Comparison of Mesotherapy and Transcutaneous Electrical Nerve Stimulation (TENS) in the Management of Chronic Non-Specific Low Back Pain: A Randomized Clinical Trial

Comparaison entre la Mésothérapie et la Stimulation Électrique Transcutanée (TENS) dans la Prise en Charge de la Lombalgie Chronique Commune: Essai Clinique Randomisé

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Abstract

Introduction-Aim: Chronic low back pain affects 80% of individuals at some point in their lives and has significant socioeconomic impacts. This study aims to compare the efficacy of mesotherapy with transcutaneous electrical nerve stimulation (TENS) in treating chronic low back pain.

Methods: A randomized bicentric study was conducted at the Military Hospital of Tunis and the Multidisciplinary Military Polyclinic of Mefeteh Saadallah between August 2023 and June 2024. Sixty patients (40 men and 20 women) with chronic low back pain were included. Group 1 (TENS) received 6 sessions of neurostimulation twice a week for 3 weeks. Group 2 (mesotherapy) received 3 sessions of mesotherapy. Measurements included pain, analgesic consumption, physical examination, Oswestry Disability Index, Hospital Anxiety and Depression (HAD) score, and patient satisfaction.

Results: Out of 293 patients consulted, 60 were included and randomized. Both groups showed significant pain improvement ($p<0.001$) with no notable difference between them ($p=0.05$). Analgesic consumption decreased more significantly with mesotherapy ($p<0.001$). Improvements in physical examination, Oswestry score, and HAD score were significant in both groups without significant differences between them. Patient satisfaction was high in both groups with an average score of 88/100 for TENS and 77/100 for mesotherapy ($p=0.154$).

Discussion: Mesotherapy and TENS are effective in treating chronic low back pain, reducing pain and improving functional and psycho-emotional scores with no significant difference between them. Mesotherapy reduces analgesic consumption more. Further studies are needed to confirm these results.

Key words: Chronic low back pain, Mesotherapy, Transcutaneous electrical nerve stimulation (TENS), Rehabilitation.

Résumé

Introduction-Objectif: La lombalgie chronique, affectant 80 % des individus à un moment donné de leur vie, a un impact socio-économique significatif. L'objectif de cette étude est de comparer l'efficacité de la mésothérapie à celle de la neurostimulation transcutanée (TENS) dans le traitement des lombalgies chroniques.

Méthodes: Étude randomisée menée à l'Hôpital Militaire Principal d'Instruction de Tunis et à la Polyclinique Militaire Multidisciplinaire de Mefeteh Saadallah entre août 2023 et juin 2024. Soixante patients (40 hommes, 20 femmes) souffrant de lombalgie chronique ont été inclus. Le groupe 1 (TENS) a reçu 6 séances de neurostimulation, 2 fois par semaine pendant 3 semaines. Le groupe 2 (mésothérapie) a reçu 3 séances de mésothérapie. Les mesures incluaient la douleur, la consommation d'antalgiques, l'examen physique, le questionnaire d'Oswestry, le score HAD pour l'anxiété et la dépression, et la satisfaction des patients.

Résultats: Sur 293 patients consultés, 60 ont été inclus et randomisés. Les deux groupes ont montré une amélioration significative de la douleur ($p<0,001$), sans différence notable entre eux ($p=0,05$). La consommation d'antalgiques a diminué davantage avec la mésothérapie ($p<0,001$). Les améliorations dans l'examen physique, le score d'Oswestry et le score HAD étaient significatives dans les deux groupes, sans différence significative entre eux. La satisfaction des patients était élevée dans les deux groupes, avec un score moyen de 88/100 pour TENS et 77/100 pour la mésothérapie ($p=0,154$).

Discussion: La mésothérapie et le TENS sont efficaces pour traiter la lombalgie chronique, réduisant la douleur et améliorant les scores fonctionnels et psycho-émotionnels sans différence significative entre eux. La mésothérapie réduit davantage la consommation d'antalgiques. Des études supplémentaires sont nécessaires pour confirmer ces résultats.

