

REPUBLIC OF CAMEROON

Peace-Work-Fatherland

MINISTRY OF HIGHER
EDUCATION

THE UNIVERSITY OF YAOUNDE
I

FACULTY OF MEDICINE AND
BIOMEDICAL SCIENCES



REPUBLIQUE DU CAMEROUN

Paix-Travail-Patrie

MINISTÈRE DE
L'ENSEIGNEMENT
SUPERIEUR

UNIVERSITE DE YAOUNDE I

FACULTE DE MEDECINE ET
DES
SCIENCES BIOMEDICALES

DEPARTMENT OF INTERNAL MEDICINE AND SPECIALTIES

A double blinded randomized controlled trial comparing genicular nerve blockade using corticosteroids versus phenol in the management of knee Osteoarthritis pain in Yaoundé

Thesis submitted and defended publicly in partial fulfilment of the
requirements for the award of MD degree by;

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Academic Year: 2023-2024

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Date of thesis defense: 30th June 2024

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DEDICATION

To my parents **BESSALA Pascal Parfait, ELEMBENG Rose Valerie, Mbang BESSALA Marguerite, KAZE Temgoua Tatiane**
and **MEKENA BESSALA Julienne**
To my Late Great Grand Mother **MEKENA**
And
To my beloved **BESSALA Family**

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To all my friends and classmates from The Circle and CAMESA

To all those who we could not thank individually

To all those who participated to the success of this work

May God bless you

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THE PHYSICIAN'S OATH

[Declaration of Geneva adopted by the Geneva Assembly of the World Medical Association in Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia (August 1968)].

On admission to the medical profession:

I will solemnly pledge myself to consecrate my life to the service of humanity

I will give my teachers the respect and gratitude which is their due

I will practice my profession with conscience and dignity

The health of my patients will be my first consideration

I will respect secrets confided in me, even after the patient has died

I will maintain by all the means in my power the honour and noble traditions of the medical profession

My colleagues will be my brothers

I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient

I will maintain the utmost respect for human life from the time of conception, even under threat I will not use my medical knowledge contrary to the laws of humanity

I make these promises solemnly, freely and upon my honour.

ABSTRACT

Introduction: Knee osteoarthritis (KOA) is a debilitating pathology and significantly impacts quality of life. Genicular nerve blockade (GNB) with corticosteroids and neurolysis with phenol are emerging treatments for KOA pain. No evaluation has compared their efficacy with revised targets in our setting.

Objective: To compare GNB with revised targets, using corticosteroids versus phenol in managing of KOA pain in Yaoundé

Methodology: This double blinded randomized controlled clinical trial enrolled 26 patients with chronic KOA pain in two hospitals in Yaounde from October 2023 to May 2024. Participants were assigned to receive either GNB with corticosteroid (2mL lidocaine 1% + 20 mg triamcinolone) (CORT) or genicular neurolysis with phenol (2mL phenol 6%) (PHEN). Pain levels were assessed using the Numeric Rating Scale (NRS) at baseline, and at 1-hour, 1 day, 1 week and 4 weeks post intervention. Functional status and quality of life were assessed using the: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Oxford Knee Score (OKS), 12-item short form health survey (SF-12), Quantitative Analgesic Questionnaire (QAQ), Central Sensitization Index (CSI), Patient-Reported Outcomes Measurement Information System (PROMIS) 4a score, Patient Global Impression of Change (PGIC), 10 meters test and the 6-min walking test at baseline, and at 4 weeks post intervention. Data were analyzed using IBM SPSS 26.0, with $p < 0.05$ was considered statistically significant.

Results: Participants' mean age was 66.1 ± 10.9 years. The sex ratio was 0.1. Sixteen (70.6%) participants received bilateral knee treatment, 8 (23.5%) left knee and 2 (5.9%) right knee totaling 42 knees. Sixteen (64.7%) participants had grade 4 and 10 (35.3) grade 3 Kellgren-Lawrence severity. After randomization, 14 received GNB with corticosteroids and 12 with phenol. Before treatment, mean NRS was 8.71 ± 0.8 , OKS was 19.65 ± 3.5 , WOMAC score was 62.7 ± 15.5 , step cadence was 1.2 ± 0.5 steps/sec, distance in 6 min was 211.9 ± 101 m, QAQ score was 4.35 ± 0.9 , SF-12 Physical score was 32.4 ± 1.9 . At 1-hour, NRS in the CORT was 1.2 ± 0.9 and in the phenol group 0.4 ± 1.1 (**p= 0.142**). At 1 day, NRS in the CORT was 1.9 ± 0.7 and the PHEN 1.3 ± 1.9 (**p=0.362**). At week 1, NRS in the CORT was 2.6 ± 0.8 and in the PHEN 1.4 ± 1.6 (**p=0.069**). At 1 month, NRS in the CORT was 3.7 ± 1.1 and in the PHEN 2.0 ± 0.8 (**p=0.003**), OKS was 39.4 ± 3.6 in the CORT and 41.3 ± 3.4 in the PHEN (**p=0.294**), WOMAC was 8.5 ± 2.3 in the CORT and 7.0 ± 1.3 (**p=0.138**), step cadence was 1.7 ± 0.2 steps/sec in the CORT and 1.9 ± 0.1 steps/sec in the PHEN (**p=0.022**),

distance in 6min was 307.0 ± 50 m in the CORT and 322.9 ± 47.85 m in the PHEN (**p=0.524**), QAQ was 1.6 ± 1.1 in the CORT and 0.71 ± 0.5 (**p=0.166**), SF-12 Physical was 37.4 ± 3.0 in the CORT and 40.6 ± 1.0 in the PHEN (**p=0.016**). PROMIS 4a ,CSI and SF-12 Mental showed varying significant levels. Skin pigmentation change in 2 patients

Conclusion: GNB with corticosteroids and neurolysis with phenol both showed significant improvement in knee pain, function and quality of life. However, neurolysis with phenol provided longer lasting effects suggesting that phenol may be more effective than GNB with corticosteroids.

Key words: *knee osteoarthritis, genicular nerve blockade, corticosteroid, neurolysis, phenol*

RESUME

Introduction : La Gonarthrose est une pathologie invalidante ayant un impact sur la qualité de vie. Le bloc nerveux geniculé (BNG) avec des corticoïdes et du phénol sont des traitements émergents dans la prise en charge de la douleur liée à la gonarthrose. Dans notre contexte, aucune évaluation n'a été effectuée pour comparer leur efficacité avec les cibles revisitées.

Objectif : Comparer le BNG aux cibles revisitées, en utilisant des corticoïdes par rapport au phénol dans la prise en charge de la douleur liée à la gonarthrose à Yaoundé.

Méthodologie : Il s'agissait d'un essai clinique contrôlé randomisé en double aveugle allant d'octobre 2023 à mai 2024, recrutant 26 patients dans deux structures hospitalières de Yaoundé. Ceux souffrant de douleurs chroniques liées à la gonarthrose ont été répartis au hasard à recevoir soit du BNG avec corticostéroïde (2 ml lidocaïne 1% + 20mg de triamcinolone), soit le phénol (2ml de phénol 6%). Le degré de douleur était évalué avec l'échelle numérique (EN) au départ, à 1 heure, 1 jour, 1 semaine et 4 semaines après l'intervention. L'état fonctionnel et la qualité de vie ont été évalués à l'aide de l'indice d'arthrose des universités Western Ontario et McMaster (WOMAC), l'Oxford Knee Score (OKS), score de qualité de vie (SF-12), questionnaire analgésique quantitatif (QAQ), indice central de sensibilisation (CSI), score 4a du système d'information sur la mesure des résultats rapportés par les patients (PROMIS), l'impression globale de changement du patient (PGIC), d'un test de 10 mètres et d'un test de marche de 6 minutes, au départ, et 4 semaines après l'intervention. Les données ont été analysées à l'aide d'IBM SPSS 26.0 et un seuil $p<0,05$ a été considérée comme significative.

Résultats : L'âge moyen était de $66,1 \pm 10,9$ ans. La sex-ratio était de 0,1. Seize (70,6 %) ont reçu un traitement bilatéral du genou, 8 (23,5 %) au genou gauche et 2 (5,9 %) au genou droit, donnant un total de 42 genoux. Seize (64,7 %) avaient un grade 4 et 10 (35,3) un grade de gravité selon Kellgren-Lawrence. Après randomisation, 14 ont reçu BNG avec corticoïdes et 12 avec du phénol. Avant le traitement, l'EN moyen était de $8,71 \pm 0,8$, l'OKS était de $19,65 \pm 3,5$, le score WOMAC était de $62,7 \pm 15,5$, la cadence de pas était de $1,2 \pm 0,5$ pas/sec, la distance parcourue en 6 min était de $211,9 \pm 101$ m, le score QAQ était de $4,35 \pm 0,9$ et le score physique SF-12 était de $32,4 \pm 1,9$. À 1 heure, l'EN dans le CORT était de $1,2 \pm 0,9$ et PHEN $0,4 \pm 1,1$ (**p=0,142**). À 1 jour, l'EN dans le CORT était de $1,9 \pm 0,7$ et le PHEN de $1,3 \pm 1,9$ (**p=0,362**). À la 1ere semaine, l'EN dans le CORT était de $2,6 \pm 0,8$ et dans le PHEN de $1,4 \pm 1,6$ (**p = 0,069**). À 1 mois, l'EN dans le CORT était de $3,7 \pm 1,1$ et

dans le PHEN $2,0 \pm 0,8$ (**p=0,003**), l'OKS était de $39,4 \pm 3,6$ dans le CORT et de $41,3 \pm 3,4$ dans le PHEN (**p = 0,294**), WOMAC était de $8,5 \pm 2,3$ dans le CORT et $7,0 \pm 1,3$ dans le PHEN (**p = 0,138**), la cadence de pas était de $1,7 \pm 0,2$ dans le CORT et de $1,9 \pm 0,1$ dans le PHEN (**p=0,022**), la distance en 6 min était de $307,0 \pm 50$ m dans le CORT et de $322,9 \pm 47,85$ m dans le PHEN (**p=0,524**), QAQ était de $1,6 \pm 1,1$ dans le CORT et de $0,71 \pm 0,5$ dans le PHEN (**p=0,166**), SF-12 Physique était de $37,4 \pm 3,0$ dans le CORT et de $40,6 \pm 1,0$ dans le PHEN (**p=0,016**).

Conclusion : Le BNG avec corticoïdes et avec du phénol ont toutes deux eu une amélioration significative de la douleur, de la fonction et de la qualité de vie du genou et sont efficaces dans la prise en charge de la douleur liée à la gonarthrose. La neurolyse avec du phénol a eu des effets plus durables, ce qui suggère que le BNG au phénol serait plus efficace que le BNG avec des corticoïdes.

Mots clés : *gonarthrose, blocage du nerf géniculé, corticoïde, neurolyse, phénol*

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List of abbreviations

ACR: American College of Rheumatology

ANOVA: Analysis Of Variance

CSI: Central Sensitization Inventory

GNB: Genicular nerve block

HA: Hyaluronic acid

IA: Intra articular

IA PRP: Intra articular platelet Rich Plasma injection

KOA: Knee Osteoarthritis

MDIC: Minimal Detectable Important Change

NRS: Numeric Rating Scale

NSAID: Non Steroid Anti Inflammatory Drug

OA: Osteoarthritis

OKS: Oxford Knee Score

PGIC: Patient Global Impression of Change

PROMIS : Patient-Reported Outcomes Measurement Information System

QAQ : Quantitative Analgesic Questionnaire

QAW: Quantitative Analysis of Walking

RCT: Randomized Controlled Trial

RF: Radiofrequency

RF: Radiofrequency Ablation

SF-12: 12-Item Short Form Health Survey

SPSS: Statistical Package for Social Sciences

SSA: Sub-Saharan Africa

TKA: Total Knee Arthropathy

WHO: World Health Organization

WOMAC: Western Ontario and Mac Master Osteoarthritis index

YCH: Yaoundé Central Hospital

YGH: Yaoundé General Hospital

CHAPTER I-INTRODUCTION

1.Background

Osteoarthritis is a degenerative condition that affects joint cartilage, subchondral bone, joint capsule, and synovial membrane [1]. When it affects the knee, is called Knee Osteoarthritis (KOA). It is the most prevalent joint condition, affecting one-third of people over 65 years old and causing pain, limited mobility, and disability [2]. This progressive disease can significantly impact a person's quality of life. Pain and limited mobility are the main reasons for seeking medical attention [3]. Traditional treatments include Non-Steroid Anti-Inflammatory Drugs (NSAIDs), analgesics, physiotherapy, joint injections, visco supplementation, and total knee replacement (TKR) as a last resort. Among the latest modalities for addressing chronic knee pain are radiofrequency denervation, chemical/physical neurolysis of genicular nerves, and genicular nerve blockade (GNB) [4–6]. Neurolysis is the temporary denervation of a targeted nerve or nerve plexus by directed infiltration of chemicals, by cryotherapy, or radiofrequency ablation. In recent years, GNB and radiofrequency ablation have emerged as relevant therapeutic alternatives in the management of chronic knee pain [7,8]. These new treatment options selectively target specific sensory nerves surrounding the knee joint capsule, therefore minimizing the flow of sensitive input to the knee, resulting in substantial pain reduction and enhanced mobility [9–20]. Alcohol and phenol are used as chemical for neurolysis with appreciable results [21–23].

Many studies were carried out comparing GNB to other treatment modalities. Recent studies such as the clinical trial by in 2020 in Egypt compared GNB using corticosteroids and phenol [24]. However, the trial was done using the classical target sites of GNB. These target sites were revised in 2020 ensuring greater accuracy and targets more nerves [16]. Furthermore, the therapeutic efficacy of GNB with the revised targets was demonstrated in 2020 in a clinical trial in Yaoundé [25]. However, 3 months after the procedure 62% of patients experienced only 50% pain reduction. Although a trial was done comparing GNB using corticosteroids versus phenol, we have not found any study in literature comparing both substances using the revised targets.

We therefore seek to compare the effectiveness on pain and knee function of therapeutic GNB with the revised anatomical targets, using corticosteroids against phenol reducing pain and improving functional disability in patients with chronic knee osteoarthritis in Yaoundé using different tools such as the Numerical rating scale, Oxford Knee Score, walking analysis tests and other measurement tools.

2. Research Question

Is genicular nerve neurolysis with revised targets using phenol more effective than GNB using corticosteroids in the management of chronic knee pain due to osteoarthritis?

3. Research Hypotheses

1. Genicular nerve neurolysis using phenol gives a **significantly better and longer pain control** in patients with painful knee osteoarthritis than GNB using corticosteroid.
2. Patients experience greater improvement in knee function and quality of life with phenol compared to corticosteroids.
3. Genicular nerve neurolysis using phenol **significantly improves gait parameters** compared to GNB with corticosteroids.

4. Objectives

4.1. Primary objective

To compare Genicular Nerve Blockade with the revised anatomical targets using corticosteroids versus phenol in management of knee osteoarthritis pain in Yaoundé.

4.2. Specific objectives:

1. Compare the efficacy on knee pain of GNB using corticosteroids vs phenol neurolysis.
2. Measure their effect on knee function and on gait parameters.
3. Evaluate the quality-of-life post GNB.

5. Outcomes

At the end of this study, we expected to

- Increase the pain control using GNB
- Ameliorate the gait parameters
- Improve the quality of life of the participants

6.Operational definition of terms

- **Knee osteoarthritis:** it refers to a degenerative condition that affects knee joint cartilage, subchondral bone, joint capsule, and synovial membrane [1].
- **Pain:** defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [26].
- **Numeric Rating Scale (NRS) for pain:** It is a self-reported measure of pain intensity. The simplest and most commonly used measurement scale to report pain. The patients rate their pain on a scale from 0 (no pain) to 10 (worst imaginable pain). It could be administered in a written format or verbally [26,27].
- **Quality of life:** The WHO defines quality of life as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”.
- **Western Ontario and McMaster Universities osteoarthritis index (WOMAC):** This is a widely used set of standardized questionnaires to evaluate the condition of patients with KOA. It consists of 24 items divided into three subscales (pain, stiffness and physical function). Scores are summed for each subscale and then normalized to a 0-100 scale, with higher scores indicating worse symptoms [28].
- **Oxford Knee Score (OKS):** It is a patient-reported outcome measure specifically designed to assess the function and pain of the knee. Consist of 12 items each scored from 0-4 with a total score range from 0 (worst outcome) to 48 (best outcome) [28].
- **Patient Reported outcomes measurement information system (PROMIS) sleep disturbance 4a:** It is a tool to measure sleep disturbance in individuals. PROMIS 4a consist of 4 items assessing sleep quality with responses scored on a 5-point Likert scale. Higher scores indicate greater disturbance [29].
- **12-items short form health survey:** Just as its name implies it is a 12-item questionnaire to measure functional health and wellbeing from the patient's point of view. It generates two summary scores: the physical component summary (PCS) and

the mental component summary (MCS). Scores range from 0 to 100 with higher scores indicating better health status [30].

- **Patient global impression of change (PGIC):** It is a self-reported measure of a patient's overall perception of improvement or change. It is assessed on a 7 point scale from 1 (very much worse) to 7 (very much improved), reflecting the patients perception of change in their condition since the beginning of the treatment [31].
- **Quantitative analgesic questionnaire (QAQ):** It is a tool to identify the use of analgesic medication by patients. It records the type, dosage and frequency of all analgesic medication taken by the patient over a specified period. Scores can be summed to reflect the overall analgesic burden with higher scores indication an overuse on analgesics [32].
- **Central sensitization inventory:** It is questionnaire used to identify symptoms related to central sensitization, a condition where the central nervous system is in a persistent state of high reactivity. CSI consists of 25 items scored on a 5-point Likert scale. Scores range from 0 to 100 with higher scores indicating a higher degree of central sensitization [33].
- **10-meter walk test:** It is a measure of gait speed and functional mobility. Participants are times as they walk a distance of 10 meters at their usual pace. The time taken is recorded and speed calculated [34].
- **6min walk test:** It is a measure of aerobic capacity and endurance. Participants are instructed to walk as far as possible in 6minutes and the total distance walked is measured in meters [35].

CHAPTER II-LITERATURE REVIEW

1. Knowledge Review

1.1 Review of knee osteoarthritis

1.1.1 Definition

Chronic disease affecting the knee joint and its tissues, primarily leading to progressive damage to articular and, subsequently to the subchondral bone and surrounding synovial structures of the knee [1].

1.1.2 Relevance

1.1.2.1 epidemiology

Knee osteoarthritis was the most common type joint disease (6% of all adults). The likelihood of developing osteoarthritis increases with age. Studies have shown that knee osteoarthritis in men aged 60 to 64 is more commonly found in the right knee (23%) than in the left knee (16.3%), while its distribution seems to be more evenly balanced in women (right knee, 24.2%; left knee, 24.7%). The prevalence of osteoarthritis of the knee is higher among 70-to 74-year-olds, rising as high as 40% [36]. When the diagnosis is based on clinical signs and symptoms alone, the prevalence among adults is found to be lower, at 10% [3]. The radiological demonstration of typical signs of osteoarthritis of the knee is not correlated with symptoms. Only about 15% of patients with radiologically demonstrated knee osteoarthritis complain of knee pain. The incidence of the disorder among persons over 70 is estimated at 1% per year [2].

In Africa, a cross sectional study was done between February and July 2012 on 148 patients followed in Douala showed the mean age being 56.9 years with 75% being females and 68% of these females were post-menopausal women. The pain duration was 1 year and obesity was found in 52% of cases, hypertension in 37.2% of cases and diabetes in 8.8% [3].

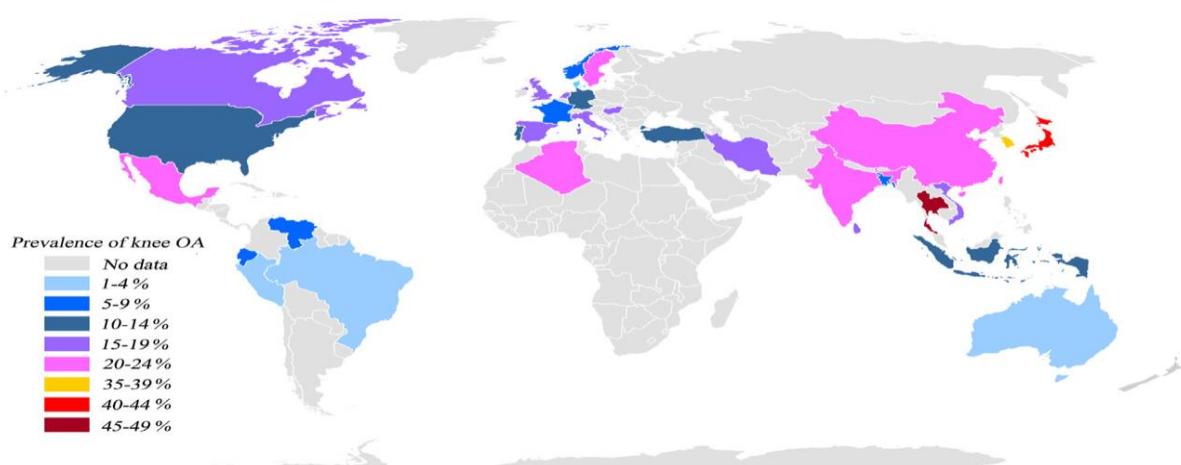


Figure 1 World Prevalence of Knee Osteoarthritis [37]

1.1.2.2 Diagnosis:

Although OA is an extremely common illness, its diagnosis may be difficult. Diagnostic criteria were developed for OA of the knee. The primary goal of the diagnostic criteria is to differentiate OA from other arthritis, such as rheumatoid arthritis and ankylosing spondylitis[38]. The American College of Rheumatology (ACR) classification criteria for OA of the knee was used widely. One study demonstrated that crepitus is specific for patellofemoral joint OA rather than tibiofemoral joint OA, as suggested by the magnetic resonance imaging definition [38]. Another arthroscopy-based study reported an association between crepitus and cartilage pathology in both knee compartments [39].

1.1.2.3 Management:

Management options vary from orthopedic (splint, physiotherapy, etc.), pharmacological (analgesics, NSAIDs, Corticosteroids, etc.) and surgical (osteotomy, TKA, GNB, stem cell cartilage regeneration) methods. For early stages of KOA pharmacological and orthopedic management are recommended [38]. For later stages of the disease surgical methods are preferred. Though Total Knee Arthroplasty is an efficient management the cost of surgical management is too high, with risk of complications and is unaffordable to most patients. However, new methods have been developed and studied over the years including radiofrequency ablation, genicular nerve blockade and phenol neurolysis which relatively reduced the cost of surgical management with less complications [4,14,40].

1.1.2.4 Prognosis:

Although with proper medication the functional prognosis is improved enabling one to carry out low-impact exercises, patients should avoid carrying out moderate to high impact exercises [36]. Functional prognosis would be affected in patients with underlying conditions such as Gout and Rheumatoid Arthritis.

1.1.3 Anatomy Review

1.1.3.1 Articular surfaces: made up of two components

- The tibiofemoral articulation between the condyles femur and tibial plateau
- The patellofemoral articulation between the anterior surface of the femoral condyles and the posterior surface of the patella

1.1.3.2 Joint structures

- **Ligaments:**
 - **Anterior Cruciate Ligament (ACL):** Prevents forward movement of the tibia in relation to the femur.
 - **Posterior Cruciate Ligament (PCL):** Prevents backward movement of the tibia in relation to the femur.
 - **Medial Collateral Ligament (MCL):** Located on the inner side of the knee, providing stability against inward forces.
 - **Lateral Collateral Ligament (LCL):** Located on the outer side of the knee, providing stability against outward forces.
- **Menisci:** Medial and lateral menisci are C-shaped cartilaginous structures between the femur and tibia, acting as shock absorbers and improving joint congruence.
- **Bursae:** Synovial fluid-filled sacs (bursae) located around the knee to reduce friction between muscles, tendons, and bones.
- **Muscles and Tendons:** Quadriceps and hamstring muscles, along with their associated tendons, contribute to knee movement and stability [41,42].

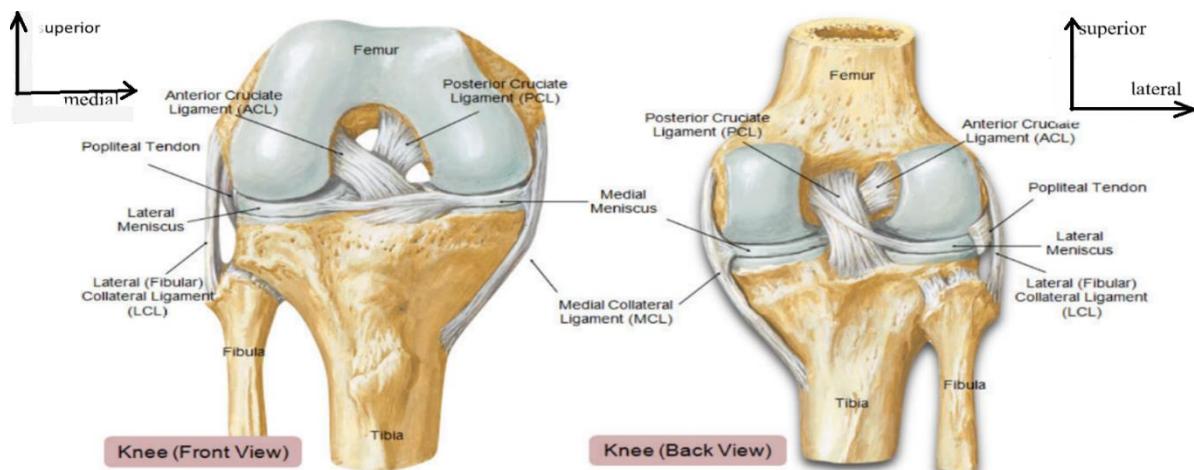


Figure 2 Anterior And Posterior View Of The Knee Joint [41]

1.1.3.3 Sliding Mechanism

Articular Surfaces: The smooth surfaces of the femur, tibia, and patella covered with articular cartilage that allow them to glide against each other.

Menisci: The medial and lateral menisci act as cushions and help distribute the load, allowing the femoral condyles to smoothly slide on the tibial plateaus.

Ligaments: The ligaments, including the anterior and posterior cruciate ligaments (ACL and PCL) and medial and lateral collateral ligaments (MCL and LCL), contribute to stability and guide the sliding motion of the knee.

Muscles and Tendons: The muscles surrounding the knee, such as the quadriceps and hamstrings, contract and relax to facilitate controlled movement, and their tendons play a role in transmitting forces.

Synovial Fluid: The synovial fluid within the joint lubricates the articular surfaces, reducing friction and allowing for smooth sliding [41,42,42].

Figure 3 shows the different structures of the knee joint.

