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Research Article

COMPARISON OF THE EFFECTIVENESS OF SODIUM SALICYLATE IONTOPHORESIS V/S CONVENTIONAL TENS ON PAIN, FUNCTION AND DISABILITY IN KNEE OSTEOARTHRITIS

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ABSTRACT

Background: Osteoarthritis is one of the common degenerative conditions. It is characterized by joint pain and stiffness, along with varying degrees of functional limitation and altered quality of life. Knee osteoarthritis is ordinarily treated by heat (superficial or deep), cryotherapy, TENS, stretching of gastrocnemius, hamstring, iliopsoas, piriformis and strengthening of quadriceps, hamstring and VMO. salicylate iontophoresis is known for its analgesic and anti-inflammatory effect and is used in various conditions including heel pain. However its effect on osteoarthritis of knee has been found in few studies. Hence, the purpose of this study was to investigate the effectiveness of salicylate iontophoresis on knee osteoarthritis and to compare it with conventional TENS.

Aim: To compare the effectiveness of Sodium Salicylate iontophoresis v/s conventional TENS on pain, function and disability in knee osteoarthritis.

Objectives: To study the effectiveness of sodium salicylate iontophoresis on pain, function and disability in knee osteoarthritis.

To study the effectiveness of conventional TENS on pain, function and disability in knee osteoarthritis.

To compare the effectiveness of sodium salicylate iontophoresis and Conventional TENS on pain, function and disability in knee osteoarthritis.

Conclusion: There was statistically significant reduction in pain, improvement in function and in quality of life in patients treated with conventional TENS (group A).

There was statistically significant reduction in pain, improvement in function and in quality of life in patients treated with sodium salicylate iontophoresis (group B).

At 2 weeks post intervention and at 4 weeks follow-up, with home exercise program, the changes were statistically significant as compared to the pre treatment values within the groups.

When both the groups were compared the experimental group (group B) with sodium salicylate iontophoresis showed no statistical significant improvement in pain, function and quality of life over control group (group A) with conventional TENS in knee osteoarthritis.

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INTRODUCTION

Osteoarthritis is a condition of synovial joints that involves the degeneration of articular cartilage which is associated with joint pain, deformity and loss of function.¹ It is the most common degenerative problem with prevalence of 22% to 39% in Indian population.² According to 92% orthopedic surgeons, knee osteoarthritis is common in women, while 8% states that it is common in men.³ It is characterized by certain signs such as irregularity of articular surfaces, osteophytes formation, stress pain, deformity, coarse crepitus and instability.⁴ Patient complains of symptoms like pain, joint swelling and morning

stiffness ≤ 30 minutes along with varying degrees of functional limitation and altered quality of life.⁵

According to onset, osteoarthritis is classified as primary and secondary osteoarthritis. Primary osteoarthritis is due to natural wear and tear that occurs with aging, overuse or obesity. Whereas, secondary osteoarthritis occurs when there is known primary cause such as tumor, infection, rheumatoid arthritis, mal-alignment of joints etc.⁶

After the age of 45 years the risk of developing osteoarthritis increases with each decade and thus older people show rapid progression of osteoarthritis.⁷

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Some of the common causes of knee osteoarthritis are as follows

1. Age: After the age of 45 years the risk of developing osteoarthritis increases.⁷ Osteoarthritic cartilage is chemically different than normal cartilage. As chondrocytes (the cells that make cartilage) age, they lose their ability to repair damage. Hence, body's ability to repair cartilage declines with increasing age, that plays an important role in development and progression of osteoarthritis.⁸
2. Gender: women have a greater prevalence of osteoarthritis than men. They show more severe form of osteoarthritis especially post-menopausal woman, because of decline in estrogen levels.^{2,5}
3. Obesity: Framingham (1990) in his longitudinal study predicted development of osteoarthritis in later life with people having high Basal Metabolic Index.⁹
4. Genetic: Osteoarthritis is multi-factorial and polygenic late onset disease in which environment factors are modulators of gene expression. Genetic linkage occurs when a locus involving osteoarthritis are high at 40-60% through the responsible genes are largely unknown.⁵
5. Occupation: Physical work that involves static loading or repetitive bending and squatting activities are related to higher prevalence of osteoarthritis of knee.¹⁰
6. Biomechanical factors: mechanical factors like muscle weakness, mal-alignment and laxity of joints leads to osteoarthritis of knee.⁵

Radiological classification of Osteoarthritis:¹¹

According to Kellgren-Lawrence grading scale, osteoarthritis is classified as follows,

- Grade 0: Normal radiograph.
- Grade I: Doubtful narrowing of joint space and possible osteophytic lipping.
- Grade II: Definite osteophytes and absent or questionable narrowing of joint space.
- Grade III: Moderate osteophytes and joint space narrowing, some sclerosis and possible deformity.
- Grade IV: Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity.

Pathophysiology

The femoral and tibial cartilage during growth and development keeps adapting over time to the cyclic loads during walking. Thickness of cartilage increases in area where there is maximum load, both in antero-posterior and medio-lateral regions. During walking, the loading patterns of tibia-fibula have an influence in growth and development of articular cartilages in those regions. Acute injury, trauma, ligamentous laxity disturbs the normal gait mechanics. This shifts the loading patterns of the areas of cartilage that are poorly adapted to bear these loads. Normal healthy cartilage will respond appropriately to the loads imposed on them and increase the regional cartilage thickness but injured or diseased cartilage degenerates and decreases cartilage thickness⁷.

