

Comparative Study of High TENS, Low TENS, Tramadol In Physiatrie Management of Primary OA Knee.

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Objectives: To compare the effectiveness and safety of High TENS, Low TENS and Tramadol in the management of OA Knee

Study Design – Prospective randomized controlled parallel group study.

Study Area – Osteoarthritis Clinic and OPD of Physical Medicine and Rehabilitation Deptt. IPGMER, SSKM Hospital.

Sample - Patients with bilateral symmetrical primary OA Knee attending Osteoarthritis Clinic and OPD of PMR. IPGMER, SSKM Hospital from November 2008 – November 2014. Patients were divided into 4 groups.

- GR 1: life style modification, Exercise, Orthoses, Paracetamol
- GR 2: above + High TENS
- GR3: above for GR1 + Low TENS
- GR4: above for GR1 + Tramadol (100mg controlled release BD)

Outcome measures- VAS score for pain, WOMAC (pain, function), ROM by goniometry,

Results- Pain is decreased in all groups significantly ($p=0.000006$). There is statistically no significant differences observed between groups.

Discussion- High TENS, Low TENS and Tramadol is effective to alleviate symptoms of OA.

• **Conclusion**- TENS has superior effect in Pain (VAS), Tenderness, and WOMAC (Pain) score. High TENS the best to control pain and stiffness and ultimately excellent to improve function. Low TENS and Tramadol is effective and safe for OA.

Key words- OA knee, High TENS, WOMAC

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I. Introduction

Osteoarthritis also erroneously called degenerative disease represents failure of the diarthrodial joints¹. In Idiopathic (primary OA), the most common form of the diseases, no predisposing factor is apparent¹. Cardinal pathologic feature of OA is a progressive loss of articular cartilage. OA is not a disease of only the cartilage but a disease of an organ, the synovial joint in which all of the tissues are affected - subchondral bone, synovium, meniscus, ligaments and supporting neuromuscular apparatus and cartilages¹. In primary OA it is believed that excessive loads cause failure of an otherwise normal joint².

Standard non-pharmacological treatments like therapeutic exercise can potentially reduce the inflammation by correcting altered joint biomechanics. Modalities like High TENS and Low TENS are known to produce reduction of pain by their action on pain gate and can bring other symptomatic improvement. Transcutaneous electrical nerve stimulation (TENS) is effective for pain relief in patients with OA

and may be particularly effective for the knee. We hypothesize that TENS will reduce pain, resulting in increased function.

Mechanism of Action of TENS by 1) Presynaptic inhibition in the dorsal horn of the spinal cord. 2) Endogenous pain control (via endorphins, enkephalins, and dynorphins). 3) Direct inhibition of an abnormally excited nerve. 4) Restoration of afferent input³.

Dose: Amplitude - Current at a comfortable, low intensity level, just above threshold. Pulse width (duration) - 10-1000 microseconds. Pulse rate (frequency) - 80-100 impulses per second (Hz); 0.5-10 Hz when the stimulus intensity is set high⁴.

The primary aim of this study is to compare the effect and safety of high (100Hz) TENS, low (10Hz) TENS and Tramadol in 120 patients with OA Knee on subjective pain scores, and function.

II. Materials and Methods

This study was conducted in the Department of Physical Medicine and Rehabilitation IPGMER, SSKM Hospital, Kolkata for a period of 6 years (November 2008 – November 2014). All the patients with bilateral symmetrical primary OA Knee attending Osteoarthritis Clinic and PMR OPD, IPGMER and SSKM Hospital were included in this study group with following exclusion criteria:

1. Received nutraceuticals (e.g. glucosamine) or Risedronate or DMOAD in last 6 months.
2. Received I/A Hyaluronic Acid/ steroid in last 6 months.
3. Pregnant or Lactating women planning to conceive
4. Hepatic or Renal dysfunction.
5. Contraindication to High TENS.
6. Contraindication to strengthening exercise.
7. Hypersensitivity to tramadol.

Informed consent was obtained from all individuals and the study was carried out in accordance with the Institutional Human Ethical Clearance Committee. A total 122 patients were included for 6 months (2 monthly follow up) in this prospective randomized controlled parallel group study.

Demographics and Medical history were taken at visit 1.0. Physical examinations were done at visit 1, 2, 3. 122 small folded papers each with one number (from no. 1 to no. 122) written inside were randomly picked up and divided into four groups. Each group received therapeutic exercises, orthosis (if needed).

- GR 1: life style modification, Exercise, Orthoses, Paracetamol (Total no. of patient 32)
- GR 2: above + High TENS (Total no. of patient 31)
- GR 3: above for GR1 + Low TENS (Total no. of patient 29)
- GR 4: above for GR1 + Tramadol (100mg controlled release BD) (Total no. of patient 30)

All patients were initially advised joint protection, education, weight reduction, ROM exercises and Multiple Angle Sub Maximal Isometric Quadriceps, Hamstring strengthening exercises 3 sets, 3 times a week, for the first 2 weeks and then daily. Isotonic strengthening exercises (both close kinetic chain and open kinetic chain) 3 times a week were added from 5th week. Knee orthosis and shoe/slipper modification (with heel wedge) were advised appropriately. High TENS was advised for 40 minutes, consecutively first ten days in a month for six months.