Mots clés: Lombalgie chronique, Mésothérapie, Neurostimulation transcutanée (TENS), Réhabilitation

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Introduction

Chronic low back pain is a major public health issue affecting a large portion of the global population due to its high prevalence and significant socioeconomic impact. According to the World Health Organization (WHO), about 80% of individuals will experience low back pain at some point in their lives, and a significant proportion will develop a chronic form of this condition (1). It is characterized by pain in the lumbar region persisting for more than three months and is often associated with significant functional limitations and decreased quality of life. While medication treatments are commonly used to manage this condition, there is growing interest in non-drug approaches due to their potential benefits and fewer side effects.

Management of these patients often involves oral medication treatment, which is poorly tolerated and quickly abandoned by patients (2,3). Other management methods exist, including local medication or non-drug therapies. These methods are of particular interest compared to general routes due to their good tolerance and better compliance (4). They are also increasingly popular with patients, with a global trend towards so-called alternative or complementary medicines (5).

Among the local medication therapies is mesotherapy. It is defined as local intradermal injections of very superficial and minimally painful injectable drugs at a chosen site and in a measured quantity (6). Several studies have proven its effectiveness in common low back pain with virtually no adverse effects (6-9). However, this technique is not yet integrated into our routine practice and lacks consensus on its use.

Among non-drug therapies, there is transcutaneous electrical nerve stimulation (TENS), an analgesic electrotherapy technique recommended since 2009 by the French National Authority for Health (HAS), and its purchase by patients is reimbursed by social security for pain management (10).

In Rehabilitation departments in Tunisia, these two analgesic techniques are commonly used and precede active rehabilitation, the only guarantee against recurrence or chronicity (11-13). Indeed, they facilitate physiotherapy exercises and increase tolerance to active exercises.

The objectives of this work were:

- To evaluate the impact of mesotherapy and TENS on lumbar pain, lumbar spine flexibility, and the functional and psychological consequences of chronic low back pain patients.
- To compare the two techniques to guide optimal management of common chronic low back pain, contributing to better allocation of therapeutic resources and improvement of patient quality of life.

Methods

Study Description

A bicentric comparative randomized study was conducted in the physical medicine and rehabilitation (PMR) departments of the Military Hospital of Tunis (HMPIT) and the Multidisciplinary Military Polyclinic of Mefeteh Saadallah (PMMMS) in Tunis, Tunisia, between August 2023 and June 2024. It included patients over 18 years old referred to the mentioned services for the management of chronic low back pain (lasting more than five weeks) of non-specific origin (degenerative). Non-inclusions were pregnant women and patients with clinical signs indicative of symptomatic low back pain (neoplasia, infectious, inflammatory, fracture), associated neurological disorders (sensory and/or motor disorders of the lower limb, urinary disorders, perineal or external genitalia hypoesthesia), contraindications to electrotherapy use (pacemaker, implantable defibrillator, deep hypoesthesia or thermoalgic sensitivity disorder, evolving skin infection/lesion at the treatment site), or contraindications to mesotherapy use (general disease affecting hemostasis functions or anticoagulant intake with INR >4, autoimmune disease, drug allergy to one of the used products, evolving skin infection/lesion at the treatment site). Exclusions included patients who refused to give consent and those who did not complete the entire therapeutic protocol or did not attend the follow-up consultation.

Interventions

After verifying the inclusion, non-inclusion, and exclusion criteria, patients were invited to participate in the study. After signing informed consent, they were randomly assigned to two groups:

- Group 1: Received 6 sessions of analgesic electrotherapy type TENS, with 2 sessions per week for 3 weeks. The electrotherapy current was applied through electrostimulation electrodes placed on trigger points and painful irradiations (Figure 1). The machine used was the TENS ECO2 from Schwa Medico 2016, France. The program used was the Gate control program (high frequency), and the intensity was adjusted to the patient's tolerance. The program choice was based on Melzack's 1965 work explaining the TENS action mechanism in chronic pain (inhibition of nociceptive impulse transmission by activating an inhibitory interneuron at the posterior horn of the spinal cord) (14). The average session duration was 20 minutes (pre-programmed programs recorded in commercially available devices).