With aging, cartilage breakdown starts in joint area where there is very little or no contact. As destruction advances, the breakdown keeps moving to more heavily loaded areas. Biomechanical factors such as tibio-femoral contact time, loading patterns and motion are altered. Due to this frictional stresses and shear forces are developed. Injury or aging of knee joint can increase laxity of joint and would lead to access or altered motion around knee joint.⁷

Improper loading in these areas leads to fibrillation of collagen network, reduce proteoglycan matrix, increased friction between articular surfaces, increased shear forces and changes also occurs in subchondral layers of joints which leads to degeneration of joints.^{7,13}

Excessive joint loading is seen in medial compartment as compared to lateral compartment in patients with knee osteoarthritis. This is because forces that are transmitted through medial compartment are more during stance phase. The rotator shear forces in lower limb are associated with position of foot in supination or pronation. Thus the movements between hip, Knee and foot are interdependent and biomechanical alteration in any one joint would affect the normal biomechanics of other joint. Lack of synchronization between tibial and femoral rotation would further cause degeneration in cartilages of these joints.¹³

The patella, a sesmoid bone in the quadriceps tendon, articulates with the intercondylar (trochlear) groove on anterior aspect of distal portion of femur. Its articulating surface is covered with smooth hyaline cartilage. The patella is embedded in anterior portion of joint capsule and is connected to tibia by ligamentum patellae¹⁴.

As the knee flexes, the patella enters the intercondylar groove with its inferior margin making first contact and then slides caudally along the groove. With extension, the patella glides superiorly.¹⁴

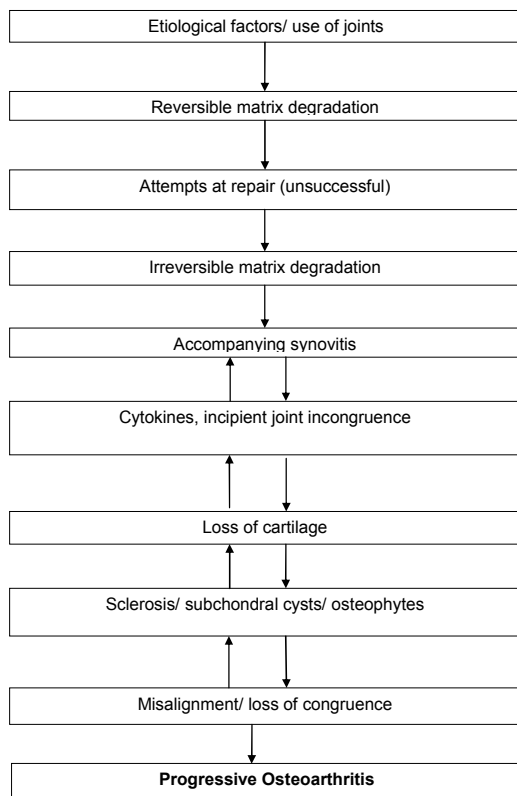


Figure 2 schematic representation of pathogenesis of osteoarthritis

The patella is stabilized by passive and dynamic (muscular) restraints in addition to bony restraints of trochlear groove. The superior portion of extensor retinaculum, to which vastus medialis and vastus lateralis muscles have an attachment, provides dynamic stability in transverse plane. The medial and lateral patello-femoral ligaments provide passive restraints to patella in transverse plane. Longitudinally, the medial and lateral patello-tibial ligaments and patellar tendon fixate the patella inferiorly against the active pull of quadriceps muscles superiorly.¹⁴

Pathomechanics

Degeneration results in medial joint space narrowing and varus alignment of lower limb. This causes the ground reaction force to pass more medially and increases the knee adduction moment (KAM) which leads to the progression of medial compartment knee osteoarthritis¹⁵.

Osteoarthritis is treated as follows

Conservative management

Pharmacological management:¹⁶

- The first line of treatment for knee osteoarthritis is Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). They reduce pain and biologic effects of inflammation.
- Topical ointments containing methyl salicylate and diclofenac sodium also brings about pain relief.
- Patients who do not benefit from pharmacological treatment and experience more chronic pain symptoms may benefit from injectable corticosteroids.

Physiotherapy management:¹⁷

- Various physical agents are routinely used as treatment for pain and stiffness. Physical therapeutic modalities commonly used for patients with knee osteoarthritis are heat (superficial and deep), cryotherapy, TENS, iontophoresis etc.
- Exercises designed for knee osteoarthritis include strengthening of knee joint musculature i.e. quadriceps, hamstrings, vastus medialis oblique (VMO); stretching of gasrocnemius, hamstring, iliopsoas and pyriformis.
- Mobilization techniques are also used to restore altered joint play and range of motion.
- Ergonomics like avoiding cross sitting and squatting are advised.
- Lifestyle modification such as use of assistive devices like knee caps, participation in weight reduction programme (if needed), aerobic exercises and appropriate management of co-morbid factors like diabetes and hypertension are advised.

Surgical management:¹⁸

If knee osteoarthritis fails to respond to conservative treatment, surgical options like excision of osteophytes, arthrotomy or total knee replacement (uni-compartmental, bi-compartmental or tri-compartmental) are considered.