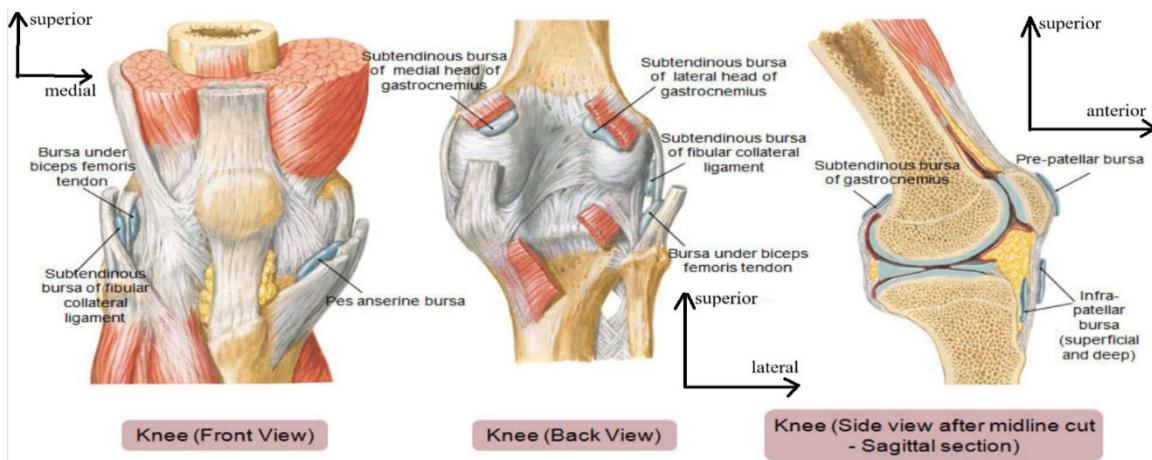


Figure 3 Joint Structures of The Knee [41]

1.1.3.4 Joint physiology and movement

The knee is a hinge joint that allows for flexion (bending), extension (straightening), and a limited degree of rotation.

Here are the key movements of the knee:

Passive Range of Motion (PROM) [43]:

1. **Flexion:** Approximately 0 to 135 degrees. Some individuals may achieve slightly greater flexion, up to 140 to 150 degrees.
2. **Extension:** 0 degrees. Hyperextension, if present, may range from 5 to 10 degrees.
3. **Internal Rotation:** Approximately 0 to 30 degrees.
4. **External Rotation:** Approximately 0 to 40 degrees.
5. **Varus Alignment:** Approximately 5 to 10 degrees.
6. **Valgus Alignment:** Approximately 5 to 15 degrees.

Active Range of Motion (AROM) [43]:

1. **Flexion:** The active range of knee flexion varies widely among individuals and depends on factors such as muscle strength, joint stability, and pain tolerance. It may range from approximately 0 to 120 degrees or more in healthy individuals.
2. **Extension:** The active range of knee extension is typically from 0 to 10 degrees of hyperextension. However, individuals with knee pathology or muscle weakness may have limited or asymmetrical extension.
3. **Internal Rotation:** Active internal rotation of the knee joint is relatively limited compared to passive range of motion. It may range from approximately 0 to 20 degrees.
4. **External Rotation:** Active external rotation of the knee joint is also relatively limited compared to passive range of motion. It may range from approximately 0 to 30 degrees.
5. **Varus and Valgus Movements:** Varus and valgus movements of the knee joint are primarily passive and are typically assessed during clinical examination rather than active range of motion.

Figure 4 illustrates the different movements of the knee



Figure 4 Joint Movement [44]

1.1.3.5 Knee blood vessels

Probably the most important thing to know about the blood supply to the knee is that it is very abundant. There are many collateral vessels (basically extra vessels) that give blood supply to the structures of the knee (Figure 5)

Back side of the knee joint is in close proximity with the major blood vessels (popliteal artery and vein) and nerves (tibial nerve and common peroneal nerve) of lower limb, which puts them at risk of injury during fractures or surgeries (Figure 5).

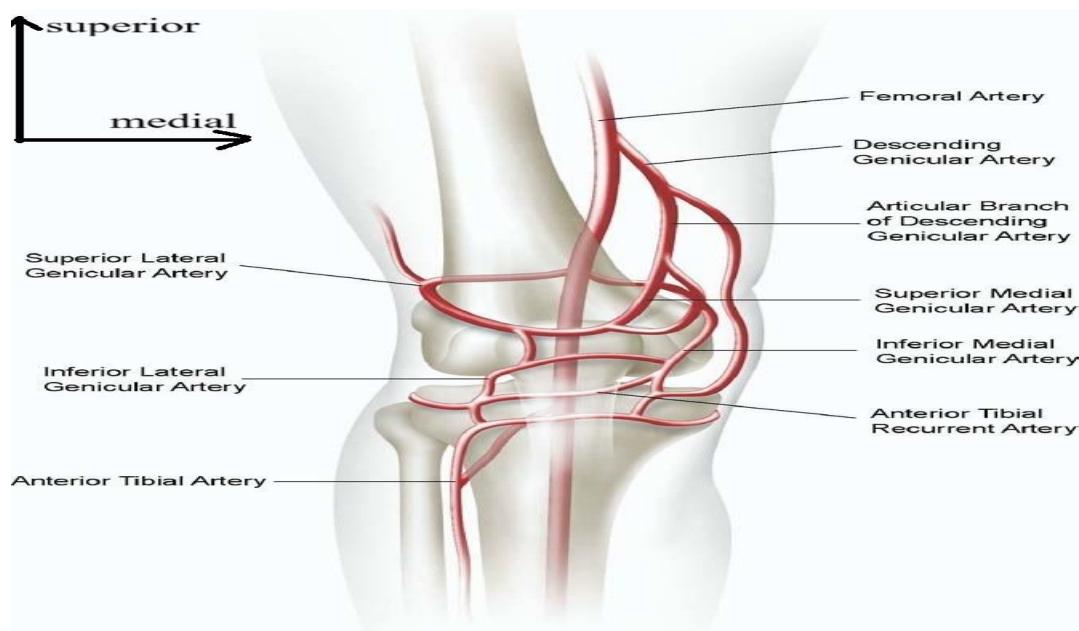


Figure 5 Blood Supply to the knee [45]

1.1.3.6 Knee nerve supply

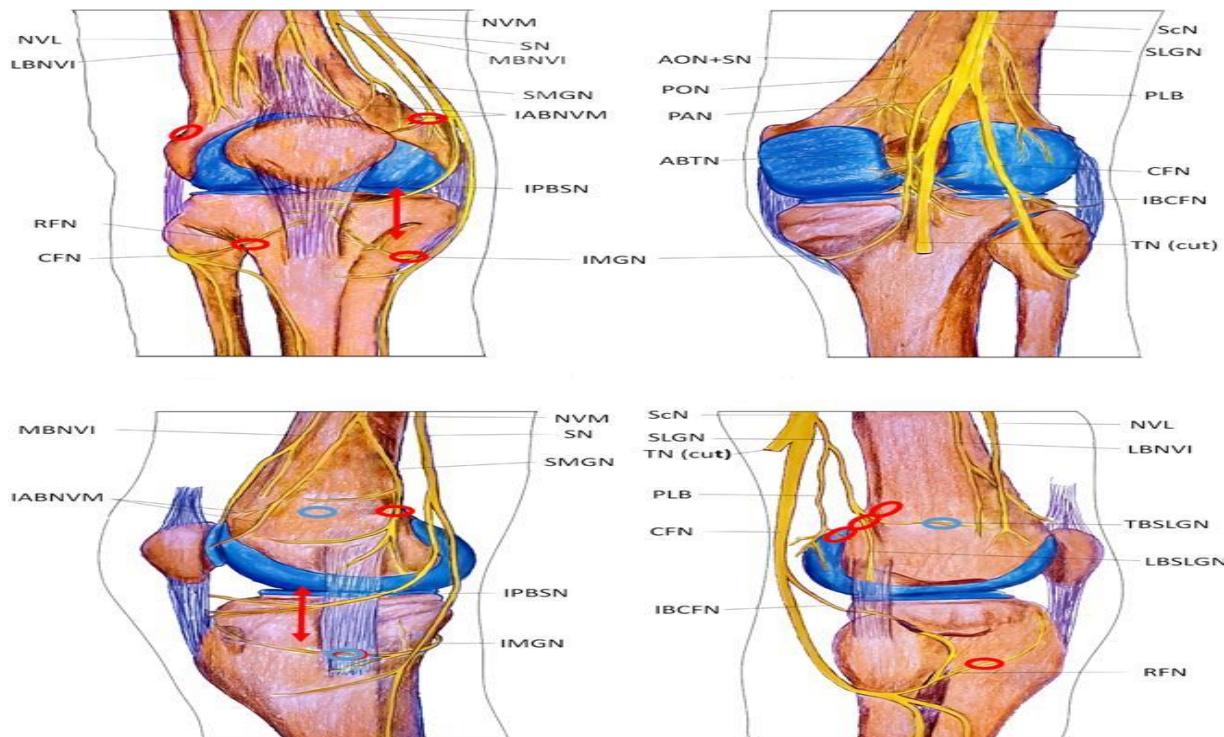


Figure 6 Nervous Supply of the knee [16]

Key : NVL, nerve to the vastus lateralis; LBNVI, lateral branch of the nerve to the vastus intermedius; RFN, recurrent fibular nerve; CFN, common fibular nerve; NVM, nerve to the vastus medialis; SN, saphenous nerve; MBNVI, medial branch of the nerve to the vastus intermedius; SMGN, superior-medial genicular nerve; IABNVM, indirect articular branches from the nerve to the vastus medialis; IPBSN, infrapatellar branch of the saphenous nerve; IMGN, inferior-medial genicular nerve; AON+SN, branch from anterior obturator nerve + saphenous nerve (inconstant) PON, posterior obturator nerve; PAN, posterior articular nerve; ABTN, articular branch from tibial nerve; ScN, sciatic nerve; SLGN, superior-lateral genicular nerve; PLB, posterior-lateral branch; IBCFN, inferior branch from common fibular nerve; TN, tibial nerve; TBSLGN, tranverse branch of the SLGN; LBSLGN, longitudinal branch of the SLGN (Reproduced With Permission from Fonkoué Et All 2021)

Table I Knee nerve supply [16]

| Original nervous trunk | Branches from the original trunk carrying knee nerves | Nerves to the knee capsule (Genicular Nerves) | Constant landmarks for genicular blockade? | Supplied part of the knee capsule |
|------------------------|---|---|--|-----------------------------------|
| Femoral | Nerve to the VM | 1 Direct branch (SMGN) | Yes | Supero-medial |
| | | 0 to 3 Indirect branches (trans-muscular) | No | Superior medial |
| | Nerve to the VL | 1 or 2 branches | No | Supero-lateral |
| | Nerve to the VI | Intermedium GN | No | Anterior Supra-patellar zone |
| Obturator | Saphenous nerve | IPBSN 1 small branch in the AC | Yes No | Infero-medial Supero-medial |
| | Anterior branch | 1 branch to the popliteal fossa via adductor hiatus | No | Postero-medial |
| | Posterior branch | 1 trans-muscular branch to the popliteal fossa | No | Posterior |
| Sciatic | SLGN | Superior lateral GN | Yes | Supero-lateral |
| | Posterior articular nerve | Infero-medial GN | Yes | Infero-medial |
| | Common fibular nerve | Lateral recurrent GN | No | Inferior lateral |
| | Tibial nerve | Inferior lateral GN 1 to 2 direct articular nerves | Yes No | Inferior lateral Posterior |

Key: VM vastus medialis muscle, VL vastus lateralis muscle, VI vastus intermedium muscle, SMGN superior medial genicular nerve, SLGN superior lateral genicular nerve, IPBSN infrapatellar branch of saphenous nerve, GN genicular nerve

1.1.5 pathophysiology and etiology

- **Factors** associated with KOA include :obesity, old age, septic arthritis, hypertension, diabetes [1].
- **Etiology**
 - ❖ **Primary**
 - Congenital
 - ❖ **Secondary**
 - Post traumatic

- Malposition(varus/valgus)
- Postoperative
- Metabolic (rickets, hemochromatosis, chondrocalcinosis, ochronosis)
- Endocrine disorders (acromegaly, hyperparathyroidism, hyperuricemia)
- Aseptic osteonecrosis

➤ **Pathophysiology**

KOA is a disease of the entire joint sparing no tissues. The cause of KOA is an interplay of risk factors (mentioned above), mechanical stress, and abnormal joint mechanics. The combination leads to pro-inflammatory markers and proteases that eventually mediate joint destruction. The complete pathway that leads to the destruction of the entire joint is unknown.

Usually, the earliest changes that occur in KOA are at the level of the articular cartilage that develops surface fibrillation, irregularity, and focal erosions. These erosions eventually extend down to the bone and continually expand to involve more of the joint surface. On a microscopic level, after cartilage injury, the collagen matrix is damaged, causing chondrocytes to proliferate and form clusters. A phenotypic change to hypertrophic chondrocyte occurs, causing cartilage outgrowths that ossify and form osteophytes. As more of the collagen matrix is damaged, chondrocytes undergo apoptosis. Improperly mineralized collagen causes subchondral bone thickening; in advanced disease, bone cysts infrequently occur. Even rarer, bony erosions appear in erosive) KOA.

There is also some degree of synovial inflammation and hypertrophy, although this is not the inciting factor as is the case with inflammatory arthritis. Soft-tissue structures (ligaments, joint capsule, menisci) are also affected. In end-stage KOA, both calcium phosphate and calcium pyrophosphate dihydrate crystals are present. Their role is unclear, but they are thought to contribute to synovial inflammation [1,2].

1.1.6 diagnosis

1.1.6.1 Clinical features/imaging and biology [1,2,46]

➤ **History**

- Early stage
- Pain: unilateral or bilateral, intermittent, onset when walking when climbing up or down stairs or brief morning stiffness (some minutes)
- Advance stage:

- Constant pain
- Swelling, effusion
- Hyperthermia
- Pain at rest and waking the patient during the night
- Longer morning stiffness(30-60min)

➤ **Physical examination**

• **Inspection**

- Axis deviation

- Swelling

- Muscle wasting

• **Palpation**

- Swelling, effusion

- Tenderness

• **Functional exam**

- Crepitations, loss of mobility

- Joint instability

- Provocation maneuvers

- Tenderness when moving

- Axial pain on slight shock

- Tenderness on extension

➤ **Lab values**

Full Blood Count (FBC), Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP), Rheumatoid Factor (RF) are usually normal but are used exclude any underlying disease.

Knee Arthrocentesis shows White Blood Cell (WBC) count <2000/mm³

➤ **Imaging**

- Knee Xray frontal and sagittal view
- Reduction of joint space
- Osteophytes
- Sub chondral sclerosis
- Bone cysts
 - MRI
- Bone marrow edema
- Effusion
- Synovitis
 - Ultrasound
 - Effusion

1.1.6.2 Classification

➤ **Ahlback classification**

Classification

- **grade 1:** joint space narrowing (less than 3 mm)
- **grade 2:** joint space obliteration
- **grade 3:** minor bone attrition (0-5 mm)
- **grade 4:** moderate bone attrition (5-10 mm)
- **grade 5:** severe bone attrition (more than 10 mm)



Figure 7 Ahlback Classification of Knee Osteoarthritis [46,47]

➤ Kellgren and Lawrence

| Grade | Radiologic Findings |
|-------|--|
| 0 | No radiological findings of osteoarthritis |
| I | Doubtful narrowing of joint space and possible osteophytic lipping |
| II | Definite osteophytes and possible narrowing of joint space |
| III | Moderate multiple osteophytes, definite narrowing of joint space, small pseudocystic areas with sclerotic walls and possible deformity of bone contour |
| IV | Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour |



GRADE 1 GRADE 2 GRADE 3 GRADE 4

Figure 8 Kellgren and Lawrence Classification of Knee Osteoarthritis [46,48]

1.1.6.3 Positive Diagnosis [49]

The American College of Rheumatology (ACR) classification criteria for KOA are beneficial for research endeavors but lack utility in the early detection of knee OA. They include:

- The ACR Clinical classification criteria of knee OA
- The ACR Clinical/Radiographic classification criteria of knee OA
- The ACR Clinical/Laboratory classification criteria of knee OA
- ❖ The ACR Clinical classification criteria for knee OA is widely utilized for categorizing the condition. According to these criteria, knee OA can be classified when knee pain is present along with at least three of the following six items:
 - Age > 50 years old
 - Morning stiffness < 30 minutes

- Crepitus on knee motion
 - Bony tenderness
 - Bony enlargement
 - No palpable warmth
- ❖ In the ACR Clinical/Radiographic classification criteria, the presence of knee pain with at least 01 of the following three items along with osteophyte in knee X-Ray can classify the knee OA:
- Age> 50 years old
 - Morning stiffness < 30 minutes
 - Crepitus on knee motion
- ❖ In the ACR Clinical/Laboratory classification criteria, the presence of knee pain along with at least 05 of the following 09 items can classify the knee OA:
- Age> 50 years old
 - Morning stiffness < 30 minutes
 - Crepitus on knee motion
 - Bony tenderness
 - Bony enlargement
 - No palpable warmth
 - ESR <40 mm/hr.
 - RF < 1 40
 - Synovial fluid compatible with OA

1.1.6.4 Differentials

- **Ligament Rupture**

- Medial, lateral pain or pain with kneeling
- Joint laxity
- Positive Lachman anterior drawer or posterior drawer test

- **Patellar and Quadriceps Tendinopathy**

- Here the pain is due to change in activity levels (increase training intensity)
- Tenderness on palpation of the patellar/quadriceps tendon

- No erythema/effusion
- Pain with resisted knee extension
- Xray is normal

- **Osgood-Schlatter Disease**

- Common in adolescents
- Activity related pain around the tibial tubercle
- Tenderness on palpation of patellar tendon insertion with knee extension or passive flexion

- **Infectious arthritis:**

- History of fever
- Inflammatory type pain
- FBC shows leukocytosis
- Elevated CRP
- Knee arthrocentesis shows WBC count $>2000/\text{mm}^3$

- **Crystal arthropathy**

- History of gout or hypercalcemia
- Knee arthrocentesis shows crystals

- **Avascular necrosis**

- Articular collapse or cortical depression on x-ray
 - **Rheumatoid arthritis**

- Multiple joints involved
- Positive rheumatoid factor

- **Radiculopathy**

- Referred pain
- Pain character no mechanical

-No joint tenderness

1.1.7 Management of knee osteoarthritis

➤ **Aim**

- Reduce the pain
- Protect the remaining cartilage
- Improve knee function
- Increase quality of day-to-day life

➤ **Means and methods**

- **Orthopedic**

- **Orthoses and footwear**

The aim of an orthosis is to reduce pain and improve function. The ideal candidate for an orthosis is a patient with passively correctable unicompartmental arthritis. A brace may function by improving the biomechanical axis of the deformity thereby unloading the compartment or by improving the perception of instability [50].

- **Non pharmacologic**

- **Physical means and hygiene**

Weight loss is strongly recommended for patients with knee OA who are overweight or obese. A loss of $\geq 5\%$ of body weight can be associated with changes in clinical and mechanistic outcomes Balance exercises include those that improve the ability to control and stabilize body position [51,52].

- **Physiotherapy**

The method of delivery of thermal interventions varies considerably in published reports, including moist heat, diathermy (electrically delivered heat), ultrasound, and hot and cold packs [51].

- **pharmacologic**

- **Analgesics (1st and 2nd ladder)**
 - **Non-Steroid Anti-inflammatory drugs (NSAID) (diclofenac, aceclofenac)**
 - **Glucocorticosteroids (betamethasone, triamcinolone)**
 - **Cartilage protectors (chondroitin sulphate)**
 - **Corticosteroid intra articular infiltrations**

In the knee joint of OA, IA corticosteroid injections are usually conditionally recommended over other forms of IA injection. There are few one-to-one comparisons; however, the evidence for the efficacy of glucocorticoid injections is significantly higher than that of other drugs [53,54].

- **Intra articular platelet Rich Plasma injection(IA PRP)**

The IA platelet-rich plasma (PRP) injection has emerged as a good treatment for knee OA. Several randomized controlled trials have been shown that PRP is a safe and effective treatment. At this time, IA PRP is not a standard treatment of the knee OA, but it is similar in efficacy to HA, and appears to be more effective than HA in young, active patients with low-grade OA [55].

- **Visco-supplementation**

Viscous supplementation through an intra articular injection of Hyaluronic acid which is a viscoelastic mucopolysaccharide component of synovial fluid is aimed at restoring the beneficial environment present in the joint. Additionally, the safety profile of such injections for painful knee OA is well established [56,57].

• **Surgical**

- **Partial Knee Replacement (Uncompartmentalized Knee Arthroplasty)**

Unicompartamental knee arthroplasty is an alternative to TKR for patients whose disease is limited to a single area of the knee, particularly the isolated tibiofemoral compartment (medial or lateral). As partial knee replacement is performed using smaller incisions, patients can generally be discharged earlier than those who undergo TKR and can return sooner to normal activities, including work and sports [58].

- **Knee Osteotomy (High Tibial Osteotomy or Femoral Osteotomy)**

High tibial osteotomy is a surgery to realign the knee joint. It is more important for the treatment of cartilage damage or OA of the medial compartment with varus deformity. High tibial osteotomy creates a postoperative valgus limb alignment by lateral movement of the load-bearing axis of the lower limb [59].

- **Genicular nerve blockade (Peri articular infiltration) and Radiofrequency ablation**

A genicular nerve blockade is a medical procedure that involves the injection of a chemical around the genicular nerves with chemicals (corticosteroids or alcohol) [22,25].

- **Radiofrequency Ablation**

Radiofrequency ablation (RFA) for the knee involves the application of radiofrequency energy to selectively target and ablate nerve fibers associated with pain transmission in the knee joint. This minimally invasive procedure aims to provide relief for chronic knee pain, typically associated with conditions such as knee osteoarthritis [4,7].

- **Knee Cartilage Repair and Cartilage Restoration**

Many surgical techniques have been developed to address focal cartilage defects. Cartilage surgery strategies include palliative (chondroplasty and debris removal); repair (perforation and microfracture); or restoration (auto chondral cell transplant, osteochondral autograft, and bone cartilage allograft) [60].

- **Knee Arthroscopy**

Knee arthroscopy is most commonly performed to treat OA or meniscus problems. An arthroscopy requires a small incision in the skin with the insertion of a camera on a stick. Another incision is needed to insert other instruments and treat the disease [61].

- **Total knee Arthroplasty (Total Knee Replacement Surgery)**

Total knee replacement (TKR) surgery involves excising the damaged ends of the tibia and femur and capping both using a prosthesis. Both prostheses comprise durable plastic. These new surfaces move smoothly with each other. Partial recovery takes 6 weeks and complete recovery takes up to 1 year [62,63].

- **Cellular and Stem Cell Therapy**
- **Cellular Therapy**

Several cell therapeutic attempts have been made to regenerate damaged joint cartilage. Autologous chondrocyte implantation (ACI) has been proposed as a surgical technique for partial cartilage lesions

- **Mesenchymal Stem Cells for Osteoarthritis [62]**

MSCs are pluripotent progenitor cells derived from a population of adult stem cells that can be isolated from numerous tissues, including bone marrow, peripheral blood, adipose tissue, synovium, placenta, and umbilical cord

Human MSCs are defined as cells that adhere to plastics; are positive for CD105, CD73 cell surface markers; negative for CD45, CD34 cell surface markers; and differentiate into osteoblasts, chondrocytes, and adipocytes

➤ **Monitoring**

Monitoring through the evaluation of pain, knee function and quality of life. Uses different scores:

- western Ontario and McMaster universities arthritis index (WOMAC)
- numerical rating score (NRS)
- oxford knee score (OKS)
- quantitative analgesic questionnaire (QAQ)
- short form Survey(sf-12)

1.2 Genicular Nerve Blockade

1.2.1 Definition

A genicular nerve blockade is a medical procedure that involves the injection of a local anesthetic (and sometimes a corticosteroid) around the genicular nerves, which are branches of the femoral and obturator nerves. These nerves are associated with the knee joint, and blocking them can help manage pain arising from certain knee conditions. The genicular nerves transmit pain signals from the knee to the brain, and by blocking these signals, the procedure aims to provide relief from chronic knee pain. Chemical genicular nerve neurolysis is effective in treating chronic knee osteoarthritis pain compared to a placebo [64]. This procedure is low-cost and readily available, even in resource-limited settings. Several longitudinal cohort studies and randomized controlled studies have supported its effectiveness [40,65,66] have confirmed certain clinical effectiveness of this treatment on knee osteoarthritis pain and persistent knee pain after TKA. These promising methods of conservative treatment, widely used for the zygapophyseal joints (spine) for decades, are currently emerging for knee pain and are attracting a lot of interest. It is a non-surgical, minimally invasive, non-narcotic solution to chronic knee pain. It is performed on an outpatient basis, and patients can find immediate and lasting relief, a better quality of life more quickly than surgery, and a clear reduction in narcotic consumption [67].

1.2.2 Principles

- Selective and distal interruption of the afferent impulse from the sensory nerves at the joint level
- Target: sensory articular nerves with a constant distal course, establishing periosteal contact before penetration into the joint capsule, therefore allowing easy localization, using bony landmarks
- Use of these anatomical landmarks to reach these nerves when placing needles under fluoroscopic or ultrasound control
- Nerve blockade by injection of local anesthetic product + corticosteroids (geniculate block) or chemical neurolysis with phenol or alcohol.
- Choice of anatomical landmarks: essential for the success of the method.
- No motor effects

1.2.3 Pharmacology of products used

i)Triamcinolone [68–70]

Triamcinolone is a product in the class of corticosteroids that can be administered topically or injectable.

1. Mechanism of Action:

- Triamcinolone is a synthetic glucocorticoid that exerts anti-inflammatory, immunosuppressive, and analgesic effects.
- Its mechanism of action involves binding to intracellular glucocorticoid receptors, leading to modulation of gene transcription and subsequent inhibition of pro-inflammatory cytokines, enzymes, and mediators involved in the inflammatory response.
- In genicular nerve blockade, triamcinolone is thought to reduce inflammation and pain by suppressing local inflammation around the genicular nerves and knee joint.

2. Pharmacokinetics:

- **Absorption:** Triamcinolone is usually administered as a suspension or solution for intra-articular injection. Following injection into the soft tissues surrounding the genicular nerves, triamcinolone is absorbed slowly into the bloodstream and distributed to target tissues.
- **Distribution:** Triamcinolone has a high protein-binding capacity and is distributed extensively throughout the body, including synovial fluid and joint tissues.
- **Metabolism:** Triamcinolone undergoes hepatic metabolism, primarily by cytochrome P450 (CYP450) enzymes, including CYP3A4. Metabolites are excreted mainly in the urine.
- **Elimination:** The elimination half-life of triamcinolone varies depending on the formulation and route of administration but is typically in the range of hours to days.

3. Dosage Considerations:

- The dosage of triamcinolone for genicular nerve blockade varies depending on factors such as the severity of inflammation, patient characteristics, and the specific technique used for the procedure.

- Typical doses range from 20 to 40 milligrams (mg) of triamcinolone acetonide suspension per knee joint targeted, with a maximum recommended dose per session to minimize the risk of systemic effects.
- Careful attention should be paid to the total dose of triamcinolone administered, as excessive doses can increase the risk of systemic side effects, including adrenal suppression, hyperglycemia, and immunosuppression.