Careful assessment of pain by Visual Analogue Scale (VAS), ROM by goniometry at all visits. Joint Tenderness and Soft Tissue Swelling were evaluated on a 4-grade scale and 2 grade scales respectively at all visits. Pain, Stiffness and difficulty performing daily activities measured with help of WOMAC (Western Ontario MC Master Universities Osteoarthritis) index at each visit. At each visit clinical assessment was done to pick up adverse effects, which were recorded and treated appropriately.

III. Result Analysis

Data collected were analyzed by -- **paired t test, Chi-square test with Yates' continuity correction, Tukey's test**. All analysis has two tailed and $p < 0.05$ is considered statistically significant. Age composition of our study population showed that 79 % of patients are more than 45 yrs old with female preponderance (72 females, 50 males). BMI study of population showed that 58 % of both the male and female patients are above desired weight range. Our study design includes patients belonging to all four radiological grades of Kellgren –Lawrence system. But most of the patients belong to grade 2 and 3 in all four study groups.

Outcome assessment:

Pain (VAS): Pain is decreased in all four groups significantly ($p=0.000000$). There is no statistically significant differences observed between groups.

In all groups there is significant improvement occurs in ROM($p < 0.0004$), WOMAC (Pain) ($p = 0.000000$), WOMAC (Stiffness) ($p < 0.05$), WOMAC (Physical Function) ($p = 0.000000$), WOMAC (Total) ($p = 0.000000$). But there is no statistically significant differences observed between groups in improvement of, ROM, WOMAC (Pain), WOMAC (Stiffness), WOMAC (Physical Function) , WOMAC (Total). From chartitis clear that, in GR.2(HIGH TENS) VAS (P) (**3.0370±1.15962**), WOMAC(PAIN)(**8.0741±3.02459**),WOMAC(FUNCTION)(**23.7407 ±9.44454**) is reduced more than any other group.

IV. Discussion

In this study 79 % of patients are more than 45 yrs old which is seen in the available study also⁵. Incidence and severity of OA are greater in women than men⁵. BMI study of population showed that 52 % of both the male and female patients are above desired weight range. This observation is consistent with the information that greater BMI in both male and female has been associated with an increased risk of OA^{6,7}

Nonpharmacological treatment i.e. orthosis, shoe modification, therapeutic exercises can reduce the inflammation, and modify the biochemical picture of the joint by improving the biomechanics of knee. It is found that CRP is elevated in all groups suggesting that OA is an inflammatory disease⁷.

High TENS, Low TENS, Tramadol has superior effect in Pain (VAS), Tenderness, WOMAC (Pain) than others. According to one study there is improvement in total WOMAC scores, pain VAS, knee range of motion and after 10 therapy sessions^{8,9,10,11,12,13,14,15}.

A study shows 40 minutes are the optimal treatment duration of High TENS, in terms of both the magnitude (VAS scores) of pain reduction and the duration of post-stimulation analgesia for knee Osteoarthritis and there is 70% to 80% pain relief success rate for High TENS⁸. Our study also supported the data. NSAIDs and opioids offer similar pain relief in OA patients. These data could help clinicians and patients discuss likely benefits of alternative analgesics.¹⁶

V. Summary And Conclusion

In conclusion this study consisting 120 patients of bilateral symmetrical primary OA Knee shows that nonpharmacologic interventions is definitely helpful for modification of sign, symptoms, morbidity, functional capacity and quality of life in OA knee patients. High TENS is best to control pain and stiffness and ultimately excellent to improve function. Low TENS and Tramadol is effective and safe for OA.

Change in pain

	Baseline	post-treatment	P-value
	Mean ± SD	Mean ± SD	
Group1—(CONTROL GROUP)	7.4815±1.67264	4.3333± 1.54422	0.000000
group2—(HIGH TENS)	7.5185±1.62600	3.0370±1.15962	0.000000
group-3—(LOW TENS)	8.2963±1.40917	5.1481±1.32153	0.000000
group-4—(TRAMADOL)	7.9286 ±1.60851	4.7500 ± 1.57821	0.000000

CHANGE IN WOMAC(PAIN) SCORE

	Baseline	post-treatment	P-value
	Mean ± SD	Mean ± SD	
Group1—(CONTROL GROUP)	31.7407±11.1582	12.8148± 6.59275	0.000000
group2—(HIGH TENS)	30.2963 ±8.63720	8.0741±3.02459	0.000000
group-3—(LOW TENS)	34.1852±7.79564	16.7407±4.17495	0.000000

group-4—(TRAMADOL) 33.0357 ±8.38642 15.7500 ± 5.04517 0.000000

CHANGE IN WOMAC(FUNCTION) SCORE

	Mean ± SD	Mean ± SD	
Group1—(CONTROL GROUP)	111.5556 ±39.38502	38.8889 ± 21.75623	0.000000
group2—(HIGH TENS)	109.9259 ±30.90298	23.7407 ±9.44454	0.000000
group-3—(LOW TENS)	122.5926 ±31.70205	58.1111 ±20.37029	0.000000
group-4—(TRAMADOL)	118.0357 ±34.48186	53.5714 ± 53.5714	0.000000

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