Iontophoresis is one of the therapeutic modalities used for the treatment of muscle spasm, inflammation and pain. Iontophoresis was described by Pivati in 1747. In 18th century, Galvani and Vota combined the concept that the electricity can

move different metal ions and movement of ions produces electricity. Leduc in 20th century made the method of administrating pharmacological ions by iontophoresis popular. He also introduced the term and formulated the laws in iontotherapy.¹⁹

Iontophoresis is described as the transfer of ions into the body by means of Direct current (DC) for the therapeutic purpose. The basic principle of iontophoresis states that “like poles repels and unlike poles attracts”. Ions being charged particles have either positive or negative valences which are repelled into the skin by an identical charge of an electrode surface placed over it. Ions once introduced into the body recombine with the existing ions and radicals floating in the blood stream which then form necessary new components for therapeutic interactions. Therefore selecting an accurate ionic polarity and checking its compatibility with the “like” electrode’s polarity for therapeutic administration is of prime importance.^{20,21}

Route of drug penetration through the skin

Ion transport across the skin is primarily through skin pores, sweat glands and hair follicles²². Penetration of drug through healthy skin is limited. The main barrier to transdermal drug uptake is stratum corneum, which is the superficial layer of skin. Iontophoresis promotes the transdermal drug penetration by increasing the permeability of stratum corneum. The depth of drug delivery with iontophoresis is around 3mm to 20mm.^{20,21}

In iontophoresis direct current should be used for continuous delivery of ionized drug. This type of current can produce some undesirable chemical changes under the electrodes. Alkaline reaction takes place under negative electrode which leads to formation of sodium hydroxide which is caustic. This reaction can produce discomfort, skin irritation and chemical burns. Such adverse effects can be decreased by increasing the size of negative electrode, which in turn will reduce the current density. Acidic reaction takes place under positive electrode which leads to formation of hydrochloric acid. Acidic reaction is generally less comfortable than alkaline reaction.^{20,21}

Effective drug delivery can be seen with current amplitude ranging between 40-80mA.minute treatment.²⁰ For example, 2mA current for 20 minute or a 4mA current for 10 minute, all give a 40mA.minute treatment (Table. 1).

Table 1 Current amplitude and treatment duration for iontophoresis treatment:²⁰

Current amplitude (mA)	Treatment time (min.)	Dose in mA.min
1	40	40
2	20	40
3	13.3	40
4	10	40

Sodium salicylate, acetic acid, magnesium sulphate, lidocane etc are commonly used ions for iontophoresis.^{20,21}

Salicylate (in the form of sodium salicylate, 2%) has a negative polarity. The principle effects of salicylate ions are anti-inflammatory and analgesic.^{20,21}

Table 2 Following ions which are used for iontophoresis:^{20,21}

Ion	Source	Polarity	Indication	Concentration
Acetate	Acetic acid	Negative	Calcium deposits, Frozen joints, Myositis ossificans	2.5-5%
Chloride	Sodium chloride	Negative	Sclerolytic	2%
Magnesium	Magnesium sulphate	Positive	Muscle relaxant, Vasodialator, Analgesic	2%
Zinc	Zinc oxide	Positive	Dermal ulcers, Open wounds	20%
Salicylate	Sodium salicylate	Negative	Inflammation, Plantar warts	2%
Tap water	---	Positive/ Negative	Hyperhydrosis	---

Following factors affect the results of iontophoresis:^{19,22}

1. Ionization and electrolysis:
2. Effect of pH:
3. Permselectivity:
4. Concentration and mixture of solutes:
5. Electro-osmosis:
6. Penetration and distribution of ions:

Advantages of iontophoresis:²⁰

- It avoids systemic drug effects, first-pass metabolism and gastrointestinal tract.
- Non-invasive technique.
- Ease of application.
- Verifiable and controllable dose delivery.
- Wide range of ionic drugs can be used.
- Minimal risk of infection.

Disadvantages of iontophoresis:²⁰

- Minor side effects like skin irritation, itching and erythema.
- Chemical burns due to improper technique of application, like high current density and long treatment durations.
- Skin pigmentation can occur with longer application of some drugs like sodium nitroprusside.

Contraindications of iontophoresis:²⁰

- Patient allergic to drug being used in iontophoresis.
- If skin over the part to be treated is not intact.

Care to be taken by therapist:²⁰

- Electrodes should not be placed on the chest or in a position in which current could flow through the heart i.e. electrodes should not be placed on different limbs.
- It should not be used in the patients with electrically sensitive support system e.g. pace makers.
- Electrodes should not be placed over damaged skin, hyposensitive skin, the orbital region or on temporal regions of the head.

Transcutaneous electrical nerve stimulation (TENS) is a simple, non-invasive analgesic technique that is used extensively in health care settings. During TENS, pulsed

currents are generated and delivered across the intact surface of the skin via conducting pads called electrodes. The conventional way of administering TENS is to use electrical characteristics that selectively activate large diameter ‘touch’ fibres (Aβ) without activating smaller diameter nociceptive fibres (Aδ and C).²³

Interest in the use of electricity to relieve pain was reawakened in 1965 by Melzack and Wall who provided a physiological rationale for electro-analgesic effects. They proposed that transmission of noxious information could be inhibited by activity in large diameter peripheral afferents or by activity in pain inhibitory pathways descending from the brain that is ‘Pain Gate mechanism’²³ Fig.7.

Mechanism of action

Stimulation-induced analgesia can be categorized according to anatomical site of action into peripheral, segmental and extra-segmental²³.

The main action of conventional TENS is segmental analgesia mediated by Aβ fibre activity.²³

Suggested characteristics to use conventional TENS:²³

- Electrode placement: straddling site of pain or over main nerve bundle proximal to pain.
- Pulse pattern: continuous.
- Pulse frequency: 80-100 p.p.s
- Pulse duration: 100-200µs
- Pulse intensity: increase intensity to produce a strong but comfortable tingling.

Need for the Study

Osteoarthritis is one of the common degenerative conditions. It is characterized by joint pain and stiffness, along with varying degrees of functional limitation and altered quality of life. Knee osteoarthritis is ordinarily treated by heat (superficial or deep), cryotherapy, TENS, stretching of gastrocnemius, hamstring, iliopsoas, piriformis and strengthening of quadriceps, hamstring and VMO. salicylate iontophoresis is known for its analgesic and anti-inflammatory effect and is used in various conditions including heel pain.