4. Adverse Effects :

- **Local Reactions:** Common local adverse effects of triamcinolone injection include pain or discomfort at the injection site, swelling, and transient flare reactions.
- **Systemic Effects:** Systemic adverse effects may occur, particularly with repeated or high-dose injections, and include adrenal suppression, hyperglycemia, hypertension, fluid retention, and immunosuppression.
- **Infection Risk:** Corticosteroid injections, including triamcinolone, may increase the risk of local or systemic infection, particularly in immunocompromised individuals or those with pre-existing joint pathology.

ii) Lidocaine [71,72]

Lidocaine is an intermediate-acting amide group local anesthetic agent mainly used for topical anesthesia. Lidocaine has a lipophilic group linked with a hydrophilic group by a hydrocarbon chain.

1. Mechanism of Action:

- Lidocaine is a local anaesthetic agent that works by blocking voltage-gated sodium channels in nerve cell membranes, thereby inhibiting the generation and conduction of action potentials.
- When injected near the genicular nerves, lidocaine interrupts pain signalling from the knee joint by blocking the transmission of nociceptive impulses to the central nervous system.
- Lidocaine's fast onset of action and relatively short duration of effect make it suitable for use in nerve blockade procedures, providing rapid pain relief with minimal systemic side effects.

2. Pharmacokinetics:

- **Absorption:** Following injection into the soft tissues surrounding the genicular nerves, lidocaine is rapidly absorbed into the bloodstream and distributed to target tissues.
- **Distribution:** Lidocaine has a moderate volume of distribution and readily crosses cell membranes, allowing it to penetrate nerve fibers and exert its local anesthetic effect.
- **Metabolism:** Lidocaine is extensively metabolized in the liver by hepatic enzymes, primarily cytochrome P450 (CYP450) enzymes, including CYP3A4 and CYP1A2.
- **Elimination:** Metabolites of lidocaine are primarily excreted in the urine, with a small fraction excreted in the faeces. The elimination half-life of lidocaine ranges from 1.5 to 2 hours in healthy individuals.

3. Dosage Considerations :

- The dosage of lidocaine for genicular nerve blockade varies depending on factors such as the patient's weight, age, comorbidities, and the specific technique used for the procedure.
- Typical doses range from 1 to 2 millilitres (ml) of lidocaine solution (usually 1-2% lidocaine) per genicular nerve targeted, with a maximum recommended dose of 5-7 ml per nerve per session to minimize the risk of systemic toxicity.
- Careful attention should be paid to the total dose of lidocaine administered, as excessive doses can lead to systemic toxicity, including CNS and cardiovascular effects.

4. Adverse Effects:

- **Local Reactions:** Common local adverse effects of lidocaine injection include pain or discomfort at the injection site, bruising, and swelling.
- **Systemic Toxicity:** Systemic adverse effects may occur if lidocaine is inadvertently injected into a blood vessel or if excessive doses are administered. Symptoms of lidocaine toxicity include CNS effects (e.g., dizziness, confusion, seizures) and cardiovascular effects (e.g., hypotension, arrhythmias).
- **Allergic Reactions:** While rare, allergic reactions to lidocaine, such as skin rash or anaphylaxis, may occur in susceptible individuals. Cross-reactivity

with other local anaesthetics should be considered in patients with a history of allergy to lidocaine.

iii) Phenol [73–75]

Phenol is a chemical composite agent that is comprised of carbolic acid, phenic acid, phenylic acid, phenyl hydroxide, hydroxybenzene, and oxybenzone. Phenol has a diverse range of applications, including its use as a disinfectant, an antiseptic, a precursor to various industrial chemicals, and in the production of plastics, pharmaceuticals, and dyes.

Pharmacodynamics:

1. **Neurolytic Action:** Phenol induces degeneration of nerve fibers by protein necrosis disrupting the myelin sheath and causing axonal destruction. This results in the interruption of nerve conduction and pain relief. Phenol in concentrations of more than 3% acts as a neurolytic agent. This can be used to manage chronic non-malignant pain.
2. **Antiseptic Properties:** Phenol acts by disrupting the cell membrane of microorganisms, leading to their death. It denatures proteins and enzymes, causing irreversible damage to microbial cells.
3. **Anesthetic Properties:** Phenol has local anesthetic properties due to its ability to block nerve conduction when applied topically which explains the transient muscle relaxation within the hour following phenol block. This effect is utilized in procedures like chemical peels and as a component of topical analgesic preparations.
4. **Neurotoxicity:** Phenol is toxic to the central nervous system in high concentrations. It can cause CNS depression, convulsions, and respiratory failure if ingested or absorbed in large amounts.
5. **Vasodilation:** Phenol can cause vasodilation through its irritant effect on blood vessels, leading to increased blood flow and potential tissue damage if exposure is prolonged.

Duration of Action: The duration of phenol neurolysis varies depending on factors such as the concentration of phenol used, the site of injection, and individual patient characteristics. Pain relief may last from weeks to months.

Pharmacokinetics :

1. **Absorption:** Phenol can be absorbed through the skin, gastrointestinal tract, and respiratory tract. Absorption rates depend on concentration, duration of exposure, and the presence of other chemicals that may enhance or inhibit absorption.
2. **Distribution:** Phenol is distributed throughout the body, with higher concentrations found in organs with rich blood supplies, such as the liver and kidneys. It can also cross the blood-brain barrier, leading to potential neurotoxic effects.
3. **Metabolism:** Phenol undergoes metabolism primarily in the liver through processes such as glucuronidation and sulfation. Metabolites are excreted primarily via urine.
4. **Excretion:** The major route of excretion for phenol and its metabolites is through the kidneys. Some phenol may also be excreted through sweat and respiratory secretions.

Available Recommendation and Dosage:

Phenol in water is the recommended preparation for peri-neural block and is available in 5, 6 or 7% concentrations. There are no clear studies about the recommended dose but the consensus from the literature recommends no more than 1200mg in total (e.g. 20mls of 6% concentration) [76]. The available data, from industrial toxicity with phenol show side effects if systemic absorption in adults is of 100mg/kg or more.

Indications:

1. **Neurolysis:** Phenol can be used for the management of chronic knee osteoarthritis pain and non-malignant pain
2. **Antiseptic:** Phenol is used as an antiseptic for disinfecting skin wounds, surgical instruments, and surfaces in healthcare settings. It's also used in various consumer products like throat sprays and mouthwashes.
3. **Local Anesthetic:** Phenol is used as a local anesthetic in procedures such as chemical peels, treatment of hemorrhoids, ingrown nail ablation and as an adjunct in topical analgesic preparations.
4. **Industrial Applications:** Phenol is a precursor to various industrial chemicals, including plastics (such as Bakelite), synthetic fibers, and pharmaceuticals (like aspirin and acetaminophen).
5. **Muscle spasticity:** Phenol is reserved for regional lower limb spasticity involving large muscles for which treatment with botulinum injections will not be appropriate due to the need for high doses of botulinum.

Side effects

Common

- Occasional redness, discomfort or bruises at the injection site

Rare side effects

- Skin infection or abscess formation
- Haematoma
- Muscle / soft tissue fibrosis
- Nerve causalgia (in sensory-motor nerve blocks)
- Prolonged or concentrated exposure to phenol can cause skin irritation, including redness, swelling, and dermatitis

Very rare side effects

- Vascular injury
- Injury to pelvic organs (applicable to obturator nerve block)
- Systemic effects: arrhythmia, pulmonary fibrosis, confusion and renal impairment
- Ingestion or excessive absorption of phenol can lead to systemic toxicity, manifesting as CNS depression, respiratory failure, cardiovascular collapse, and even death
- Prolonged exposure to phenol has been associated with an increased risk of certain cancers, particularly in occupational settings where exposure levels are high

Contraindications and Precautions:

Pregnancy and Lactation: Phenol should be used with caution in pregnant or breastfeeding women due to potential risks to the fetus or nursing infant.

Hypersensitivity: Individuals with a known hypersensitivity to phenol should avoid exposure to prevent allergic reactions.

Children and Elderly: Special caution should be exercised when using phenol in children and elderly individuals due to their increased susceptibility to adverse effects

Occupational Exposure: Workers in industries where phenol is used should follow strict safety protocols to minimize exposure and prevent adverse health effects.

1.2.4 Preparations for injections

For the preparation, a 2 ml mixture of lidocaine 1% (1.5 ml) and 20 mg of triamcinolone (0.5 ml of triamcinolone 40 mg/ml) will be administered at each target side Champ [67] or one of three phenol preparations based on the literature: phenol plus glycerin, phenol plus water, or phenol plus lipid. Phenol is available in an 60% solution and requires preparation by the hospital pharmacy. However, it is unstable at room temperature and will oxidize in the presence of air and light, turning red. Depending on the desired pharmacokinetic and therapeutic effect, phenol may be prepared in an aqueous, glycerin, or lipid solution and diluted to a concentration of 2% to 3%. When mixed with glycerin, phenol diffuses slowly, resulting in a limited spread pattern that is maintained at the injection site. This viscous preparation of phenol diluted with glycerin is hyperbaric about cerebrospinal fluid (CSF). Aqueous preparations of phenol are more potent neurolytic agents with a wider spread. Contrast may also be mixed in to aid in visualization during fluoroscopy [65,67].

Phenol is a chemical composite agent that is comprised of carbolic acid, phenic acid, phenylic acid, phenyl hydroxide, hydroxybenzene, and oxybenzone. It denatures protein readily and may cause denervation when injected near neural structures, leading to loss of cellular fatty content, separation of the myelin sheath from the axon, and axonal oedema. Phenol's effects may be a combination of both neurotoxicity and ischemia. Histologic specimens have demonstrated non-selective nerve destruction, muscle atrophy, and necrosis with phenol injections. Although the ideal concentration of phenol for neurolysis is not well-studied, studies report an ideal range from 3% to 12%. Dilute concentrations less than 5% result in protein denaturation of axons and blood vessels, while concentrations greater than 12% may produce protein coagulation and nonselective segmental demyelination. The neurolytic effect is immediate after administration [77].The maximum daily dose is 1 gram, and caution must be taken in patients with advanced liver disease given that the liver metabolizes phenol. For this study, we used 2 mL of 6% glycerinated phenol solution [65].

1.2.5 Anatomic Landmarks

The classical targets included

- Superolateral, Superomedial and Inferior medial genicular nerves which pass periosteal

areas connecting the shaft of the femur to bilateral epicondyles and the shaft of the tibia to the medial epicondyle (Figure 9) [4,78].

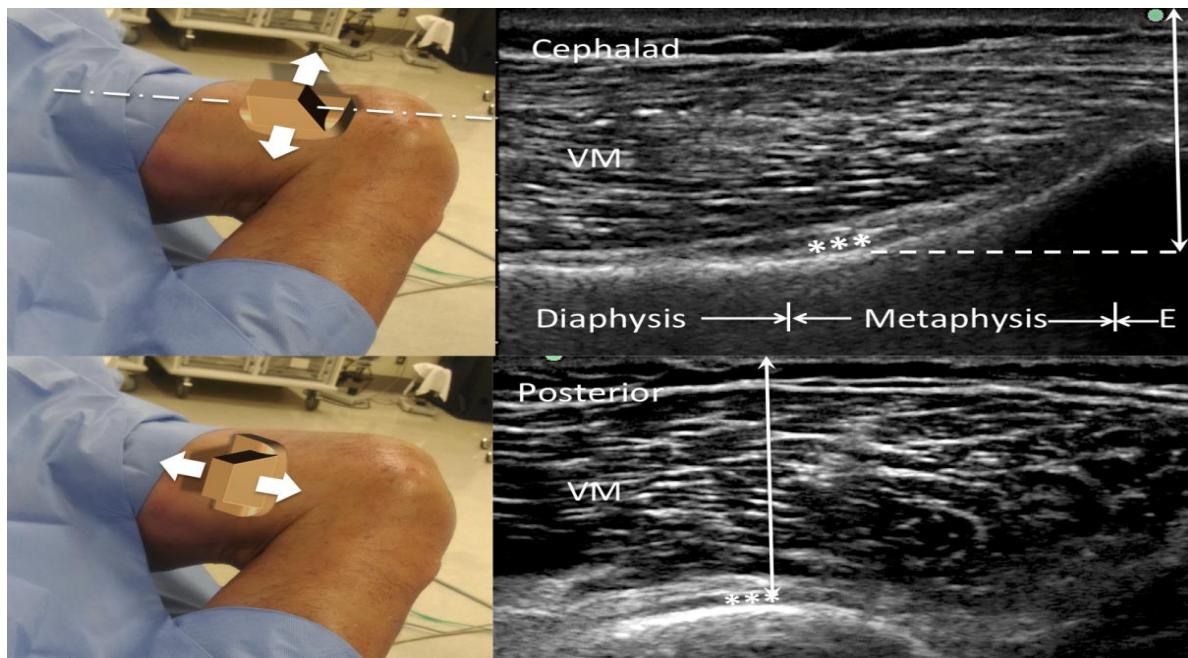


Figure 9 Classical Landmarks Using Ultrasound Probe [65]

The revised landmarks [14–16] are shown in Figure 10 and 11, and include

- The superomedial geniculate nerve: On a frontal view, the landmark is located at the confluence between the medial condyle and the femoral shaft; and in the profile view, it is located in front of the adductor tubercle, just 1 cm in front of the posterior cortex of the femur.
- The superolateral geniculate nerve: On a frontal view, the landmark is located at the confluence between the lateral condyle and the femoral shaft; and in the profile view, it is located at the junction between the posterior cortex of the femur and the lateral condyle.
- The inferior-medial geniculate nerve: On a frontal view, the landmark is located at the confluence between the medial condyle and the tibial shaft; and on the profile view, it is located halfway between the anterior and posterior cortex
- The inferolateral geniculate nerve: The landmark is located on the longitudinal line passing through the top of Gerdy's tubercle, 01 cm below this tubercle.
- The infrapatellar branch of the saphenous nerve: The treatment site is a vertical line joining the following 2 transverse lines: the transverse line passing through the apex of the patella, and the transverse line passing through the top of the anterior tibial tuberosity [79]. The area to be treated is the vertical line joining the two previous ones, 4 cm medially from the tip of the patella.

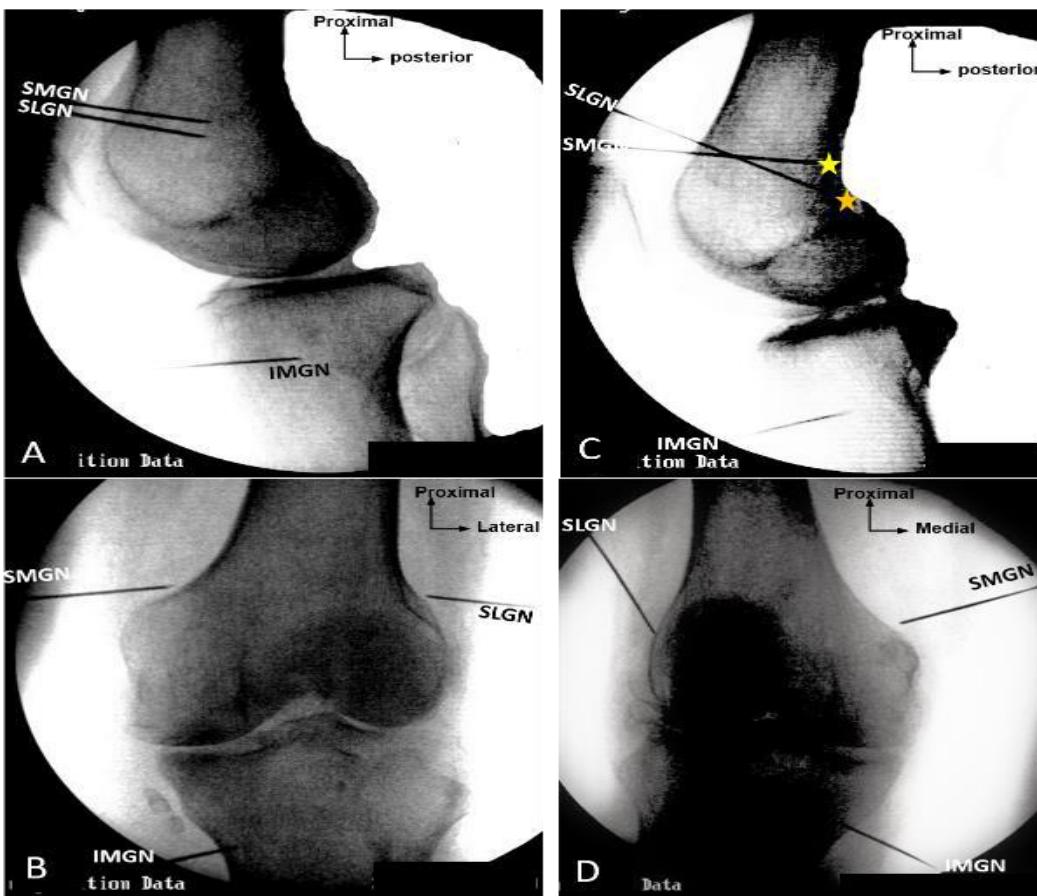


Figure 10 Revised Anatomic Landmarks of GNB

Anterior/Posterior and Lateral Fluoroscopic Images of The Final Needle Position for Genicular Nerve Blockade Targeting The SMGN, SLGN, And IMGN. (A) And (B) Classical Targets. (C) And (D) Revised Targets. SMGN, Superior-Medial Genicular Nerve; IMGN, Inferior-Medial Genicular Nerve; SLGN, Superior-Lateral Genicular Nerve, Yellow Star, Position of The Needle Tip for the SMGN; Orange Star, Position of The Needle Tip for the SLGN. (Reproduced With Permission from *Fonkoué Et All 2021*)

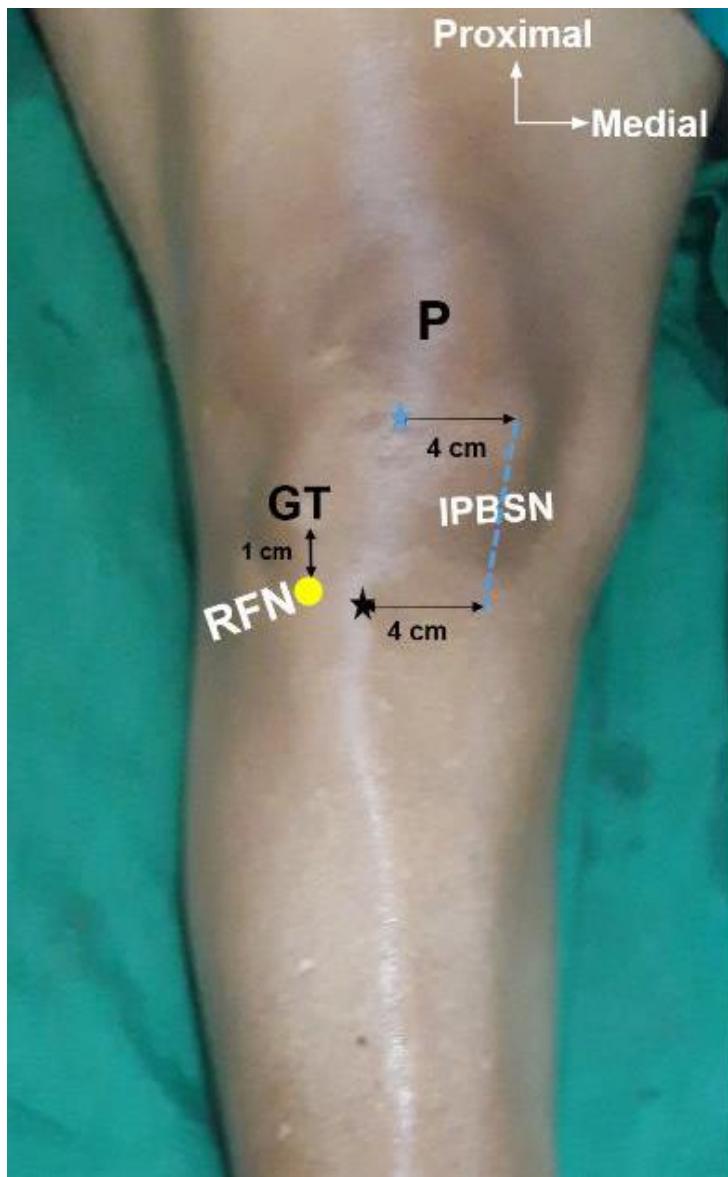


Figure 11 Clinical landmarks of GNB
Clinical landmarks for the RFN and
IPBSN (without imaging).

IPBSN, infrapatellar branch of the saphenous nerve; RFN, recurrent fibular nerve; P, patella; GT, Gerdy's tubercle; black star, tibial tuberosity; blue star, apex of the patella; yellow circle, target point for RFN; blue dashed line, treatment line for the IPBSN. (reproduced with permission

1.2.6 Technique

The patient is in a supine position, the knee slightly flexed (20-30°), and aseptic conditions are respected. Fluoroscopy provides an x-ray image of the knee showing front and strict profile views. Using an insulin needle, local cutaneous anesthesia with 1% lidocaine (1 to 2 ml) is carried out superficially in the areas where the electrodes will be placed. Then, a needle (25 Gauge) is introduced and advanced under fluoroscopic control towards a precise anatomical site (easily identifiable bony landmark) to block each targeted geniculate nerve. Once the correct placement of all needles has been verified and confirmed by a strict frontal and profile image, a mixture of 02 ml of lidocaine 2% + 20 mg of triamcinolone is injected at

each site to block each geniculate nerve for group 1 and 2 mL of 6% glycerinated phenol solution for group 2.

1.2.7 Adverse effect

Adverse effects and complications were very rarely observed in studies [79]. This is a technique with almost no significant danger [79]. Very rare cases of superficial hematoma at the injection site and one case of local skin burn have been reported [80]. Although very rare, we will report any adverse effects or complications that may occur during our study.

For phenol: As with other interventional procedures, common complications include pain on injection, bleeding, and infection. There may be damage to the skin and necrosis of surrounding muscles, blood vessels, and soft tissues. An accidental intravascular injection may cause tinnitus and flushing.

1.3. measurement tools

1.3.1 Pain measurement:

Pain rating scales include Visual Analog Scale (VAS), the Numerical Rating Scale (NRS), and the Verbal Rating Scale (VRS) [26].

- The numerical rating scales

The numerical rating scale is the simplest and most commonly used pain measurement scale [81]. In this scale, the patient picks (verbal version) or draws a circle around the number that best describes the pain dimension, usually intensity. The numbers from zero representing “no pain”, to 10 representing “the worst imaginable pain.” (Appendix 9.1). Advantages of the NRS include simplicity, reproducibility, easy comprehensibility, and sensitivity to small changes in pain. It can also be administered through telephone calls, justifying our use in this study [27]. Studies have shown a high correlation between the numerical rating scale and the visual analog scale [27]. Its interpretation is similar to the visual analog scale.

Table II :NRS interpretation

| Score | Interpretation |
|--------|----------------|
| [0,4[| Mild |
| [4,8[| Moderate |
| [8,10] | Severe |

1.3.2 Knee function

Measurement tools used for assessing the knee function include :International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS) [28].

OKS [28]:

Brief questionnaire for patients undergoing total knee replacement (TKR) that reflected the patient's assessment of their knee-related health status and benefits of treatment. A new version was proposed on the basis that some surgeons believed that the scoring of the original version was nonintuitive (i.e., lower scores represented better outcome, higher scores represented worse outcome), where the original 12 items are used but the scoring is different. Single index pertaining to knee pain and function (pain severity, mobility, limping, stairs, standing after sitting, kneeling, giving way, sleep, personal hygiene, housework, shopping, and transport). Each item is followed by 5 responses (scores ranging from 15), where 1 = best and 5 = worst outcomes. The modified version also has 5 responses to each item, but the scoring is from 0–4, where 0 = worst and 4 = best outcome Scoring—Originally, each response to each item was assigned a score from 1–5 (where 1 = no problem and 5 = significant disability). The modified version assigns a score from 0–4 (where 4 = no problem and 0 = significant disability) (Appendix 9.2). The total score is calculated as the sum of scores from responses to all 12 items.

In the original version, the total score ranges from 12–60, while in the modified version the total score ranges from 0–48. Higher scores in the original version reflect poor outcome and lower scores reflect better outcomes. In the modified version, this is reversed Ability to detect change—The OKS demonstrates good sensitivity and responsiveness to change (Table 2). Large effect sizes have been reported 6–12 months after TKR. The OKS has also been found to be a good predictor of revision TKR within 6 months. The minimum clinically important difference (MCID) and patient-acceptable symptom state have not been reported.

Strengths: The OKS is a self-administered questionnaire developed to measure outcome following TKR. Due to simplicity and ease of administering, it has been used widely. For the same reasons, it can be used as a cost-effective screening tool in short-term (<2 years) follow-up of TKR compared to physician administered instruments. Although simple, some items are “double barreled” and may be confusing to patients (e.g., trouble getting in and out of a car or using public transportation). Some response options potentially overlap with others, which may also cause confusion. The use of an aggregate score combining pain and function may mask changes in 1 domain, particularly given that only 1 of the 12 items relates solely to pain.

WOMAC

To assess the course of disease or response to treatment in patients with knee or hip osteoarthritis Initially developed in 1982, the WOMAC has undergone multiple revisions. It has Three subscales: 1) pain severity during various positions or movements (5items), 2) severity of joint stiffness, and 3) difficulty performing daily functional activities

In the Likert version, each item offers 5 responses: “none” scored as 0, “mild” as 1, “moderate” as 2, “severe” as 3, and “extreme” as 4 (see Appendix 9.3). Alternatively, the VAS and numerical rating scale versions permit responses to be selected on a 100-mm or 11-box horizontal scale, respectively, with the left end marked as “none” and the right end marked as “extreme.

Method of administration: Self-administered or interview-administered questionnaire. It has been validated for use in person, over the telephone, or electronically via a computer or mobile phone Scoring—The total score for each subscale is the sum of scores for each response to each item, and can be calculated manually or using a computer. The range for possible subscale scores in the Likert format is: pain (0–20; 5 items each scored 0–4), stiffness (2 items, 08), and physical function (17 items, 0–68). In the VAS format, the ranges for the 3 subscale scores are: pain, 0–500; stiffness, 0–200; and physical function, 0–1,700 Higher scores indicate worse pain, stiffness, or physical function.

Ability to detect change: The WOMAC appears to be responsive to change following surgical and nonsurgical interventions for knee OA and chondral defects. In patients with knee OA, large effect sizes are consistently reported on all 3 subscales up to 2 years post-TKR. Following exercise intervention, the stiffness subscale shows small effect sizes at 2 weeks compared to moderate to large effect sizes for the pain and function subscales; however, these also are small at 6 months he WOMAC is one of the most commonly used patient-reported outcomes for knee OA. It is simple and quick to administer and score using guidelines provided.

1.3.3 Gait parameters

- **10-meter walk test**

The 10-meter walk test (10MWT) is a simple, quick, and widely used assessment to measure walking speed and gait in patients with various conditions, including those with knee problems. It is especially useful in evaluating mobility and functional status in individuals with knee osteoarthritis, after knee surgery, or other knee-related issues (Appendix 11).

Overview

Purpose: The 10MWT assesses walking speed over a short distance, providing insights into a patient's functional mobility, balance, and gait efficiency.

Population: It is commonly used in patients with knee osteoarthritis, post-knee surgery patients, and those with other mobility impairments.

Procedure

Setup: A 10-meter walkway is marked with clear start and finish lines. Two additional meters are marked at the beginning and end for acceleration and deceleration, making the total distance 14 meters.

