121.35(13.49) mm Hg for the PRP. The minimum systolic BP was 98 mm Hg and Maximum was 152 mm Hg

**Table: Diastolic BP distribution among the population**

<b>Characteristics</b>	<b>GNB + PRP (in mm Hg)</b>	<b>PRP (in mm Hg)</b>
Mean	80.20	80.68
Standard deviation (SD)	9.30	8.64
Mode	78	76
Median	82	81
Minimum	64	64
Maximum	102	98

The table shows that mean (SD) of the diastolic BP was 80.20(9.30) mm Hg for the GNB+PRP and 80.68(8.64) mm Hg for the PRP. The minimum diastolic BP was 64 mm Hg and Maximum was 102 mm Hg.

**Figure: Diastolic BP distribution among the population**



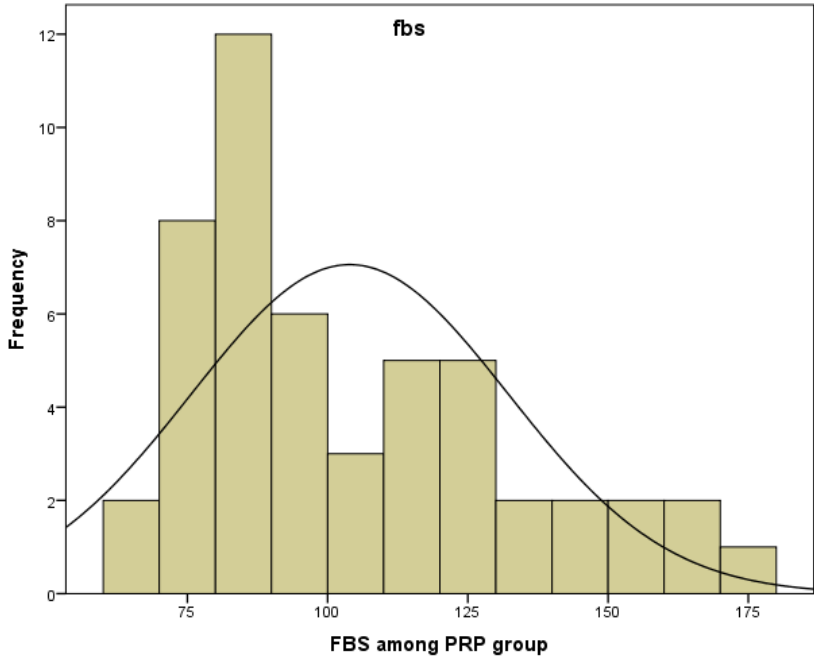
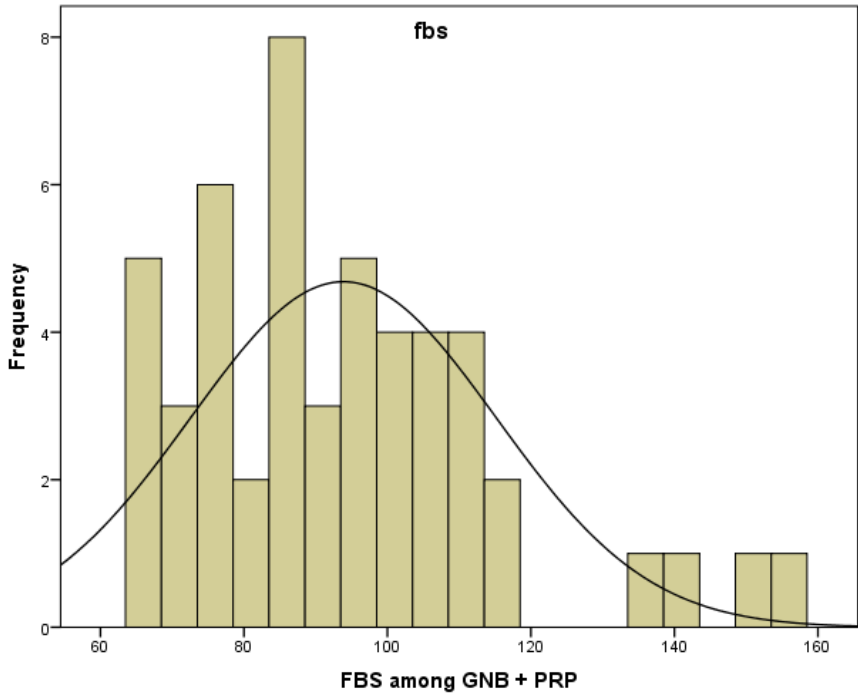
The figure shows that mean (SD) of the diastolic BP was 80.20(9.30) mm Hg for the GNB+PRP and 80.68(8.64) mm Hg for the PRP. The minimum diastolic BP was 64 mm Hg and Maximum was 102 mm Hg

**Table: FBS distribution among the population**

<b>Characteristics</b>	<b>GNB + PRP (in mg/dl)</b>	<b>PRP (in mg/dl)</b>
Mean	93.86	103.94
Standard deviation (SD)	21.29	28.26
Mode	67	87
Median	89.50	93.50
Minimum	66	67
Maximum	156	178

The table shows that mean (SD) of the FBS was 93.86(21.29) mg/dl for the GNB+PRP and 103.94(28.26) mg/dl for the PRP. The minimum FBS was 66 mg/dl and Maximum was 178 mg/dl.

**Figure: FBS distribution among the population**





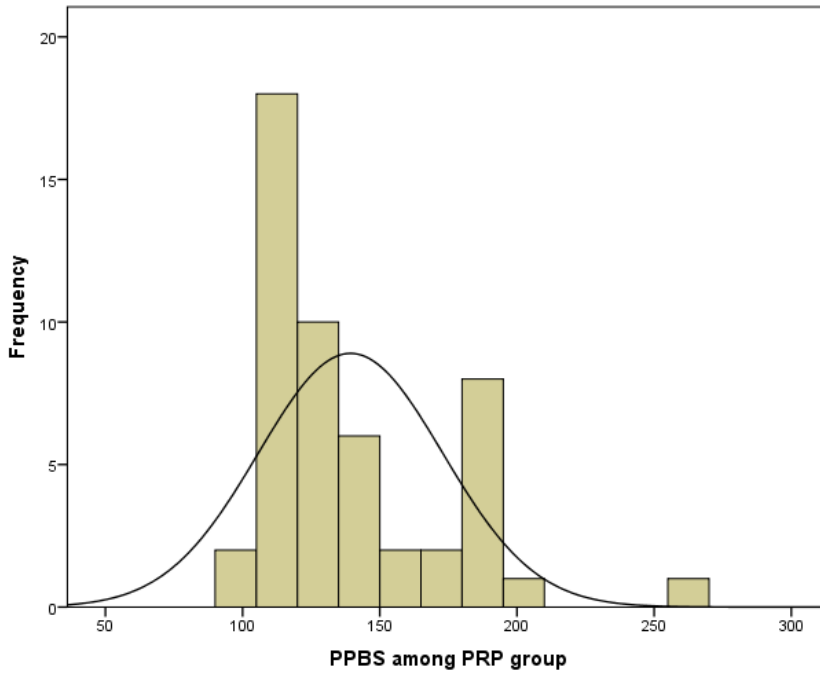
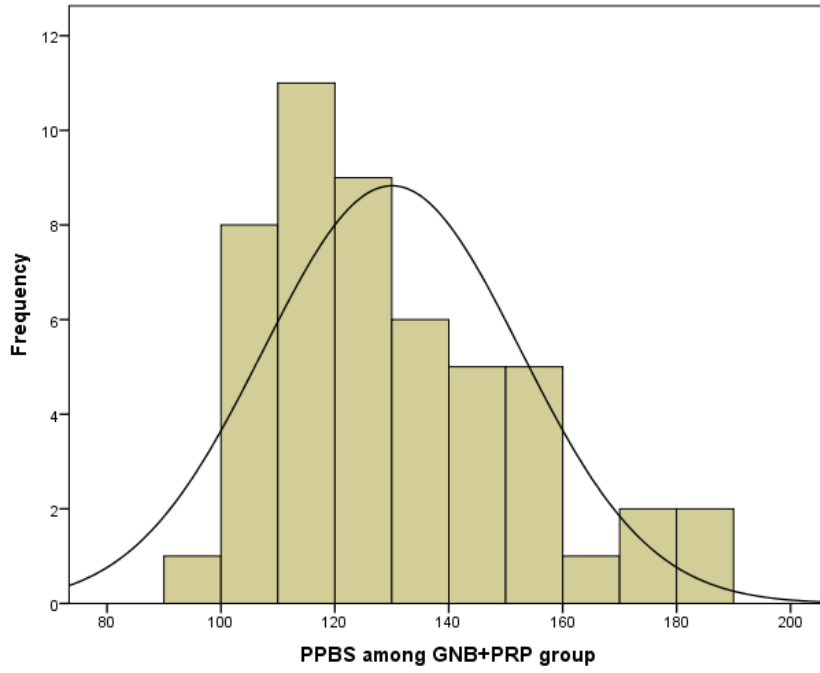
The figure shows that mean (SD) of the FBS was 93.86(1.29) mg/dl for the GNB+PRP and 103.94(28.26) mg/dl for the PRP. The minimum FBS was 66 mg/dl and Maximum was 178 mg/dl