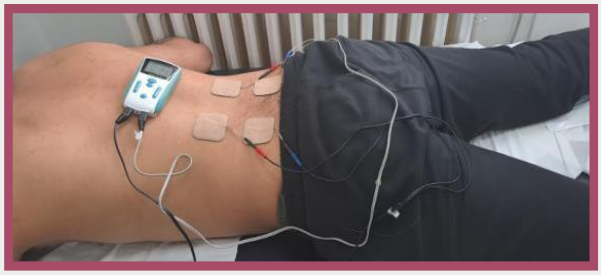

Figure 1. Analgesic electrotherapy TENS session for low back pain treatment.

- Group 2: Received 3 mesotherapy sessions combining two techniques (epidermal and intradermal) using

medications proven effective either by general or mesotherapeutic route in symptomatic pain treatment (1% Lidocaine, magnesium, Piroxicam, and Thiocholchicoside) with specific mesotherapy needles of 4 and 13 mm (Figure 2).

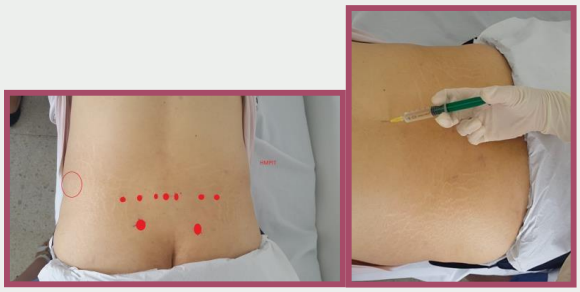

Figure 2. Analgesic mesotherapy session for low back pain treatment.

The injection points were those designated as painful by the patient, painful points found during the examination, and tendomyalgia. The number of sessions, drugs, and injection points were based on literature data (6-16) and the Practical Guide to Mesotherapy by Doctors Christian Bonnet, Denis Laurens, and Jean-Jacques Perrin, considered mesotherapy pioneers (17).

- For the epidermal technique, the chosen mixture was 2 cc of 1% Lidocaine + 2 cc of magnesium sulfate + 1 cc of Thiocholchicoside injected at 1 mm depth using a 13 mm needle.
- For the deep dermal technique, the chosen mixture was 2 cc of 1% Lidocaine + 1 cc of Piroxicam + 1 cc of Thiocholchicoside injected at 4 mm depth using a 4 mm needle.

Since the patients were not undergoing any long-term prescribed medical treatment, they were prescribed paracetamol (a level 1 analgesic) on an as-needed basis (in case of pain)

Evaluation Methods

Patients were evaluated before the treatment and one month after its cessation. Evaluated items included pain using the visual analog scale (VAS), antalgic posture, palpation contractures, frequency of analgesic use {0: Never; 1: Rarely; 2: Occasionally; 3: Daily}, the Oswestry Disability Index validated in Arabic (18), and the Hospital Anxiety and Depression (HAD) score validated in Arabic (19). Patient satisfaction with the received treatment and possible adverse effects were also noted.

The Oswestry Disability Index questionnaire for low back pain-related disability is a self-administered questionnaire developed in the 1980s and evaluates the following items: pain intensity, personal care ability, lifting objects, walking, sitting, standing, sleeping, sexual life, social life, and traveling (20). It is interpreted as follows (20):

- Score between 41 and 60%: severe disability; all activities are affected in these patients who require thorough investigations.
- Score between 61 and 80%: major disability; these patients should be referred to a specialist.
- Score between 81 and 100%: bedridden patient.