However its effect on osteoarthritis of knee has been found in few studies. Hence, the purpose of this study was to investigate the effectiveness of salicylate iontophoresis on knee osteoarthritis and to compare it with conventional TENS.

Aim and Objectives

Aim

To compare the effectiveness of Sodium Salicylate iontophoresis v/s conventional TENS on pain, function and disability in knee osteoarthritis.

Objectives

- To study the effectiveness of sodium salicylate iontophoresis on pain, function and disability in knee osteoarthritis.
- To study the effectiveness of conventional TENS on pain, function and disability in knee osteoarthritis.

- To compare the effectiveness of sodium salicylate iontophoresis and Conventional TENS on pain, function and disability in knee osteoarthritis.

Hypothesis

Alternate hypothesis

Sodium Salicylate iontophoresis will have a differential effect on pain, function and disability in knee osteoarthritis.

Null hypothesis

Sodium Salicylate iontophoresis will be as effective as conventional TENS on pain, function and disability in knee osteoarthritis.

MATERIALS AND METHODOLOGY

Study design

Comparative interventional study.

Study size

40 patients with knee osteoarthritis (20 in each group). (As per the data obtained from previous studies and by using Epi info software, the approximate sample size was 20 in each group).

Type of sampling

Convenience sampling with random allocation.

Sample source

Tertiary health care centre

Duration of study

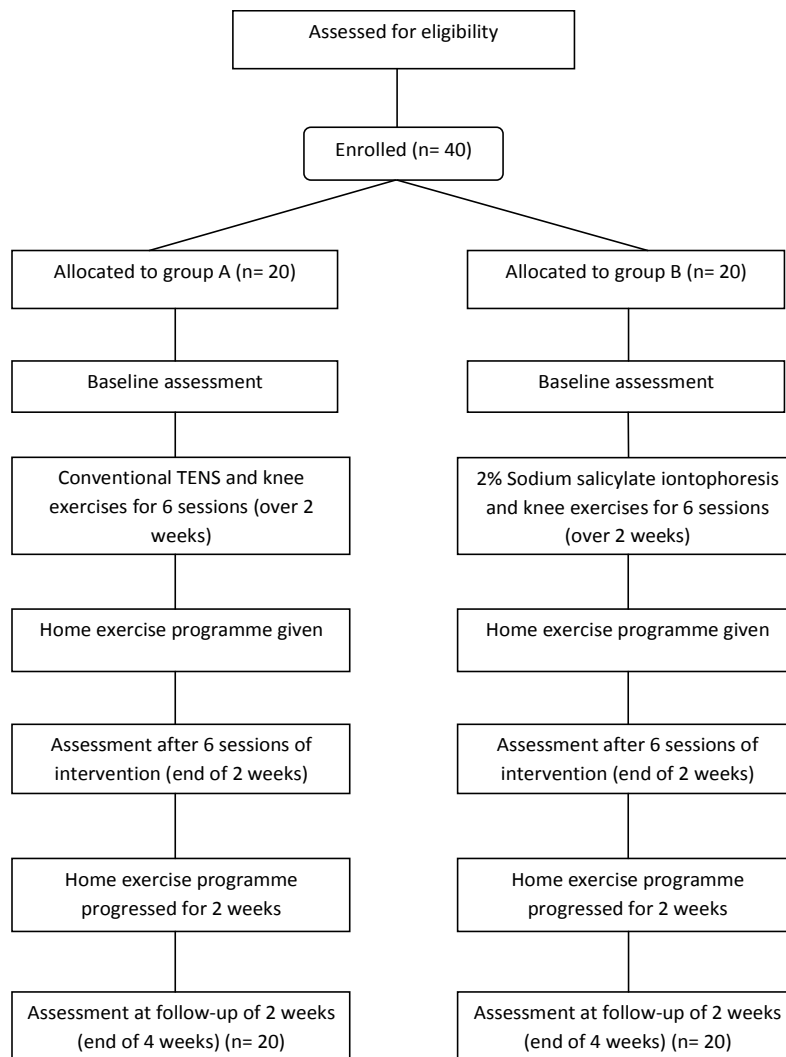
12 months.

Inclusion Criteria

- Males and females with age between 40-60 years, with unilateral knee osteoarthritis of grade I-III on Kellgren and Lawrence (K-L) classification.
- Subjects with pain 4-7 on numerical pain rating scale.

Exclusion Criteria

- Subjects with any traumatic, metabolic, infective or rheumatic condition affecting knee joint.
- Subjects with pain referred from proximal joints like, hip joint, sacroiliac joint or lumbar spine.
- Subjects contra-indicated for treatment with TENS and/or Sodium Salicylate iontophoresis.



Materials Used

Multi-stimulator unit (for conventional TENS and for direct galvanic current), Carbon impregnated rubber electrodes, 2% Sodium Salicylate solution, Gel, Velcro straps, Gauze, Chair, Measuring tape, Stop watch.

METHODOLOGY

The study was approved by the ethics committee prior to commencement. It was conducted at Physiotherapy department of a tertiary health care center. Patients with knee osteoarthritis were screened according to inclusion and exclusion criteria. All the patients who fulfilled the inclusion criteria and willing to participate were included in the study. A total 40 patients were taken for the study. Written consent was obtained, after explaining the study procedure and benefits of the study in the language best understood by them. Basic information was recorded.

Numerical Pain Rating Scale (NPRS) was administered and Timed Up and Go (TUG) test was conducted, following which they were asked to complete the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Patients were then allocated either to group A or group B by computer generated random allocation list.

Outcome Measures

Numerical Pain Rating Scale (NPRS)

Timed Up and Go test (TUG)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Procedure

40 patients were divided by computer generated random allocation list into two groups of 20 each.