**Table: PPBS distribution among the population**

Characteristics	GNB + PRP (in mg/dl)	PRP (in mg/dl)
Mean	130.02	139.32
Standard deviation (SD)	22.59	33.62
Mode	123	114
Median	123	128.50
Minimum	98	98
Maximum	189	259

The table shows that mean (SD) of the PPBS was 130.02(22.59) mg/dl for the GNB+PRP and 139.32(33.62) mg/dl for the PRP. The minimum PPBS was 98 mg/dl and Maximum was 259 mg/dl

**Figure: PPBS distribution among the population**



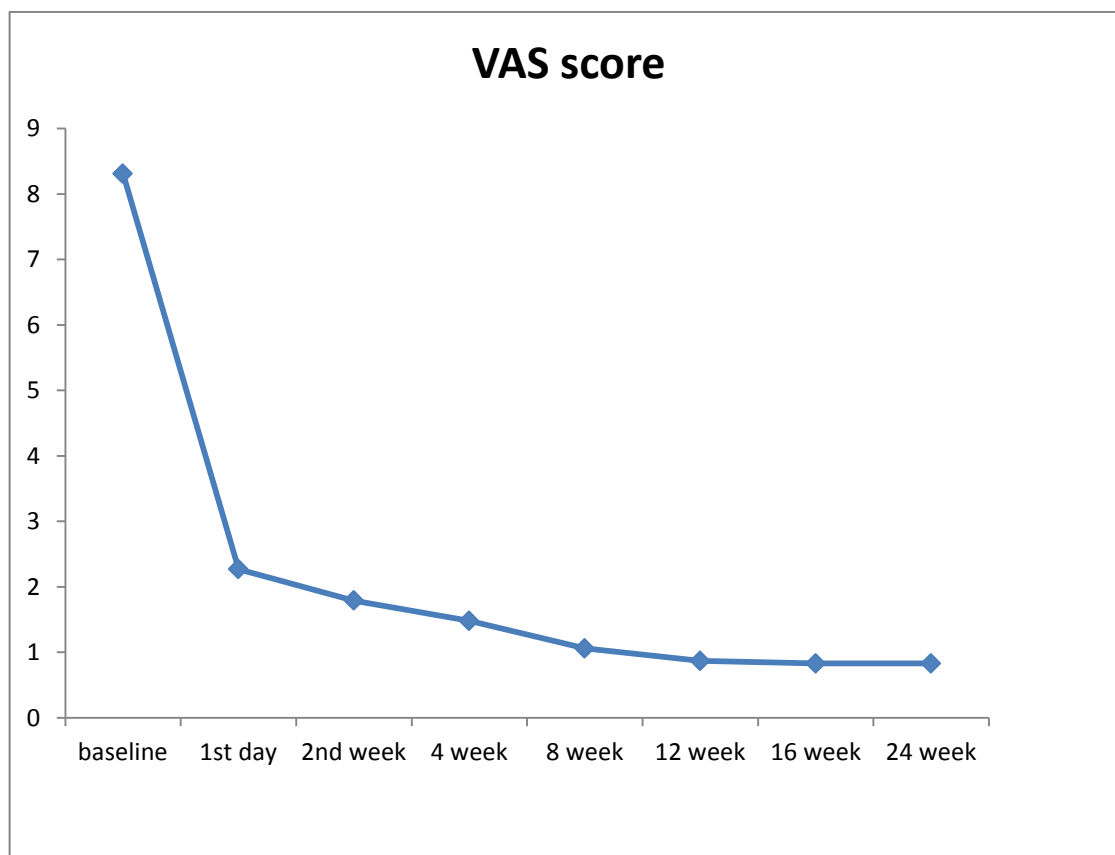
The figure shows that mean (SD) of the PPBS was 130.02(22.59) mg/dl for the GNB+PRP and 139.32(33.62) mg/dl for the PRP. The minimum PPBS was 98 mg/dl and Maximum was 259 mg/dl

**Table: Distribution of VAS score among the population**

<b>Characteristics</b>	<b>Base line</b>	<b>1<sup>st</sup> day</b>	<b>2 weeks</b>	<b>4 weeks</b>	<b>8 weeks</b>	<b>12 weeks</b>	<b>16 weeks</b>	<b>24 weeks</b>
Mean	8.31	2.27	1.79	1.48	1.06	0.87	0.83	0.83
Standard deviation (SD)	0.72	1.57	1.25	1.16	0.84	0.77	0.75	0.75
Mode	9	2.27	1	1	1	1	1	1
Median	8	2	2	1	1	1	1	1
Minimum	7	0	0	0	0	0	0	0
Maximum	9	7	6	6	4	4	4	4

The table shows the mean (SD) of the VAS score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.31(0.72), 2.27(1.57),1.79(1.25),1.48(1.16), 1.06(0.84),0.87(0.77), 0.83(0.75) and 0.83(0.75) respectively.

**Figure: Distribution of VAS score among the population**



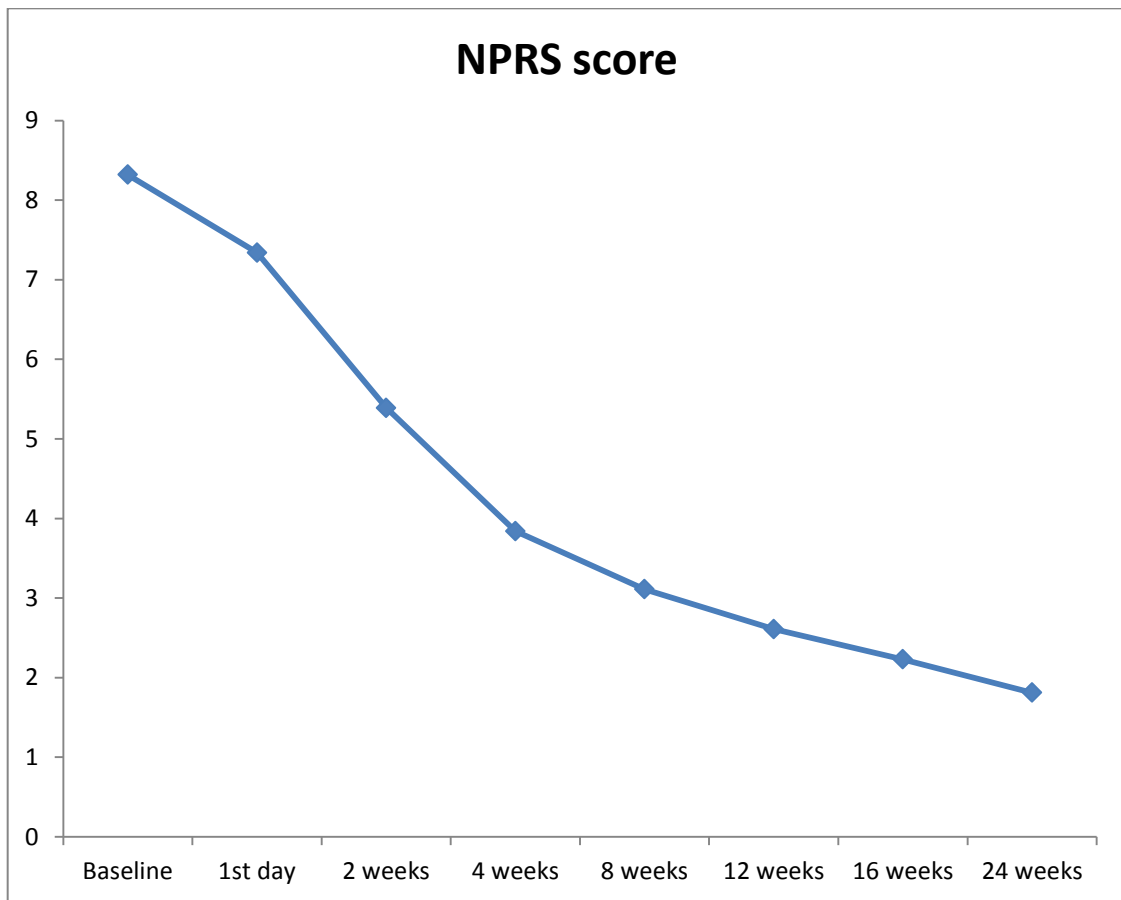
The figure shows the mean (SD) of the VAS score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.31(0.72), 2.27(1.57), 1.79(1.25), 1.48(1.16), 1.06(0.84), 0.87(0.77), 0.83(0.75) and 0.83(0.75) respectively.