Statistical Analysis

Data were entered and analyzed using SPSS version 22.0 (Statistical Package for social Science Inc., Chicago, IL, USA). Descriptive analysis was performed by calculating frequency, percentage, and averages with standard deviation. The comparison of quantitative variables between the two groups was performed using Student's t-test for independent samples (normal distribution). The comparison of qualitative variables was performed using Pearson's Chi-squared test or Fisher's exact test. A p-value <0.05 was considered statistically significant.

Ethical Considerations and Disclosure of Interest

We declare to have no conflict of interest with the study. Full written informed consent was obtained from all participants. The approval of the hospital's ethics committee has been obtained.

Results

A total of 293 patients consulted for low back pain in the PMR services of HMPIT and PMMMS during the study period. Among them, only 70 did not meet the exclusion criteria. They were randomized in 2 groups (38 in the first group, and 32 in the second group). Finally, 10 patients did not attend the follow-up visit after one month and were excluded. The flow diagram is summarized in Figure 3.

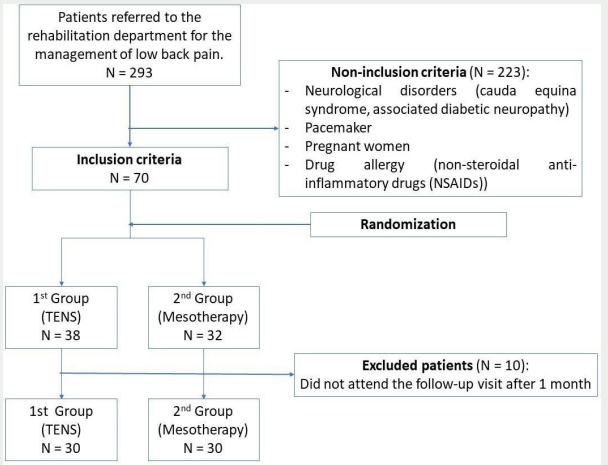

Figure 3. Flow chart

Demographic characteristics of patients and underlying pathology

Forty men and twenty women, with a mean age of 39.8 years (SD ± 8.2), were included in the study. The most common etiology of low back pain was degenerative disc disease (55% of the sample), followed by disc herniation (18%), functional origin (15%), and congenital lumbar spinal stenosis (12%). The average duration of symptom progression was 11.7 months (SD ± 8.3). Approximately 73% (n=44) of the patients took sick leave during their illness, with an average duration of 20.4 days (SD ± 7.12).

Pain and analgesic consumption

There was a significant improvement in low back pain in both groups ($p < 0.001$), but there was no significant difference between the two groups (p=0.5) (Table 1).

Table 1. Improvement of pain before and after treatment in the two groups

Pain (VAS)		Average	Standard Deviation	p
Groupe 1	Before TENS	7,230	1,478	<0,001
	After TENS	4,790	1,214	
Groupe 2	Before Mesotherapy	7,160	0,934	<0,001
	After Mesotherapy	4,757	1,168	

VAS: visual analog scale, TENS: transcutaneous electrical nerve stimulation

There was a significant reduction in as-needed paracetamol consumption in both groups ($p < 0.001$), with mesotherapy being superior to TENS ($p < 0.001$) (Figure 4).

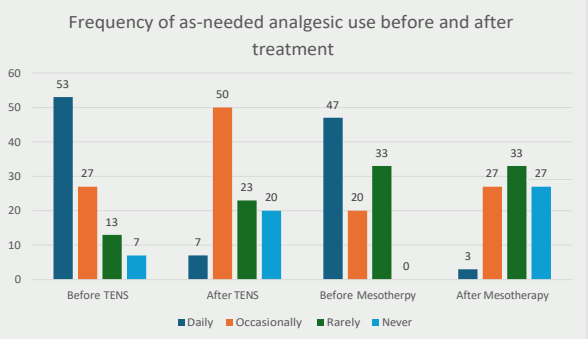

Figure 4. Frequency of as-needed analgesic use before and after treatment

TENS: transcutaneous electrical nerve stimulation

Physical examination data

There was a significant improvement ($p < 0.001$) in both groups with a decrease in maladaptive antalgic spinal postures and palpable contractures during the examination, but without any difference between the two groups.