Instructions: The patient is asked to walk at their comfortable walking speed from the start line to the finish line. Timing starts when the toes cross the 2-meter mark and stops when the toes cross the 12-meter mark. The test can also be performed at the patient's maximum walking speed, if assessing both comfortable and maximum speeds.

Trials: Typically, two trials are conducted, and the average time is taken. Walking aids can be used if needed, but should be consistent across trials and assessments.

Calculation: Walking speed is calculated by dividing the distance (10 meters) by the time taken to walk that distance (in seconds).

Interpretation

Speed Categories:

Walking speeds are categorized to assess functional mobility. Common benchmarks include:

- Less than 0.4 m/s: Household ambulator
- 0.4-0.8 m/s: Limited community ambulator
- Greater than 0.8 m/s: Community ambulator

Clinical Relevance:

Changes in walking speed can indicate improvements or declines in mobility. A 0.1 m/s change is considered clinically meaningful in various populations.

Applications

Knee Osteoarthritis: Useful in evaluating the impact of interventions like physical therapy, medication, or surgery on walking ability. Helps in monitoring disease progression and treatment efficacy.

Post-Knee Surgery: Assesses recovery progress and functional outcomes after knee surgeries, such as total knee arthroplasty. Guides rehabilitation and return-to-activity planning.

Research: Utilized in clinical trials to evaluate the effectiveness of new treatments or interventions aimed at improving knee function.

- **6-Minute Walk Test**

The 6-Minute Walk Test (6MWT) is commonly used to assess functional capacity and endurance in patients with knee conditions, such as knee osteoarthritis or post-knee surgery (e.g., total knee arthroplasty). It provides valuable information about the impact of knee problems on a patient's ability to perform daily activities that require walking (Appendix 11).

Overview

Purpose: To evaluate the impact of knee conditions on walking capacity, endurance, and functional mobility.

Population: Particularly useful for patients with knee osteoarthritis, those recovering from knee surgeries, and individuals with other knee-related impairments.

Procedure

Setup: A flat, straight, 30-meter course is ideal, but shorter distances with multiple turns are acceptable if space is limited. Clear markings every 3 meters for distance measurement. Use of a stopwatch or timer.

Instructions: The patient is instructed to walk back and forth along the marked course for six minutes. The goal is to walk as far as possible in six minutes. Patients can slow down, stop, and rest if necessary but should resume walking as soon as they are able. Standardized encouragement can be provided to ensure consistency.

Safety Considerations: Ensure the environment is free of obstacles and safe. Monitor the patient for signs of distress. Have emergency equipment and personnel available if necessary.

Measurement

Distance: The primary outcome is the total distance walked in six minutes (6MWD), measured in meters.

Vital Signs and Symptoms: Optional but recommended: monitor heart rate, blood pressure, and oxygen saturation before and after the test. Record patient-reported symptoms such as pain, fatigue, and dyspnea using scales like the Borg Scale.

Interpretation

Distance Benchmarks: Reference values and benchmarks for 6MWD vary based on age, sex, and health status. Decreases in 6MWD can indicate worsening knee function or mobility limitations.

Clinical Relevance: The 6MWT can track changes in functional mobility over time, particularly before and after interventions such as physical therapy, surgery, or medication. Improvements in 6MWD are associated with better functional outcomes and quality of life.

Applications for Knee Conditions

Knee Osteoarthritis: The 6MWT helps evaluate the functional limitations caused by pain, stiffness, and reduced mobility. Used to monitor the effectiveness of treatments like exercise programs, pharmacotherapy, and joint injections.

Post-Knee Surgery: Assess recovery progress following knee surgeries such as total knee arthroplasty. Helps guide rehabilitation programs and determine readiness for increased physical activity.

Rehabilitation and Treatment Planning: Provides baseline and follow-up data to tailor individual rehabilitation programs. Helps in setting realistic goals and expectations for patients.

1.3.4 Quality of life (QOL)

Definition:

Quality of life as defined by the World-Health Organization in 1994, is “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. Quality of life is an important endpoint in medical and health research, as it is used as a criterion integrated into health evaluation be it in assessing the consequences of pathologies or in comparing different treatment strategies [82,83]. The concept arose from the necessity to measure outcomes beyond morbidity and mortality, and became increasingly important in health care as medical treatment became able to extend length of life, sometimes at the expense of quality of life or improve quality of life without extending length of life.

Evaluation of quality of life

As earlier stated, quality of life assessment should encompass both subjective and objective components. It should cover physical (physical activity, autonomy), psychological (anxiety, depression, emotion), relational (family, social, professional) and clinical components (disease and treatment outcomes) amongst others. With regards to this, there is no universal tool used in the evaluation of quality of life but broadly speaking, QOL could be evaluated directly or indirectly.

Qualitative (direct): This is done by interview. It enables global assessment. However, it is expensive, difficult to standardize and to compare especially for large populations.

Quantitative (indirect): This is done using well defined psychometric tools in the form of scales or questionnaires which could be self-administered. Though it is more restrictive, it is easy to use and could be standardized.

Questionnaires could be generic or condition-specific, enabling a rating in the form of an overall score called an index (profile providing a global view) or to give an analytical view of quality of life, i.e. for each dimension explored.

Generic questionnaires used in QOL evaluation

These questionnaires can be used in different populations (ill or not ill) and enable comparison of the quality of life of subjects with different diseases. However, they lack sensitivity when it comes to assessing changes in quality of life over time (cohort studies). The most commonly used generic questionnaires include: The Medical Outcomes Study Short Form Survey (MOS SF-36) [82] with 36 items grouped into 8 sections: physical

activity, physical limitation/state, physical pain, perceived health, vitality, life/relationships, psychological health, psychological limitation/state The Nottingham Health Profile (NHP) [82] which has two parts. The first part includes 38 items divided into six categories: sleep, physical mobility, energy, pain, emotional reactions, and social isolation. The second part includes seven statements related to the areas of life most affected by health: employment, household activities, social life, home life, sex life, hobbies and interests, and holidays. The European Questionnaire-5 Dimensions-3 Levels (EQ-5D-3L) [82], a 5-item questionnaire comprising assessment of: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression with three levels of severity per item. The WHO Quality of Life assessment (WHOQOL) [83] with 100 items grouped into 6 broad domains: physical, psychological, level of independence, social relationships, environment and spirituality/religion/personal beliefs. The WHOQOL BREF [83] with 26 items grouped into 4 domains: overall QOL and health, physical health, psychological health, social relationships and environment. It can be contextualized to a given setting.

Condition-specific questionnaires used in QOL evaluation

Condition-specific questionnaires pertain to a particular disease (e.g lumbar spinal stenosis, etc.), specialty (neurology, rheumatology, etc.) or symptom (back pain, fatigue, etc.). They are more sensitive to change than generic questionnaires, but comparing results between different populations is more difficult.

Quality of life evaluation in GNB

Quantitative Analgesic Questionnaire (QAQ) [32]:

This is a structured tool used to systematically capture information about a patient's use of analgesic medication. It collects detailed data on the type, dosage, frequency and duration of analgesic use providing a comprehensive overview of a patient's pain management regimen. Typically includes sections of various classes of analgesics such as NSAIDs, opioids, and adjuvant medications like antidepressants and anticonvulsants. The questionnaire can be administered in different settings, including clinical visits, research studies or via self-reporting. It is designed to be straight forward and user-friendly facilitating accurate and consistent data collection.

The QAQ comprises a questionnaire and a scoring system. The questionnaire asks the participant to report the number of days per week a medication was taken and the number of pills per day. The resulting QAQ questionnaire has three sections (A, B, and C) as illustrated in Appendix 9.4. Part A asks the patient to quantify oral medication use in a usual week, Part

B inquires about use of fentanyl or buprenorphine patches, and Part C asks the patient to list any topical agents

QAQ scores are calculated from the questionnaire as follows:

1. The total amount of each individual drug taken per week is calculated (dosage days per week pills per day).
2. The values calculated in Step 1 for opioids are converted into equivalent mg of oral morphine and summed. The values calculated in Step 1 for all other oral medications are converted into percentage of maximum recommended dose according to the product labeling (percentages may be greater or less than 100%).
3. The values calculated in Step 2 are converted into points. One point is assigned for taking any opioids at all, and an additional point is assigned for every equivalent of 100 mg of oral morphine used per week (e.g., 1-99 mg = 1 point; 100-199 = 2 points, etc.). For all other oral medications, one point is assigned for taking the medication at all, and an additional point is assigned for each 25% of the maximum dose taken (e.g., 1%-24% = 1 point; 25%-49% = 2 points, etc.). For topicals, one point is assigned for each topical the patient reports using (e.g., lidocaine patch) regardless of dose or frequency.
4. A total score is then generated by summing all the points from Step 3.

Example

For chronic knee pain a patient takes diclofenac 50mg*2/day for 7 days, acetaminophen 500mg*4/day for 7 days and tramadol 50mg*3/day for 7 days

We convert tramadol dosage to morphine milligram equivalent: conversion factor 0.1, weekly dosage 1050mg = 105mg of morphine

Assigning points based on dosage

-Diclofenac = 3 points

-Acetaminophen = 3 points

-Tramadol = 3 points

Total QAQ score :9

12-item Short Form Health Survey (SF-12) [30]

The SF-12 Health survey is a widely used tool for measuring health related quality of life.it is derived from the SF-36 health survey and provides a concise, yet comprehensive assessment of physical and mental health. The SF-12 particularly valuable in clinical practice and research due to its brevity and ease of administration. The SF-12 was developed to create a shorter version of the SF-36 which is a more extensive health survey containing 36 items. The goal was to maintain the reliability and validity of the sf-36 while reducing the burden on

respondents. It includes 12 questions that cover the same eight health domains as sf-36: physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional health and mental health. Consist of 12 items that are answered based on respondent's self-assessment of their health over the past 4 weeks (see Appendix 9.5). The items are a mix of multiple-choice questions and scaled responses, covering various aspects of physical and mental health. Sf-12 consist of two components: the physical component summary and the mental component summary. The scores are derived using a weighted algorithm that takes into account the responses to all 12 items. The PCS and MCS are standardized to a mean of 50. In research the sf-12 is employed to measure outcomes in clinical trials and epidemiological studies.

Advantages: Much shorter than sf-36 reducing burden and time required for completion.

Limitations: less detailed and subject to cultural sensitivity.

Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance 4a

The Patient-Reported Outcomes Measurement Information System (PROMIS) is a set of measures designed to evaluate and monitor physical, mental, and social health in adults and children. PROMIS tools are developed through rigorous research to ensure they are reliable and valid for assessing a wide range of health domains.

PROMIS Overview

Purpose: PROMIS aims to provide precise, efficient, and comprehensive measures of patient-reported health status for clinical research and practice.

Domains: PROMIS covers multiple domains, including physical health (e.g., pain, fatigue), mental health (e.g., anxiety, depression), and social health (e.g., social roles and activities).

Instruments: PROMIS instruments include short forms, computerized adaptive tests (CATs), and profiles. These are used to assess various health domains efficiently and accurately.

PROMIS Sleep Disturbance Measures

The PROMIS Sleep Disturbance instruments evaluate the extent and impact of sleep-related problems such as difficulty falling asleep, staying asleep, and overall sleep quality. These measures help in understanding how sleep disturbances affect individuals' overall health and daily functioning.

PROMIS Sleep Disturbance 4a

The PROMIS Sleep Disturbance 4a is a short form specifically designed to measure sleep disturbance. It consists of four items that capture key aspects of sleep quality and problems (Appendix 9.7).

Items: The 4a short form includes four questions, each focused on a different aspect of sleep disturbance.

Response Options: Each question typically has five response options, ranging from "Not at all" to "Very much" or similar scales.

Scoring: Responses are scored based on a pre-determined scoring algorithm, with higher scores indicating greater sleep disturbance.

Domains Covered: Difficulty falling asleep, Trouble staying asleep, Overall sleep quality and Satisfaction with sleep.

Example Questions

The PROMIS Sleep Disturbance 4a may include questions such as: "In the past 7 days, I had difficulty falling asleep.", "In the past 7 days, I had trouble staying asleep.", "In the past 7 days, my sleep was refreshing." or "In the past 7 days, I had trouble sleeping."

Administration and Use:

Population: The PROMIS Sleep Disturbance 4a can be used in various populations, including those with chronic health conditions, mental health issues, or other sleep-related concerns.

Settings: It is used in both clinical and research settings to monitor sleep disturbance over time or evaluate the effectiveness of interventions.

Benefits: The short form is quick to administer, making it practical for use in busy clinical environments or large-scale studies.

Interpretation

Scoring and Interpretation: Scores typically range from 1 to 20 with higher scores indicating poor sleep quality.

Clinical Use: Clinicians can use these scores to identify patients needing further evaluation or intervention for sleep problems, track changes over time, and assess the impact of treatments.

research.

Patient Global Impression of Change (PGIC) [31]

The Patient Global Impression of Change (PGIC) is a widely used patient-reported outcome measure in clinical trials and healthcare settings. It assesses a patient's overall perception of improvement or change in their condition over time.

Overview

Purpose: The PGIC measures a patient's self-assessment of change in their condition, usually after an intervention or over a specified period.

Importance: It provides a global index of treatment efficacy from the patient's perspective, complementing clinical and objective measures of health.

Structure

Single Item Scale: PGIC typically consists of a single question asking patients to rate their overall change in condition (Appendix 9.6).

Response Options: The scale usually includes seven response options: Very much improved, Much improved, Minimally improved, No change, Minimally worse, Much worse, Very much worse.

Administration

Timing: PGIC is administered at follow-up visits or at the end of a clinical trial to assess perceived changes from baseline.

Population: It can be used across various patient populations and conditions, including chronic pain, psychiatric disorders, and neurological diseases.

Example Question

"Since the beginning of the treatment, how would you describe the change (if any) in your overall condition?"

Interpretation

Scoring: The responses are ordinal, with higher scores indicating greater perceived improvement.

Clinical Use: Clinicians use PGIC to gauge patient satisfaction with treatment and to identify significant changes in patient-reported outcomes.

Research Use: Researchers use PGIC to complement other outcome measures and to capture the patient's perspective on the efficacy of interventions.

Advantages

Simplicity: The single-item nature of PGIC makes it easy to administer and interpret.

Patient-Centered: It focuses on the patient's own perception of change, which is crucial for patient-centered care.

Versatility: Applicable to a wide range of conditions and treatments.

Limitations

Subjectivity: As a subjective measure, it may be influenced by patient expectations, mood, and other personal factors.

Lack of Specificity: Being a global measure, it does not provide detailed information about specific symptoms or domains of health.

Central Sensitization Inventory (CSI) [33]:

The Central Sensitization Inventory (CSI) is a self-report questionnaire designed to assess symptoms related to central sensitization (CS), a condition in which the central nervous system becomes hyper-responsive, leading to heightened sensitivity to pain and other stimuli. Central sensitization is a key feature of various chronic pain conditions, such as fibromyalgia, chronic fatigue syndrome, and irritable bowel syndrome.

Overview

Purpose: The CSI aims to identify patients who may have central sensitization syndrome (CSS), helping to guide diagnosis and treatment strategies for chronic pain conditions.

Domains: The CSI covers a range of symptoms associated with central sensitization, including pain, fatigue, sleep disturbances, and emotional distress.

Structure

Sections: The CSI consists of two parts (see Appendix 9.8):

Part A: Contains 25 items that assess the severity of symptoms related to central sensitization.

Part B: Contains questions about previous diagnoses of CSS-related conditions (e.g., fibromyalgia, irritable bowel syndrome).

Response Options: Each item in Part A is rated on a 5-point Likert scale:

0: Never

1: Rarely

2: Sometimes

3: Often

4: Always

Scoring: The total score for Part A ranges from 0 to 100, with higher scores indicating a greater severity of symptoms related to central sensitization.

Example Items from Part A

"I feel tired and unrefreshed when I wake from sleeping."

"My muscles feel stiff and achy."

"I feel anxious and nervous."

"I have headaches."

Interpretation

Scoring Interpretation:

0-29: Subclinical symptoms

30-39: Mild symptoms

40-49: Moderate symptoms

50-59: Severe symptoms

60-100: Extreme symptoms

Clinical Use: Clinicians use the CSI to screen for central sensitization in patients with chronic pain and to monitor symptom changes over time. It can help tailor treatment plans that address the specific needs of patients with CSS.

Research Use: The CSI is used in research to study the prevalence and impact of central sensitization in various populations and to evaluate the effectiveness of interventions aimed at reducing central sensitization symptoms.

Advantages

Comprehensive: Covers a broad range of symptoms associated with central sensitization.

Patient-Friendly: Easy for patients to understand and complete.

Diagnostic Aid: Helps in identifying patients who may benefit from specific treatments targeting central sensitization.

Limitations

Subjectivity: As a self-report measure, the CSI relies on patient perceptions, which can be influenced by various factors.

Overlap: Symptoms of central sensitization can overlap with other conditions, potentially complicating the diagnostic process.

2.State of the art

➤ In America:

In 2023 in USA at Tertiary Academic Medical Center, a retrospective and observational cohort study was done on consecutive patients who had undergone genicular nerve chemical neurolysis > 3 months prior. At the time of follow-up 9 months post procedure, 43.5% of patients reported > 50% sustained pain reduction. On patient global impression of change assessment 45.9% of participants reported themselves to be ‘very much improved’. Of participants taking opioids at baseline, 11 (27.5%) ceased use [23].

In 2023 in USA, case series of Genicular nerve neurolysis with phenol for chronic knee pain showed that genicular nerve neurolysis has potential to add increased benefits of low cost, ease of procedure, less logistical support and potential for more widespread neurolysis compared to RFA. Molecule mostly used was neurolytic agent phenol. Immediately post procedure 75-100% overall pain relief was obtained [40].

In 2019 in Sao Paolo, Brazil and Toronto, Canada a prospective study going from August 2018-2019 was carried on 43 patients with advanced KOA and pain intensity score (NRS) > 4 who underwent genicular nerve neurolysis with phenol. They were assessed at 2 weeks, 1-, 2-, 3- and 6-month following intervention and the results showed improvement in NRS and WOMAC scores at all time points. WOMAC score improved from 48.7 to 20.7 at 6 month follow up [65].

➤ In Asia:

In 2023 a clinical trial was performed in Ankara, Turkey on 64 patients comparing the efficacy of genicular nerve phenol neurolysis and RFA for knee pain management. The patients were divided into two groups; group 1 (GNB with 2ml phenol) and group 2 (RFA 80°C temperature for 60sec). the study showed that both RFA and phenol neurolysis provided effective analgesia at 1week, 1 and 3 months compared to baseline. Also there was significant difference in terms of NRS and WOMAC scores at all measurement times [66].

➤ **In Africa:**

In 2020 an experimental study was carried in Mansoura University in Egypt on 46 patients with advanced KOA from October 2019 to September 2020.they were divided into 2 groups; group 1 (GNB with corticosteroids) and group 2 (phenol neurolysis). NRS and WOMAC scores improved significantly in group 2 up to 6 months while group 1 for only 1 month [24] .

In Cameroon we did not find a study on genicular neurolysis with phenol. However, a randomized controlled trial was done in 2019-2020. The study was carried on 55 patients divides into 2 groups; group I (GNB with corticosteroids using classical sites) and group II (GNB with corticosteroids using revised targets). The results showed in group II greater reduction in NRS mean score at 1-hour post-intervention of 2.46±2.1 vs 0.46±0.9, 95. The proportion of patients achieving more than 50% knee pain reduction was higher in group II at each follow up interval, yet these differences were statistically significant only at 1-hour post intervention (82.1% vs 100%). Both protocols resulted in significant pain reduction and joint function improvement up to 12 weeks post-intervention [25].

CHAPTER III- METHODOLOGY

1.Study design

- Interventional
- Double-blind, randomized control clinical trial (RCT)

2.Study Setting:

The study was carried out in 2 hospitals in Yaoundé; Yaoundé General Hospital (HGY) and Yaoundé Central Hospital (YCH). Recruitment was done YCH and YGH. GNB and genicular neurolysis were done at Yaoundé General Hospital.

3.Study period and duration

The total duration of the study was 12 months from July 2023 to June 2024. Data collection was from the 1st of October 2023 to the 31st of May 2024.

4.Study Population

Target Population: Individuals with knee pain who sought consultations at the Yaounde Central Hospital and the Yaounde General Hospital.

Source Population: Individuals with knee pain who sought consultations in the orthopedic and rheumatology departments of the Yaounde Central Hospital and the Yaounde General Hospital.

4.1. Inclusion criteria

- Age 18 years or above at the time of the study
- Chronic knee pain greater than 3 months, with NRS > 5/10;
- Diagnosis of knee osteoarthritis (confirmed by the report of a radiologist), stage 3 to 4 of Kellgren–Lawrence;
- No scheduled knee surgery in the last 03 months

- Patient having benefited from at least one well-conducted conservative treatment in their lifetime (NSAIDs, Visco-supplementation, Corticosteroids, physiotherapy, orthoses) without satisfaction for 1month
- Acceptance to take part in the study

4.2. Non-inclusion criteria

- Acute knee pain with signs of local inflammation
- Skin lesions at treatment sites
- Visco-supplementation or corticosteroid therapy carried out less than 3 months previously
- Lumbar Radiculopathy
- Known connective tissue disease of the knee
- Follow-up for neuropsychiatric disorders
- Anticoagulant treatment in progress
- Cardiac pacemaker
- Patient with complex regional pain syndrome

4.3. Exclusion Criteria

- Patient loss to follow-up

5.Sample size

The sample size was estimated based on:

- Primary assessment criteria: mean change in pain score (measured by the visual numerical rating scale (NRS)) between the pre-intervention assessment and the assessment at 1-month post-intervention (“ Δ NRS”).
- Minimal clinically important change (MDIC) for NRS score: 1.7 [84,85]
- Accuracy: 1.3 [84]
- Power: 90%
- Bilateral test

From Cohen's formula [86]

$$n = \frac{2 \times (Z\alpha/2 + Z\beta)^2 \times \sigma^2}{\Delta}$$

Given :

- Significance level (α) = 0.05 (for a two-tailed test, corresponding to $Z_{\alpha/2}=1.96$)
- Power (1 - β) = 0.90 (corresponding to $Z_{\beta}=1.28$ for a two-tailed test)

- Minimal clinically important change (Δ) = 1.7
- Standard deviation (σ) = 1.3

$$n = \frac{2 \times (1.96 + 1.28) \times (1.3)^2}{(1.7)^2}$$

n≈12.21

The minimal sample size for the study was estimated to **13 patients per group** and we estimated a patient drop out of 10%. We aimed to ensure the study's scientific integrity and generate meaningful results. If no satisfactory results were attained after 3months post intervention a new treatment modality had to be proposed to the participant like orthoses, foot wear, physical therapy and intra articular injection.

Minimal number of participants for this study: **26**

6. Resources

Human resources: The supervising team was made up of our director, professor of rheumatology and two codirectors, one orthopedic surgeon and one rheumatologist. We were also assisted by other orthopedist, the nursing staff at the different study sites, and a statistician. Data collection was done by the principal investigator.

Material resources

For patient evaluation: A stop watch, a decameter, an electronic pedometer, a goniometer

For the intervention: Phenol solution 6%, Triamcinolone 20mg, Lidocaine 1%, Sterile Gloves, cotton, alcohol, yellow povidone, red povidone, 10ml syringe, forceps, Fluoroscopic Image Intensifier, sterile gauze, surgical marker.

For data collection and analysis: A computer; Software (IBM SPSS 26.0), a USB (Universal Serial Bus) key; Office equipment: A4 paper reams, printer, pens, pencils, erasers

Financial resources

This study was financed by personal funds with support of the research team

7. Study procedure

7.1 Outline

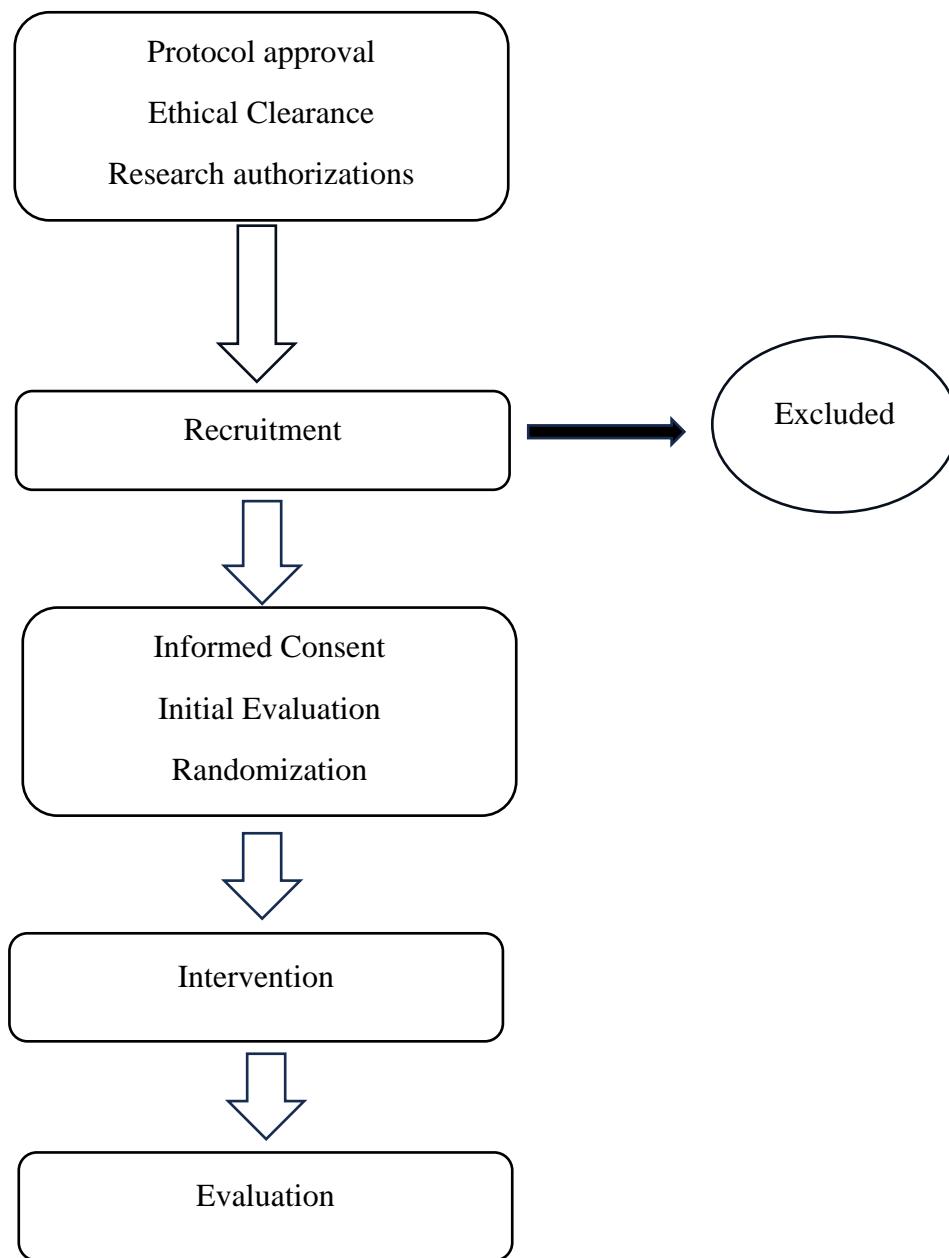


Figure 12 Study procedure

7.2 Research authorizations

Before implementation, this study received approval from the Cameroonian National Ethics Committee for Research for Human Health (Appendix 2). We obtained ethical clearance from the Institutional Review Board (IRB) of the Faculty of Medicine and

Biomedical Sciences of the University of Yaounde I (Appendix 1), and administrative authorizations from the Directors of the YCH and YGH (Appendix 3 and 4)

7.3 Voluntary patient sampling

After submitting our protocol and obtaining authorizations from the Directors of the study sites. Patients who were identified during consultations were connected with ZE BESSALA Kevin Donald, whose contact details are as follows: Tel: 00237 698298152, E-mail: bessalazeh@gmail.com. The investigators were to assess the patients based on the inclusion and exclusion criteria. Afterward, they were provided with detailed explanations both orally and in written form to the patients, as outlined in the patient information (see appendix) document. If the patients agreed to participate in the study, the investigators were to obtain their free and informed consent, both orally and in written form, as stipulated in the informed consent form (see appendix). From then, they were directed to YGH for the initial evaluation and intervention

7.4 Sampling (Randomization and double blinding)

To establish a fair comparison between both groups, consecutively recruited patients were randomly assigned to one of two treatment groups. The randomization process was conducted by a researcher who was not involved in either the evaluations or the treatments. The process was both independent and balanced, with blocks of four patients being assigned in each round. Consequently, each patient had to select one of four sealed envelopes containing the code for their treatment group. The envelope had to be opened only by the interventionist doctor in the treatment room, and the code was recorded without the knowledge of the patient or investigators.