Group A (conventional group): Patients in this group were treated with conventional TENS followed by knee exercises.

Group B (experimental group): Patients in this group were treated with 2% sodium salicylate iontophoresis followed by knee exercises.

All the patients were prescribed a non-steroidal anti-inflammatory drugs and an antacid for 5 days by an orthopedic.

Baseline assessment was done using NPRS, TUG and WOMAC prior to commencement of the treatment in both the groups.

In Group A (conventional group), each patient was asked to lie supine on plinth with their affected knee on pillow so as to attain a relax position. Once comfortable, maximum painful area was located i.e. either medio-lateral or antero-lateral and marked on the knee by the examiner. Conventional TENS was used for patients in group A. Electrodes were placed to affected knee. Current frequency and pulse duration was set at 100Hz and 100 μ s respectively. Current intensity was set to provide strong but comfortable tingling. Each treatment session lasted for 20 minutes.

In Group B (experimental group), each patient was asked to lie in supine position. Once comfortable, maximum painful area was located and marked on the affected knee. 2% sodium salicylate iontophoresis was used for group B patients. Gauze

uniformly moistened with the solution was kept under the active electrode i.e. cathode and was secured with strap over the most painful area of the affected knee. Other gauze uniformly moistened with plain tap water was kept under indifferent or dispersive electrode i.e. the anode and was secured with strap, 7.6cms away on the bulk of gastrocnemius muscle postero-laterally. Gauze under the delivery electrode was 1 cm thicker and 1 cm wider than the electrode. Cathode was bigger than the anode to minimize chances of cathodal burn. Gauze used under the dispersive electrode was of 8 folds and 16 layers Fig.14. Current intensity of 2mA was applied. Each treatment session was lasted for 20 minutes. During the 1st session, skin color under the electrodes was checked approximately 3 minutes after starting the treatment for any adverse reactions. The treatment dosage did not exceed the maximum recommended dosage of 40mA.min.

In addition to conventional TENS and iontophoresis, both the groups received,

- Knee exercises includes, static exercises, knee range of motion exercises, stretching exercises and patella-femoral glides i.e. Maitland's mobilisation.⁴⁸
- Ergonomic advices.

All patients received, 6 sessions of TENS or iontophoresis (lasting for 20 minutes each) over a period of 2 weeks. All the patients were assessed pre- intervention (at 0 weeks), post-intervention (at 2 weeks) and at follow-up (at 4 weeks). All the patients were instructed to continue all the exercises everyday as home exercise programme, till subsequent follow-up visit. They were asked to demonstrate exercises on follow-up visit, so that any corrections required could be made.

Data collected was statistically analyzed.

Knee exercises protocol:⁴⁸

Static quadriceps sets: 1 set of 10 repetitions with 5 seconds hold, 10 seconds rest between repetitions, 2 times a day.

Patient position and procedure

In supine position small towel roll was kept under the knee. The patient was asked to tighten the quadriceps muscle by straightening the knee completely and to attempt to push the backside of the knee onto the towel roll.

Static hamstring sets: 1 set of 10 repetitions with 5 sec, hold, 10 sec. rest between repetitions, 2 times a day.

Patient position and procedure

Supine lying. Patient was asked to tighten the hamstring muscles by pressing the heels into the bed. Force from the heels was given slightly back towards the body.

Supine heel slides: 10 repetitions, 2 times a day.

Patient position and procedure: In supine position with knee flexed (as much as patient could do), patient was asked to slide the heel along the floor to extend the knee and return it to starting position.

Supine straight leg raise: 10 repetitions, 2 times a day.

Patient position and procedure

Supine position with feet together and toes pointed straight up to the ceiling and the soles of feet perpendicular to the ground.

Hands were down by side. Patient was asked to lift the leg up as high as possible with keeping knee in extension and returned it to the starting position.

Supine terminal knee extension (VMO): 10 repetitions, 2 times a day.

Patient position and procedure

In supine position, bolster was kept under the knee (with 30° of knee flexion). Patient was asked to straighten the knee and slowly return to the starting position.

Prone knee bends: 10 repetitions, 2 times a day.

Patient position and procedure

In prone position, the patient was asked to bend the knee so that heel of the foot could move toward the buttocks, then relax and allow foot to return to its starting position.

Calf stretch: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position: Supine

To stretch gastrocnemius muscle keep knee in extension

3 repetitions with 30 sec. hold, 1 time a day.

Hand placement and procedure

The patient's heel (calcaneus) was grasped with one hand, subtalar joint was maintained in a neutral position, and forearm was placed along the plantar surface of the foot. The anterior aspect of the tibia was stabilized with other hand. Talocrural joint of the ankle was dorsiflexed by pulling the calcaneus in the inferior direction with thumb and fingers while gently applying pressure in a superior direction just proximal to the heads of the metatarsals with forearm.

To stretch soleus muscle keep knee in flexion

3 repetitions with 30 sec. hold, 1 time a day.

The knee was kept in flexed position to eliminate the effect of two-joint gastrocnemius muscle. Hand placement, stabilisation and stretch force were the same as when stretching the gastrocnemius muscle.

Self stretching for gastrocnemius and soleus

3 repetitions with 30 sec. hold, 1 time a day.

Patient position and procedure

The patient was asked to stand in stride forward position with one foot, keeping the heel of the back foot flat on the floor (the back foot was the one being stretched). To provide stability to the foot, the patient partially rotated the back leg inward so the foot assumed a supinated position and lock the joints. The patient then shifted body weight forward onto the front foot. To stretch the gastrocnemius muscle, the knee of the back leg was kept extended. To stretch the soleus knee of the back leg was kept flexed.

