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High-tone external muscle stimulation (HTEMS) for radicular leg pain
compared to transcutaneous electrical nerve stimulation (TENS)
Dissertation

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DEDICATION

I would like to dedicate my thesis to my father who has always been there for me, for his support and guidance and for urging me to carry on with scientific research and i would like to thank my mother and sister for their love and support. I dedicate my thesis to my wife and my son Yusuf for their unconditional love support and sacrifice.

DECLARATION

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material extent has been accepted for the award of any other degree or diploma of the university or other institute of higher learning, except where due to acknowledgment has been made in the text.

Eslam Darwish Mohamed

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ABSTRACT

Sciatica is a common pain problem that affects not only the patient but also constitutes a socioeconomic burden and thus concerns the whole society. So far, current pharmacologic therapies are inadequate for many patients. Only few non drug-based therapies have proven a positive impact. We evaluated application of high-tone electrical muscle stimulation (HTEMS) compared to transcutaneous electrical nerve stimulation (TENS) on radicular pain associated with sciatica.

Hospital patients (n = 100) with chronic sciatica and stable oral analgesic regimen were included into this randomized controlled cross-over trial. Each intervention was administered for a period of 45 min 5 times within 10 days, with a 3-day wash-out period before cross-over. Pain impairment was assessed using the visual analog scales (VAS) for radicular pain before and after intervention. Differences in radicular pain between groups were analysed with the Mann-Whitney test.

During the 1st phase of intervention radicular pain intensity was significantly reduced during HTEMS treatment ($p < 0.0001$), while no statistically significant improvement occurred with TENS. Pain reduction was reported by 56% of the participants after HTEMS and by 41% using TENS (Odds Ratio 1.83[1.05–3.21]). After cross-over, significant pain reduction was observed for both groups ($p < 0.0001$ with HTEMS and $p = 0.0015$ with TENS). While carry-over effects could be excluded, the difference of radicular pain reduction demonstrated a higher pain improving potential for HTEMS than for TENS ($p = 0.011$).

Conclusions

HTEMS bares a higher potential for short term reduction of radicular pain than TENS and might offer new therapeutic strategies for treatment of chronic sciatica.

Keywords

high-tone external muscle stimulation (HTEMS), transcutaneous electrical nerve stimulation (TENS), chronic sciatica, Cauda equina syndrome (CES), Chronic pain syndrome (CPS)

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ABBREVIATIONS

(TENS)	Transcutaneous electrical nerve stimulation
(HTEMS)	High-tone external muscle stimulation
(PAG)	The periaqueductal grey
(RVM)	The rostral ventral medulla
(LF-TENS)	Low frequenz TENS
(HF- TENS)	High frequenz TENS
(NSAIDs)	Non-Steroidal-Anti-Inflammatory-Drugs

CHAPTER 1

INTRODUCTION

1.1 Definition of Sciatica:

Sciatica is defined as radicular leg pain and it is considered as a common pain problem. Radicular leg pain is actually a symptom and not a disease; mostly occurs in the lumbar spine due to compression of a nerve root. Lumbar nerve roots provide motor and sensory innervation of the buttocks and legs. Nerve root compression causes weakness, numbness, tingling and pain along the dermatome innervated by the nerve root. (1)(2)

1.2 Anatomy of sciatic nerve:

Background and origin:

The sciatic nerve is the largest, thickest and longest nerve in the human body. Sciatic nerve is the largest branch of sacral plexuses, it runs through Buttock and thigh muscles. The sciatic nerve provides innervation for nearly the whole of skin and muscles of the back of thigh, leg and foot.

- a) **Course:** it leaves the pelvis through greater sciatic foramen below piriformis muscle, then descends first in gluteal region undercover of long head of biceps.
- b) **End:** it ends by dividing into medial and lateral popliteal nerves at the middle of the thigh.
- c) **Branches:**
 - Motor branches: to hamstring muscles (biceps, semimembranosus & semitendinosus) + ischial part of adductor magnus
 - Articular branches: to the hip joint

The sciatic nerve then divides into its two main branches:

I. **The medial popliteal nerve: (also known as Tibial nerve)**

Which originate at the middle of back of thigh as the larger of the 2 terminal branches of Sciatic nerve.

1. **Course:** it traverses the popliteal fossa from upper angle to lower angle
(This means Superficial to popliteal vessels from lateral to medial.)

2. **Branches of tibial nerve:**

- Motor; to 4 muscles of back of leg (Gastrocnemius, Plantaris, Popliteus and Soleus)
- Cutaneous; sural nerve, which runs on back of leg and lateral side of foot
- Articular; 3 genicular branches to knee joint

3. **End:** ends by becoming posterior tibial nerve at the lower border of popliteal muscle.

The Tibial nerve gives:

- Motor innervation: to 4 muscles on the back of the leg (Soleus, Tibialis posterior, Flexor digitorum longus and Flexor hallucis longus)
- Cutaneous branch to the skin of the heel

II. **Lateral popliteal nerve: (also known as common peroneal nerve)**

Which innervates the anterolateral compartment of leg and foot and gives genicular branches to knee joint.

-**Course:** descends in popliteal fossa from upper angle to its lateral angle along medial side of biceps muscle then pierces peroneus longus muscle.

-End: inside peroneus longus muscle on the lateral aspect of neck of fibula into 2 branches:

1) Musculocutaneous nerve:

Known also as superficial peroneal nerve innervating lateral compartment of leg muscles

- **Motor branches:** (Peroneus longus and Peroneus brevis)

- **Cutaneous:** lower 2/3 of anterolateral aspect of leg and dorsum of foot except the cleft between the first and second toes.

2) Anterior tibial nerve:

Known also as deep peroneal nerve giving the following branches:

- **Motor:** anterior compartment of leg and dorsum of foot, to 5 muscles; Tibialis anterior, Extensor hallucis longus, Extensor digitorum longus, Peroneus tertius and Extensor digitorum brevis.
- **Sensory:** Skin of the first cleft between first and second toes
- **Articular:** to the ankle joint and joints of foot.