To maintain consistency between groups throughout follow-up, both the patients and evaluators remained unaware of which treatment group they belonged to. The same procedures were applied to both groups, including the application of identical dressings to the knees of all patients after the procedure was complete.

7.5 Patient withdrawal from the study

Patients have the right to withdraw from the study at any point, for any reason. In the case of withdrawal after the intervention, the baseline and evaluation data already obtained will be used in the analysis. The patient will continue to receive follow-up care from their doctor. If withdrawal occurs prior to the procedure, the patient will receive standard care from their doctor and will not be included in the analysis. To maintain group balance and treatment blinding, the withdrawn patient will be replaced.

7.6 Treatment administration: intervention

The interventionist pain physician (Dr Loïc Fonkoue) was solely responsible for performing the procedure. Using both techniques, he performed the geniculate blocks. In the operating room, he would open a sealed envelope to determine which treatment group the patient belongs to. The doctor had to record the patient's treatment code and proceeded to perform the treatment according to the patient's group assignment, all while remaining unbiased and blinded to the patient and the evaluating doctors.

Intervention Group (PHEN Group): Neurolysis with 2ml of 6% glycerinated phenol solution

Control group (CORT Group): GNB using 2ml of lidocaine 1% and 20mg of triamcinolone

7.7 Evaluation

Each patient was evaluated before and after the intervention. The main investigator (ZE BESSALA Kevin 7th year medical student) of the study conducted the evaluations while remaining unaware of the patient's treatment group. The physician also analyzed the patient's walking using the standard protocol provided in the appendix. The investigations will focus on (see details in appendix). The evaluation schedule is shown in Table

- Pain: NRS
- Knee function: WOMAC, OKS
- Consumption of pain medications: QAQ
- Pain central sensitization intensity: CSI
- Quality of life: SF- 12, PROMIS 4a,
- Patient's global satisfaction: PGIC
- Quantitative analysis of walking: 10 meters test, 6 min walking test

Tableau III: Evaluation Schedule

| | Pre-treatment (H0) | H1 | D 1 | D 7 | D 30 |
|--|-------------------------------|-----------|------------|------------|-------------|
| Socio-demographic and clinical data collection sheet | χ | | | | |
| Numeric rating scale | χ | χ | ✗ | ✗ | χ |
| Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) | χ | | | | χ |
| Oxford Knee Score (OKS) | χ | | | | χ |
| Quantitative Analgesic Questionnaire (QAQ) | χ | | | | χ |
| Central sensitization inventory | χ | | | | |
| Patient Global Impression Scale of change (PGIC) | | | | ✗ | χ |
| 12-Item Short Form Health Survey (SF-12) | χ | | | | χ |
| PROMIS | χ | | | ✗ | χ |
| Quantitative analysis of walking (QAW) | χ | χ | | | |

χ: face-to-face assessment; ✗: telephone assessment; H1: 1st hour after treatment; D1: 1st day after treatment; D 30: Thirty days (01 month) after treatment;

Patients completed the questionnaires themselves or with the assistance of an interpreter if needed. Objective monitoring of treatment effects on gait was conducted through quantified gait analysis, which utilizes validated low-cost methods such as the 10-meters and 6-minute walking tests.

7.8 Outcome Measures

At the end of the study, we expected to get;

- **Reduction in Knee Pain Intensity:** The primary outcome measure was the change in knee pain intensity from baseline to 30 days post-intervention, assessed using the Numerical Rating Scale (NRS). Participants rate their knee pain on a scale of 0 to 10, with higher scores indicating greater pain intensity. The mean change in NRS from baseline to follow-up was compared between the corticosteroid and phenol treatment groups.
- **Improvement in Knee Function:** Knee function was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the 10-meters and the 6-minute walking tests. The WOMAC questionnaire evaluates pain, stiffness, and physical function related to knee osteoarthritis. Changes in WOMAC scores from baseline to 30 days post-intervention were compared between treatment groups.
- **Patient-Reported Outcomes:** Participants completed a satisfaction survey and a quality-of-life questionnaire (i.e. SF-12 score, PGIC score,) to assess their subjective experiences and perceived benefits of treatment. Patient-reported outcomes were compared between the corticosteroid and phenol groups to determine treatment preferences and satisfaction levels.
- **Adverse Events and Complications:** Adverse events related to genicular nerve blockade, such as injection site reactions or systemic side effects, were monitored throughout the study period. The incidence and severity of adverse event were compared between treatment groups to evaluate the safety profile of corticosteroid and phenol injections.
- **Duration of Pain Relief:** The duration of pain relief following genicular nerve blockade was assessed by tracking the time to recurrence of knee pain or the need for additional pain management interventions. Kaplan-Meier analysis was used to estimate the cumulative probability of sustained pain relief over time in each treatment group.

- **Health Resource Utilization:** Healthcare resource utilization, including the use of pain medications, and utilization of physical therapy services, was recorded for each participant using the QAQ score. Healthcare resource utilization was compared between the corticosteroid and phenol groups to assess the economic implications of each treatment strategy.

7.9 Judgement Criteria

- **Efficacy:** The efficacy of genicular nerve blockade with corticosteroids versus phenol was evaluated based on the magnitude of pain reduction (an improvement of more than 50% reduction in NRS), improvement in knee function, and patient-reported outcomes. The treatment group demonstrating superior efficacy in achieving meaningful improvements in pain relief and functional outcomes was considered more effective.
- **Safety:** The safety of genicular nerve blockade with corticosteroids versus phenol was assessed based on the incidence and severity of adverse events and complications. The treatment group with a lower incidence of adverse events and a more favorable safety profile was considered safer for patients.

8.Data Management and Analysis

Data was encoded and analyzed using SPSS version 26.0 software. Charts were made in Microsoft Excel 2016.

Qualitative variables were expressed as frequencies and percentages, while quantitative variables were expressed as means and standard deviations. To compare the average pain score before treatment and at 1-month post-treatment in each group, we used a t-test for paired data. A two-way repeated measures ANOVA (group × time) was used to compare the mean scores at different times of the evaluation in each group, followed, if necessary, by post hoc tests with Bonferroni or Tukey correction.

- To compare the variations in scores between the 2 treatment groups, we used the non-parametric Mann-Whitney U test.
- For comparison of categorical data, we used the Chi-square test or Fischer's exact test.
- For all our analyses, the significance threshold was set at 5%.

9.Ethical Considerations

The study was conducted in accordance with guidelines governing human research as stated in the Nuremberg code of 1947 and the Helsinki declaration of 1964 revised in October 2013. Research authorizations were obtained from the Directors of the YCH and YGH

Ethical clearance was obtained from the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences of the University of Yaounde I N° 1012 (Appendix 1) and the center regional Ethics Committee for Human Health Research. N°000854 (Appendix 2)

Prior to participation in this study, each patient's consent was obtained freely and voluntarily, both orally and in written form, after the investigators had fully disclosed all pertinent details. The patient first provided with a comprehensive information document (located in the appendices) before making any decisions. Both the patient and investigator signed and dated the informed consent form before the patient could be included in the study, with the patient also receiving a copy for their records.

The protection of personal data was ensured by the law in force in Cameroon and in Europe (General European regulation on the protection of personal data [GERPPD] of May 25, 2018). Personal data was anonymized. Subjects were not identified by name or in any other recognizable manner in any of the files, results or publications relating to the experiment. We authorized monitoring, verifications, review and regulatory inspections from competent authorities related to the experimentation, allowing direct access to the basic data/documents and complete confidentiality.

Adverse effects and complications were very rarely observed in studies [22,25]. This is a technique with almost no significant danger [22]. Very rare cases of superficial hematoma at the injection site and one case of local skin burn have been reported [24]. Although very rare, we reported any adverse effects or complications that occurred during our study. Patients with post injection superficial hematoma were managed with an alcoholic dressing. For burns special ointments were locally applied on the burn site. Patients participating in the study benefitted from the management of their pain through an innovative, potentially very effective and minimally restrictive, non-drug therapeutic method that could considerably reduce their dependence on analgesics and significantly improve their quality of life. The injections were carried out free of charge for participants, as were the follow-up consultations for the duration of their participation in the study.

CHAPTER IV-RESULTS

1.Enrolment Profile

From the October 1st, 2023 to May 31st, 2024, our study at YGH and YCH involved 54 patients who sought consultation for chronic knee pain. For selected patients, genicular nerve blocks were done at the YGH following our protocol. Out of the initial sample, 28 patients were not included for various reasons, such as lumbar radiculopathy (11), Kellgren and Lawrence grade 1 and 2 knee osteoarthritis (9), refusal to participate (7) and recent infiltration treatment (1). The remaining 26 patients agreed to participate in the study and were randomized into the two treatment groups: GNB with corticosteroids (14 patients) and GNB with phenol (12 patients). All participants received their respective treatments successfully and completed the follow-up as outlined in the consort diagram (Figure 13).

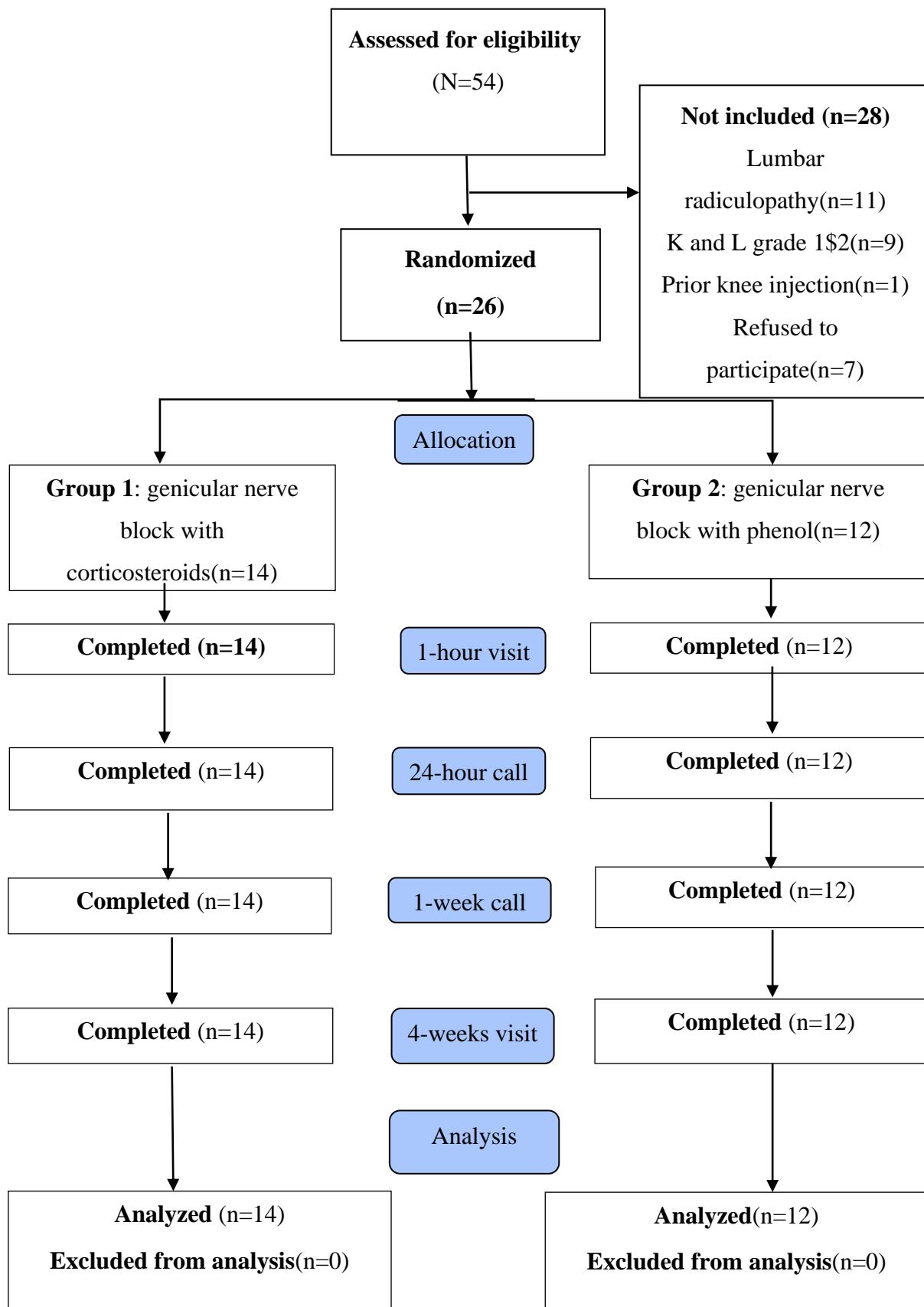


Figure 13: Consort Diagram

2.Characteristics of the study population

2.1 Socio-demographic profile

2.1.1 Age

The mean age of the participants at the time of the intervention was 66.1 ± 10.9 years with extreme values 43 years and 84 years. The mean age of the participants allocated to CORT-group was 63.0 ± 10.4 years and to the PHEN-group 70.6 ± 10.7 years ($p=0.165$) (figure 14).

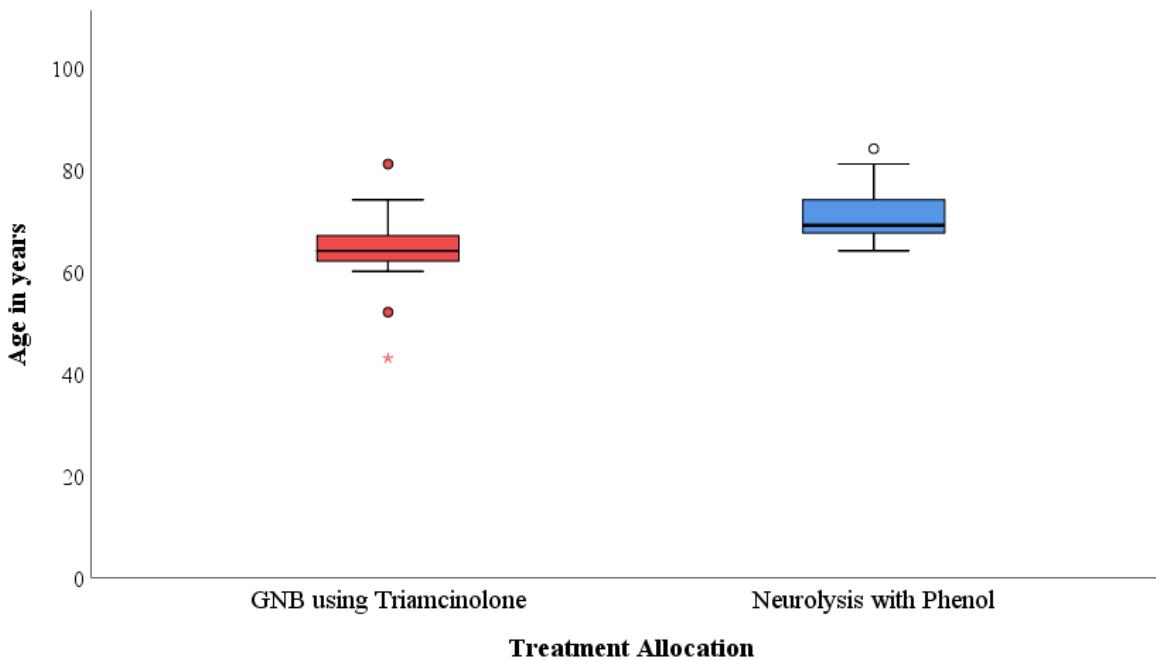


Figure 14 .Distribution of Age in Corticosteroid and Phenol Treatment Groups

2.1.2 Sex distribution

Of the participants 88.46% were female with a sex ratio of 0.1. The sex distribution (M/F) was as such: 1 (7.1%) / 13 (92.9%) in the corticosteroid group and 2 (16.7%) / 10 (83.3%) in the phenol group There was no significant difference in treatment allocation between both genders ($p=0.440$) (Figure 15).

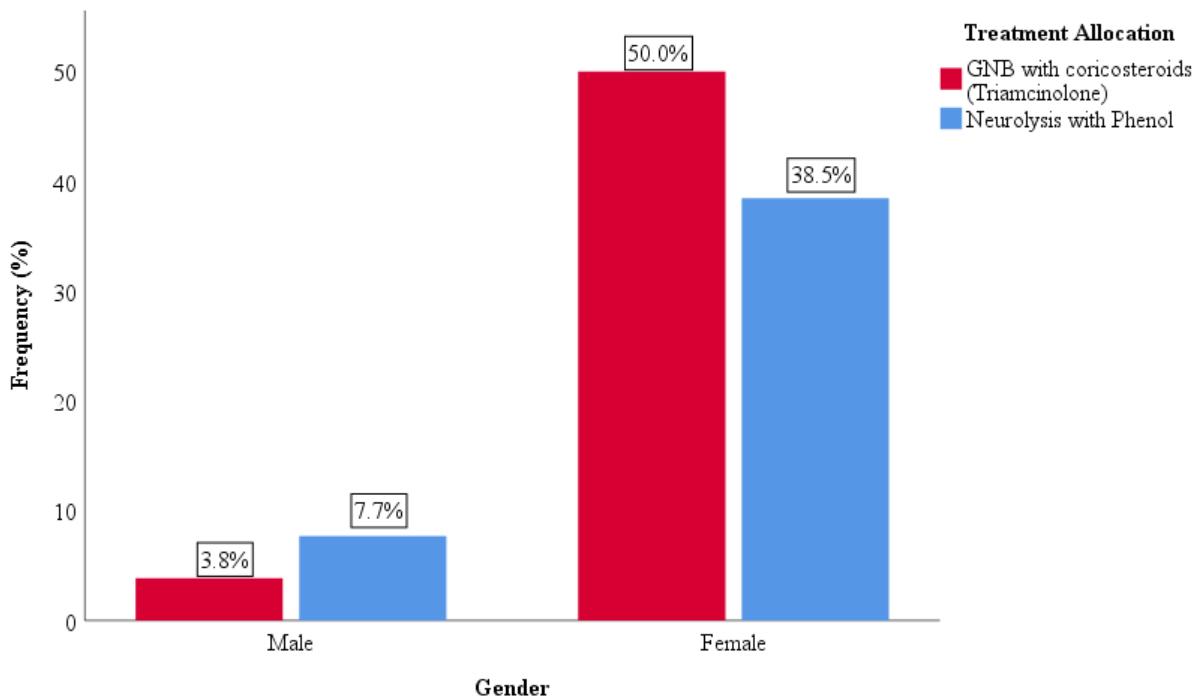


Figure 15 Gender Distribution Between Treatment Groups

2.1.3 Level of Education and Occupation

Of the participants 41.7% had completed their education at the secondary education and 41.2% of the participants enrolled in this study were farmers. There were no significant differences in level of education ($p=0.112$) and profession ($p=0.962$).

2.2 Clinical Profile and Baseline Characteristics

2.2.1 Clinical Profile

2.1.1.1 Comorbidities and Body Mass Index (BMI)

The mean BMI was $33.7 \pm 5.3 \text{ kg/m}^2$ with extreme values of 25.2 to 44.2 kg/m^2 , and 76.5%. were obese. There were no significant differences in BMI between both treatment groups regarding BMI ($p = 0.756$). The only comorbidity present among the participants was hypertension (15.4%). The distribution of BMI within each treatment group is shown in Table IV.

Table IV Comorbidities and BMI

| Variables | GNB with Corticosteroid (triamcinolone) | Neurolysis with Phenol | P-value |
|--------------------------------|--|---------------------------|---------|
| Body mass index (Kg/m2) | 33.3 ± 6.2 | 34.2 ± 4.1 | 0.736 |
| Hypertension | 1(0.7) | 3(25.0) | 0.651 |

2.2.1.2 Knees treated, Pain duration and Severity of Disease

Overall, 16 (70.6%) received bilateral knee treatment, 8 (23.5%) received left knee treatment and 2 (5.9%) on the right knee giving a total of 42 knees treated. Distribution of treated knees between both treatment groups is illustrated in Table V. For the Kellgren-Lawrence severity ;16 (64.7%) had grade 4 and 10 (35.3) had grade 3 knee severity and distribution between both groups is shown in Table V. There was no significant effect of duration of pain and disease severity on group allocation with p-values of 0.441 and 0.664 respectively. (Table V)

Table V Distribution of Treated Knees, Pain duration and disease severity

| Variables | GNB with Corticosteroid (triamcinolone) | Neurolysis with Phenol | P-value |
|--------------------------------------|---|---------------------------|---------|
| Knees Treated (n=42) | | | 0.1 |
| Left | 6 (42.9) | 2 (16.7) | |
| Right | 0 (0) | 2 (16.7) | |
| Bilateral | 8 (57.1) | 8 (66.6) | |
| Duration of Knee pain(months) | 63.5 ± 7.5.8 | 94.9 ± 86.8 | 0.441 |
| Kellgren-Lawrence Grade | | 0.644 | |
| 3 | 5 (35.7) | 5 (41.6) | |
| 4 | 9 (64.3) | 7 (68.4) | |

2.2.2 Baseline Characteristics

The baseline characteristics for each treatment group can be seen in Table VI. There were no significant differences between both treatment groups regarding, pain score, OKS, WOMAC score, CSI score, analgesic consumption, PROMIS 4a, SF-12 and walking tests (Table VI).

Table VI Baseline characteristics per group

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|--|-----------------------------------|---|---------|
| NRS score | 8.8 ± 0.8 | 8.57 ± 0.8 | 0.565 |
| Central sensitization | | | |
| index | 30.8 ± 8.0 | 28.3 ± 8.1 | 0.536 |
| OKS | 19.90 ± 3.8 | 19.3 ± 3.3 | 0.731 |
| WOMAC | 66.8 ± 14.0 | 56.7 ± 16.6 | 0.195 |
| SF-12 score | | | |
| Physical | 32.4 ± 2.0 | 32.4 ± 1.8 | 0.976 |
| Mental | 39.7 ± 5.1 | 41.6 ± 0.6 | 0.365 |
| QAO score | 4.0 ± 0.9 | 4.9 ± 0.4 | 0.059 |
| PROMIS 4a | 14.3 ± 1.6 | 14.6 ± 1.4 | 0.726 |
| 10-meter test | | | |
| Normal speed | 15.3 ± 7.2 | 18.6 ± 7.3 | 0.540 |
| Max speed | 12.8 ± 7.2 | 14.7 ± 9.0 | 0.679 |
| Step Cadence | | | |
| (steps/second) | 1.30 ± 0.3 | 0.9 ± 0.7 | 0.108 |
| 6min walking test | | | |
| Distance travelled | 214.5 ± 62.2 | 208.3 ± 46.2 | 0.905 |
| Number of times stopped during test | 4.2 ± 2.5 | 5.0 ± 3.7 | 0.583 |
| PCI | 0.7 ± 0.7 | 0.8 ± 0.4 | 0.537 |
| Joint mobility of the knee(degrees) | | | |
| | 101.2 ± 9.2 | 100.1 ± 9.5 | 0.463 |

Key: NRS: Numerical Rating Scale; OKS: Oxford Knee Score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; SF-12:12 item short form health survey

3.Efficacy of GNB with corticosteroids versus phenol on knee pain

Overall, the mean NRS before treatment was 8.71 ± 0.8 with extremes 8 and 10. At 1 hour post intervention the NRS in the corticosteroid group was 1.2 ± 0.9 with extremes 0 and 3, in the phenol group 0.4 ± 1.1 with extremes of 0 and 3. There were no significant differences between both groups ($p= 0.142$) at 1 hour. At 1 day the NRS in the corticosteroid group was 1.9 ± 0.7 with extremes 1 and 3, in the phenol group 1.3 ± 1.9 with extremes 0 and 4. There were no significant differences between both groups at day 1 ($p=0.362$). At week 1 NRS in the corticosteroid group was 2.6 ± 0.8 with extremes 1 and 4 and in the phenol group 1.4 ± 1.6 with extremes 0 and 5. There was no significant difference between both groups at week 1 post intervention ($p=0.069$). At 1 month the NRS in the corticosteroid group was 3.7 ± 1.1 with extremes 2 and 5 and in the phenol group 2.0 ± 0.8 with extremes 1 and 3. There was a statistically significant difference between both treatment groups at 1-month post-intervention (**$p=0.003$**). Furthermore, the NRS mean scores differences at 1-hour, day-1, week-1 and week 4 post intervention were 8.2, 7.3, 7.2 and 6.6 respectively in the phenol group and in the corticosteroid, group was 7.6, 6.9, 6.2 and 5.1 respectively. Figure 16 illustrates the changes in NRS with time from baseline throughout the measurement time points in both treatment groups.