**Table: Distribution of NPRS score among the population**

<b>Characteristics</b>	<b>Base line</b>	<b>1<sup>st</sup> day</b>	<b>2 weeks</b>	<b>4 weeks</b>	<b>8 weeks</b>	<b>12 weeks</b>	<b>16 weeks</b>	<b>24 weeks</b>
Mean	8.32	7.34	5.39	3.84	3.11	2.61	2.23	1.81
Standard deviation (SD)	0.72	0.76	0.99	0.79	0.92	0.72	0.66	0.68
Mode	9	8	6	3	3	3	2	2
Median	8	8	5	4	3	3	2	2
Minimum	7	6	3	3	3	1	1	1
Maximum	9	8	8	6	6	5	4	3

The table shows the mean (SD) of the NPRS score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.32(0.72), 7.34(0.76),5.39(0.99),3.84(0.79), 3.11(0.92),2.61(0.72), 2.23(0.66) and 1.81(0.68) respectively.

**Figure: Distribution of NPRS score among the population**



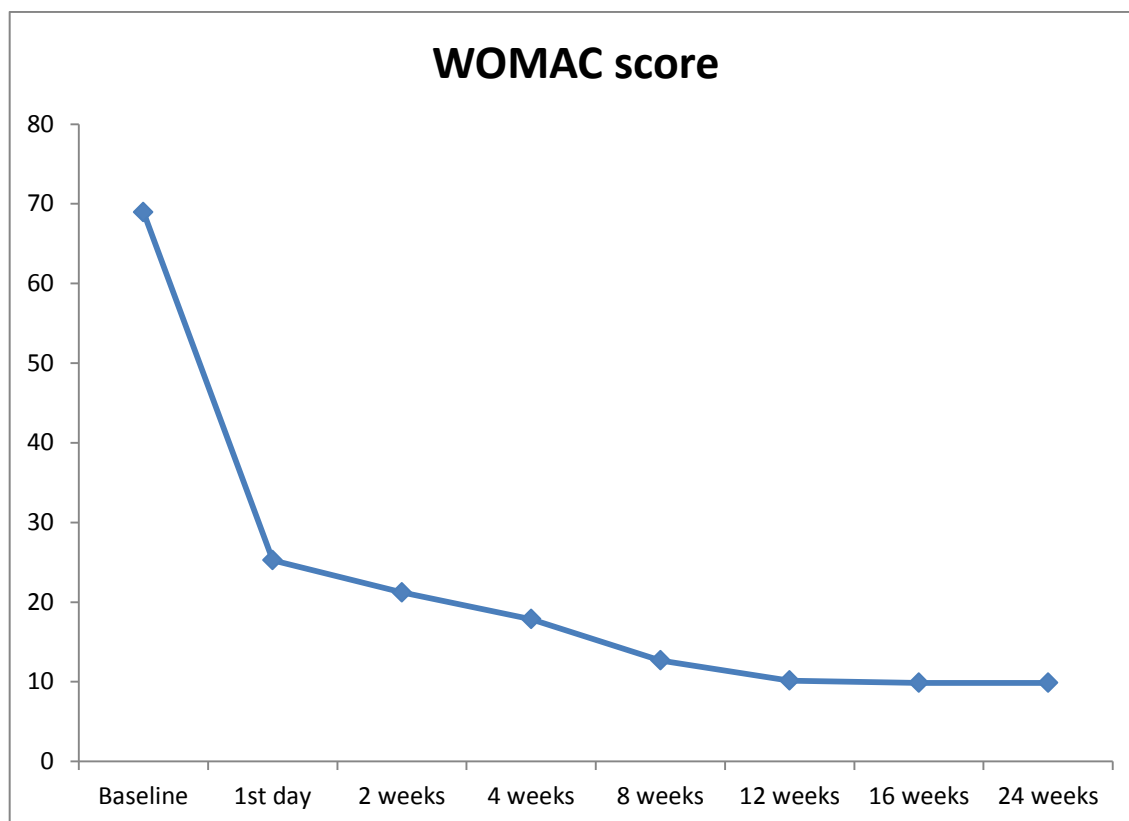
The figure shows the mean (SD) of the NPRS score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.32(0.72), 7.34(0.76), 5.39(0.99), 3.84(0.79), 3.11(0.92), 2.61(0.72), 2.23(0.66) and 1.81(0.68) respectively.

**Table: Distribution of WOMAC score among the population**

<b>Characteristics</b>	<b>Base line</b>	<b>1<sup>st</sup> day</b>	<b>2 weeks</b>	<b>4 weeks</b>	<b>8 weeks</b>	<b>12 weeks</b>	<b>16 weeks</b>	<b>24 weeks</b>
Mean	68.97	25.25	21.21	17.86	12.67	10.15	9.87	9.87
Standard deviation (SD)	13.25	15.75	14.19	13.02	10.41	9.74	9.41	9.41
Mode	67	22	22	22	0	0	0	0
Median	69	23	22	18	14	11	8.50	8.50
Minimum	44	0	0	0	0	0	0	0
Maximum	91	63	63	63	43	43	43	43

The table shows that the mean (SD) of the WOMAC score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 68.97(13.25), 25.25(15.75), 21.21(14.19), 17.86(13.02), 12.67(10.41), 10.15(9.74), 9.87(9.41) and 9.87(9.41) respectively.

**Figure: Distribution of WOMAC score among the population**



The figure shows that the mean (SD) of the WOMAC score across the time periods. The table shows that mean (SD) of the baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 68.97(13.25), 25.25(15.75), 21.21(14.19), 17.86(13.02), 12.67(10.41), 10.15(9.74), 9.87(9.41) and 9.87(9.41) respectively.



## Inferential statistics

**Table: Baseline characteristics of both the groups**

Variables		GNB+PRP	PRP	Table value	p value
Age in years (SD)		56.78(9.70)	57.90(8.89)	0.74	0.39a
Gender	Male	22(68.8%)	10(31.2%)	6.62	0.010b*
	female	28(41.2%)	40(58.8%)		
Grade of OA	Grade I	19(50%)	19(50%)	0	1.00b
	Grade II	31(50%)	31(50%)		
Side affected	B/L, L>R	8(72.7%)	3(27.3%)	3.76	0.27c
	B/L, R>L	5(55.6%)	4(44.4%)		
	Left Knee	23(51.1%)	22(48.9%)		
	Right Knee	14(40%)	21(60%)		
Systolic BP		121.20(13.75)	121.04(13.54)	0.11	0.74a
Diastolic BP		80.20(9.30)	80.68(8.64)	0.16	0.69a
FBS		93.86(21.29)	103.94(28.26)	5.69	0.019a*
PPBS		130.02(22.59)	139.32(33.62)	6.59	0.012a*
Baseline VAS		8.30(0.76)	8.32(0.68)	1.22	0.27a
Baseline NPRS		8.30(0.76)	8.34(0.69)	0.96	0.33a
Baseline WOMAC		68.60(14.03)	69.34(12.56)	0.13	0.72a

a- Independent t test

b- Chi square test

c- Fischer's exact test

\*- significant p value<0.05

The table shows the comparison of baseline characteristic between two groups. The variables of gender, FBS and PPBs were found to be significant. Non significance of the variables shows that there is no difference among the groups for these variables and this shows the success of randomisation.