Functional and psychological evaluation

Oswestry Low Back Pain Disability Questionnaire

There was a significant improvement in both groups for the Oswestry Low Back Pain Disability Questionnaire scores ($p<0.001$), but no significant difference between the two groups (p=0.154) (Table 2).

Psychological Evaluation by the HAD Score

There was a significant improvement in both groups for the HAD questionnaire scores ($p<0.001$), but no significant difference between the two groups (p=0.212). (Table 2)

Satisfaction and Adverse Effects

The satisfaction evaluation by the visual analog scale was 88/100 (SD=12) for the TENS group and 77/100 (SD=15) for the mesotherapy group, with no significant difference between the two groups (p=0.154). No adverse effects were observed in the TENS group. One patient in the mesotherapy group reported the occurrence of hematomas at the injection sites.

Table 2. Improvement of the Oswestry Low Back Pain Disability Questionnaire and HAD Scores

Scale	Items	Groupe 1		Groupe 2		p
		Before TENS	After TENS	Before Mesotherapy	After Mesotherapy	
Oswestry Low Back Pain Disability Questionnaire	Minimal disability	10 %	57 %	13 %	53 %	0,154
	moderate disability	67 %	43 %	50 %	47 %	
	severe disability	20 %	0	37 %	0	
	major disability	3 %	0	0	0	
	bedridden patient	0	0	0	0	
Hospital Anxiety and Depression (HAD) score (%)	No symptoms	10	60	0	60	0,212
	Bordeline symptoms	53	37	67	40	
	Probable symptoms	37	3	33	0	
p		<0,001		<0,001		

TENS: transcutaneous electrical nerve stimulation, **HAD**: Hospital Anxiety and Depression

Discussion

Both mesotherapy and transcutaneous electrical nerve stimulation (TENS) have demonstrated significant efficacy in the symptomatic treatment of low back pain. These techniques effectively alleviate pain, reduce maladaptive pain-coping attitudes, lessen muscle contractures, improve functional scores, and decrease anxiety-depressive symptomatology, with no significant difference between the groups. The consumption of demand-based analgesics (paracetamol) is significantly reduced in both groups, with a slight advantage in the mesotherapy group.

Efficacy of Mesotherapy in the Symptomatic Treatment of Common Low Back Pain

Mesotherapy, also known as intradermotherapy, is a medical technique developed by Dr. Michel Pistor in the 1950s (21). It involves the injection of medications into the skin. This method combines the action of puncture, similar to acupuncture, with the diffusion of the medication towards underlying anatomical structures (7,16). Several studies have demonstrated its effectiveness

in alleviating pain and improving algo-functional scores (Oswestry) in the management of chronic low back pain (8,9). Mesotherapy is reported to be even more effective than treatment with intravenous or oral steroidal (AIS) and non-steroidal anti-inflammatory drugs (NSAIDs) (9,22). It also has a role in the management of acute low back pain or "lumbago" in general practice consultations or emergency departments (23). A randomized trial in 2019 compared the efficacy of mesotherapy with oral NSAIDs in the treatment of sciatica associated with low back pain, finding that mesotherapy was superior in pain relief and in improving spinal joint range of motion and Oswestry scores (24). Mesotherapy has also been compared to epidural injections in low back pain associated with lumbar spinal stenosis, with comparable results in both groups (25). Various medications have been used in mesotherapy sessions and are reported to be effective: NSAIDs (ketoprofen, diclofenac, tenoxicam) (9,22,24), muscle relaxants (thiocolchicoside) (8), calcitonin (25), anesthetics (lidocaine, bupivacaine) (9,25), and collagen (25). Even intradermal injections of saline solution and sterile water have shown efficacy in low back pain (26–28), and their use could be beneficial in cases of drug allergies, shortages of certain products, or in pregnant women.