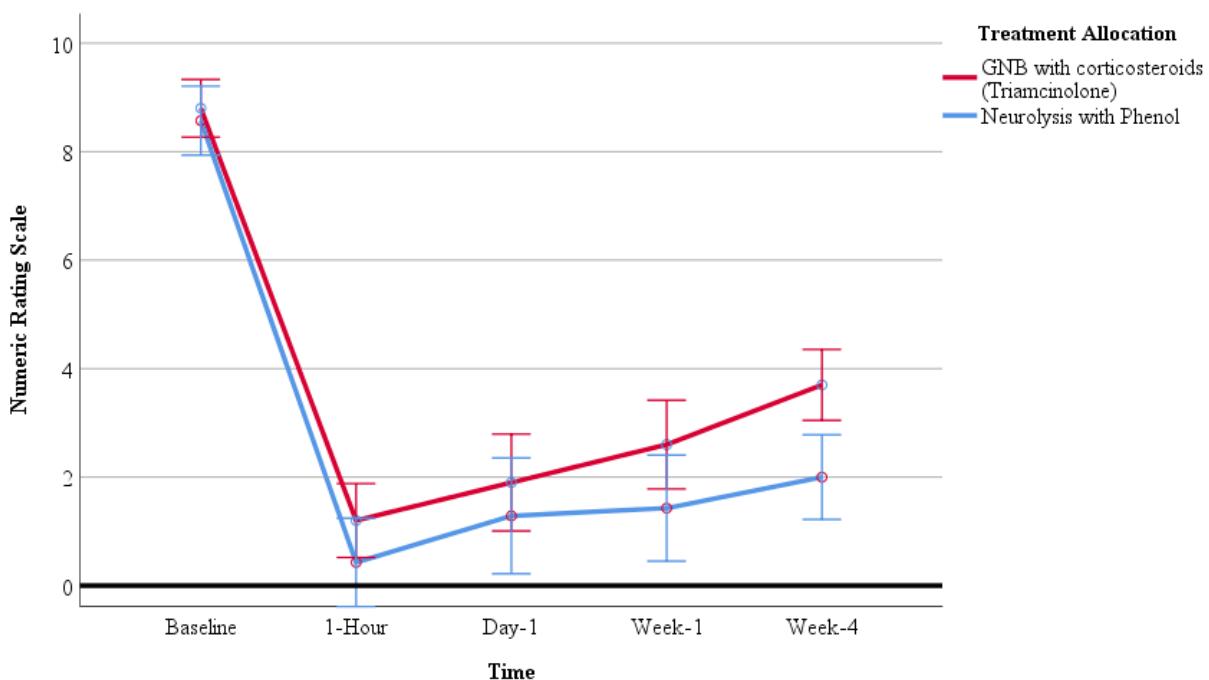


Figure 16 NRS Score Evolution

4. Comparison of the effect of GNB with corticosteroids versus phenol on knee function and gait parameters

4.1 knee function

Oxford Knee score

The mean OKS at baseline was 19.65 ± 3.5 with extremes of 15 and 28. Results for OKS 4 weeks after the intervention are shown in table VII. The OKS of participants in the corticosteroid group had a mean difference of 19.5 compared to baseline and those in the phenol group a mean difference of 22. There were no significant differences in the OKS values between both treatment ($p=0.294$) (table VII)

Table VII OKS evolution over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|------------|-----------------------------------|---|---------|
| OKS | | | |
| Baseline | 19.9 ± 3.8 | 19.3 ± 3.3 | 0.731 |
| Week-4 | 39.4 ± 3.6 | 41.3 ± 3.4 | 0.294 |

Key: OKS: Oxford Knee Score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

Figure 17 illustrates the change in the OKS values in both treatment groups from baseline evaluation to 4 weeks post intervention.

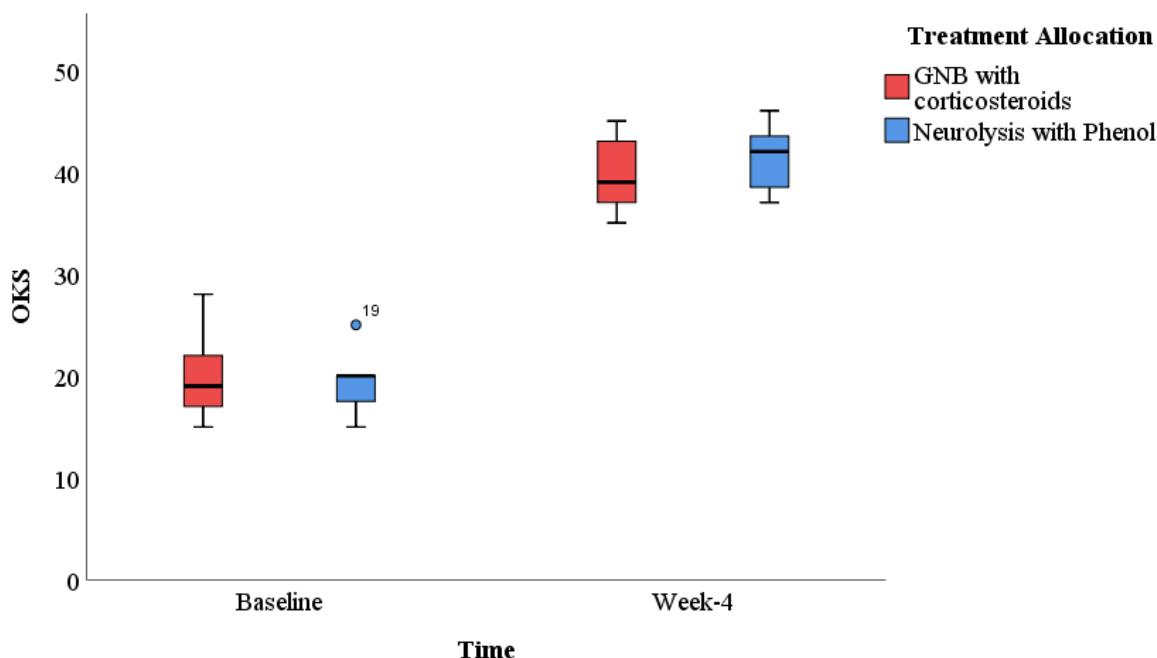


Figure 17 OKS Evolution Over Time

WOMAC score

The mean WOMAC scores at baseline was 62.7 ± 15.5 with extremes of 41.0 and 86.0. Table VIII shows the values of WOMAC score in both treatment groups before and after treatment. The mean difference in WOMAC total score in the corticosteroid group and phenol group was respectively 58.3 and 49.7. There were no significant differences in the WOMAC total score between both treatment groups at Week-4 ($p=0.138$). (Figure 18 and table VIII)

Table VIII WOMAC Evolution

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|--------------------------|--------------------------------|--|---------|
| WOMAC total score | | | |
| Baseline | 66.8 ± 14.0 | 56.7 ± 16.6 | 0.195 |
| Week-4 | 8.5 ± 2.3 | 7.0 ± 1.3 | 0.138 |

Key: WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

Figure 18 illustrates the evolution of WOMAC score after GNB with corticosteroids and phenol

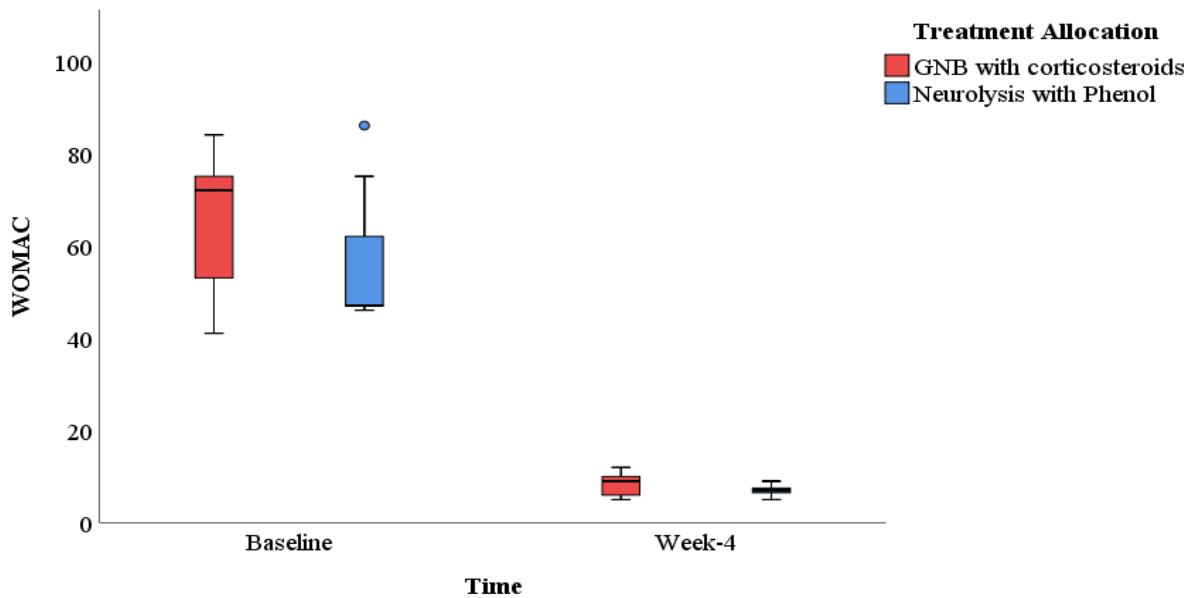


Figure 18: WOMAC Score Over Time

4.2 Gait parameters

4.2.1 10-meters test

Average duration

The average duration at baseline was 16.7 ± 10.7 with extremes of 10.3 and 50.5. As shown in table IX shows the effects of GNB on duration during the 10 meter test at normal pace and at maximum pace. The average duration at 10-meter test was not significantly different between both groups at 4 weeks post intervention (Normal speed, $p=0.333$; Max speed, $p=0.646$) (Table IX).

Step Cadence

Initial step cadence was 1.2 ± 0.5 with extremes of 0.0 and 1.92). Values of the step cadence between both treatment groups are shown in table X. There was a significant difference in step cadence between both groups at 4 weeks post intervention (**$p=0.022$**) (Figure 20 and Table IX)

Table IX 10-meter walk test

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|--------------------------------|-----------------------------------|---|--------------|
| 10-meter test | | | |
| Normal speed (m/s) | | | |
| Baseline | 15.3 ± 7.2 | 18.6 ± 7.3 | 0.540 |
| Week-4 | 10.9 ± 1.9 | 9.77 ± 2.6 | 0.333 |
| Max speed (m/s) | | | |
| Baseline | 12.8 ± 7.2 | 14.7 ± 9.0 | 0.679 |
| Week-4 | 9.2 ± 2.5 | 8.5 ± 3.0 | 0.646 |
| Step Cadence (steps/second) | | | |
| Baseline | 1.30 ± 0.3 | 0.9 ± 0.7 | 0.108 |
| Week-4 | 1.7 ± 0.2 | 1.9 ± 0.1 | 0.022 |

Figure 20 shows the evolution of step cadence before and after intervention in both treatment groups.

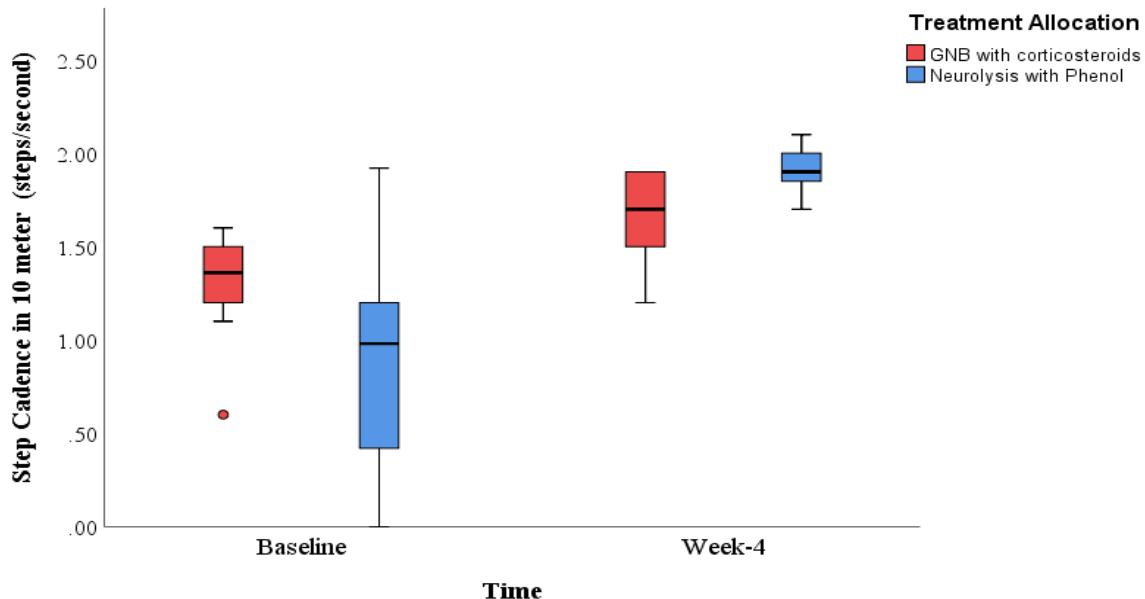


Figure 19: Step Cadence Change

4.2.2 6-minutes Walking Test

Distance Travelled

Initially the distance travelled was 211.9 ± 101 with extremes of 0 and 350. There was a change in distance travelled in 6 minutes within both groups at 4 weeks with corticosteroid group from 214.5 ± 62.2 meters to 307.0 ± 50 meters and the phenol group from 208.3 ± 46.2 meters to 322.9 ± 47.9 meters. The mean difference between the distance travelled at 4 weeks post intervention and baseline of the corticosteroid and phenol group were 92.5 and 114.6 meters respectively. The distance travelled was not significantly different between both groups at 4 weeks ($p=0.524$) (Table X).

Number of Times Stopped

The number of times stopped during the 6 minutes walk test is shown on table X. There were no significant differences in the number of times stopped between both treatment groups at 4 weeks ($p=0.953$) (Table X).

Table X 6-minute walk test

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|--------------------------|-----------------------------------|---|---------|
| 6min walking test | | | |
| Distance travelled (m) | | | |
| Baseline | 214.5 ± 62.2 | 208.3 ± 146.2 | 0.905 |
| Week-4 | 307.0 ± 50 | 322.9 ± 47.85 | 0.524 |
| Number of times stopped | | | |
| Baseline | 4.2 ± 2.5 | 5.0 ± 3.7 | 0.583 |
| Week-4 | 0.9 ± 1.1 | 0.9 ± 1.9 | 0.953 |

4.2.3 Joint mobility of the Knee

Table Xi below shows the effect of GNB on the range of motion of the knee within both groups at 4 weeks. The range of motion was not significantly different between both groups at 4 weeks ($p=0.32$) (Table XI).

Table XI Joint Mobility

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|--|-----------------------------------|---|---------|
| Joint mobility of the knee(degrees) | | | |
| Baseline | | | |
| Week-4 | 101.2 ± 9.2 | 100.1 ± 9.5 | 0.463 |
| Week-4 | 116.5 ± 8.3 | 120.9 ± 9.1 | 0.32 |

5. Comparison of the effect of GNB with corticosteroids vs phenol on quality of life

Pain Medication Consumption

In all the participants the mean QAQ score was 4.35 ± 0.9 with extremes 3 and 5. The analgesic consumption at 4-weeks follow-up in both groups is given in table XII (Figure 18). There was a change in the consumption of pain medication in corticosteroid group from 4.7 ± 0.9 to 1.6 ± 1.1 (mean difference=3.1) and phenol group from 4.9 ± 0.4 to 0.7 ± 0.5 (mean difference=4.2). No significant difference was found in QAQ score in both groups ($p=0.166$) (Table XII).

Table XII QAQ over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|------------------|-----------------------------------|---|---------|
| QAQ score | | | |
| Baseline | | | |
| Week-4 | 4.7 ± 0.9 | 4.9 ± 0.4 | 0.069 |
| Week-4 | 1.6 ± 1.1 | 0.71 ± 0.5 | 0.166 |

Key : QAQ : Quantitative Analgesic Questionnaire

Figure 20 below illustrates the change in pain medication consumption of patients at 4 weeks post intervention

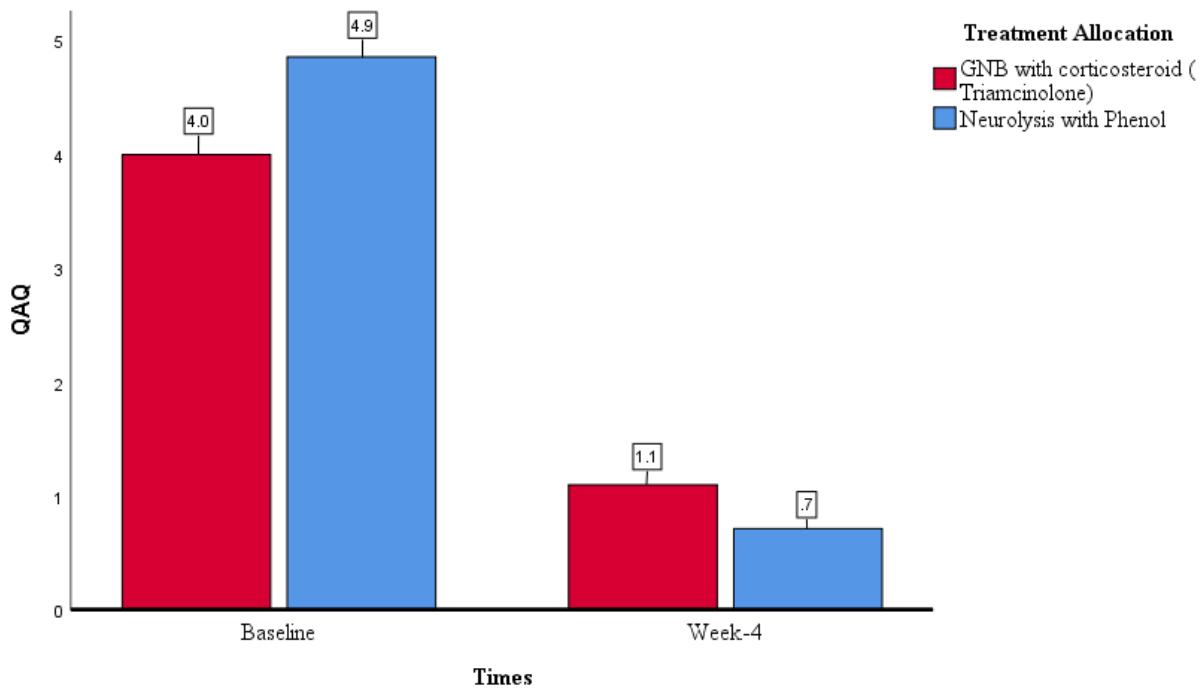


Figure 20: QAQ Score Over Time

Short Form Health Survey (SF-12)

Both Mental and Physical SF-12 scores post intervention are shown in table XIII. There were no significant differences in SF-12 mental summary ($p=0.108$) at 4 weeks post intervention. However, there was a significant difference in the physical score at 4 weeks post intervention($p=0.016$) (Table XIII).

Table XIII SF-12 over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|-----------------------------|--------------------------------|--|--------------|
| SF-12 Physical score | | | |
| Baseline | 32.4 ± 2.0 | 32.4 ± 1.8 | 0.976 |
| Week-4 | 37.4 ± 3.0 | 40.6 ± 1.0 | 0.016 |
| SF-12 Mental score | | | |
| Baseline | 39.7 ± 5.1 | 41.6 ± 0.6 | 0.365 |
| Week-4 | 46.4 ± 1.5 | 47.4 ± 0.4 | 0.108 |

Patient Global Impression of Change

There was an improvement in patient global impression of change within both groups at 4 weeks post intervention. The PGIC score was not significantly different between both groups at 4 weeks nor for both groups between week 1 and week 4 ($p=0.138$) (Table XIV)

Table XIV PGIC over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|-------------|-----------------------------------|---|---------|
| PGIC | | | |
| Week-1 | 6.7 ± 0.2 | 6.5 ± 0.5 | 0.244 |
| Week-4 | 6.4 ± 0.3 | 6.8 ± 0.2 | 0.138 |

Key: PGIC: Patient Global Impression of Change;

Quality of sleep

Overall initial PROMIS 4a was 14.4 ± 1.5 with extremes 12 and 16. Results obtained for PROMIS sleep disturbance 4a at 1 week and 4 weeks post intervention are shown in table XV. There were no significant differences between each treatment group on changes in PROMIS 4a scores at 1 week and 4 weeks ($p=0.302$ and $p=0.174$ respectively)

Table XV Quality of life over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|------------------|-----------------------------------|---|---------|
| PROMIS 4a | | | |
| Baseline | 14.3 ± 1.6 | 14.6 ± 1.4 | 0.726 |
| Week-1 | 8.2 ± 3.4 | 6.4 ± 3.3 | 0.302 |
| Week-4 | 7.2 ± 2.8 | 5.3 ± 2.6 | 0.174 |

Key: PROMIS: Patient-Reported Outcomes Measurement Information System

Figure 21 illustrates the evolution of PROMIS 4a at all evaluation periods from baseline to 4 weeks post intervention.

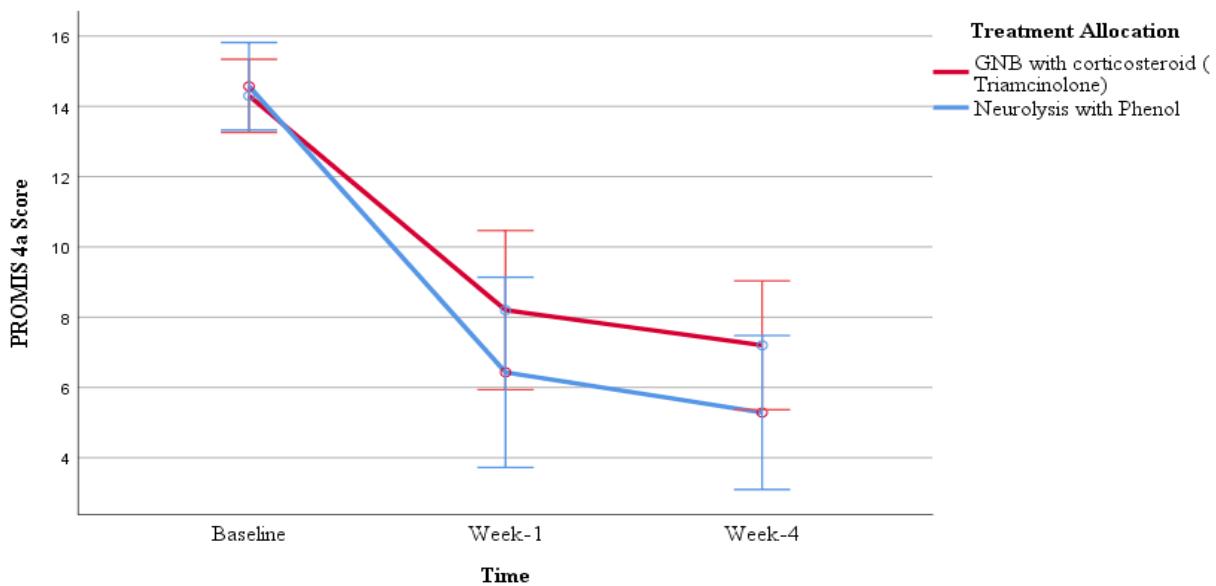


Figure 21: PROMIS 4a Change over Time

Central Sensitization Index

Initially the CSI in participants was 29.8 ± 7.9 with extremes 17 and 44. Results comparing CSI at baseline and 4 weeks post intervention are shown in table X. There was a statistically significant difference in CSI values between both treatment groups at 4 weeks ($p=0.008$) (Table VI)

Table XVI Quality of life over time

| | GNB with corticosteroids(n=14) | Genicular Neurolysis with phenol(n=12) | P-value |
|------------------------------------|--------------------------------|--|--------------|
| Central sensitization index | | | |
| index | | | |
| Baseline | 30.8 ± 8.0 | 28.29 ± 8.1 | 0.536 |
| Week-4 | 23.3 ± 6.8 | 14.86 ± 3.1 | 0.008 |

6. Adverse Effects

Although no major adverse effects were observed during our study, 1 participant in the CORT-group had hypopigmentation of the skin and 1 participant of the PHEN-group had hyperpigmentation of the skin. Both were located at the injection site of the infrapatellar branch of the saphenous nerve.

CHAPTER V-DISCUSSION

To our knowledge, our study is the first comparing GNB with the revised anatomical target sites using corticosteroids and neurolysis with phenol in patients with chronic knee osteoarthritis pain. The aim of our study was to compare the effectiveness of GNB with corticosteroids versus phenol for the management of chronic knee osteoarthritis pain in Yaoundé. Following a double blinded randomized clinical trial over a period of 8 months, we enrolled 54 patients and included 26 patients in our final sample. These patients were randomized and allocated into two groups; a CORT-group for GNB with corticosteroids and a PHEN-group for genicular neurolysis with phenol.

In our setting, the results of the study comparing GNB with corticosteroids and genicular nerve neurolysis with phenol showed that: corticosteroids had an analgesic effect comparable to that of phenol for the management of osteoarthritis knee pain for the first hour to the seventh day post intervention. However, at 4 weeks post intervention phenol showed a significantly greater analgesic effect compared to corticosteroids (**p=0.003**). Although both treatment protocols showed a significant improvement in the WOMAC scores, OKS, pain medication consumption, quality of life and knee function, participants to who received phenol showed a greater improvement in these aspects.

The main limitations of our study were the short follow-up period of the patients (one month) and the sample size (26 patients). Taking these factors into consideration would be important in bringing about the long-term applicability and generalizability of our results. Moreover, the WOMAC scores were not taken into subgroups to assess how the treatment groups separately affected. Data according to personal patient past history was not taken into much consideration. This could help determine the outcome of the treatment while being affected by the patient's comorbidity.

However, the key strengths of our study are innovative technique, balanced randomization, double blinding and lost to follow up reported. This helped ensure that selection bias was minimized and that all groups were being comparable at baseline, prevention performance bias, detection bias and attrition bias thereby guaranteeing the validity and reliability of our results.

1.Sample size

Overall, the treatment was administered to 26 patients which is approximately equal to the estimated sample size. Our sample size was different from the one obtained in clinical trials by Gokhan et al [66] in Turkey in 2023, Elashmawy et al [24] in Egypt in 2020 and

Fonkoue et al [25] in 2020 who had a sample size of 64, 46 and 55 patients respectively. This difference could be attributed to the greater accessibility of health to the population in their context and the longer period of assessment for their study. Moreover, the large number of refusals to participate to the study could be explained by the stereotyping of the population about invasive knee procedures and limb paralysis in our setting believed to affect the common fibular nerve and cause permanent limb palsy.

2.Sociodemographic profile

The mean age of patients at the time of the intervention was 63.0 ± 10.4 years for the corticosteroid group and 70.6 ± 10.4 years for the phenol group. There was no significant effect of age on group allocation (**p=0.165**). Most of the participants were women and obese with mean BMI at 33.7 ± 5.3 . These results are similar to those found by Gokhan et al [66] in Turkey in 2023 and Fonkoue et al [25] in Cameroon in 2020 who found respective BMIs of 30.9 ± 3.7 and 29.8 ± 6.2 . The higher female distribution could be explained by the reduction of estrogen after menopause which normally has positive effects on cartilage by promoting the synthesis of cartilage matrix. Furthermore, obesity is a main risk factor of knee osteoarthritis due to the increase in weight bearing force in the knees [3].

3.Clinical profile

Knee osteoarthritis is a leading cause of functional disability in our setting. In our study, the predominant site of affection of knee osteoarthritis was bilateral in both treatment groups (60% for the corticosteroid group and 85.7% for the phenol group).These results were different from the clinical trial by Fonkoue et al in Cameroon in 2020 who had a proportion of 60.7% for the control group and 46.4 for the RCT group [25].This difference could be attributed to the small sample size of our study limiting the generalizability of the affected sides. Moreover the duration of knee pain observed in our study (63.5 months for the corticosteroid group and 94.9 months for the phenol) was different from those observed from Fonkoue et al [25] in 2020 in Cameroun and Gokhan et al [66] in Turkey in 2023 who had durations of 43.30 ± 3 and 15.4 ± 2.2 months for the corticosteroid group and 14.8 ± 2.2 months for the phenol group respectively. However these results were similar to those obtained by Elashmawy et al [24] in 2020 who had a duration of 117.36 ± 21.36 months for the corticosteroid group and 110.64 ± 21.96 months .These differences could be explained by subjective response of patients without differentiation between the duration of pain and the duration of the disease.