(Grants Atlas of Anatomy ninth Edition by Anne M. R. Agur & Synopsis of surgical Anatomy by Sameh Doss Ph.d)

1.3 Socioeconomic dimension of Sciatica

Sciatica is a common problem, the lifetime prevalence of low back and radicular leg pain is reported to be as high as 84%, and the prevalence of chronic pain development is about 23%, with 11-12% of the population being disabled. (3) Sciatica affects not only the patient but also constitutes a socioeconomic burden and thus concerns the whole society. Sciatica and low back pain are the leading cause of disability for people < 45 years old, nearly 50% of the people who experience radicular leg pain suffer the initial episode before the age of 30 years. (1) No correlation between the incidence of low back pain and referred pain and occupational posture was found. (1)(2) Sciatica is the 2nd leading cause for physician visits, the 3rd most common cause for surgical procedures and the 5th most common reason for hospitalization. (4) The costs associated with low back and radicular leg pain include the direct cost of medical care and the indirect costs of time lost from work, disability payments, and diminished productivity. In the workplace, low back and radicular leg pain are the most costly ailment, with an average cost of \$8,000 per claim, and accounts for one third of workers' compensation costs. The estimated annual national bill for the care of low back and radicular leg pain problems in USA is \$38 to \$50 billion. (4)(5) This radicular pain, commonly referred to as sciatica, when not associated with a neurologic deficit, bladder or bowel dysfunction then a conservative therapy is indicated. This includes systemic or local drug administration, physical therapy and chiropractic treatment. Nevertheless, despite those and many other therapeutic options about 10 percent of the people suffering sciatic pain remain unable to work and about 20 percent of them have persistent symptoms at one year. (2). This essentially impairs quality of life and ability to work with a high rate of sick leave. (1)(2)

1.4 Causes of Sciatica

Sciatica occurs mostly due to nerve root compression causing inflammation, pain and numbness. This could be due to different reasons such as disc herniation, lumbar spinal stenosis, spondylolisthesis, piriformis syndrome, compression by a tumor, post-nucleotomy syndrome (failed back surgery), and nerve damage. (6)(7)

1.4.1 Disc herniation

Disc herniation pressing on lumbar or sacral nerve roots is the primary cause of sciatica, being present in about 90% of cases. (6)(7) 40% of the population under 35 years do have a disc degeneration and by the age of 60 almost 100% do have signs of disc degeneration in Magnetic resonance imaging. (8) The intervertebral discs consist of an anulus fibrosus ring, which surrounds an inner nucleus pulposus. When there is a tear in the anulus fibrosus, the nucleus pulposus then extrude and press against exiting spinal nerve roots, causing inflammation, numbness, or pain. Inflammation can also cause low back pain through spreading to the adjacent facet joints and there may also be pain referral in the thighs referred to as pseudo-radicular pain. Pain can spontaneously subside if inflammation ceases in case the disc prolapse regress in size and the tear in anulus fibrosus ring heals (Figure1.1).

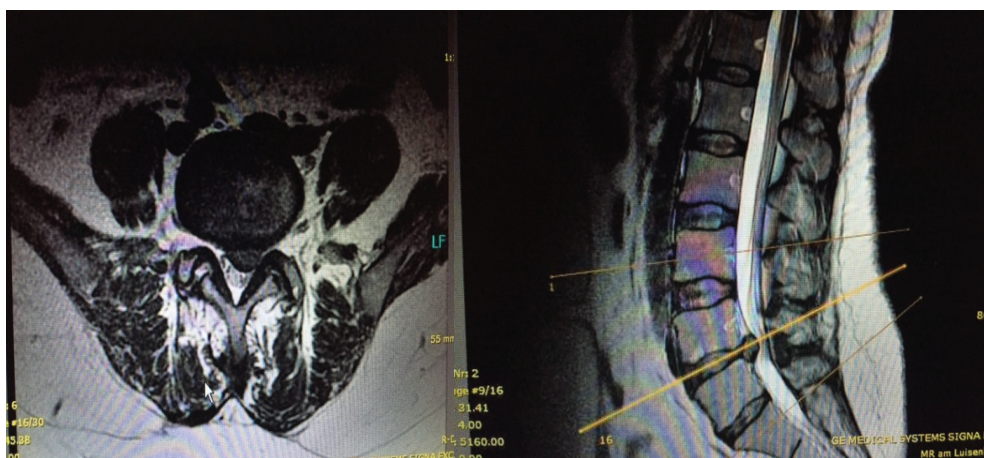


Fig.1.1 Disc Prolaps L4/5

1.4.2 Lumbar spinal stenosis

Narrowing of the spinal canal, it could be bony or ligament hypertrophy. The typical clinical picture is spinal claudications, pain in both legs and usually associated with decreased walking distance (Figure 1.2). The lumbar spinal canal is to be considered narrow when its diameter is fewer than 10 mm. After these radiological criteria, Almost 21% of all patients over 60 years old do have lumbar spinal canal stenosis. (9)

Causes of lumbar spinal canal stenosis:

-Congenital narrow spinal canal.

-Acquired: degenerative, Spondylolisthese, Trauma



Fig. 1.2 Spinal canal stenosis L4/5

1.4.3 Spondylolisthesis

It is defined as a forward displacement of one vertebra over another one (Figure 1.3). Spondylolisthesis is classified according to the etiology or according to severity. Through the forward displacement of one vertebra over the other one, narrowing of the neuroforamen occurs and thus sciatic pain occurs. (10)

Classification according to etiology after Wiltse

- Isthmic (the most common type), which have many, subtypes characterized mainly by having a defect in Pars interarticularis either through a congenital lyse or through fracture in pars interarticularis.
- Degenerative through disc- and facet joint degeneration.
- Pathological; through tumor causing a defect in Pars interarticularis for example an osteolyse.
- Dysplastic.

Classification according to severity after Meyerding

- MDI° : Slip of Vertebra under 25 % of the vertebral body depth.
- MDII° : between 25–50 %.
- MDIII° : between 50-75 %.
- MDIV° : more than 75 %.



Fig. 1.3 Spondylolisthesis L4/5

1.4.4 Post-Nucleotomy Syndrome (Failed back surgery)

It is defined as feeling strong radicular leg pain few weeks following a short period without pain after spinal surgery. It is usually due to scar tissue, also known as epidural fibrosis. It is inevitable to open the epidural space during disc operation. Despite the modern microsurgical techniques and very meticulous hemostasis and fine mechanics, it has not been possible to significantly reduce fibrosis. Magnetic resonance tomography with contrast shows the difference between scar or disk tissue.