**Table: Comparison of VAS score among the two group across different time period**

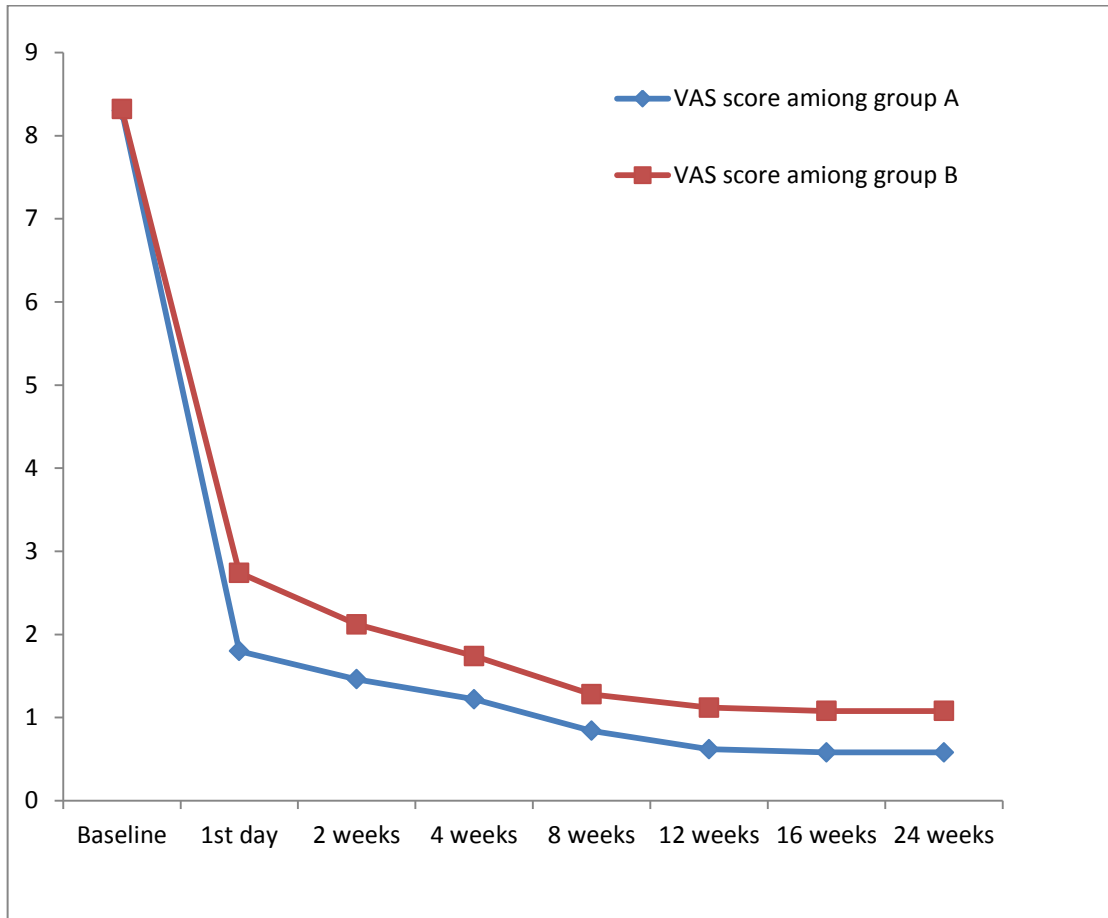
	<b>GNB+PRP Median (interquartile range)</b>	<b>PRP Median (interquartile range)</b>	<b>Table value</b>	<b>p value</b>
1 <sup>st</sup> day	2(1,2)	2(2,3)	802	0.001*
2 weeks	1(1,2)	2(1,3)	821	0.002*
4 weeks	1(1,2)	1.5(1,2)	897	0.009*
8 weeks	1(0,2)	1(1,2)	839	0.002*
12 weeks	0.50(0,1)	1(1,2)	751.5	<0.001*
16 weeks	0(0,1)	1(1,1)	735.5	<0.001*
24 weeks	0(0,1)	1(1,1)	735.5	<0.001*

Mann Whitney U test

\*- significant p value<0.05

The table shows that there is significant difference between the two groups across the time periods. Group A (GNB+PRP) showed better outcome in terms of decreased VAS score.

**Figure: VAS score distribution among the two groups across different time periods**



The figure shows the mean value of the VAS score across different time periods among the groups. This shows that there is significant difference between the two groups across the two time periods. Group A (GNB+PRP) showed better outcome in terms of decreased VAS score.

**Table: Comparison of WOMAC score among the two group across different time period**

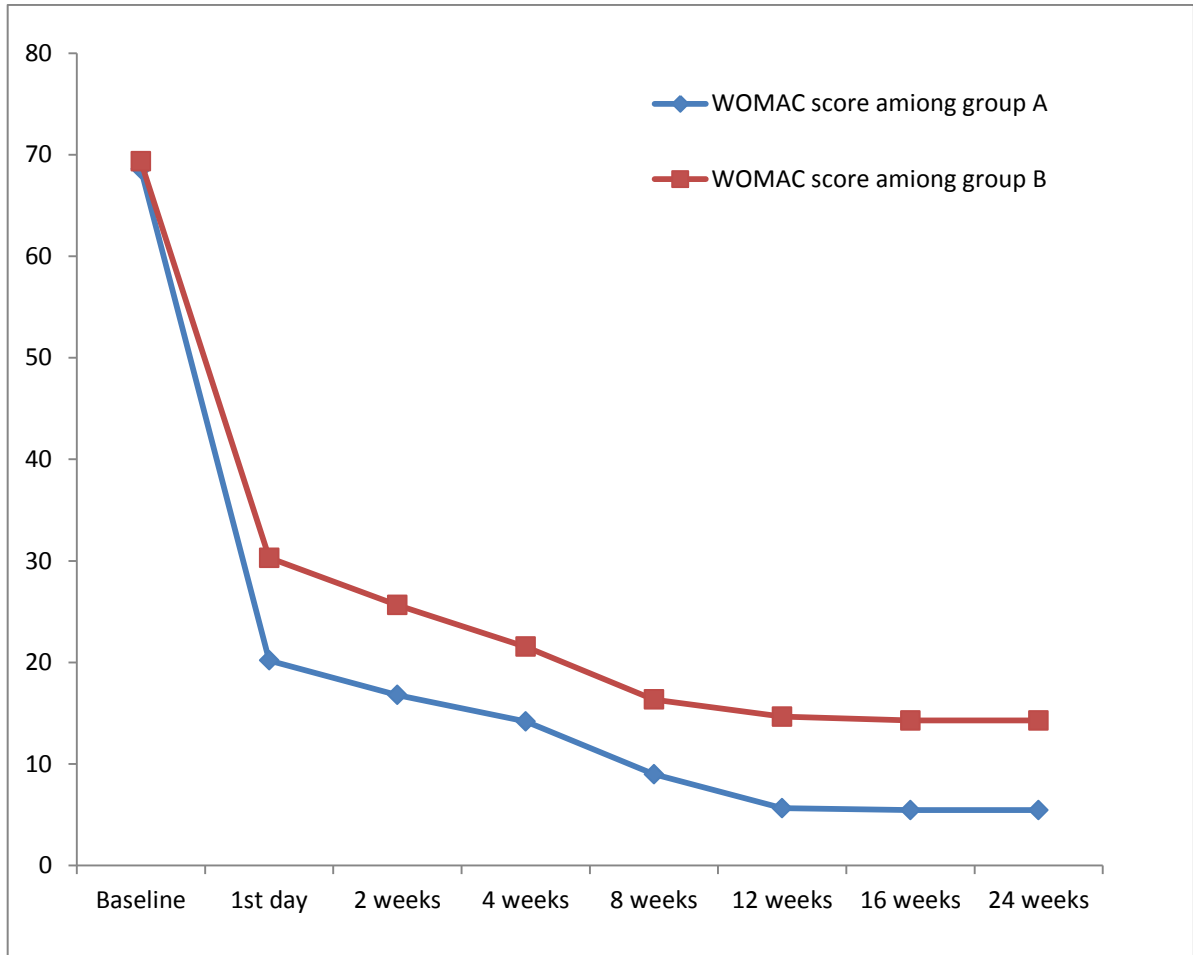
	<b>GNB+PRP Median (interquartile range)</b>	<b>PRP Median (interquartile range)</b>	<b>Table value</b>	<b>p value</b>
1 <sup>st</sup> day	22(7,24.25)	27(21,45)	758	0.001*
2 weeks	17(6,23)	23(17,29.75)	765	0.001*
4 weeks	14.50(2,22)	22(13.75,25)	844.50	0.005*
8 weeks	2.50(0,17.25)	18(13,22)	747	<0.001*
12 weeks	1(0, 7)	16(12.75,19.75)	595.50	<0.001*
16 weeks	0(0,7)	16(12.75,19.75)	585.50	<0.001*
24 weeks	0(0,7)	16(12.75,19.75)	585.50	<0.001*

Mann Whitney U test

\*- significant p value<0.05

The table shows that there is significant difference between the two groups across the time periods. Group A (GNB+PRP) showed better outcome in terms of decreased WOMAC score.

**Figure: WOMAC score distribution among the two groups across different time periods**



The figure shows the mean value of the WOMAC score across different time periods among the groups. The figure shows that there is significant difference between the two groups across the time periods. Group A (GNB+PRP) showed better outcome in terms of decreased WOMAC score.