The Kellgren-Lawrence grade of the participants was predominantly grade 4 in both treatments with participants allocated to GNB with corticosteroid having a frequency of 70% within the group and 57.1% within the phenol allocated group. These results were different from those by Fonkoue et al [25] who had respective frequency within the RT and the CT group of 46.4% grade 4 and 40.7% grade 3 and those by Elasmawy et al [24] who predominantly had grade 3 in both treatment groups with a frequency of 62.5% for corticosteroid group and 68.7% for the phenol group. This could be explained by the fact that there is no relationship between the severity of knee osteoarthritis and the intensity of the pain [2].

Knee pain

Compared to the patients who received GNB with corticosteroids, a greater pain reduction was experienced with the participants who had neurolysis with phenol. No recent studies comparing phenol neurolysis and GNB with corticosteroids evaluated the patients one hour and one day after the procedure. However, one hour after the procedure we had a significant reduction in the NRS mean score of about 8.2 in the phenol group versus 7.6 in the corticosteroid although there were no significant differences between both treatment groups one hour post intervention ($p=0.565$). Both results could be explained by the action of corticosteroids which provide analgesia by acting in the potassium channel on the nociceptive fibers through glucocorticoid receptor thereby affecting the activity of the nerve fiber. Coupled with lidocaine this enables a faster diffusion and faster onset of action of triamcinolone [25,69,72]. On the other hand, phenol at a concentration of more than 3% provide a neurolytic action by disrupting the cell membrane inducing degeneration nerve fiber by protein necrosis affecting the myelin sheath and causing axonal destruction. Prior injection with 1% lidocaine at the target sites prevents pain at the injection and enables an immediate effect of phenol [87–89]. In our study both NRS scores were significantly reduced one hour post intervention. These results showing the immediate action of phenol one hour after injection differ from the study Elashmawy et al [24] in 2020 in which phenol was stated to take at least 3-5 days post intervention for the onset of action and such had not evaluated the participants one hour post intervention.

There was a significant reduction in the NRS score in both treatment groups 1 week after intervention. There were no significant differences in the NRS score between both treatment groups 1 week after intervention ($p= 0.069$) These results were similar to those

obtained by Gokhan et al [66] in 2023 who had no significant differences 1 week post intervention. However, the mean difference between the NRS score at 1 week compared to baseline was 6.2 for the corticosteroid group and 7.1 for the phenol. Results differ from the study of the above author who respectively had mean differences of 4.0 for the corticosteroids groups and 4.5 for the phenol. This difference in the results could be attributed to the intervention in the above study being executed following the classical anatomical targets of the geniculate nerve which are the superolateral, superomedial and inferior medial genicular nerves which pass periosteal areas connecting the shaft of the femur to the bilateral epicondyles and the shaft of the tibia to the medial epicondyle [66,78] whose accuracy was discussed and revised by Fonkoue et al [15,16,25] unlike our study in which the intervention was executed following the revised targets of the genicular nerves involving more genicular nerves(5) and ensured a greater amount of the product being injected. These were the superomedial genicular nerve, superolateral, inferomedial and inferolateral genicular nerves, and the infrapatellar branch of the saphenous nerve. These revised target site provide more accuracy to the sensory innervation of the knee capsule and provide more quantity of substance to be injected as proven by Fonkoue et al [25]. Moreover the difference in the method of identifying the landmarks could also affect the accuracy of the target sites being used Gokhan et al [66] identified the landmarks using an ultrasound probe with aim of identifying the genicular arteries then estimating the location of the genicular nerves from them whereas the revised target sites in our study were identified using fluoroscopic guided images thereby enhancing the accuracy of injecting into the identified target sites.

At 4 weeks post intervention there was a significant difference between the NRS score between the treatment groups (**p=0.003**). These results were different from those obtained by Gokhan et al in 2023 with a p value of 0.421 but similar to those obtained by Elashmawy et al [24] in 2020 with p-value <0.001 4 weeks post intervention. These results could be explained by the difference in the control groups observed between both studies with one using radiofrequency ablation and the other with GNB with corticosteroids respectively. Moreover, the significant difference with the greater reduction of pain tending to the neurolysis with phenol could be explained by the different pharmacokinetic properties of both substances. Ernest M shanahan et al [8,25] in 2022 in a randomized placebo control study concluded that corticosteroid GNB pain relief was short-term. Phenol however has a longer duration of action which ranges from weeks to months depending on the quantity administered and the

concentration (phenol in glycerin has a longer duration of action than aqueous phenol which in turn has a longer duration than phenol in lipid) [73,90].

Knee function and gait parameters

In this study both treatment groups resulted in a significant overall improvement in the values of WOMAC and OKS scores 4 weeks post intervention. There were no significant differences in the previous scores between the corticosteroid group and the phenol group with respective p values 0.138 and 0.731 .These results are similar to those obtained by Gokhan et al [66] in Turkey in 2023 ($p=0.870$) but different from Elashmawy et al [24] in who had a significant difference between the WOMAC scores at 4 weeks compared to baseline ($p<0.001$).This could be explained by a longer period of study in their setting and a larger sample size compared to our study.

To our knowledge no previous studies comparing GNB with corticosteroids and neurolysis with phenol put into consideration the physical assessment of the knee function through follows up visits physical test. Participants assessment on the 10-meter test showed no significant differences between both treatment groups at 1 month post intervention. However, the step cadence in the phenol group was significantly more improved in the phenol group. Through the 6-minute walk test and the range of motion of the knee results showed no statistically significant difference between both treatment groups. These results could be attributed to both treatment group molecules (triamcinolone and phenol) not only reducing the pain through their different mechanism of actions but triamcinolone also affect the local inflammation of the knee due to osteoarthritis there improving knee mobility and reducing stiffness throughout the study.

Quality of life

There was a greater improvement in the quality of life at 4 weeks post intervention in the phenol group compared to the corticosteroid group at 1 month post intervention. However, there were no significant differences between the two treatment groups on the changes in SF-12 physical ($p=0.976$) and mental scores ($p=0.365$) and quality of sleep through the PROMIS 4a score ($p=0.726$). These results were similar to those obtained by Fonkoue et al in 2020 [25] in which both protocols experienced an overall significant improvement in the previous scores.

Furthermore, the changes in the CSI score were not measured during previous studies. In our study there was a significant difference between the two groups on the CSI scores (**p=0.008**) with greater improvement in the participants in the phenol group. This could be attributed to the greater reduction in the pain assessment scores by the phenol protocol which in turn indirectly reduce the sensitization to central pain (pain due to damage or dysfunction within the Central Nervous System (CNS)).

Adverse Effects

Compared to other studies, no major adverse effects were found. These results were different from those obtained by Gokhan et al [66] in Turkey in 2023, Elashmawy et al [24] in Egypt in 2020 and Fonkoue et al [25] in Cameroon 2020 who had local pain at injection site, hypoesthesia and swelling. This could be attributed to the interventionist orthopedic surgeon whose mastery of the technique provided exact injection to the genicular nerves with greater accuracy thereby limiting errors during the intervention. Furthermore, the change in pigmentation of the skin around the injection site of the infrapatellar branch of the saphenous nerve could be explained by the close proximity of the target site to the skin compared to other genicular nerves which are deeper. This resulted in the partial diffusion of the injected substances to the overlying skin thereby causing the pigmentation changes.

CONCLUSION

At the end of this study, a double blinded randomized controlled clinical trial conducted in Yaoundé whose aim was to compare the efficacy of GNB with corticosteroids versus neurolysis with phenol in the management of chronic knee osteoarthritis pain.

- The primary finding of this study was a statistically significant reduction in NRS scores Both groups demonstrated significant improvements compared to baseline values, suggesting that both interventions are effective in managing chronic knee OA pain, but phenol neurolysis may offer enhanced pain relief in the short term.
- Both treatment options comparably showed a great reduction in knee function and gait parameters with no great significant differences between both.
- Both treatment options improved the patient quality of life through great reduction of the pain.

These procedures have been shown to be a relevant therapeutic option in patients with chronic KOA pain in our setting. Nevertheless, further studies are needed to evaluate the long-term effect.

RECOMENDATIONS

➤ **To Practitioners:**

- Adopt a Multidisciplinary approach to knee OA management

➤ **To Researchers:**

- Conduct larger, longitudinal studies to evaluate long-term efficacy and safety of phenol.
- Investigate the comparative effectiveness of phenol neurolysis overother emerging treatments for knee OA.
- Explore patient specific factors (clinical biomarkers) that may predict response to phenol neurolysis versus corticosteroid GNB.

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APPENDIX

Appendix 1: Faculty of Medicine Ethical Clearance



Ref. : N° 1012 /UY1/FM&B/VDRC/DASSR/CSO

CLAIRANCE ÉTHIQUE **10 JUIN 2024**

Le COMITÉ INSTITUTIONNEL D'ÉTHIQUE DE LA RECHERCHE (CIER) de la FMSB a examiné

La demande de la clairance éthique soumise par :

M.Mme : ZE BESSALA KEVIN DONALD

Matricule: 17M100

Travaillant sous la direction de :

- ♦ Pr SINGWE NGANDEU Madeleine
- ♦ Dr FONKOUÉ Loïc
- ♦ Dr FOJO TALONGONG Baudelaire

Concernant le projet de recherche intitulé : **A double blinded randomized controlled trial comparing genicular nerve blockade using corticosteroids versus phenol in management of knee osteoarthritis pain in Yaoundé**

Les principales observations sont les suivantes

| | |
|---|--|
| Evaluation scientifique | |
| Evaluation de la convenance institutionnelle/valeur sociale | |
| Equilibre des risques et des bénéfices | |
| Respect du consentement libre et éclairé | |
| Respect de la vie privée et des renseignements personnels (confidentialité) : | |
| Respect de la justice dans le choix des sujets | |
| Respect des personnes vulnérables : | |
| Réduction des inconvenients/optimalisation des avantages | |
| Gestion des compensations financières des sujets | |
| Gestion des conflits d'intérêt impliquant le chercheur | |

Pour toutes ces raisons, le CIER émet un avis favorable sous réserve des modifications recommandées dans la grille d'évaluation scientifique.

L'équipe de recherche est responsable du respect du protocole approuvé et ne devra pas y apporter d'amendement sans avis favorable du CIER. Elle devra collaborer avec le CIER lorsque nécessaire, pour le suivi de la mise en œuvre dudit protocole. La clairance éthique peut être retirée en cas de non - respect de la réglementation ou des recommandations sus évoquées.

En foi de quoi la présente clairance éthique est délivrée pour servir et valoir ce que de droit



APPENDIX 2: Center Regional Ethics Committee Ethical clearance

REPUBLIQUE DU CAMEROUN
Paix - Travail - Patrie
MINISTERE DE LA SANTE PUBLIQUE
SECRETARIAT GENERAL
COMITE REGIONAL D'ETHIQUE DE LA
RECHERCHE POUR LA SANTE HUMAINE DU CENTRE
Tél : 222 21 20 87/ 677 94 48 89/ 677 75 73 30

CE N° 0008-/-/CRERSHC/2024



REPUBLIC OF CAMEROON
Peace - Work - Fatherland
MINISTRY OF PUBLIC HEALTH
SECRETARIAT GENERAL
CENTRE REGIONAL ETHICS COMMITTEE
FOR HUMAN HEALTH RESEARCH

Yaoundé, the 30 JAN 2024

ETHICAL CLEARANCE

The Centre Regional Ethics Committee for Human Health Research (CRERSH-Ce) has received the request for an ethical approval for the project entitled: "Comparison of Genicular Nerve Blockade Using Triamcinolone Versus Phenol Nerve Blockade in Management of Knee Osteoarthritis Pain in Yaoundé", submitted by Mr ZE BESSALA Kevin.

After evaluation, it appears that the subject is worthy of interest, the objectives are well defined, and the research procedure does not include invasive methods harmful to the participants. In addition, the informed consent form intended for participants is acceptable.

For these reasons, the CRERSH-Ce issued a six (06) months approval for the implementation of the current version of the protocol.

The Principal Investigator is responsible for scrupulous compliance with the protocol and must not make any amendments, however minor, without the favourable approval of the CRERSH-Ce. In addition, the Principal Investigator is required to:

- Collaborate on any descent from the CRERSH-Ce for monitoring the implementation of the approved protocol.
- And submit the final report of the study to the CRERSH-Ce and to the competent authorities concerned by the study.

This clearance may be withdrawn in the event of non-compliance with the regulations in force and the directives mentioned above.

In witness whereof the present Ethical Clearance is issued with the privileges thereunto pertaining. /-

Copy: CNERSH.

www.minsante.gov.cm



THE PRESIDENT,

Dr. Didier Bessala
Pharmacien

APPENDIX 3: General Hospital Authorization

REPUBLIQUE DU CAMEROUN
Paix - Travail - Patrie

MINISTERE DE LA SANTE PUBLIQUE

HOPITAL GENERAL DE YAOUNDE

DIRECTION GENERALE

BP 5408 YAOUNDÉ - CAMEROUN
TÉL : (237) 22 21 31 81 FAX : (237) 22 21 20 15.

N/Réf.: **13 6 - 24** /HGY/DG/DPM/APM-TR.



REPUBLIC OF CAMEROON
Peace - Work - Fatherland

MINISTRY OF PUBLIC HEALTH

YAOUNDE GENERAL HOSPITAL

GENERAL MANAGEMENT DEPARTMENT

22 FEV 2024

Yaoundé, le

Le Directeur Général

A/TO

Monsieur ZE BESSALA Kevin Donald
Etudiant en 7^{ème} année d'Etudes Médicales
Tél : (+237) 698 298 152 Mle : 17M100

FMSB - UNIVERSITE DE YAOUNDE I

Objet/subject :

V/Demande d'autorisation de recherches.

Monsieur,

Faisant suite à votre courrier du 23 janvier 2024 dont l'objet est repris en marge,

Nous marquons un avis favorable pour la réalisation de vos travaux de recherches au Service CHIRURGIE GENERALE ET VISCERALE dans le cadre de votre étude portant sur : « A Double Blinded Randomized Controlled Trial Comparing Genicular Nerve Blockade using Corticosteroids Versus Phenol in management of Knee Osteoarthritis Pain in Yaoundé », sous la supervision du Docteur FONKOUÉ Loïc, Chirurgien orthopédiste-traumatologue.

Vous observerez le règlement intérieur de l'établissement pendant la durée des recherches. Toutefois, les éventuelles publications à l'issue de ce travail devraient inclure les médecins de l'Hôpital Général de Yaoundé.

Recevez, Monsieur, nos salutations distinguées.



Le Directeur Général,

Prof. EYENGA Victor

Copies :

- DPM
- Chef Service Chirurgie Générale et Viscérale
- Archives/chrono.

APPENDIX4: Yaoundé Central Hospital Authorization



APPENDIX 5: INFORMATION LEAFLET

Title: A Double Blinded Randomized Controlled Trial Comparing Genicular Nerve Blockade using corticosteroids versus phenol in management of knee osteoarthritis pain in Yaoundé

Main Investigator: ZE BESSALA Kevin, EM7 FMSB UY1

Assistant Investigator: -Dr. FONKOUÉ Loïc, Orthopedic Surgeon – Traumatologist

-Dr FOJO Baudelaire Rheumatologist

Supervisor: Pr NGANDEU SINGWE Madeleine Physician Rheumatologist

You are invited to voluntarily participate in a clinical research study on the non-operative management of chronic knee pain related to knee osteoarthritis. Before giving your consent, it is important to read this form to find out the purpose, the legal provisions and the practical details.

Description of the study

Osteoarthritis of the knee is the leading cause of chronic knee pain. In the early phases, the treatment is conservative (non-surgical), and in the advanced phases, knee replacement (TKA) remains the standard treatment. A good number of patients continue to suffer from chronic knee pain despite well-conducted conservative treatment or a well-constructed knee replacement. In Cameroon, the problem is compounded by the fact that TKA is inaccessible to the general population, and the conservative treatment methods available are quickly outdated. The problem of chronic knee pain therefore remains an important field of research in order to find better alternative solutions.

Genicular nerve block and geniculate radiofrequency are emerging methods of conservative treatment of chronic knee pain. They are based on studies that have shown that blocking the small sensory nerves in the knee that are responsible for pain significantly relieves pain, improves knee function and improves patients' quality of life. It is a fairly simple method, not very invasive, does not require hospitalization, and does not present any major risks.

The geniculate block procedure lasts about 20 – 30 minutes and consists of giving injections at specific points in the knee where the small nerves responsible for pain are located, and administering a local anesthetic combined with a corticosteroid or phenol. Clear

pain relief is achieved immediately after the block, for a variable duration depending on the patient.

The risks are minor, the possible (very rare) adverse events that have been reported are:

- A hematoma (small collection of blood) at the injection site
- An injection site infection (never reported to our knowledge)

The precision of the anatomical identification to place the needles during the injections is the real key to the success of this therapeutic method. Recent anatomical studies suggest new anatomical landmarks that would be more accurate than those currently used.

Objectives of the study:

This clinical study will therefore compare the results of knee nerve blocks with phenol or a corticosteroid. It therefore aims to improve the management of chronic knee pain by a method that does not require the continuous use of analgesic and anti-inflammatory drugs whose harmful consequences (stomach, kidney, etc.).

Procedure:

If you voluntarily agree to participate in the study, you will be asked to sign an informed consent form.

The study concerns patients with chronic knee pain due to knee osteoarthritis who have not been relieved by other treatments.

If you give your voluntary consent to participate in the study, you will be randomly assigned to one of two treatment groups:

- Group A: Corticosteroid genicular nerve block
- Group B: geniculatar neurolysis with phenol

The procedure for the 2 techniques is similar, the only difference is in the products used. Neither you nor the principal investigator will be informed of your treatment group until the end of the study, to ensure the reliability and scientific validity of the results.

During your 1st appointment:

- You will be asked to complete questionnaires assessing pain, knee function, use of analgesic medications, quality of life. Duration : *20 – 30 minutes*.

- A quantified analysis of your walk will then be carried out *Duration: about 30 minutes*
- You will be taken to the intervention room where the infiltrations will be carried out. *Duration : about 20 minutes*
- You will again be asked to complete a questionnaire to assess your relief, and then a new walk analysis will be performed. *Duration 30 minutes.*
- You will then be able to go home, and you will be asked to stop any analgesic or anti-inflammatory treatment for the days following the block, to measure its effectiveness.
- You will be contacted by phone after 24 hours and after 7 days to assess the pain.

During your 2nd appointment, 7 days after the procedure:

- You will be asked to complete an evaluation questionnaire. *Duration : 30 minutes*

During your third appointment, 30 days after the procedure:

- You will be asked to complete an evaluation questionnaire. *Duration : 30 minutes*
- A quantified walking test will be carried out. Duration: 45 minutes.

Ethical Considerations

Your participation in this study is completely voluntary; You have the right to refuse to participate or withdraw for any reason, even after signing the informed consent form. However, the data collected up to your withdrawal will be an integral part of the study. Your refusal to participate will not result in any loss of benefits or penalties for you.

Potential benefits and risks of participating

Adverse effects and complications have been very rarely observed in the literature. This is a technique that is almost harmless and very safe. Risk of septic arthritis is low and not reported in studies yet. However, if any occurrence occurs patients will be followed up and managed

Patients participating in the study will benefit from pain management through an innovative, potentially highly effective and low-burden, non-drug therapeutic method that can significantly reduce their dependence on analgesics and significantly improve their quality of life. Infiltrations will be performed free of charge to participants, as will follow-up consultations for the duration of your participation in the study.

Protection of privacy

Your identity and participation in this study are kept strictly confidential. You will not be identified by name or in any other recognizable way in any results, communications or publications related to this study. Questionnaires and data related to this study will be kept strictly confidential; The protection of personal data is ensured by law.

Ethics Committee

This experiment is evaluated by an independent Ethics Committee, the National Committee on Research Ethics for Human Health.

Who to contact if you have any questions about the study

If you have any questions or feel that you have suffered any harm related to the study, if you wish to express concerns about the study or your rights as an independent participant at the beginning, during or at the end of the study, you may wish to contact:

The Investigators of the Study: M. ZE BESSALA

Tel +237 698 298 152

Dr Loïc Fonkoué

Tel : +237 699666757

E-mail : fonkoueloic@yahoo.fr

APPENDIX 6 INFORMED CONSENT(FRENCH)

Titre : Un Essai Clinique Contrôlé Randomisé En Double Aveugle Comparant Le bloc nerveux genicule a L'aide De Corticostéroïdes et de la Neurolyse au Phénol Dans La Prise En Charge De La Douleur Due à la Gonarthrose A Yaoundé

Investigateur Principal : ZE BESSALA Kevin, EM7 FMSB UY1

Investigateurs secondaires : Dr FONKOUÉ Loïc, Chirurgien Orthopédiste – Traumatologue

Superviseur : Pr NGANDEU SINGWE Madeleine Rhumatologue-Interniste

Vous êtes invité (e) à participer de façon volontaire à une étude dans le cadre d'une recherche clinique sur la prise en charge non opératoire des douleurs chroniques du genou, liées à une gonarthrose. Avant de donner votre consentement, il est important de lire ce formulaire pour en connaître l'objectif, les dispositions légales et les modalités pratiques.

Description et justification de l'étude

La gonarthrose est la première cause de douleurs chroniques du genou. Dans les phases précoce, le traitement est conservateur (non chirurgical), et dans les phases avancées, la prothèse du genou (PTG) reste le traitement de référence. Un bon nombre de patients continue de souffrir de douleurs chroniques du genou malgré un traitement conservateur bien conduit ou une prothèse du genou bien réalisée. Au Cameroun, le problème est d'autant plus grave que la PTG est inaccessible pour la population générale, et les méthodes de traitement conservateur disponibles sont très vite dépassées. La problématique de la douleur chronique du genou demeure donc un important champ de recherche afin d'y trouver de meilleures solutions alternatives.

Le Bloc nerveux géniculé et la radiofréquence géniculée sont des méthodes émergentes de traitement conservateur des douleurs chroniques du genou. Elles se basent sur les études qui ont démontré que bloquer les petits nerfs sensitifs du genou qui sont responsables de la douleur soulage significativement celle-ci, améliore la fonction du genou

et la qualité de vie des patients. C'est une méthode assez simple, peu invasive, qui ne nécessite pas d'hospitalisation, et ne présente pas de risque majeur.

La procédure du Bloc géniculé dure environ 20 – 30 minutes et consiste à réaliser des injections à des points précis du genou où se trouvent les petits nerfs responsables de la douleur, et d'y administrer un produit anesthésique local associé à un corticoïde ou alors du phénol. Un soulagement net de la douleur est obtenu immédiatement après le bloc, pour une durée variable selon les patients.

Les risques sont mineurs, les éventuels évènements indésirables (très rares) qui ont été rapportés sont :

- Un hématome (petite collection de sang) au site d'injection
- Une infection du site d'injection (jamais rapportée à notre connaissance)

La précision du repérage anatomique pour placer les aiguilles au cours des injections est la véritable clé de la réussite de cette méthode thérapeutique. Des études anatomiques récentes proposent de nouveaux repères anatomiques qui seraient plus précis que ceux qui sont utilisés actuellement.

Objectifs de l'étude :

Cette étude clinique va donc comparer les résultats des blocs des nerfs du genou avec du phénol ou alors un corticoïde. Elle vise donc à améliorer la prise en charge des douleurs chroniques du genou par une méthode qui ne nécessite pas la prise continue de médicaments antalgiques et antiinflammatoires dont les conséquences néfastes (estomac, rein...).

Procédure :

Si vous acceptez volontairement de participer à l'étude, il vous sera demandé de signer un formulaire de consentement éclairé.

L'étude concerne les patients souffrant de douleurs chroniques du genou due à une gonarthrose, non soulagés par d'autres traitements.

Si vous donnez votre consentement volontaire pour participer à l'étude, vous serez réparti (e) au hasard dans l'un des deux groupes de traitement :

- Groupe A : Bloc géniculé au corticoïde
- Groupe B : Bloc géniculé au phénol

La procédure pour les 2 techniques est similaire, la seule différence concerne les produits utiliser. Ni vous, ni l'investigateur principal ne serez informés de votre groupe de traitement avant la fin de l'étude, pour assurer la fiabilité et la validité scientifique des résultats.

Au cours de votre 1^{er} rendez-vous :

- Vous serez invité (e) à remplir des questionnaires évaluant douleur, la fonction du genou, la consommation de médicaments antalgiques, la qualité de vie. Durée : 20 – 30 minutes.
- Une analyse quantifiée de votre marche sera ensuite réalisée *Durée : environ 30 minutes*
- Vous serez conduit en salle interventionnelle où les infiltrations seront réalisées. *Durée : environ 20 minutes*
- Vous serez à nouveau invités à remplir un questionnaire pour évaluer votre soulagement, puis une nouvelle analyse de marche sera effectuée. *Durée 30 minutes.*
- Vous pourrez ensuite rentrer, et il vous sera demandé d'arrêter tout traitement antalgique ou antiinflammatoire pendant les jours suivant le bloc, pour en mesurer l'efficacité.
- Vous serez contacté (e) par téléphone après 24h et après 7 jours pour évaluer la douleur.

Au cours de votre 2eme rendez-vous, 7 jours après l'intervention :

- Vous serez invités à remplir un questionnaire d'évaluation. *Durée : 30 minutes*

Au cours de votre troisième rendez-vous, 30 jours après l'intervention :

- Vous serez invité à remplir un questionnaire d'évaluation. *Durée : 30 minutes*
- Une analyse quantifiée de marche sera réalisée. Durée : 45 minutes.

Considérations éthiques

Votre participation à cette étude est entièrement volontaire ; vous avez le droit de refuser d'y participer ou de vous retirer pour une raison ou une autre même après avoir signé la fiche de consentement éclairé. Toutefois, les données collectées jusqu'à votre retrait feront partie intégrante de ladite étude. Votre refus de participer n'entraînera pour vous aucune perte d'avantages ni de pénalités.

Bénéfices et risques potentiels liés à votre participation

Les effets indésirables et les complications ont été très rarement observés dans la littérature. Il s'agit d'une technique presque sans danger notable. Le risque d'arthrite septique

est faible et n'a pas encore été rapporté dans les études. Cependant, si un événement se produit, les patients seront suivis et pris en charge

Les patients participant à l'étude bénéficieront d'une prise en charge de leur douleur par un moyen thérapeutique innovant, potentiellement très efficace et peu contraignant, non médicamenteux pouvant réduire considérablement leur dépendance aux antalgiques et améliorer significativement leur qualité de vie. Les infiltrations seront réalisées gratuitement aux participants, de même que les consultations de suivi pendant la durée de votre participation à l'étude.