1.4.5 Piriformis Syndrome:

Pseudosciatic pain caused by compression of peripheral sections of the nerve, usually from soft tissue tension in piriformis muscle.

1.4.6 Malignancy:

It usually occurs through a metastasis. The spine is the third most common site for cancer cells to metastasize, following the lung and the liver. Some studies estimated that over 30 to 70% of patients with primary tumor do have spinal metastasis at autopsy.

Primary sources:

-Lung 31%

-Breast 24%

-GI Tract 9%

-Prostate 8%

-Lymphoma 6 %

1.4.7 Nerve damage:

This could happen through displaced fracture or by a disease such as diabetes.

1.5 Clinical Picture Sciatica

(See table 2.1 for detailed symptoms and signs) A typical clinical history usually shows pain increase upon coughing, sneezing and usually accompanied by nerve stretching pain, known as; Lasegue Sign, Bragard-Gowers-sign and Femoralis stretching pain sign. (6)(7)

1.6 Complications that could endanger sciatica patient

1.6.1 Chronic pain syndrome (CPS)

It is considered as a challenging major problem that requires attention in order to decrease its progress, which is responsible for the deterioration of the patient's quality of life. Mostly ongoing pain of 3-6 months is highly indicative of increased risk of developing chronic pain syndrome. This condition is managed best with a multidisciplinary approach. The patients who seek and find help in the first six months usually have the best prognosis. (6)(7)

1.6.2 Nerve damage resulting in numbness or weakness of affected leg

It usually occurs due to persisting pressure on the nerve root, usually complains the patients about numbness or weakness of affected leg, if it is not taken seriously and ignored, it may lead up to what is known as nerve death where the pain subsides but the muscle weakness progresses, in some cases a full muscle paralysis can develop. That's why the treatment of sciatic patients requires alertness of medical practitioners in order to be able to determine when to refer the patient to a spine specialist, who should determine whether to carry on with conservative therapy trial or to favor a surgical decompression. (6)(7)

1.6.3 Loss of control over bowel &/or bladder function

This could happen due to pressure on the nerves innervating the bladder and regulating the bowel function. As previously mentioned, this entails the vital role of interdisciplinary work between family doctor and spine specialist surgeon to avoid these complications that affect the patient's quality of life and his productive ability and thus have also a socioeconomic burden. (2)(6)

1.7 Management

Management of sciatica requires alertness of treating physician and interdisciplinary narrow contact between family physician and specialist, as the decision of referral should be made in some cases without any delay to avoid developing chronic complications. Management entails diagnosis and therapy. (7)

1.7.1 Diagnosis

The diagnosis of radicular leg pain has solely 2 main targets:

- Recognizing and analyzing symptoms, signs and speculation of the cause. (7)
- Exclusion of severe underlying causes and complications, which could eventual require nearby medical or surgical intervention. (7)

1.7.1.1 Clinical picture

The clinical manifestation and the careful clinical examination could elicit at which level is the pathology to be anticipated and which nerve is mostly compressed. The physician should carefully examine the muscle strength and reflexes. He should also examine whether the radiating pain is accompanied with any other disabilities, like sensation defect or Bladder-/bowel dysfunction. The psychic evaluation plays also a fundamental role in the examination and therapy planning (7) (Table1.1).

Tab. 1.1 Symptoms and signs by radicular leg pain (mod. after Börm 2005)

Nerve root	Peripheral pain and sensation field	Motor defect	Reflex affected	Nerve stretching pain
L1 and L2	Groin region	-Iliopsoas muscle	None	-Femoralis stretching pain
L3	Front of thigh	-Iliopsoas muscle -Femoris muscle	-Adductor reflex -Patellar reflex	-Femoralis stretching pain
L4	Front of thigh + Medial side of leg	-Quadriceps femoris Muscle	-Patellar Reflex	-Positive Lasegue sign -Femoralis stretching pain
L5	Lateral side of thigh, Leg and medial side Of foot + big toe	-Extensor hallucis longus Muscle	-Tibialis Posterior Reflex	-Positive Lasegue sign
S1	-Back of thigh and Heel + lateral side of Foot + toes 3,4 and 5	-Triceps surae muscle	-Achillis Reflex	-Positive Lasegue sign

1.7.1.2 Diagnostic imaging tools

For the therapy planning, the treating physician usually needs imaging tools to be able to identify the underlying cause of radicular leg pain. (7)

- **Magnetic resonance tomography (MRI):** is the method of choice for diagnosing diseases of the lumbar spine. It can detect whether there is a spinal canal stenosis, disc prolapse, Infection, fracture or even a tumor, mostly in form of metastasis, could also be detected. Nowadays MRI became indispensable diagnostic tool in every spine clinic for its crucial role in diagnosis and management. (7)
- In case of previous spine surgeries then a MRI with contrast should be made in order to differentiate between fibrous scar tissue and disc material.
- **Computer Tomography (CT):** In case there is an obstacle, which prevents the patient from doing MRI-Spine study, for example, having a heart pacemaker then a computer tomography (CT)-lumbar spine will do. (7)
- **X-rays,** although traditional plain X-rays are limited in their ability to image soft tissues such as discs, muscles, and nerves, they are still used to confirm or exclude other possibilities such as fractures or Spondylolisthesis. (7)
- **Electromyogram (EMG):** This test measures the electrical impulse along nerve roots, which indicates whether there is ongoing nerve damage, if the nerves are in a state of healing from a past injury, or whether there is another site of nerve compression. EMG/NCS studies are typically used to pinpoint the sources of nerve dysfunction distal to the spine and to diagnose myelopathy and even in the follow up. (11)

1.7.2 Therapy Concept

Treating sciatic pain is sometimes challenging and needs awareness and alertness from the treating physician. A conservative therapy defined as non-operative therapy is always indicated before a surgical decision is to be made unless there is **red flag symptom or sign** that favors the surgical therapy. (7)