**Table: Comparison of NPRS score among the two group across different time period**

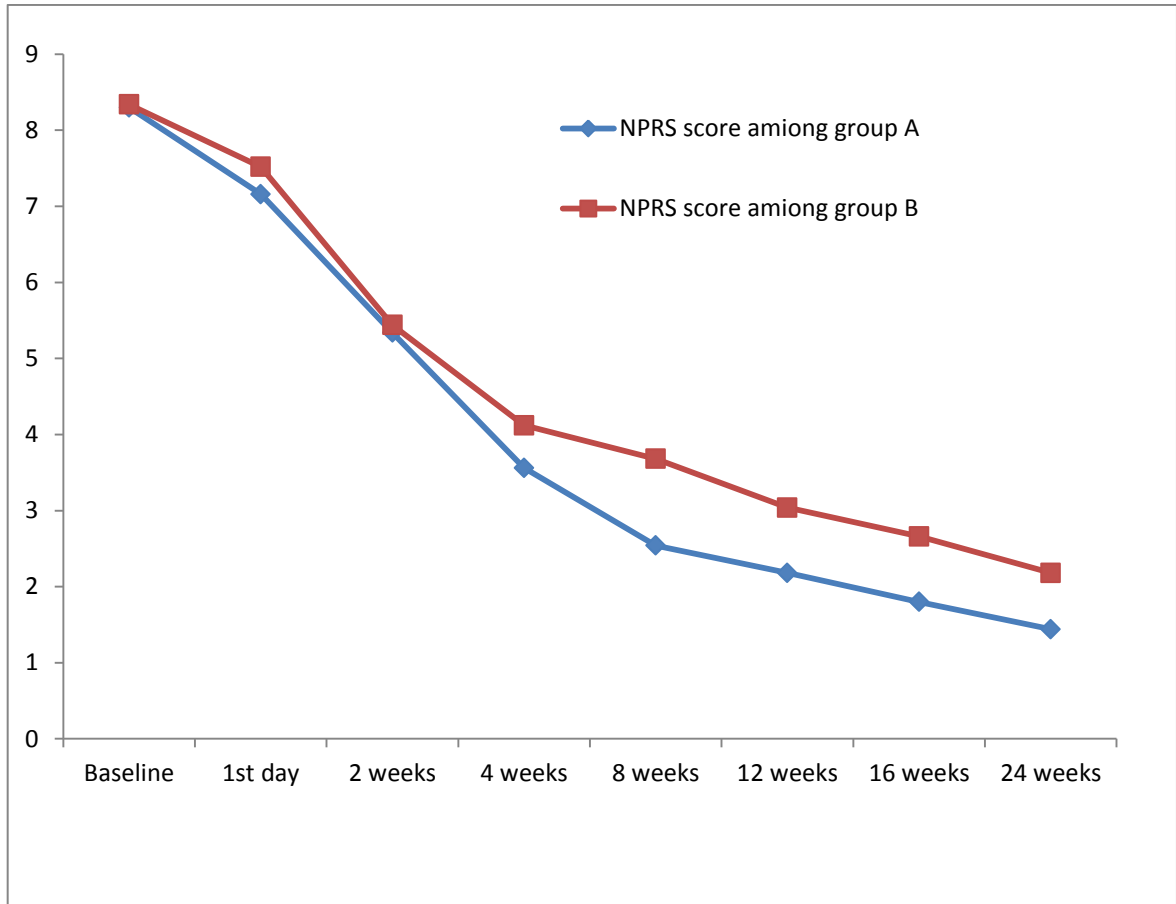
	<b>GNB+PRP Mean ± SD</b>	<b>PRP Mean ± SD</b>	<b>Table value</b>	<b>p value</b>
1 <sup>st</sup> day	7.16±0.77	7.52±0.71	0.10	0.75
2 weeks	5.34±0.79	5.44±1.16	10.02	0.002*
4 weeks	3.56±0.67	4.12±0.79	0.19	0.67
8 weeks	2.54±0.58	3.68±0.84	7.43	0.008*
12 weeks	2.18±0.56	3.04±0.60	0.26	0.61
16 weeks	1.80±0.40	2.66±0.59	17.21	<0.001*
24 weeks	1.44±0.50	2.18±0.63	0.0	0.99

Independent t test

\*- significant p value<0.05

The table shows the association between NPRS score across different time periods between the groups. There is a significant difference between the two groups after 2 weeks, after 8 weeks and 16 weeks.

**Figure: Comparison of NPRS score among the two group across different time period**



The figure shows the mean value of the NPRS score across different time periods among the groups. The figure shows that there is difference between the two groups across the time periods. Group A (GNB+PRP) showed better outcome in terms of decreased NPRS score.

# *Discussion*



## 7) DISCUSSION

The study was aimed to assess the efficacy of Genicular nerve block using local anaesthetic and PRP versus only PRP among patients suffering from grade I and II knee OA.

The mean (SD) age of the GNB+PRP group and PRP group was 57.10(9.53) years and 57.90(8.89) years respectively. The minimum age of the population was 40 years and maximum age was 82 years. The mean (SD) age of the population was 57.34 (9.28) years, with a median of 57 years and mode of 60 years. This result coincides with many studies where the average age falls anywhere close after 55 to 60 years.(83–87) The rise in occurrence of OA with age probably is a result of snowballing of a variety of risk factors and biologic changes that happen with aging that may create a joint which is more susceptible to the adversities, such as cartilage thinning, reduced muscle strength and damage due to oxidative stress.

In the study majority 68(68%) of the study subjects were females and 32(32%) of the subjects were males. 28 (56%) and 40 (80%) among the GNB + PRP and PRP groups were females. This result of increased incidence of knee OA among females was also found in other studies which showed a reduced risk among men in case of knee OA.(83,85,88) The increased occurrence in post-menopausal age can be associated with hormonal changes or sudden change in weight for the females due to the hormonal changes. The exact reason is not known as there are studies showing limited evidence of difference in gender occurrence in case of OA of hip, hand and spine.(88)

The mean (SD) of the systolic BP was 121.20(13.75) mm Hg for the GNB+PRP and 121.04(13.54) mm Hg for the PRP. The minimum systolic BP was 98 mm Hg and Maximum was 152 mm Hg. The mean (SD) of the diastolic BP was 80.20(9.30) mm Hg for the GNB+PRP and 80.68(8.64) mm Hg for the PRP. The minimum diastolic BP was 64 mm Hg and Maximum was 102 mm Hg. The mean (SD) of the FBS was 93.86(21.29) mg/dl for the GNB+PRP and 103.94(28.26) mg/dl for the PRP. The minimum FBS was 66 mg/dl and Maximum was 178 mg/dl. The mean (SD) of the PPBS was 130.02(22.59) mg/dl for the GNB+PRP and 139.32(33.62) mg/dl for the PRP. The minimum PPBS was 98 mg/dl and Maximum was 259 mg/dl. The mean values of Systolic BP, diastolic BP, FBS and PPBS showed that there was reduced risk of hypertension and diabetes in this group. Even though many were diagnosed to have one disease or both may have been under control. But studies have shown an association of cardiovascular risk factors and OA. This association was reasoned based on the proposition that along with changes in articular cartilage and joint surroundings due to oxidative stress subsequent changes occurs in blood vessels. These changes in turn affects the organs and shown out as non communicable diseases. Studies have shown that overweight (OW), hypertension (HT), dyslipidaemia (DL), and impaired glucose tolerance (IGT) have a significant association with knee OA.(89–93)

The mean (SD) of the VAS score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.31(0.72), 2.27(1.57),1.79(1.25),1.48(1.16), 1.06(0.84),0.87(0.77), 0.83(0.75) and 0.83(0.75) respectively. The mean (SD) of the NPRS score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.32(0.72), 7.34(0.76),5.39(0.99),3.84(0.79), 3.11(0.92),2.61(0.72), 2.23(0.66) and

1.81(0.68) respectively. The mean (SD) of the WOMAC score at baseline, 1st day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 68.97(13.25), 25.25(15.75), 21.21(14.19), 17.86(13.02), 12.67(10.41), 10.15(9.74), 9.87(9.41) and 9.87(9.41) respectively. There is significant difference between the two groups across the time periods in terms of VAS score. Group A (GNB+PRP) showed better outcome in terms of decreased VAS score. There was significant difference between the two groups across the time periods in terms of WOMAC score. Group A (GNB+PRP) showed better outcome in terms of decreased WOMAC score. There was an association between NPRS score across different time periods between the groups. There is a significant difference between the two groups after 2 weeks, after 8 weeks and 16 weeks.

The study showed a significant difference between the scores (VAS, NPRS, WOMAC) across the time periods between the GNB+PRP group and PRP group. All the scores have a decreased value compared to the baseline and among that also decreased for the GNB group.