Supine hamstring stretch: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position: Supine

Hand placement and procedure

With patient's knee fully extended, lower leg was supported with arm or shoulder.

The opposite extremity was stabilized along the anterior aspect of the thigh with other hand.

With the knee at 0° extension and the hip in neutral rotation, hip was flexed as far as possible.

Self stretching for hamstring: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position and procedure

Patient was made to stand with extremity to be stretched on a stool or the seat of chair. The patient was then asked to lean the trunk forward toward the thigh, keeping the back extended so that motion is only at the hip joint.

Prone quadriceps stretch: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position: Prone

Hand placement and procedure

Pelvis was stabilized by applying downward pressure across the buttocks. Anterior aspect of distal tibia was grasped and knee was flexed.

Self stretching for quadriceps: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position and procedure

Prone with the knee flexed on the side to be stretched. Patient was asked to grasp the ankle on that side and flex the knee.

Supine iliopsoas stretch: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position

Patient was positioned close to the edge of the treatment table so the hip being stretched was extended beyond neutral. The opposite hip and knee were flexed toward the patient's chest to stabilize the pelvis and spine

Hand placement and procedure

The opposite leg was stabilized against the patient's chest with other hand or if possible the patient was made to assist by grasping around the thigh and holding it to the chest to prevent an anterior tilt of the pelvis during stretching. Hip to be stretched was moved into extension or hyperextension by placing downward pressure on the anterior aspect of distal thigh with hand.

Self stretching for iliopsoas: 3 repetitions with 30 sec. hold, 1 time a day.

Patient position and procedure

Supine with hips near the end of the bed, both hips and knees were flexed and the thigh on the side opposite the tight hip held against the chest. Patient was made to slowly lower the thigh to be stretched toward the bed in controlled manner and allow the knee to extend, so the two-joint rectus femoris would not limit the range. Thigh was not allowed to externally rotate or abduct. The patient was directed to let the weight of the leg cause the stretch force and to relax the tight muscles at the end of the range.

Patello-femoral medial and lateral mobilisation: 2 sets of 30 glides, Maitland's mobilization. 1 time a day.

Patient position: Supine with the knee extended.

Hand placement: The heel of hand was placed along either medial or lateral aspect of patella. The other hand was placed under the femur for stabilization.

Mobilizing force: The patella was glided in medial or lateral direction, against the restriction.

Ergonomic advices

- To avoid prolong standing, cross sitting and squatting.
- Frequent breaks should be taken in profession requiring long hours of standing.

Toilet modification

Avoid Indian toilets, instead use commode, if not possible, use toilet chair.

RESULTS

Statistical analysis

- The data was entered using MS-EXCEL 2013 and analysed using New Primer and SPSS version 20 software.
- Descriptive analysis for numerical data consists of mean with standard deviation (SD) for various parameters.
- Frequencies for categorical data are expressed in percentage.
- Normality test was done by using Kolmogorov Smirnov test.
- Parametric test was used wherever the data passed the test of normality and non parametric test was used wherever the data did not pass the test of normality.
- Repeated measure ANOVA was used for comparison within the groups (for comparison of means of variable recorded at 0 weeks, 2 weeks and 4 weeks).
- Unpaired-t test and Mann-Whitney U test were used for comparison of differences of means of 0-2 weeks, 2-4 weeks and 0-4 weeks between two groups.
- The p value less than 0.05 considered as statistically significant.
- The data of the present study is quantitative and continuous in nature

Table 1 Comparison of Nprs Within The Group

	NPRS	N	Mean	Std. Deviation	Median	P value	Significance
Group A	At 0 weeks	20	6.1	1.0	6.5	-----	-----
	At 2 weeks	20	2.55	1.2	2	0.000	Significant
	At 4 weeks	20	3.2	1.5	3	0.000	Significant
Group B	At 0 weeks	20	6.25	1.11	7	-----	-----
	At 2 weeks	20	2.75	1.11	3	0.000	Significant
	At 4 weeks	20	2.9	1.16	3	0.000	Significant

Table 2 Comparison of Differences of Means of Nprs between the Two Groups

	NPRS	Group	N	Mean	Std. Deviation	P value	Significance
At 0-2 weeks		Group A	20	3.65	1.348	0.686	Not significant
		Group B	20	3.50	0.9459		
At 2-4 weeks		Group A	20	-0.65	1.663	0.158	Not significant
		Group B	20	-0.15	0.670		
At 0-4 weeks		Group A	20	3.00	1.777	0.776	Not significant
		Group B	20	3.35	1.268		

Table 3 Comparison of Tug within the Group

	TUG	N	Mean	Std. Deviation	Median	P value	Significance
Group A	At 0 weeks	20	14.35	3.03	13	----	-----
	At 2 weeks	20	11.95	2.70	11	0.000	Significant
	At 4 weeks	20	12.40	2.06	12	0.000	Significant
Group B	At 0 weeks	20	14.85	2.134	15.5	----	-----
	At 2 weeks	20	13.00	2.103	13	0.000	Significant
	At 4 weeks	20	13.30	2.430	13.5	0.000	Significant

Table 4 Comparison of Differences of Means of Tug between the Two Groups

	TUG	Group	N	Mean	Std. Deviation	P value	Significance
At 0-2 weeks		Group A	20	2.4	1.353	0.119	Not significant
		Group B	20	1.85	0.933		
At 2-4 weeks		Group A	20	-0.45	2.064	0.303	Not significant
		Group B	20	-0.30	0.571		
At 0-4 weeks		Group A	20	1.95	2.350	0.616	Not significant
		Group B	20	1.55	1.146		