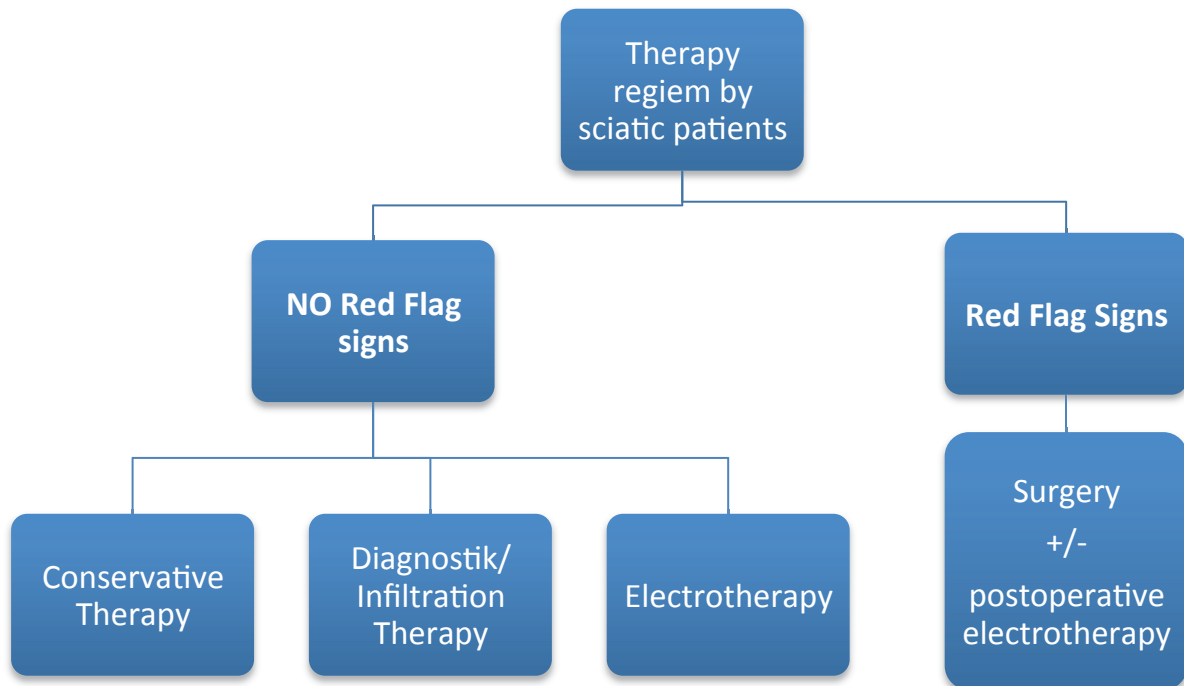


Fig. 1.4 Therapy regimen

These red flag symptoms or signs could be one of the following:

- **Paresis or paralysis:** of one of the affected muscle groups; in form of muscle weakness, usually the patient notices the weakness and of course through careful medical examination the examining physician could elicit the weakness. (7)
- **Cauda equina syndrome (CES):** is a serious neurologic condition in which damage to the cauda equina causes loss of function of the lumbar plexus, (nerve roots) of the spinal canal below the termination (conus medullaris) of the spinal cord. CES is a lower motor neuron lesion. (7)

Otherwise a conservative therapy trial is usually indicated, of course this depends also on the clinical and radiological criteria and it varies also according to the treating physician

experience. The normal course in absence of muscle weakness and Bowel-/Bladder dysfunction is that the patient being subjected through the family doctor to conservative therapy trial for the first weeks, sometimes months and in case of persisting pain, the patient will be referred to either orthopaedic or neurosurgeon specialist and he or she will mostly decide whether the patient should have invasive intervention whether infiltration therapy or operation. It is to be mentioned that the studies showed that if the patient had the radicular pain for more than 3 months then risk of developing chronic pain increases, that's why there should be an intense interdisciplinary contact between the family doctors and the specialists in order to avoid increasing the number chronic pain patients.

Conservative Therapy

The conservative therapy is the non-invasive therapy. In case there are no red flag signs then it is usually indicated for at least the first 6 weeks. Usually it is a multimodal interdisciplinary approach and it has many aspects. It includes medications, physiotherapy, ultrasound, orthoses, physiotherapy and electrotherapy.

1.8.1 Medications

It is considered principally symptomatic treatment. (7)(12)

1) Analgesics: they are classified into two main categories:

- Non-Opioid analgesics

The non-opioid analgesics work mainly through inhibiting cyclooxygenase and thus decreasing prostaglandin synthesis and pain. They are classified into:

a) **Antipyretic:** like paracetamol, Aspirin and metamizol

- Paracetamol appears to act centrally in the brain rather than peripherally in nerve endings through reversible inhibition of cyclooxygenase but it does not possess an anti-inflammatory effect. No studies to verify its role in treating radicular leg pain. (7) In high doses it could affect the liver and cause serious damage.

- Aspirin acts through irreversible inhibition of cyclooxygenase.
- Metamizol (Novalgin) is the strongest analgetic and antipyretic non-opioid analgesic works through reversible inhibition of cyclooxygenase.

b) **Anti-inflammatory:** like Diclofenac, indomethacin and Celecoxib

Non-Steroidal-Anti-Inflammatory-Drugs (NSAIDs). The most common side effects are the gastrointestinal symptoms. They do inhibit cyclooxygenase, leading to a decrease in prostaglandin production. In contrast to paracetamol and the opioids, this reduces not only pain but inflammation as well.

COX-2 inhibitors

These drugs have been derived from NSAIDs. The cyclooxygenase enzyme inhibited by NSAIDs have 2 different entities: COX1 and COX2. Most of the adverse effects of NSAIDs to be mediated by blocking the COX1 enzyme, while the analgesic effects being mediated by the COX2 enzyme.

Thus, the selective COX2 inhibitors were developed to inhibit only the COX2 enzyme (traditional NSAIDs block both versions in general). These drugs celecoxib are equally effective analgesics when compared with NSAIDs, but cause less gastrointestinal hemorrhage in particular. Schjerning Olsen et al. stated that most of the NSAIDs drugs increase the risk of cardiovascular events by 40% on average.