These results are comparable with other studies where PRP showed a better result in terms of functional and quality of life compared to other modalities. Sánchez et al was initial one to report the Intra Articular injection of plasma rich in growth factors to handle an articular cartilage damage in a football player. Even with having a poorer future total articular cartilage curing was significantly accelerated, and the final result was out standing, allowing a fast carrying on of symptom free sporty activity.(74)

Another study group reported initial results of an auto logous arrangement rich in growth factors injection for knee OA, signifying the security and utility of this management advancement. They have done study by means of HA injections as a

control. 30 subjects with OA selected and give 3 weekly injections. Medical result was calculated by means of the WOMAC questionnaires previous to the start and at 5 weeks after. The observed achievement rates by week 5 for the pain sub scale attained 33.4% for the PRP group and 10% for the HA group. The physical function and on the whole score according to WOMAC was better in PRP group.(75) Sampson et al done 3 sets of IA PRP injections at 4 weeks intervals for 14 patients concerned by knee OA and reported a constructive result in most of the patients at 12 months of follow-up.(76)

Kon et al had done 3 sets of intra articular PRP injections at 3 week intervals to 115 osteoarthritic knees. Noteworthy improvements happened in all clinical scores from the basal evaluation to the end of the therapy and at 6- 12 months follow-up. The outcome was same from the end to 6 months, but starts worsening at 12 months follow up. The initial results point out that the management with PRP injections is secure and has the likelihood to reduce pain and get better knee purpose and worth.(77) Another study was done among 91 patients for 1 year follow up. All the patients were managed with 3 IA PRP injections. Every measured factor got deteriorated at the 2 years follow up: these parameters were at significantly lesser levels with respect to the 12 month evaluation. The results demonstrated 9 months of median duration of the supportive effects and were better in young patients with lower degrees of OA.(78)

A study by Peer booms et al was done among 100 with chronic lateral epi condylitis They were randomly allocated in the PRP group or cortico steroid group (n = 49). According to the visual analogue scores, 49% in the cortico steroid group and 73% in the PRP group were considerably diverse. Also, according to the DASH scores, 51% in the cortico steroid group and 73% in the PRP group were statistically diverse. The cortico steroid group was superior at first and then declined, where as the PRP group

gradually more got better.(79) In a study by Patel et al amid 78 subjects with bilateral OA were separated randomly into 3 groups. Group A got a sole injection of PRP, group B received 2 injections of PRP 3 weeks apart, and group C be given a sole injection of normal saline. Result was assessed using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire before conduct and at 6 weeks, 3 months, and 6 months after management. Noteworthy improvement in all WOMAC parameters was noted in groups A and B within 2 to 3 weeks and lasting until the final follow-up at 6 months, with minor deterioration at the 6-month follow up. The average WOMAC scores for group A at base line was 49.86, respectively, and at final follow up was 27.18, respectively, showing significant improvement. Similar improvement was noted in group B with 53.20 at base line and average WOMAC scores at final follow up: 30.48. In group C, the average WOMAC scores deteriorated from base line from 45.54, to last follow up 53.09.(80)

In a study by Li et al among 30 patients with knee articular cartilage degeneration were randomly divided into PRP group (n = 15) and Sodium Hyaluronate group (n = 15). Both treatments were governed in series of 3 IA injections at 3 weekly intervals. The patients of 2 groups were followed up 6 months. There were significant disparities in the scores between pre and post injection in 2 groups ( $P < 0.05$ ). There occurred no significant disparity across time periods in PRP group. The efficiency of test group was significantly better than that of control group at 6 months after application by means of score.(81) In a study by Wang et al among 261 patients, 109 women and 152 men, with an average age of 48.39. 3 IA injections of autologous PRGF were given at 2-week intervals in out patient surgery. Statistically noteworthy disparity ( $P < 0.0001$ ) amid pre-treatment and follow-up values were established for pain, stiff ness and functional capability in the WOMAC Index.(82)

*Limitation*

## **8) LIMITATION**

The study was aimed to assess the efficacy of Genicular nerve block using local anaesthetic and PRP versus only PRP among patients suffering from grade I and II knee OA.

- The study included only grade I and II knee OA, so the assessment of usage of GNB and PRP in severe forms of OA was not measured.
- Only subjective assessment in terms of VAS, NPRS and WOMAC was done it would have been lead to larger over reporting of the measurements.
- Radiographic techniques should have been added as an assessment measure so that the changes inside the joints could have been evaluated.

# *Recommendations*



## **9) RECOMMENDATION**

The study was aimed to assess the efficacy of Genicular nerve block using local anaesthetic and PRP versus only PRP among patients suffering from grade I and II knee OA.

- The usage of PRP which lacks any of the adverse effects as the PRP is taken from patient's own blood could be the next line treatment for refractory OA not responding to other managements.
- The addition of GNB to PRP increased the effectiveness which can be used further provided evidence for radiologic changes also there.
- Studies should be done based on the number of dosages of PRP, increased concentration of platelets in PRP and addition of adjuvant along with PRP to identify the most effective treatment for the management of knee OA

# *Conclusion*

## 10 ) CONCLUSION

- The mean (SD) age of the GNB+PRP group and PRP group was 57.10(9.53) years and 57.90(8.89) years respectively. The minimum age of the population was 40 years and maximum age was 82 years. The mean (SD) age of the population was 57.34 (9.28) years, with a median of 57 years and mode of 60 years.
- Both the group had most subjects in 50-59 years. [18(36%) in GNB+PRP vs 21(42%) in PRP group]. Next maximum is in the age group of 40-49 years [15(30%) in GNB+PRP group vs 13(26%) in PRP group].
- In the study majority 68(68%) of the study subjects were females and 32(32%) of the subjects were males.
- Most 45(45%) of the population had their left knee affected. Next commonly affected was right knee 35(35%). The bilateral involvement is there in 19(19%) with left more than right in 11(11%).
- 38(38%) of the subjects had an X ray grade I and 62(62%) of the subjects had an X ray grade II.
- The mean (SD) of the systolic BP was 121.20(13.75) mm Hg for the GNB+PRP and 121.04(13.54) mm Hg for the PRP. The minimum systolic BP was 98 mm Hg and Maximum was 152 mm Hg.
- The mean (SD) of the diastolic BP was 80.20(9.30) mm Hg for the GNB+PRP and 80.68(8.64) mm Hg for the PRP. The minimum diastolic BP was 64 mm Hg and Maximum was 102 mm Hg.

- The mean (SD) of the FBS was 93.86(21.29) gm/dl for the GNB+PRP and 103.94(28.26) gm/dl for the PRP. The minimum FBS was 66 gm/dl and Maximum was 178 gm/dl
- The mean (SD) of the PPBS was 130.02(22.59) gm/dl for the GNB+PRP and 139.32(33.62) gm/dl for the PRP. The minimum PPBS was 98 gm/dl and Maximum was 259 gm/dl
- The mean (SD) of the VAS score at baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.31(0.72), 2.27(1.57),1.79(1.25),1.48(1.16), 1.06(0.84),0.87(0.77), 0.83(0.75) and 0.83(0.75) respectively.
- The mean (SD) of the NPRS score at baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 8.32(0.72), 7.34(0.76),5.39(0.99),3.84(0.79), 3.11(0.92),2.61(0.72), 2.23(0.66) and 1.81(0.68) respectively.
- The mean (SD) of the WOMAC score at baseline, 1<sup>st</sup> day, after 2 weeks, after 4 weeks, after 8 weeks, after 12 weeks, after 16 weeks and after 24 weeks were 68.97(13.25), 25.25(15.75), 21.21(14.19), 17.86(13.02), 12.67(10.41), 10.15(9.74), 9.87(9.41) and 9.87(9.41) respectively.
- The variables of gender, FBS and PPBs in the baseline among the groups were found to be significant. Non significance of the variables shows that there is no difference among the groups for these variables and this shows the success of randomisation
- There is significant difference between the two groups across the time periods in terms of VAS score. Group A (GNB+PRP) showed better outcome in terms of decreased VAS score.

- There was significant difference between the two groups across the time periods in terms of WOMAC score. Group A (GNB+PRP) showed better outcome in terms of decreased WOMAC score.
- There was an association between NPRS score across different time periods between the groups. There is a significant difference between the two groups after 2 weeks, after 8 weeks and 16 weeks.

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# *Annexures*



# ANNEXURE-I

## STUDY PROFORMA

Name Age Sex Occupation

OP Number Thesis Registration Number

Address

Contact Number

Height: cm Weight: Kg BMI: BP: mmHg

Complaints : Knee pain: Right Left

Duration: \_\_\_\_days/months/years Pain Score: VAS\_\_\_\_/10

NPRS: \_\_\_\_/10 Womac: \_\_\_\_/96 Knee ROM:

Site of Pain: Anterior MJL

Aggravating factors If yes \_\_\_\_\_ Relieving factors

If yes \_\_\_\_\_

Sense of grinding or locking of joint:

Stiffness: If yes, duration:\_\_\_\_ days/months/years

Co-Morbidities: Diabetes mellites: Systemic Hypertension

Coronary artery disease:

Examinations

Inspection: swelling

Palpitation on standing/ supine Tenderness Crepitus Deformity:  
T.Varum G. Varum G. Valgum

Bony enlargement Patellar tap test Patellar bulge test

Investigations: FBS: \_\_\_\_mg/dl PPBS: \_\_\_\_mg/dl X-ray- Knee Osteophytes

Management: Genicular nerve block and intra articular injection of platelet rich plasma.