Table 5 Comparison of Womac Score within The Group

	WOMAC	Mean	N	Std. Deviation	Median	P value	Significance
Group A	At 0 weeks	34.90	20	14.690	37	---	-----
	At 2 weeks	14.45	20	8.864	13.5	0.000	Significant
	At 4 weeks	17.25	20	2.081	15	0.000	Significant
Group B	At 0 weeks	40.20	20	12.110	41	---	-----
	At 2 weeks	17.40	20	8.062	17.5	0.000	Significant
	At 4 weeks	18.80	20	7.388	19	0.000	Significant

Table 6 Comparison of Differences of Means of Womacscore between the Two Groups

	WOMAC	Group	N	Mean	Std. Deviation	P value	Significance
At 0-2 weeks		Group A	20	20.35	11.63	0.561	Not significant
		Group B	20	22.30	10.04		
At 2-4 weeks		Group A	20	-2.8	3.518	0.516	Not significant
		Group B	20	-1.4	4.570		
At 0-4 weeks		Group A	20	17.15	12.02	0.160	Not significant
		Group B	20	21.60	10.35		

DISCUSSION

The objective of this study was to investigate the effect of sodium salicylate iontophoresis and conventional TENS on pain, function and quality of life as well as to compare which of the treatment was more effective.

After screening for inclusion criteria a total of 40 patients, 29 females and 11 males were included for the study. There were 4 males and 16 females with mean age of 49.80 ± 6.66 years in group A and 7 males and 13 females with mean age of 51.35 ± 8.19 years in group B. The ratio of females to males was higher in both the groups.

Group A i.e. conventional group received conventional TENS and knee exercises.

Group B i.e. experimental group received sodium salicylate iontophoresis and knee exercises.

The results of the study revealed that,

- There was significant decrease in pain on NPRS, decrease in time taken on TUG test i.e. improvement on function and decrease in WOMAC score indicating improvement in activities of daily living and quality of life in patients treated with sodium salicylate iontophoresis and knee exercises.
- There was significant decrease in pain on NPRS, decrease in time taken on TUG test i.e. improvement on function and decrease in WOMAC score indicating improvement in activities of daily living and quality of life in patients treated with conventional TENS and knee exercises.
- The effect between group A and B was found not significant post intervention i.e. at 2 weeks and at 4 weeks follow up.

Numerical Pain Rating Scale (NPRS)

Comparison within the group

As evident from table no. 1 for group A and B, this study showed significant improvement in pain in both, group A and group B.

Improvement in pain in group A can be attributed to conventional TENS. Its pain modulatory effect may not be associated with any peripheral anti-inflammatory or analgesic effects but to centrally mediated analgesic process. The centrally mediated analgesic effect of TENS via the release of endogenous opiates from centres in the periaqueductal grey matter, rostral ventral medulla, substantia gelatinosa etc into cerebrospinal fluid may have played significant role.⁵¹

Conventional TENS i.e. high frequency, low intensity electric pulses; which works on "Pain Gate Mechanism" proposed by Melzack and Wall in 1965, has effect on both A δ (fast) and C (slow) pain fibres in posterior horn, due to stimulation of mechanoreceptors A β fibres.⁵² These A β fibres give off collaterals which impinge on nociceptor cells of the A δ and C pain fibres in laminae of posterior horn. It is believed that the input of these mechanoreceptors effectively reduces the excitability of the nociceptor cells to pain generated stimuli.⁵² These relatively large diameter nerves (A β) are capable of being stimulated at low current intensities and conveys impulses at high frequencies. Therefore, conventional TENS was appropriate and effective.⁵²

Improvement was also seen in pain in group B i.e. in sodium salicylate iontophoresis group. The reduction in pain is a resultant effect of salicylate ions being repelled from the cathode and penetrating through the superficial and deep fascia into the periarticular and articular structures.⁵³ Salicylate ions might have induced analgesia by inhibiting the enzyme cyclooxygenase (COX-2) involved in the production of prostaglandin which is a potent pain mediator.²¹ A study of rhesus monkey has shown that therapeutic dosage can be delivered to deeply placed joint structures by Glass (1980).⁵⁴

The reduction in pain could also be corroborate by reports of researchers, who carried out sodium salicylate iontophoresis on painful warts located on the weight bearing surface of the feet

and discovered that iontophoresis had the advantage of being painless and most patients were able to bear weight on the area with no pain immediately following treatment.⁴² Hence, in current study sodium salicylate iontophoresis shows improvement in pain in patients in group B.

There was a statistically significant improvement in pain between group A and group B at post intervention i.e. at 2 weeks and at follow-up i.e. at 4 weeks. Slight increase in pain was observed at follow up, but was not as much as that of pre-intervention level.

Comparison between groups

As evident from table no. 2 the current study showed statistically no improvement in pain in experimental group i.e. group B of sodium salicylate iontophoresis when compared to conventional group i.e. group A of conventional TENS.

Timed Up and Go test (TUG)

Comparison within the group

As evident from table no. 3 for group A and B, this study showed significant reduction in time taken over TUG test in both, group A and group B.

Reduction in time taken over TUG test in group A and group B can be attributed to strengthening of quadriceps femoris and hamstring muscles in addition to conventional TENS and sodium salicylate iontophoresis in group A and group B respectively.

Abnormal tracking of patella and weakness of VMO contribute to faulty patellofemoral joint mechanics and hence results in anterior knee pain. Role of VMO is to stabilize the quadriceps femoris and prevent its abnormal tracking which helps in reducing pain and improve function.⁵⁵

AMI Oliveira (2012)⁵⁶ found that, quadriceps strengthening exercises are effective to improve pain, function and stiffness in patients with knee osteoarthritis.