NSAID: Evidence class II Cox-2-Inhibitor as placebo, it should be only short use in acute pain exacerbations. (7)

- Opioid analgesics:

For example (Tilidin, Morphin, Oxycodon, Fentanyl)

Opioid analgesics work at three levels:

- Spinal:

Through activation of descending inhibitory tracts and inhibition neural activity in thalamus and limbic system

- Spinal:
Through inhibition of afferent nerves in spinal cord
- Peripheral:
Through inhibition of pain in nocioreceptores

They do have many side effects like nausea, vomiting, sedation, miosis, increased intracranial pressure, tolerance, respiratory depression and central sympatholyse effects on cardiovascular system. All of which limit their use. (7)(12)

Tab. 1.2 Application of analgesic medications according the WHO- Pain therapy regime

Level I	Little pain	Non opioid
Level II	Moderate pain	Non opioid + low potent opioid
Level III	Strong pain	Non opioid + highly potent opioid

- 2) **Oral Cortisone** e.g. Prednisolone 50 mg / day for 3-5 days, then Optionally tapering off to 10 mg per day (7)(12). It is commonly used in the acute pain attacks.

Cortisone possesses a potent anti-inflammatory through which the nerve inflammation subsidens and thus the pain decreases. Ofcourse cortisone has many side effects on the different body systems:

- Cardiovascular: fluid and sodium retention, congestive heart failure, potassium loss, hypokalemic alkalosis and hypertension.
- Gastrointestinal: peptic ulcer with potential perforation and haemorrhage, abdominal dissention, nausea, increased apetite and ulcerative esophagitis.

- Musculoskeletal: osteoporosis resulting vertebral compression fractures and other pathological fractures, muscle weakness, steroid myopathy, loss of muscle mass, aseptic necrosis of femoral heads and tendon ruptures.
- Psychiatric: euphoria, mood swings, severe depression and personality changes.
- Nervous system: convulsions, headache, vertigo and increased intracranial Pressure.
- Endocrine: Cushing syndrome, growth suppression in children.
- Ocular: cataract, glaucoma and exophthalmos
- Hematologic: thromboembolism has been rarely reported.
- Genitourinary: menstrual irregularities and disturbance in number of spermatozoa.

3) Muscle relaxant: (Benzodiazepine, Tolperison, Cyclobenzaprin)

Muscle relaxants are a heterogeneous group of medications acting both centrally and peripherally to relieve muscle spasms. They are indicated for the treatment of two different types of conditions: spasticity from upper motor neuron syndromes and muscular pain or spasms from peripheral musculoskeletal diseases or injury such as low back pain. They cause asymptomatic elevations in serum aminotransferase levels in up to 5% of subjects. Cases of acute liver failure and death have been reported after chlorzoxazone and dantrolene therapy. (12)

4) Antidepressives: (Amitriptylin, Imipramin) Antidepressives reduce pain but do not enhance the function. (7)

5.) Anticonvulsives: (for example Carbamazepin, Valproate, Gabapentin) Clinical studies could not prove a positive effect for Gabapentin in radicular leg pain reduction. (12)

1.8.2 Physical Therapy

Physical therapy plays a vital role in both conservative and surgical therapy regimes. This entails many aspects as:

Physiotherapy aims to: (7)

- Achieving posture correction and to strengthen the spinal column and the supporting muscles, ligaments and tendons, it also aims to strengthen the abdominal muscles, gluteus and hip muscles for example 'McKenzie exercises' and 'Dynamic Lumbar Stabilization'.
- Pain relief through stretching to alleviate sciatic pain for example the Piriformis and Hamstrings.
- Strength training atrophied muscles or prevention of muscular atrophy.
- Improvement of coordination and stabilization.
- Enhancing body awareness through stress perception training specific stabilizing exercises.

In addition to muscular strengthening, mobilization and posture correction, there are other physiotherapy means, these are:

- **Thermotherapy:** treatment includes blasted warming. This is supposed to enhance arterial hyperemia and thus enhance blood circulation and metabolism. Studies for efficacy are lacking.
- **Massage:** studies for efficacy are lacking.
- **Hydrotherapy:** includes all therapies using water or heat transfer fluids. The goal is to influence muscle tone and thus promoting muscle relaxation and enhancing muscle strengthening, also the hydrostatic effect reduces edema. Studies for efficacy are lacking.

- **Manual therapy:** the manipulation is a defined procedure, which entails a fast or slow, single or repetitive movement of the joint and associated muscles of the spine or sacroiliac joint.

1.8.3 Ultrasound

The goal of treatment in the application of ultrasound is to influence the results of degenerative disc problems. Convincing studies for efficacy are lacking. (7)

1.8.4 Orthoses

Orthoses are tools that are applied to the spine in order to contribute to the support and stabilisation. It usually has the following effects:

- Stabilization of affected segments + heat effect.
- They are known internationally for the body segments that they bridge such as: LSO Lumbo-sacral orthosis.

The orthoses are usually used as a conservative supplementary therapy, as well postoperatively in some selected cases to provide extra stability. (7)

1.8.5 Psychotherapy

This plays nowadays a vital role in the therapy of sciatica patients especially those having been suffering from pain from over 3 months with the risk of developing chronic pain syndrome, it entails talking about mental or emotional problems and providing help and support for the patient and nowadays it is fundamental part of the therapy regime in centers specialized in treating pain. (13)

1.8.6 Occupational therapy, aftercare and professional reintegration

Occupational therapy supports people who are suffering of sciatic pain, being treated conservatively or even operated, who are encountering a restriction in their ability to work.

The objectives and methods of therapy depend on the individual rehabilitation objectives and needs according to its somatic and psychological condition. For example adjusting the place of work in accordance with grade and nature of disability. (7)

Aftercare and professional reintegration include the following measures. Organization and implementation of professional participation and integration through socio-legal advice and counseling to measures such as home care or placement inpatient or day-patient care facilities. (7)

1.9 Invasive Therapy

The patients, who do not respond to the conservative therapy regimes and complain about persistence of pain, will be referred to a specialist who will by his role determine whether these patients should have an invasive therapy trial. Invasive therapy could be non-surgical or surgical. (7)

1.9.1 Invasive non-surgical Infiltrations

The non-surgical therapy usually consists of X-ray C-Arm or CT- guided spinal infiltration, usually carried out by orthopedic surgeon or by radiologist. (7)(16)

- Epidural injections: There is no hard evidence that epidural cortisone application useful by radicular leg pain although it is widely used but there is still no study that ends this debate and its use is still controversial Evidence class III (Hopayian 1999).
- Facet-joint blockage and denervation: It has been proven of benefit in treating back Pain and pseudoradicular pain. It is widely used to treat back pain especially in case of activated arthritis of facet joint. It usually gives dramatic pain relieve but usually the effect does not last long enough.