Intra articular injection of platelet rich plasma

## II- Consent Form

ஆய்வில் பங்கேற்பாளரின் ஒப்புதல் படிவம்

### ❖ ஆய்வு செய்யப்படும் தலைப்பு:

முழங்கால் மூட்டு வாத நோய் நிலை -1 மற்றும் 2க்கு வழமையான சிகிச்சை முறை செயல்பாட்டு விளைவைப் பொறுத்து ஜெனீக்குலர் நரம்பு மூட்டுக்கு சிகிச்சை மற்றும் முழங்கால் மூட்டு ப்ளேட்லெட் ரிச் பிளாஸ்மா ஊசி. செலுத்தும் சிகிச்சைகளின் செயல்பாட்டு விளைவு ஒப்பீடு - ஒரு முறையிலடங்கா கட்டுப்படுத்தப்பட்ட ஆய்வு.

### ❖ ஆய்வாளர் பெயர்: மரு. சத்தீஷ் கி.

### ❖ ஆய்வு நடக்கும் இடம்: உடலியல் மற்றும் புனர்வாழ்வு மருத்துவ துறை, அரசு புனர்வாழ்வு மருத்துவ நிலையம், சென்னை மருத்துவக் கல்லூரி, சென்னை -3.

ஆய்வில் பங்குபெறுவரின்

பெயர் :  
வயது :  
பாலினம் : ஆண்./பெண்  
பதிவு எண் :  
விலாசம் :  
கைப்பேசி எண் :

### ❖ ஆய்வில் பங்கேற்க ஒப்புதல்:

இந்த ஆய்வின் விவரங்களும், அதன் நோக்கமும் எனக்கு முழுமையாகவும், தெளிவாகவும் விளக்கப்பட்டது.

எனது சந்தேகங்களை தெளிவாக கேட்டு அறிந்து நிவர்த்தி செய்து கொண்டேன்.

இந்த ஆய்வில் பங்கெற்பதும். ஆய்விலிருந்து எந்த நேரத்திலும் விலகிக் கொள்வதும் எனது தனிப்பட்ட உரிமை என்பதையும் தெரிந்து கொண்டேன்.

ஆய்வில் பங்கெற்பவர்களின் தனியுரிமை இந்த ஆய்வு முழுவதும் பாதுகாக்கப்படும் என்பதை தெரிந்து கொண்டேன்.

எனது முழங்கால் மூட்டு வாத நோய் ஆய்வில் குறிப்பிடப்பட்டுள்ள இரண்டில் ஏதேனும் ஒரு சிகிச்சையை மேற்கொள்ளவும் அதனைத் தொடர்ந்து இயல்முறை பயிற்சி சிகிச்சை மேற்கொள்ளவும் சம்மதிக்கிறேன்.

ஆய்வாளர் பிற மருத்துவர்கள் நெறிமுறைக் குழு மற்றும் கட்டுப்பாட்டு அதிகாரிகள் ஆய்வின் தணிக்கையாளர்கள் எனது மருத்துவத் தகவல்களை தெரிந்து கொள்ளவும் ஆய்வின் முடிவுகளை வெளியிடவும் அனுமதிக்கிறேன்.

இந்த ஆய்வில் பங்குகொள்ள யாருடைய நிர்வாகத்தின் மூலமாக என்னுடைய சொந்த விருப்பத்தின் பெயரில் சுயநினைவுடனும் முழுமனதுடனும் சம்மதிக்கிறேன்.

ஆய்வாளர் கையொப்பம்

பங்கு பெறுபவரின் கையொப்பம்

**மரு. சத்தீஷ் கி.**

பெயர் :

முதுநிலை பட்டதாரி மாணவர்,

இடம்:

அரசு புனர்வாழ்வு மருத்துவ நிலையம்,

தேதி:

கே.கே. நகர், சென்னை 600 083.

சென்னை மருத்துவக் கல்லூரி சென்னை 600 003.

ஆய்வில் பங்கேற்பாளருக்கான தகவல் தாள்

❖ **ஆய்வு செய்யப்படும் தலைப்பு:**

முழங்கால் மூட்டு வாத நோய் நிலை -1 மற்றும் 2க்கு வழமையான சிகிச்சை முறை செயல்பாட்டு விளைவைப் பொறுத்து ஜெனிக் குலர் நரம்பு முடக்கு சிகிச்சை மற்றும் முழங்கால் மூட்டு ப்ளேட்லெட் ரிச் பிளாஸ்மா ஊசி. செலுத்தும் சிகிச்சைகளின் செயல்பாட்டு விளைவு ஒப்பீடு - ஒரு முறையிலடங்கா கட்டுப்படுத்தப்பட்ட ஆய்வு.

❖ **ஆய்வாளர் பெயர்: மரு. சத்தீஷ் கி.**

❖ **ஆய்வு நடக்கும் இடம்:** உடலியல் மற்றும் புனர்வாழ்வு மருத்துவ துறை, அரசு புனர்வாழ்வு மருத்துவ நிலையம், சென்னை மருத்துவக் கல்லூரி, சென்னை -3.

ஆய்வில் பங்குபெறுவரின் பெயர்

:

வயது

:

பாலினம்

: ஆண்./பெண்

பதிவு எண்

:

விலாசம்

:

கைப்பேசி எண்

:

❖ **பங்கேற்பாளருக்கான தகவல்:**

முழங்கால் மூட்டு வாத நோய் ஆண், பெண் இருபாலரையும் (பெண்கள் மற்றும் ஆண்கள்) பாதிக்கக்கூடியது.

நோயின் நிலையைப் பொருத்து முழங்கால் மூட்டு அசைவின் போது மட்டும் (அ) ஓய்வு நிலையிலும் வலி, நெறுநெறுத்தல் முறுகல் போன்ற அறிகுறிகள் இருக்கும். சர்க்கரை நோய், முழங்கால் மூட்டு அதிகப்பயன்பாடு, போன்றவை இணைந்த காரணிகளாக இருக்கலாம்.

❖ **திட்டமிடப்பட்டுள்ள ஆய்வின் நோக்கம்:**

முழங்கால் மூட்டு நோய் முதல் இரண்டு நிலைகளில் ஜெனிக் குலர் நரம்பு முடக்கு சிகிச்சை நரம்பு முடக்கு சிகிச்சை மற்றும் முழங்கால் மூட்டு ப்ளேட்லெட் ரிச் பிளாஸ்மா ஊசி செலுத்தும் சிகிச்சை, வழமையான

சிகிச்சைகளின் வலிநிவாரணம் மற்றும் செயல்பாட்டு விளைவை ஒப்பீடு செய்தல்.

❖ **ஆய்வு நடைமுறைகள்:**

பங்கேற்பாளரின் ஒப்புதலுக்குப் பிறகு ஒரு பிரிவினருக்கு 0.5 மூ ப்யூபிவகெய்ன் மருந்து கொண்டு ஜெனிக் குலர் நரம்பு முடக்கு மற்றும் முழங்கால் மூட்டு ப்ளேட்லெட் ரிச் பிளாஸ்மா ஊசி சிகிச்சையும் அதனைத் தொடர்ந்து இயல்முறை பயிற்சி சிகிச்சையும் அளிக்கப்படும்.

இரண்டாம் பிரிவினருக்கு முழங்கால் மூட்டு ப்ளேட்லெட் ரிச் பிளாஸ்மா ஊசி செலுத்தும் சிகிச்சையும் அதனைத் தொடர்ந்து முதல் பிரிவினரைப் போலவே இயல்முறை பயிற்சி சிகிச்சையும் அளிக்கப்படும்

இரண்டு பிரிவினரிடையே வலி நிவாரணம் மற்றும் செயல்பாட்டு விளைவு ஆகியவை ஒப்பீடு செய்யப்படும்.

❖ **பதிவேடுகளின் ரகசியத் தன்மை:**

உங்கள் மருத்துவப் பதிவேடுகள் மிகவும் ரகசியமாக வைத்துக் கொள்ளப்படும். அதேசமயம் இந்த

ஆய்வில் உங்களது மருத்துவத் தகவல்களை மற்ற ஆய்வாளர்கள், பிற மருத்துவர்கள், விஞ்ஞானிகள், நெறிமுறைக்குழு மற்றும் கட்டுப்பாட்டு அதிகாரிகள் ஆய்வுத் தணிக்கையாளர்கள் ஆகியோர் படித்து தெரிந்து கொள்ள அனுமதிக்கப்படலாம். ஆய்வின் முடிவுகள் பிரசுரிக்கப்படலாம்.

ஆனால் எக்காரணம் கொண்டும் உங்கள் தனிப்பட்ட அடையாளம் வெளியிடப்படமாட்டாது.