Protection de la vie privée

Votre identité et votre participation à cette étude demeurent strictement confidentielles. Vous ne serez pas identifié (e) par votre nom ni d'aucune autre manière reconnaissable dans des résultats ou communications ou publications en rapport avec cette étude. Les questionnaires et les données liées à cette étude seront gardés strictement confidentiels ; la protection des données personnelles étant assurée par la loi.

Comité d'éthique

Cette expérimentation est évaluée par un Comité d'Ethique indépendant, le Comité national d'Ethique de la Recherche pour la Santé Humaine.

Personnes à contacter si vous avez des questions éventuelles à propos de l'étude

Si vous avez des questions ou estimatez avoir subi un dommage lié à l'étude, si vous voulez exprimer des craintes à propos de l'étude ou concernant vos droits en tant que participant libre au début, en cours ou à la fin de l'étude, vous pourriez contacter :

Les investigateurs de l'étude : M. ZE BESSALA

Telephone +237 698 298152

Dr Loïc Fonkoué

Telephone: +237 699666757

E-mail: fonkoueloic@yahoo.fr

APPENDIX 7: INFORMED CONSENT FORM

I,Mr/Mrs./Miss

..... certifies that he has been invited to participate in the clinical research work entitled “A Double Blinded Randomized Controlled Trial Comparing Genicular Nerve Blockade using corticosteroids versus phenol in management of knee osteoarthritis pain in Yaoundé” whose principal investigator is ZE BESSALA Kevin 7th year medical student supervised by Pr NGANDEU SINGWE Madeleine-Physician Rheumatologist.

- I understand the information form that was given to me about this study
- Or someone read and explained to me the information form about this study
- I have a clear understanding of the purpose and objectives of this study
- I have received all the answers to the questions I asked
- The risks and benefits were presented to me and explained to me
- I understand that I am free to accept or refuse to participate
- My consent does not relieve the research investigators of their responsibilities, I retain all my rights guaranteed by law.

I freely agree to participate in this study under the conditions specified in the information notice, i.e.:

- Answer all questionnaires objectively and truthfully
- Cooperate in walking test
- To benefit from a peri-articular infiltration of the knee.
- Honour medical follow-up appointments

I agree that the data collected will be used for scientific purposes and for further studies.

Done at Yaoundé, on

Principal Investigator

Participant (name, address, and signature)

APPENDIX 8 : FORMULAIRE DE CONSENTEMENT ÉCLAIRÉ

Je soussigné, Mr/Mme/Mlle

..... atteste avoir été invité à participer au travail de recherche clinique intitulé « *Un Essai Clinique Contrôlé Randomisé En Double Aveugle Comparant Le bloc nerveux géniculé a L'aide De Corticostéroïdes et de la Neurolyse au Phénol Dans La Prise En Charge De La Douleur Due à la Gonarthrose A Yaoundé* » dont l'investigateur principal est ZE BESSALA Kevin 7eme année d'études médicales sous la supervision du Pr NGANDEU SINGWE Madeleine Interniste-Rhumatologue.

- J'ai bien compris la notice d'information qui m'a été remise concernant cette étude
- Ou bien on m'a lu et expliqué la notice d'information relative à cette étude
- J'ai bien compris le but et les objectifs de cette étude
- J'ai reçu toutes les réponses aux questions que j'ai posées
- Les risques et bénéfices m'ont été présentés et expliqués
- J'ai bien compris que je suis libre d'accepter ou de refuser d'y participer
- Mon consentement ne décharge pas les investigateurs de la recherche de leurs responsabilités, je conserve tous mes droits garantis par la loi.

J'accepte librement de participer à cette étude dans les conditions précisées dans la notice d'information, c'est-à-dire :

- De répondre objectivement et sincèrement à tous les questionnaires
- De coopérer pour l'analyse de marche
- De bénéficier d'une séance d'infiltration périarticulaire du genou.
- D'honorer les rendez-vous de suivi médical

Je donne mon accord pour que les données récoltées soient utilisées dans un but scientifique, et pour des études ultérieures.

Fait à Yaoundé, le

Investigateur Principal

Participant (nom adresse et signature)

APPENDIX 9: Participant Assessment Questionnaires.

(To be filled by the patient)

This questionnaire is intended for patients with painful knee osteoarthritis who voluntarily participate in this clinical study, aimed at improving the management of this pain. The completion of this questionnaire is anonymized. The investigators agree not only not to disclose your name in connection with a publication or conference, but also to replace your identity with codes before transmitting your data to the collected database manager for analysis. The sponsor undertakes to use the data collected only in the context of the study in which you are participating.

Please complete this questionnaire to the end.

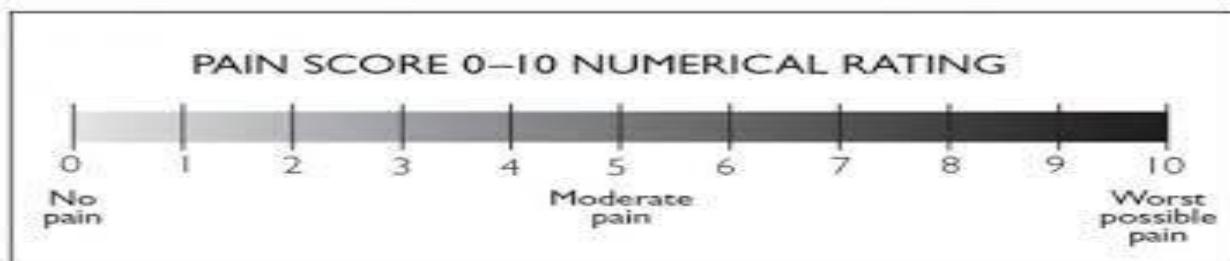
Date:/...../20....

Patient ID code:

Evaluation Base H1 D1 D7 D30 D90

1. Numeric Rating Pain Scale (NRPS)

On a scale of 0 (No pain) to 10 (maximum pain imaginable) Please indicate the intensity of your current pain, your best and worst level of pain experienced in the past week



Current Pain:

Minimal pain at rest:

Maximum pain on exertion:

2. Oxford Knee Score

| | |
|--|---|
| Oxford KNEE Score | |
| Patient's name: _____ | |
| Timeframe: pre op 3/52 6/52 3/12 6/12 12/12 | |
| Side L / R | Appt date _____ Date of Birth:_____ Age:_____ |

Patient to complete. Tick (✓) one box for every question

| | |
|---|---|
| 1. During the past 4 weeks How would you describe the pain in your knee? <input type="checkbox"/> None <input type="checkbox"/> Very Mild <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe | 7. During the past 4 weeks Have you been limping when walking because of your knee? <input type="checkbox"/> Rarely/never <input type="checkbox"/> Sometimes, or just at first <input type="checkbox"/> Often, not just at first <input type="checkbox"/> Most of the time <input type="checkbox"/> All of the time |
| 2. During the past 4 weeks How long can you walk (with or without stick) before the pain in your knee becomes severe? <input type="checkbox"/> No pain/more than 30mins <input type="checkbox"/> 16-30 mins <input type="checkbox"/> 5-15 mins <input type="checkbox"/> Around the house only <input type="checkbox"/> Not at all/pain severe | 8. During the past 4 weeks Have you felt that your knee might suddenly "give way" or let you down? <input type="checkbox"/> Rarely/never <input type="checkbox"/> Sometimes, or just at first <input type="checkbox"/> Often, not just at first <input type="checkbox"/> Most of the time <input type="checkbox"/> All of the time |
| 3. During the past 4 weeks After a meal (sat at a table), how painful is the knee to stand up? <input type="checkbox"/> Not at all painful <input type="checkbox"/> Slightly painful <input type="checkbox"/> Moderately painful <input type="checkbox"/> Very painful <input type="checkbox"/> Unbearable | 9. During the past 4 weeks Could you kneel down and get up again afterwards? <input type="checkbox"/> Yes, easily <input type="checkbox"/> With little difficulty <input type="checkbox"/> With moderate difficulty <input type="checkbox"/> With extreme difficulty <input type="checkbox"/> No, impossible |
| 4. During the past 4 weeks Have you been troubled by pain from your knee in bed at night? <input type="checkbox"/> No nights <input type="checkbox"/> Only 1 or 2 nights <input type="checkbox"/> Some nights <input type="checkbox"/> Most nights <input type="checkbox"/> Every night | 10. During the past 4 weeks Have you had any trouble with washing and drying yourself (all over) because of your knee? <input type="checkbox"/> No trouble at all <input type="checkbox"/> Very little trouble <input type="checkbox"/> Moderate trouble <input type="checkbox"/> Extreme trouble <input type="checkbox"/> Impossible to do |
| 5. During the past 4 weeks How much has pain from your knee interfered with your usual work (including housework)? <input type="checkbox"/> Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Moderately <input type="checkbox"/> Greatly <input type="checkbox"/> Totally | 11. During the past 4 weeks Have you had any trouble getting in and out of a car or using public transport because of your knee? <input type="checkbox"/> No trouble at all <input type="checkbox"/> Very little trouble <input type="checkbox"/> Moderate trouble <input type="checkbox"/> Extreme trouble <input type="checkbox"/> Impossible to do |
| 6. During the past 4 weeks Could you walk down one flight of stairs? <input type="checkbox"/> Yes, easily <input type="checkbox"/> With little difficulty <input type="checkbox"/> With moderate difficulty <input type="checkbox"/> With extreme difficulty <input type="checkbox"/> No, impossible | 12. During the past 4 weeks Could you do the household shopping on your own? <input type="checkbox"/> Yes, easily <input type="checkbox"/> With little difficulty <input type="checkbox"/> With moderate difficulty <input type="checkbox"/> With extreme difficulty <input type="checkbox"/> No, impossible |

3: WOMAC Knee Questionnaire

P: The following questions relate to the **degree of pain** you are currently experiencing due to your knee osteoarthritis. Please note the degree of pain you have experienced recently

| HOW MUCH PAIN DO YOU HAVE? | NONE | MILD | MODERATE | SEVERE | EXTREME | SCORE |
|-------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1) In walking on flat surface | <input type="checkbox"/> |
| 2) Going up or down stairs | <input type="checkbox"/> |
| 3) At night while in bed | <input type="checkbox"/> |
| 4) Sitting or lying | <input type="checkbox"/> |
| 5) Standing upright | <input type="checkbox"/> |

S : Ces questions concernent **le degré de raideur articulaire** que vous ressentez actuellement en raison de l'arthrose de votre genou

| HOW MUCH IS YOUR STIFFNESS? | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 6) After first wakening in the morning | <input type="checkbox"/> |
| 7) After sitting, lying or resting later in the day | <input type="checkbox"/> |

D: These questions are about your physical abilities. It's about the possibilities for getting around and going about your business. Please indicate the **degree of difficulty** currently attributable to your knee(s).

How difficult do you feel in the following activities?

| HOW MUCH DIFFUCULTY DO YOU HAVE? | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | <input type="checkbox"/> |
| 8) Descending stairs | <input type="checkbox"/> |
| 9) Ascending stairs | <input type="checkbox"/> |
| 10) Standing up from a chair | <input type="checkbox"/> |
| 11) While standing | <input type="checkbox"/> |
| 12) Bending to floor (to pick up object) | <input type="checkbox"/> |
| 13) Walking on flat ground | <input type="checkbox"/> |
| 14) Getting in and out of auto Rickshaw / Bus / Car | <input type="checkbox"/> |
| 15) Going shopping | <input type="checkbox"/> |

| | NONE | MILD | MODERATE | SEVERE | EXTREME | SCORE |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 16) On rising from bed | <input type="checkbox"/> |
| 17) While lying on bed | <input type="checkbox"/> |
| 18) While sitting on chair | <input type="checkbox"/> |
| 19) Going on /off □ Indian □ Western | <input type="checkbox"/> |
| 20) Doing heavy domestic duties (moving heavy boxes, scrubbing floor, lifting shopping bags) | <input type="checkbox"/> |
| 21) Doing light domestic duties (cleaning room / table cooking / dusting) | <input type="checkbox"/> |
| 22) While sitting cross legged floor | <input type="checkbox"/> |
| 23) Rising from cross legged position | <input type="checkbox"/> |
| 24) While squatting on floor | <input type="checkbox"/> |

4: Quantitative Assessment of Analgesic Questionnaire

Medications you have recently (last 4 weeks) taken for your knee pain(s)

Drug Name :

1. Dosage (mg) :
2. Dosage (mg) :
3. Dosage (mg) :

What kind of pain are you taking these medications for?

How many **days a week** do you **usually** take these medications? circle a number below.

0 1 2 3 4 5 6 7

When you take this medication, how many **pills on average do** you take **per day**? circle a number below for each medication

Drug 1: 0 1 2 3 4 5 6 7 8 9 10 or more

Medication 2: 0 1 2 3 4 5 6 7 8 9 10 or more

Drug 3: 0 1 2 3 4 5 6 7 8 9 10 or more

- I take these medications(s) on a regular basis
 I only take this medication(s) when I need them

b. Use of analgesic patches

Do you use **fentanyl patches** for your knee pain? YES

If yes, Dosage:

How many days a week on average do you wear the patch:

Do you use **Buprenorphine patches** for your knee pain? YES

If yes, Dosage:

How many days a week on average do you wear the patch:

c. Use of topical analgesics

Do you use **gels/ointments/creams** that you **regularly apply** to your knees for pain?

YES NO

If yes, please list them:

.....
.....

TOTAL QAQ SCORE:

5: QUALITY OF LIFE QUESTIONNAIRE (short form) SF-12

1. Overall, do you think your health is:

- 1 Excellent 2 Very Good 3 Good 4 Mediocre 5 Poor

2. Due to your current state of health, are you limited for moderate physical exertion (moving a table, vacuuming, bowling)?

- 1 Yes, very limited 2 Yes, not limited 3 No, not limited at all

3. Due to your current health condition, are you limited to going up several flights of stairs?

- 1 Yes, very limited 2 Yes, not limited 3 No, not limited at all

In the last 4 weeks, and due to your physical condition:

4. Have you accomplished less than you would have liked?

- 1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

5. Were there any things you were limited in doing?

- 1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

In the past 4 weeks, and due to your emotional state (such as feeling sad, nervous, or depressed):

6. Have you accomplished less than you would have liked?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

7. Did you find it difficult to do what you had to do with as much care and attention as usual?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

8. In the past 4 weeks, to what extent have your physical pains limited you in your work or domestic activities?

1 not at all 2 a little bit 3 Medium 4 A lot 5 Never

The following questions are about how you've been feeling over the past 4 weeks. For each question, indicate the answer that you think is most appropriate

9. Were there times when you felt calm and relaxed?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

10. Have there been times when you have felt full of energy?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

11. Have there been times when you have felt sad and dejected?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

12. In the past 4 weeks, have there been times when your physical or emotional health has hindered your social life and your relationships with others, family, friends, acquaintances?

1 Always 2 Most of the time 3 Often 4 Sometimes 5 Never

6 : PATIENT SATISFACTION INDEX

(PATIENT GLOBAL IMPRESSION OF CHANGE QUESTIONNAIRE)

Since the beginning of this treatment, how would you describe **the change** (if any) in the **limitation of your activities, your symptoms, your emotions** and everything else that makes up **your quality of life, in relation to your pain?**

Make a cross in the box on the right (only one answer possible)

| | | |
|---|---|--|
| 1 | No change or it got worse | |
| 2 | Almost the same, hardly any improvement | |
| 3 | A little better, but no noticeable change | |
| 4 | Somewhat better, but change doesn't make much difference | |
| 5 | Better still, the change is moderate but noticeable | |
| 6 | Better, with no doubt a real improvement that makes the difference | |
| 7 | Much better, a considerable improvement that makes all the difference | |

7 :PROMIS SCORE 4a

| In the past 7 days... | Very poor | Poor | Fair | Good | Very good |
|----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| 1. My sleep quality was... | <input type="checkbox"/> 05 | <input type="checkbox"/> 04 | <input type="checkbox"/> 03 | <input type="checkbox"/> 02 | <input type="checkbox"/> 01 |

| In the past 7 days... | Not at all | A little bit | Somewhat | Quite a bit | Very much |
|-------------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| 2. My sleep was refreshing. | <input type="checkbox"/> 05 | <input type="checkbox"/> 04 | <input type="checkbox"/> 03 | <input type="checkbox"/> 02 | <input type="checkbox"/> 01 |
| 3. I had a problem with my sleep. | <input type="checkbox"/> 01 | <input type="checkbox"/> 02 | <input type="checkbox"/> 03 | <input type="checkbox"/> 04 | <input type="checkbox"/> 05 |
| 4. I had difficulty falling asleep. | <input type="checkbox"/> 01 | <input type="checkbox"/> 02 | <input type="checkbox"/> 03 | <input type="checkbox"/> 04 | <input type="checkbox"/> 05 |

8 :Central Sensitisation Inventory

CSI Inventory (Part A)

Name _____ Date _____

Please circle the best response to the right of each statement.

Key for Scoring: Never = 0, Rarely = 1, Sometimes = 2, Often = 3, Always = 4

| 1. I feel tired and unrefreshed when I wake from sleeping. | Never | Rarely | Sometimes | Often | Always |
|---|-------|--------|-----------|-------|--------|
| 2. My muscles feel stiff and achy. | Never | Rarely | Sometimes | Often | Always |
| 3. I have anxiety attacks. | Never | Rarely | Sometimes | Often | Always |
| 4. I grind or clench my teeth. | Never | Rarely | Sometimes | Often | Always |
| 5. I have problems with diarrhea and/or constipation. | Never | Rarely | Sometimes | Often | Always |
| 6. I need help in performing my daily activities. | Never | Rarely | Sometimes | Often | Always |
| 7. I am sensitive to bright lights. | Never | Rarely | Sometimes | Often | Always |
| 8. I get tired very easily when I am physically active. | Never | Rarely | Sometimes | Often | Always |
| 9. I feel pain all over my body. | Never | Rarely | Sometimes | Often | Always |
| 10. I have headaches. | Never | Rarely | Sometimes | Often | Always |
| 11. I feel discomfort in my bladder and/or burning when I urinate. | Never | Rarely | Sometimes | Often | Always |
| 12. I do not sleep well. | Never | Rarely | Sometimes | Often | Always |
| 13. I have difficulty concentrating. | Never | Rarely | Sometimes | Often | Always |
| 14. I have skin problems such as dryness, itchiness, or rashes. | Never | Rarely | Sometimes | Often | Always |
| 15. Stress makes my physical symptoms get worse. | Never | Rarely | Sometimes | Often | Always |
| 16. I feel sad or depressed. | Never | Rarely | Sometimes | Often | Always |
| 17. I have low energy. | Never | Rarely | Sometimes | Often | Always |
| 18. I have muscle tension in my neck and shoulders. | Never | Rarely | Sometimes | Often | Always |
| 19. I have pain in my jaw. | Never | Rarely | Sometimes | Often | Always |
| 20. Certain smells, such as perfumes, make me feel dizzy and nauseated. | Never | Rarely | Sometimes | Often | Always |
| 21. I have to urinate frequently. | Never | Rarely | Sometimes | Often | Always |
| 22. My legs feel uncomfortable and restless when I am trying to go to sleep at night. | Never | Rarely | Sometimes | Often | Always |
| 23. I have difficulty remembering things. | Never | Rarely | Sometimes | Often | Always |
| 24. I suffered trauma as a child. | Never | Rarely | Sometimes | Often | Always |
| 25. I have pain in my pelvic area. | Never | Rarely | Sometimes | Often | Always |
| Total Each Column | | | | | |

CSI Inventory (Part B)

Name _____

Date _____

Have you been diagnosed by a doctor with any of the following disorders?

Please check the box to the right for each diagnosis and write the year of the diagnosis.

| | | No | Yes | Year Diagnosed |
|----|----------------------------------|----|-----|----------------|
| 1 | Restless Leg Syndrome | | | |
| 2 | Chronic Fatigue Syndrome | | | |
| 3 | Fibromyalgia | | | |
| 4 | Temporomandibular Joint Disorder | | | |
| 5 | Migraine or tension headaches | | | |
| 6 | Irritable Bowel Syndrome | | | |
| 7 | Multiple Chemical Sensitivities | | | |
| 8 | Neck injury (including whiplash) | | | |
| 9 | Anxiety or panic attacks | | | |
| 10 | Depression | | | |

Have you completed everything correctly?

Thank you for your participation

APPENDIX 10: PATIENT DATA SHEET

(To be filled by the investigator)

Date : / /20...

Patient ID Code :

1. SOCIO-DEMOGRAPHIC DATA

1. **phone number :**

2. **Age :** (Years)

3. **Gender :** (1 = male, 2 = female)

4. **Weight :** (Kg)

5. **Height :** (cm)

6. **Level of education:**

No Primary

General Secondary 1st Cycle General Secondary 2nd Cycle

Technical & Professional Higher

7. **Socio-professional category.** Select the corresponding checkbox

Farmers , Artisans, Traders and Entrepreneurs

Managers and higher intellectual professions Intermediate professions

Employees Manual workers Retired Other persons not in employment

8. **Relationship to Tobacco:**

Non-Occasional Smoker Regular Former Smoker

2. RADIO-CLINICAL DATA

1. **Knee pain:** L R bilateral

2. **Duration of knee pain progression** (in months):

3. **Previous treatments:** (0 = no, 1 = yes)

- Visco-supplementation. If yes, number:
- Corticosteroid infiltration. If yes, number:
- Neurotomies. If yes, type and time period:
- Physical therapy. If yes, period:
- Knee arthroscopy. If yes, period:
- Painkillers. If yes, which ones:
- Other. If yes, please specify:

4. **Other medical-surgical pathologies being monitored?** (0 = no, 1 = yes)

If yes, please cite them:
.....
.....

5. **Kellgren–Lawrence classification of osteoarthritis of the knee** (check the corresponding box)

- Grade 1 (*doubtful: minimal osteophyte of doubtful significance*)
- Grade 2 (*minimal: Osteophyte certain, respect of line spacing*)
- Grade 3 (*moderate: moderate decrease in joint spacing*)
- Grade 4 (*severe: severe joint pinching with subchondral sclerosis*)

APPENDIX 11: WALKING DISTANCE TEST

Date:

Patient ID:

Evaluation Base H1 post block D30 D90

Age: (years) Gender: M F Weight:kg Height:cm

1. 10-meter test

| 10-meter test | <i>Spontaneous Speed</i> | <i>At Maximum Speed</i> |
|---------------------------------|--------------------------|-------------------------|
| <i>Duration 1 (sec)</i> | | |
| <i>Duration 2 (sec)</i> | | |
| <i>Average Duration(s)</i> | | |
| <i>Number of steps</i> | | |
| <i>Pitch length (m)</i> | | |
| <i>Pitch speed (m/s)</i> | | |
| <i>Step cadence (steps/sec)</i> | | |

2. 6-minute walk test

Six-Minute Walk Test

Resting Vital Signs: Heart Rate _____ Systolic BP _____ Diastolic BP _____ Pulse Oximetry _____

Mark number of laps made: _____

Total distance completed: _____ feet

Level I (<984 ft) _____ Level II (985–1229 ft) _____

Level III (1230 – 1476 ft) _____ Level IV (>1477 ft) _____

Number of times stopped: _____ Duration of rest times _____

End of walk test:

Heart Rate _____ Systolic BP _____ Diastolic BP _____ Pulse Oximetry _____

| EXERTION SCALE | ANGINA SCALE | DYSPNEA SCALE |
|---|---|---|
| 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 Very, Very Light Very Light Fairly Light Somewhat Hard Hard Very Hard Very, Very Hard | 0 1 2 3 4 No Angina Light, barely noticeable Moderate, bothersome Severe, very uncomfortable Most severe pain ever experienced | 0 1 2 3 4 No Dyspnea Mild, noticeable Mild, some difficulty Moderate difficulty, can continue Moderate difficulty, cannot continue |

Fall Risk Assessment (if any risk factor is observed or reported, document on problem list)

_____ Unsteady gait/dizziness/imbalance

_____ Impaired memory or judgment

_____ Weakness

_____ History of falls

_____ Uses ambulatory assistance (e.g. cane, walker, w/c)

Test administered by: _____ Date: _____

Distance traveled (m) :

3. Joint mobility of the knee (in degrees)

| | Left knee | Right knee |
|-----------------|-----------|------------|
| Passive bending | | |
| Active Flexing | | |

APPENDIX 12: ICONOGRAPHY



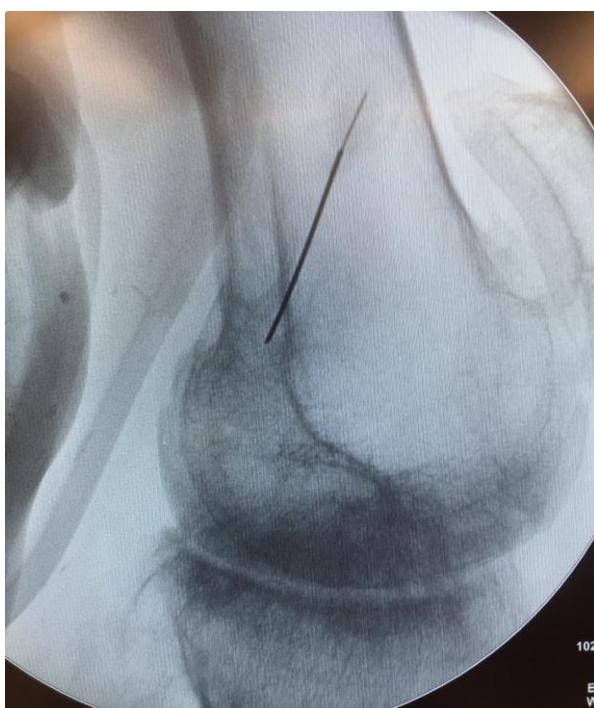
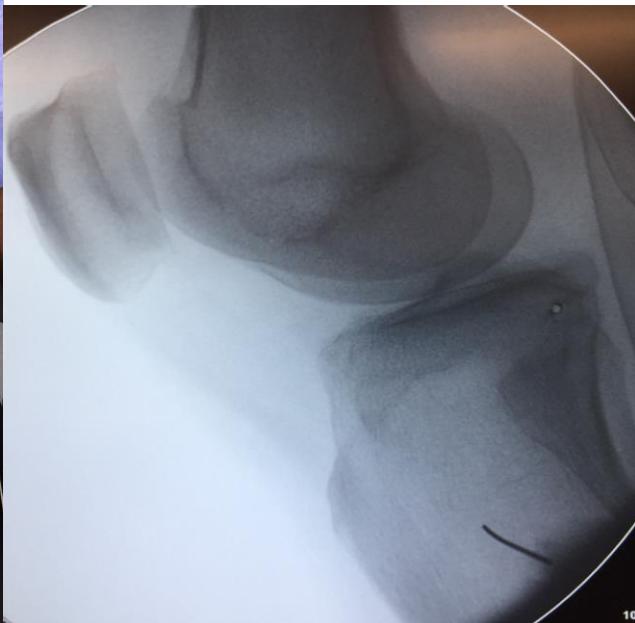
1-Participant Randomization with sealed envelopes

2- 10-meters test





3-Procedure in surgical theater
under fluoroscopic guidance



4-Revised Anatomical Targets



5- Drugs used left: Lidocaine Middle: Phenol Right: Triamcinolone





6-Goniometer, pedometer, stop watch and decameter used for evaluation

7-Skin hypopigmentation post intervention