Usually during spine infiltration a local anesthetic, for the rapid pain relieve effect, will be used in combination with corticosteroid, which is responsible for the long-term effect through its well-known anti-inflammatory characteristics. (7)

1.9.2 Invasive surgical

By patients who do not respond to the infiltration therapy, the treating physician will favourite the surgical decompression of the nerve root, this decision could be of course from the beginning the method of choice in case of mass prolapse, presence of red flag sign, accompanying dislocated fracture or in case of tumor compromising the nerve root.

Nowadays the surgical intervention widely used nowadays is the microscopic or endoscopic decompression.

In case of accompanying dislocated fracture or Spondylolisthese an extra surgical stabilizing procedure will be needed. The surgical management in spine surgery is usually carried out through spine surgeon; who could be either orthopedic surgeon or neurosurgeon.

In this study we do focus on the alternative conservative therapy regimes. So far, current pharmacologic therapies are inadequate for many patients. Only few non Drug-based therapies have proven a positive impact. We introduced the use of high-tone electrical muscle stimulation (HTEMS) in treating sciatic patients and demonstrated its analgesic potency compared to that transcutaneous electrical nerve stimulation (TENS) on radicular pain associated with nerve root compression.

Chapter 2

Electrotherapy

It is considered as a part of the conservative therapy regime and postoperative therapy regime as well. (14)(15)

2.1 History of usage of electrical muscle stimulation in Pain management

Electrotherapy was used as a pain relief method thousand of years BC, the electric shocks generated from electrical fishes were used by ancient Egyptians for relieving pain. The Romans prescribed the direct contact with the ray fish which produces discharges with an average of ~50 volts for pain relief in patients with gout, arthritis or headaches. Man invented devices that were able to generate electrical current in the 18th century which was later on was used in medical field to relieve pain. (14)

❖ The medical development of electrotherapy passed through four main phases, these are:

- **Franklinism**
- **Galvanism**
- **Faradism**
- **Arsonvalisation**

A German engineer Otto von Guericke used a frictional machine to induce a static electrical current in what is known as 'Franklinism'. It is characterized by having a high voltage and low milliampere currents. The German physician Christian Kratzenstein performed the first medical use of static electricity in Europe in 1744. (14)(17) In 1780 Galvani introduced contact electricity through his experiments on frogs in which a dynamic current was directly applied over the nerve in what is known as 'Galvanism'. Later on Alessandro Volta demonstrated that the electricity leading to contraction of the frog muscle was not of animal source but of electrochemical origin, he showed also that when two dissimilar metals and brine-soaked cloth are placed in a circuit, an electric current could be produced. This discovery resulted in the invention of the first form of a battery. The prolonged use of Galvanic current leads to necrotic changes in the tissues. This damaging action was later employed for destruction of superficial tumors including prostate cancer. (14)(17)

Later on, the British scientist Michael Faraday induced an intermittent current and in

alternate directions thereby preventing any risk of tissue damage, this was known as Faradism. The most important promoter of Faradism in the mid 19th century was the French physician, Guillaume Duchenne, (“father of electrotherapy”), used this technique in particular for muscle stimulation. (14)(17)

The fourth phase known as `Arsonvalisation` was introduced by the french physician, Jacques Arsène d'Arsonval, in 1888 he observed that frequencies beyond 5.000 Hz decreased the excitation of muscles (14) and thus the use of high frequency currents was introduced. (17)

The 19th century was considered the golden age for analgesic electrotherapy. In 1935, Siegfried Koeppen thought about the possibilities to use tone frequency therapy. Dr. Med. Hans-Ulrich May is recognized as the „father “of the modern High Tone therapy. Since 1988, he has been studying the variously effective applications very successfully.

Nowadays electrotherapy is applied in many neurological, dental, gynecological and psychiatric disturbances. Electrical muscle stimulation (EMS) is frequently used as a form of non-pharmacological pain management. (14)(17)

2.2 Availabe forms of electrotherapy:

- Transcutaneous electrical nerve stimulation (TENS)
- High-tone external muscle stimulation (HTEMS)

- **Transcutaneous electrical nerve stimulation (TENS)**

It is the use of electric current produced by a device to stimulate the nerves and through the nerve excitation an analgesic action will develop. TENS was first used in pain management in 1970. It consists of electrical portable constant current units with electrical impulses in the range of 80–100 Hz. Standard carbon rubber electrodes of 14 cm² coated with conducting gel are to be placed within or around the painful area or over nerve branches innervating the painful dermatome accordingly (14)

➤ **High-tone external muscle stimulation (HTEMS)**

It entails the external application of high frequency electrical current, through which high energy will be delivered to the tissues enhancing cell metabolism and alleviating pain. The HTEMS device generates pulse widths of $\leq 350\mu\text{s}$, $\leq 70\text{ V}$ with an initial frequency of 4,096 Hz that increases over 3 sec to 32,768 Hz, held at maximum for 3 sec and then down modulated to the initial frequency. For each participant the intensity can be adjusted to a level that did not produce any pain or discomfort. (14) see Figure 2.1



Fig 2.1 HTEMS device with its electropads for transcutaneous usage (gbo.de)

2.3 Potential mechanisms involved in the analgesic action of electrical stimulation

The electric muscle stimulation relieves pain through neurophysiological modulations. Basically it acts through two main mechanisms: (14)(18)(19)

- ❖ **First mechanism:** electrotherapy acts through segmental inhibition of pain signals in the dorsal horn of the spinal cord from being transmitted to the brain, which is explained through the gate control theory of pain. (18)(19)

Melzack and Wall developed “The Gate Control Theory of Pain” in 1965 as they suggested that the substantia gelatinosa in the dorsal horn acts as a gate control system regulating and modulating the synaptic transmission of nerve impulses from peripheral fibers to the central cells. (18)(19)

According to this hypothesis there are two types of fibers regulating the pain perception;

- i) **The small nociceptive A- δ and C fibers**, which hold the hypothetical gate in a relative opened position
- ii) **The large mechanoreceptive A- β fibers** stimulated by touch, pressure or vibration, which inhibit the pain transmission to the brain through closing the gate.