❖ **ஆய்வில் பங்கேற்பாளரின் பொறுப்புகள்:**

உங்களுக்கு சிகிச்சை அளிக்கும் ஆய்வு செய்யும் மருத்துவருடன் முறையான சிகிச்சை மற்றும் பயிற்சிக்காக முழுமையாக ஒத்துழைக்குமாறு கேட்டுக்கொள்ளப்படுகிறீர்கள். மருத்துவரின் அறிவுரைகளை முறையாக பின்பற்றுமாறும், செய்யக் கூடியன கூடாதவற்றை தெளிவாக கேட்டு அறிந்து பின்பற்றுமாறும் கேட்டுக்கொள்ளப்படுகிறீர்கள்.

❖ ஆய்வில் உங்கள் பங்கேற்பு மற்றும் உங்கள் உரிமைகள்:

இந்த ஆய்வில் உங்கள் பங்கேற்பு தன்னிச்சையானது மற்றும் காரணம் எதையும் கூறாமலேயே நீங்கள்

எந்த ஒரு நேரத்திலும் இந்த ஆய்விலிருந்து விலகிக் கொள்ளலாம். நீங்கள் ஆய்வில்

பங்கேற்றாலும், பங்கேற்காவிட்டாலும் உங்கள் உடல்நிலைக்கு ஏற்ப உங்கள் நோய்க்கு தகுந்த சிகிச்சை அளிக்கப்படும்.

நீங்கள் ஆய்வில் பங்கேற்க மறுத்தால் நோய்க்கான சிகிச்சைக்கோ அல்லது

அடுத்து வரும் ஆய்வில் பங்கேற்கவோ எவ்வித மறுப்போ, தடையோ விதிக்கப்படாது.

எந்த ஒரு நேரத்திலும் நீங்கள் மோசமாக உணர்ந்தாலோ அல்லது உடல்நலக் குறைவு உண்டானாலோ உடனடியாக மருத்துவரைத் தொடர்பு கொள்ளலாம்.

சிகிச்சை உங்களுக்குப் பொருத்தமானதாக இருக்காது என்று தோன்றினால் உடனடியாக நிறுத்தப்படும். உங்கள் சம்மதம் இன்றியே கூட ஆய்வு நிறுத்தப்படுவது சாத்தியமே.

வேறு ஏதேனும் கேள்விகள்: . பிரச்சினைகள் பற்றி நீங்கள் கேட்க விரும்பினால், ஆய்வாளரைத் தொடர்பு கொள்ளவும்.

ஆய்வாளர் கையொப்பம்

பங்கு பெறுபவரின் கையொப்பம்

மரு. சத்தீஷ் கி.

(மருத்துவரால் படித்துக்காட்டப்பட்டது)

முதுநிலை பட்டதாரி மாணவர்,

பெயர் :

அரசு புனர்வாழ்வு மருத்துவ நிலையம்,

இடம் :

கே.கே. நகர், சென்னை 600 083.

தேதி:

சென்னை மருத்துவக் கல்லூரி,

சென்னை 600 003.

## PATIENT CONSENT FORM

**Study Detail: “Comparative Efficacy in the outcome of Genicular Nerve block and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of Patients with Grade I and II Osteo Arthritis of Knee – A Randomized Control Trial”**

**Study Centre** : Government Institute of Rehabilitation Medicine, Chennai.

**Patient’s Name** :

**Patient’s Age** :

**Identification Number** :

Patient/Patient’s Parents/Guardian may check (√) these boxes

- a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.
- b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.
- c) I understand that sponsor of the clinical study, others working on the sponsor’s behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access.
- However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.
- d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or wellbeing or any unexpected or unusual symptoms.
- e) I hereby consent to participate in this study.
- f) I hereby give permission to undergo detailed clinical examination, radiographs, blood investigations and surgical procedure as required.

Signature of the investigator

Signature/Thumb impression of the patient

Study Investigator: **Dr SATHISH .K**

Patient’s name & address:

### **III- Patient Information Sheet**

A study titled **“Comparative Efficacy in the outcome of Genicular Nerve block and Intra articular injection of Platelet Rich Plasma Versus Intra articular injection of Platelet Rich Plasma in the treatment of Patients with Grade I and II Osteo Arthritis of Knee – A Randomized Control Trial”** is being conducted at Government Institute of Rehabilitation Medicine, KK Nagar, Chennai 600083.

The purpose of this study is to compare the pain relief and functional outcome among the two treatment groups of patients with Grade I and II osteoarthritis of the Knee.

The patients with above said condition will be treated with either Genicular nerve block and intra articular injection of platelet rich plasma or intra articular injection of platelet rich plasma followed by scheduled exercise

The privacy of the patients in the research will be maintained throughout the study.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator

Signature of participant

Place: Chennai

Date:

## V- Institutional Ethical Committee Clearance

### **INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013  
Telephone No.044 25305301  
Fax: 011 25363970

#### **CERTIFICATE OF APPROVAL**

To  
Dr.Sathish.K.  
First Year Post Graduate in MD PMR  
GIRM, KK Nagar  
Chennai

Dear Dr.Sathish.K.,


The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARATIVE EFFICACY IN THE OUTCOME OF GENICULAR NERVE BLOCK AND INTRA ARTICULAR INJECTION OF PLATELET RICH PLASMA VERSUS INTRA ARTICULAR INJECTION OF PLATELET RICH PLASMA IN THE TREATMENT OF PATIENTS WITH GRADE I AND II OSTEO ARTHRITIS OF KNEE - A RANDOMIZED CONTROL TRIAL"** - NO.12122017

The following members of Ethics Committee were present in the meeting hold on **05.12.2017** conducted at Madras Medical College, Chennai 3

- |  |                      |
|--|----------------------|
| 1. Prof.P.V.Jayashankar  | :Chairperson         |
| 2. Prof.R.Narayana Babu,MD.,DCH., Dean,MMC,Ch-3                  | : Deputy Chairperson |
| 3. Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3             | : Member Secretary   |
| 4. Prof.N.Gopalakrishnan,MD,Director,Inst.of Nephrology,MMC,Ch   | : Member             |
| 5. Prof.S.Mayilvahanan,MD,Director,Inst. of Int.Med,MMC, Ch-3    | : Member             |
| 6. Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai        | : Member             |
| 7. Prof. Susila, Director, Inst. of Pharmacology,MMC,Ch-3        | : Member             |
| 8.Prof.K.Ramadevi,MD., Director, Inst. of Bio-Chemistry,MMC,Ch-3 | : Member             |
| 9.Thiru S.Govindasamy, BA.,BL,High Court,Chennai                 | : Lawyer             |
| 10.Tmt.Arnold Saulina, MA.,MSW.,                                 | :Social Scientist    |
| 11.Thiru K.Ranjith, Ch- 91                                       | : Lay Person         |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

  
Member Secretary - Ethics Committee  
MEMBER SECRETARY  
INSTITUTIONAL ETHICS COMMITTEE  
MADRAS MEDICAL COLLEGE  
CHENNAI-600 003



## KEY TO MASTER CHART

### 1. Random Number :

- 1 - Platelet Rich Plasma
- 2 - Platelet Rich Plasma + Genicular Nerve Block

### 2. Age :

- 1 - 40 – 49 years
- 2 - 50 – 59 years
- 3 - 60 – 69 years
- 4 - > 70 years

### 3. Gender :

- 1 - Male
- 2 – Female

### 4. Side Affected :

- 1 – Left side
- 2 – Right side
- 3 – Bilateral Lt > Rt
- 4 – Bilateral Rt > Lt

### 5. X Ray Grade :

- 1 – Grade I
- 2 – Grade II

### 6. Fasting Blood Sugar (mg/dl)

- 1 – 61-80
- 2 – 81-100
- 3 – 101-120
- 4 – 121-140
- 5 – 141-160
- 6 - > 160

### 7. Post Prandial Blood Sugar (mg/dl)

- 1 – 81-100
- 2 – 101-120
- 3 – 121-140
- 4 – 141-160
- 5 – 161-180
- 6 - >180

**8. Systolic Blood Pressure (mm Hg)**

- 1 - < 100
- 2 - 101-120
- 3 - 121-140
- 4 - 141-160
- 5 - >160

**9. Diastolic Blood Pressure (mm Hg)**

- 1 - < 80
- 2 - 81-90
- 3 - 91-100
- 4 - 101-110
- 5 - > 110

**10. Diabetic Mellitus**

- 1 - Present
- 2 - Absent

**11. Systemic Hypertension**

- 1 - Present
- 2 - Absent

**12. Medial Joint Line Tenderness**

- 1 - Present
- 2 - Absent

**13. Crepitations**

- 1 - Present
- 2 - Absent

**14. Early Morning Stiffness**

- 1 - Present
- 2 - Absent