Efficacy of TENS in the Symptomatic Treatment of Common Low Back Pain

Transcutaneous electrical nerve stimulation (TENS) is the therapeutic application of electrical nerve stimulation through the skin (29,30). It is primarily used to relieve pain in various acute and chronic conditions. TENS units typically use adhesive electrodes applied to the skin's surface to deliver pulsed electrical stimulation that can be adjusted in terms of frequency (stimulation rate), intensity, and duration (29,31). The process by which TENS induces analgesia is considered multifactorial, likely involving peripheral, spinal, and supraspinal mechanisms. The peripheral mechanism was suggested by an animal study in which the heightened mechanical sensitivity caused by peripheral serotonin injection (a substance naturally produced after injury and inflammation) was reduced by TENS application, and this improvement was inhibited by pre-injection of a peripheral opioid receptor blocker (32). The spinal effect of electrical stimulation operates via the "Gate control" mechanism through large diameter afferent fibers (Aβ), thereby inhibiting nociceptive transmission to the brain and reducing the perception of pain (14,33). The supraspinal effect is modulated by activating descending inhibitory pain pathways (34–36).

A systematic review with meta-analysis published in 2022, including 381 randomized controlled trials (RCTs), aimed to compare TENS with placebo and conventional physiotherapy in managing acute or chronic musculoskeletal pain in adults (37). The authors concluded that there is moderate-quality evidence indicating that pain intensity is lower during or immediately after TENS compared to placebo, without serious adverse events. Several European guidelines recommend its use in treating chronic pain, particularly in low back pain (38,39). The effect of TENS on spinal flexibility and muscle quality was also studied in a systematic review and meta-analysis published in 2023 (40). The included RCTs showed a significant improvement in spinal range of motion, especially in forward flexion, but the meta-analysis did not provide conclusive evidence to recommend TENS (40). Regarding muscle trophicity improvement, active exercise far surpassed TENS (40). TENS also significantly improved functional disability measured by the Oswestry score, more so than physical exercise (41).

Comparison between Mesotherapy and TENS in Symptomatic Treatment of Common Low Back Pain

No equivalent study to ours has been identified in the indexed literature. The study most similar is Florio's 1995 trial comparing mesotherapy with TENS in post-whiplash cervicalgia in terms of pain, cervical posture, quality of life, and disability (42). This study concluded that there was no difference between the intervention groups. Other studies have attempted to compare mesotherapy with various physiotherapy treatments, including extracorporeal shock waves (43,44). These studies focused on Achilles tendinopathy and myofascial syndrome, with results favoring shock waves (43,44).

Nonetheless, mesotherapy remains a valuable tool in physical medicine and rehabilitation departments because it allows physicians to offer active, pain-free exercises that can accelerate recovery (6). It provides pain relief and improves functional scores, which are key objectives in managing musculoskeletal pathologies (6). Standardized protocols combining rehabilitation with mesotherapy for the treatment of spinal pain have been published (45).

Conclusion

Mesotherapy and TENS are both significantly effective in the symptomatic treatment of low back pain. Both techniques alleviate pain, reduce antalgic postures and muscle spasms, improve functional scores, and decrease anxiety-depressive symptoms, with no significant difference between the two groups. The consumption of analgesics (paracetamol) as needed is significantly reduced in both groups, with a slight superiority in the mesotherapy group. Several studies in the literature support this efficacy, although few have compared the two methods directly.

Practically, in Tunisia, mesotherapy offers the advantage of requiring fewer sessions compared to physical therapy and is readily available in medical offices. TENS, on the other hand, is more accessible through paramedical professionals, and the device can be purchased by patients for home use. Therefore, either technique could be proposed, in the absence of contraindications, as a symptomatic treatment for common low back pain before starting active rehabilitation, which is essential for long-term improvement.

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