Melzack and Wall stated that analgesic effect of electrotherapy occurs through activating descending pain inhibitory mechanisms originating in the periaqueductal grey (PAG) in midbrain, which by its role sends projections to the rostral ventral medulla (RVM), followed by projections to the spinal dorsal horn (18)(19) and thus results a synergetic analgesic effect.

Furthermore in order to understand how electrotherapy works, scientists carried out experiments, through applying electrotherapy in cats, they managed to detect a reduction in the activity of dorsal horn cells (20). A similar effect was detected in arthritic rats where electrotherapy-induced activation of PAG and RVM followed by projections to spinal dorsal horn, through which a descending pain inhibitory mechanism originate as previously suggested by Melzack and Wall and thus reduction of the hyperalgesia occurred (18).

❖ **Second mechanism:** electrotherapy activates descending inhibitory pathways and thus enhances the release of endogenous opioids and other neurochemical compounds such as serotonin, noradrenaline, gamma aminobutyric acid (GABA), acetylcholine and adenosine (24)(25)

In order to prove that electrotherapy induces and enhances the release of endogenous opioids and other neurochemical compounds, researchers carried out experiments on arthritic rats. It was found that applying low frequency TENS (LF-TENS) enhances the μ -opioids level in spinal fluid, while high frequency (HF-TENS) increased the δ -opioids level concentrations and accordingly a test was made to prove this hypothesis in which a pre-treatment with the μ -opioid receptor antagonist, naloxone blocked the effect of LF-TENS, while pre-treatment with the δ -opioid receptor antagonist, naltrindole, prevented the action of HF-TENS. (21)

As it was suggested by Melzack et al. electrotherapy affects the PAG-RVM pathway through activating descending pain inhibitory mechanisms and thus enhances the release of endogenous opioids and serotonin. (22) Applying HF and LF-electrotherapy increases the level of the β -endorphin in both spinal fluid and blood plasma. (23)(24) Serotonin has an analgesic action spinally and supraspinally depending on the activated receptor and the dosage used, it also enhances the effect of HTEMS and its depletion reduces it correspondingly. (25)

In order to observe the effect of electrotherapy on endogenous opioids scientists applying HF and LF-electrotherapy in arthritic rats, which by its role reduced the hyperalgesia through activating spinal GABA-A receptors while HF-TENS enhanced the release of neuroinhibitory transmitter GABA in the deep dorsal horn of the spinal cord. (25)

Electrotherapy was also found to be able to reduce the production of substance P. (26) Moreover, HF-TENS, but not LFTENS were found to be able to lower the levels of some excitatory amino acids such as glutamate and aspartate in the dorsal horn in arthritic rats (27) and thus the motor-cortex excitability can be modulated by peripheral nerve stimulation with LF- and HF-electrotherapy. (28)(29)

Electrical muscle stimulation activates purinergic (adenosine) receptors at peripheral and spinal sites (30) and this by its role enhances the electrotherapy analgesic effect.

Regular administration of TENS was found to have an analgesic tolerance at the spinal opioid receptor as early as on the 4th day (31). This tolerance could be delayed by simultaneous activation of μ -opioid and δ -opioid receptors. Therefore, a mixed or alternating frequency (for example HF and LF-electrotherapy at the same session) or (HF- and LF-TENS applied separately on alternating days) should be used (32)

As time elapsed researchers tried to test the effect of electrotherapy application on microcirculation. They were able to detect the effect of electrotherapy on circulatory system using Laser Doppler investigations, which showed that electrotherapy application stimulate the peripheral microcirculation. (33) Based upon this observation and the fact that in diabetic neuropathy, a relationship between capillary abnormalities and severity of neuropathy has been observed. (32) Electrotherapy was tested in patients suffering from diabetic neuropathy. Electrotherapy induced vasodilation and thus enhanced microcirculation and increased endoneural blood flow (34)(35). Furthermore it was observed that electrotherapy enhances the blood flow in ischemic peripheral vascular and coronary heart disease. (36) The vasodilation may be induced by release of vasoactive substances such as calcitonin gene-related peptide and possibly nitric oxide (NO). (35)(36) An inhibition of sympathetic afferent activity may contribute to vasodilatation. (39)(40)

3.4 Hypothesis suggesting enhanced analgesic effect of HTEMS

The classical electrotherapy is based on modulating the amplitude: where the current intensity is modulated, but the frequency remains constant. Electro therapy uses modulation frequencies between 0 and 200 Hertz in the low frequency range. In High Tone power therapy the amplitude and the frequency are modulated simultaneously.

The higher the frequency, the more energy can be introduced correlating to the individual threshold curve of the patient's electro-sensitivity. Thus, it is a simultaneous Frequency and Amplitude Modulation. The intensity increases simultaneously with rising frequency. (28)

The applied frequencies range from 4.096 to 32.768 Hertz. These high tone frequencies pass through the body in form of an electrical field that makes the charged particles oscillate. The frequencies of the oscillations introduced create resonance in the molecules and cell structures. Different frequencies activate structures of different size. For this reason it is important to offer a broad spectrum of frequencies.

The oscillations of the different particles in the tissue lead to many effects. One of them is a strongly increased distribution of pain and inflammation mediators as well as a positive effect on the transport of nutritive and waste substances. Thus, the result is an improvement of cell metabolism and pain relief. In a short-term comparative study (3 consecutive days for 30 min) between TENS and HTEMS in painful diabetic polyneuropathy. HTEMS was almost three times more effective than TENS in relieving pain symptoms and discomfort. Furthermore this analgesic action was also found to be extended. (41)(42)

There is an increasing demand to find alternative conservative therapy methods to treat radicular leg pain, as it does not only affect the patient and his family but also the whole community through the high rate of sick leave causing an enormous economic burden.

Therefore, we investigated for the first time the effect of high-tone external muscle stimulation (HTEMS) in treating sciatic pain. Previously HTEMS has been proven to have a positive influence in treating polyneuropathic pain. In this trial we compared the effect of transcutaneous electrical nerve stimulation (TENS), which is widely used nowadays as pain therapy mean in different fields, one of which treating radicular leg pain, with effect of HTEMS for the first time being introduced through our study in treating sciatic pain.