Ng GYF (2006)⁵⁷ found that, generalised strengthening combined with biofeedback for the vastus medialis may have an additional benefits. Also, Slemenda C. (1997)⁵⁸ found that, weakness is a primary risk factor for knee pain, disability, and progression of joint damage in persons with osteoarthritis of the knee.

Hamstring muscles attach to both the medial and lateral aspect of the knee joint, hence pure knee flexion requires activity of both the medial and lateral muscle mass. Contraction of the only medial hamstring produces knee flexion with medial rotation of the knee and vice versa. Hence, weakness of both or either of the heads of hamstring interferes with the function.⁵⁵

AR Hafez (2013)⁵⁹ found that, Strengthening the hamstring muscles in addition to strengthening the quadriceps muscles proved to be beneficial for perceived knee pain, range of motion, and decreasing the limitation of functional performance of patients with knee OA. Also, Hortobagyi T. (2005)⁶⁰ found that, increased hamstring muscle activation while executing activities of daily living. Altered muscle activation at the knee may interfere with normal load distribution in the knee and facilitate disease progression. Therapeutic interventions should focus not only on quadriceps

strengthening but also on improving muscle balance at the knee.

Improvement in function on TUG test can be attributed to strengthening exercises supported by previous studies.

Comparison between groups

As evident from table no. 4 the current study showed statistically no difference in time taken over TUG test in experimental group i.e. group B of sodium salicylate iontophoresis when compared to conventional group i.e. group A of conventional TENS.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Comparison within the group

As evident from table no. 5 for group A and B, this study showed significant reduction in WOMAC score in both, group A and group B.

Reduction in WOMAC score in both group A and group B can be attributed to strengthening exercises for both the groups and conventional TENS and sodium salicylate iontophoresis respectively.

Centrally mediated analgesic effect of conventional TENS in group A and locally induced analgesia by sodium salicylate ions in iontophoresis in group B brought significant reduction in pain in both the groups. In addition to this, patients in both the groups received strengthening exercises which improved their functional ability. This reduction in pain and improvement in functional ability contributed to improvement in ADLs and ultimately quality of life with reduction in WOMAC score.

F. Dincer (2006)⁶¹ found that, physical therapy including both physical agents and exercise leads to significant improvement in pain, physical function and quality of life.

This is similar to the results of current study which also shows an improvement in activities of daily living (ADLs) and in quality of life.

Comparison between groups

As evident from table no.6 the current study showed statistically no difference in WOMAC score in experimental group i.e. group B of sodium salicylate iontophoresis when compared to conventional group i.e. group A of conventional TENS.

CONCLUSION

- There was statistically significant reduction in pain, improvement in function and in quality of life in patients treated with conventional TENS (group A).
- There was statistically significant reduction in pain, improvement in function and in quality of life in patients treated with sodium salicylate iontophoresis (group B).
- At 2 weeks post intervention and at 4 weeks follow-up, with home exercise program, the changes were statistically significant as compared to the pre treatment values within the groups.
- When both the groups were compared the experimental group (group B) with sodium salicylate iontophoresis

showed no statistical significant improvement in pain, function and quality of life over control group (group A) with conventional TENS in knee osteoarthritis.

Limitations

No means (except for verbal) of assuring compliance with home exercise programme were utilized.

Suggestions

- Further study with a longer duration of follow-up may be carried out to determine the carry over effect of sodium salicylate iontophoresis.
- Assessment of knee range of motion and strength should be done.
- Exercise sheet with dosage of exercise and pictorial presentation may be given to the patients for home program.
- Efficacy of increasing the number of treatment sessions may be studied.

Clinical Implications And Applications

- Results of the study showed that conventional TENS and sodium salicylate iontophoresis were equally effective in reducing pain, improving function and quality of life in patients with knee osteoarthritis, when combined with exercises.
- Conventional TENS and sodium salicylate iontophoresis in combination with exercises and ergonomics can be used alternatively for better improvement in pain, function and quality of life in patients with knee osteoarthritis.

Summary

The aim of the study was to observe the effectiveness of sodium salicylate iontophoresis in patients with knee osteoarthritis.

It was an interventional study, in which 40 patients with knee osteoarthritis were included as they fulfilled the criteria and were allocated to either group A or group B by computer generated random allocation list.

Group A was the conventional group and Group B was the experimental group. 11 males and 29 females were included in the study with their age ranging between 40-60 years. There were 4 males and 16 females with mean age of 49.80 ± 6.66 years in group A and 7 males and 13 females with mean age of 51.35 ± 8.19 years in group B.

Numerical Pain Rating Scale, Timed Up and Go test and Western Ontario and McMaster Osteoarthritis Index were used as outcome measures.

Patients were assessed pre intervention at 0 week, post intervention at 2 weeks, and follow up at 4 weeks. 6 sessions of intervention was given over a period of 2 weeks.

The conventional group received conventional TENS and knee exercises. The experimental group received sodium salicylate iontophoresis and knee exercises.

Data was collected and statistical analysis was done. Repeated measure ANOVA was used for comparison within the groups (for comparison of means of variable recorded at 0 weeks, 2

weeks and 4 weeks). Unpaired-t test and Mann-Whitney U test were used for comparison of differences of means of 0-2 weeks, 2-4 weeks and 0-4 weeks between two groups.

Results suggested that conventional TENS and sodium salicylate iontophoresis both showed improvement in pain, function and quality of life, which was statistically significant within the group ($p < 0.001$).

Comparison of the two groups showed, no statistically significant difference in improvement in pain, function and quality of life in group B (experimental group) as compared to group A (conventional group).

Thus from the results of the present study it can be concluded that conventional TENS and sodium salicylate iontophoresis along with exercises and ergonomics can be used alternatively for a better improvement in pain, function and quality of life in patients with knee osteoarthritis.

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