Chapter 3

MATERIALS AND METHODS

- West-German Center of Diabetes and Health, Düsseldorf Catholic Hospital Group, Duesseldorf, Germany.
- Heinrich Heine University Hospital, Neurology Department, Duesseldorf, Germany.

3.1 Study population

Patients suffering from severe attacks of sciatica and requiring hospital treatment at the Spine Unit and Center of Pain Management of the St. Vinzenz Krankenhaus, Duesseldorf, Germany were invited for participation in this study. Eligible patients (n=100) were randomized according to an electronically generated randomization list (generated by the trial statistician) into two groups (E-Flowchart). In detail, each participant was assigned a serial study identifier (ID).

For each ID there was a closed envelope with the group assignment. The trial physician enrolled patients during a period of 12 months; the first participant was enrolled on 30.11.2012; the last subject finished the intervention on 11.11.2013. The study was conducted in accordance with the health care ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments and approval of the research protocol was obtained from the ethics committee of the Ärztekammer Nordrhein, Düsseldorf, Germany. All participants gave informed consent prior to their inclusion into the study. The patients knew to no time which intervention they are subjected to, the treating physician and nurse opened the envelop directly before application of the intervention.

Eligible patients (n=100)

• *Inclusion criteria:*

- Sciatica patients who do have a degenerative lumbar spine disorders with documented MRI or CT finding that correlates to the complain
- Pain since at least since 3 months
- Stable oral analgesic regimen
- Written consent of the patient indicating his approval

• *Exclusion criteria*

- History of drug or alcohol abuse
- Cardiac pacemaker or defibrillator
- Pregnancy
- Having a symptom or a sign that favorites surgical intervention: paralysis or bowel – /bladder dysfunction
- Tumor patients requiring intense analgesic regime adjustments and frequent changes of the oral medications and of course frequent intravenous analgesics
- Active bacterial infection
- Recent fracture
- Acute thrombosis
- Epilepsy

3.2 Study Design

Our randomised cross over study started in November 2013 and ended in December 2014, in which the effect of both HTEMS and TENS on radicular leg pain was tested and compared. The cutaneous electrode pads were applied to the skin dermatome of the affected nerve root, e.g. L3, L4, L5 or S1 dermatomes. (Fig 3.1)

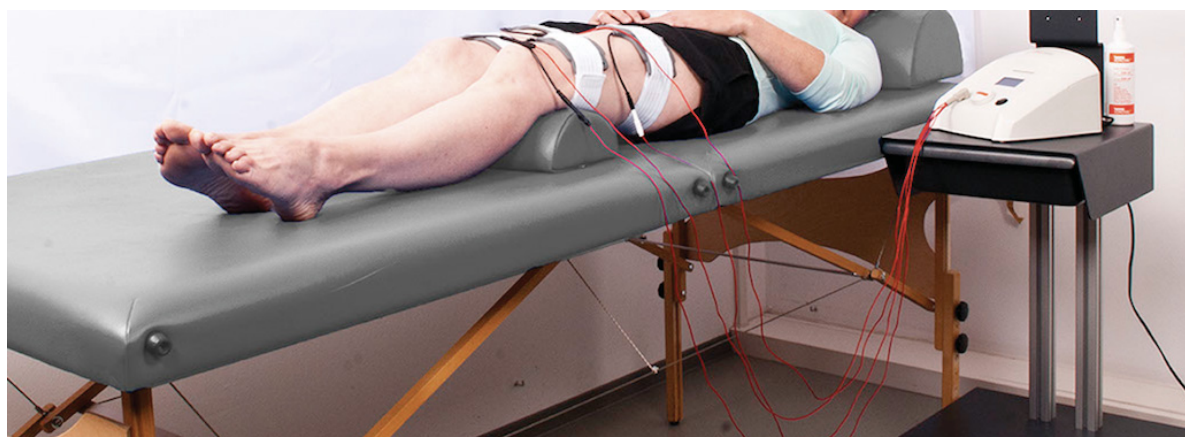


Fig. 3.1 (HTEMS, gbo-med.de)

Each administration lasted for 45 min 5 times within 10 days, with a washout period of 3 days before cross over. The HTEMS device HITOP 191 (gbo Medizintechnik AG, Rimbach, Germany) generated pulse widths of. 350 mA, .70 V with an initial frequency of 4,096 Hz that was increased over 3 sec to 32,768 Hz, held at maximum for 3 sec and then down modulated to the initial frequency. For each participant the intensity was adjusted to a level that did not produce any pain or discomfort. TENS was applied with the H-Wave device Dumo 2.4 (CEFAR Medical, Lund, Sweden), a portable, rechargeable unit that generates a biphasic exponentially decaying wave form with pulse widths of 4 msec, .35 mA, .35 V and 180 Hz. Intensity was adjusted according to the patient, and ranged from 20 to 30 mA [33]. The pre-treatment assessment included the health status survey short form. Radicular pain was assessed using an 11-point visual analogue scale (VAS) with 0 = none and 10 = worst pain imaginable before and after treatment. The patients fill the 11-point visual analogue scale before and after every intervention.

3.3 Statistical Analysis

Sample size had been calculated assuming that HTEMS might improve pain by 15 ± 14 mm VAS, while for the control group a reduction of only 5 mm VAS was estimated. To be able to measure such a difference with a power of 90% and a level of significance of 5%, at least 42 datasets per group would be needed. Since a dropout rate of about 20% was estimated, the plan was to recruit a total of 100 persons. Intention-to-treat analyses were performed. Missing values were substituted by the 'last-observation-carried-forward' principle.

Shown are means \pm standard deviations or standard error of means. Mann-Whitney and Fishers exact test were used for comparisons of the two groups. Group allocation had been blinded for outcome assessment. Wilcoxon signed rank test was used to analyse differences within groups and to test differences differed from zero. Level of significance was set to $p < 0.05$. Statistical analyses were performed using GraphPad Prism 4.03 (GraphPad Software, San Diego, CA, USA) and SAS statistical package version 9.3 (SAS Institute, Cary, NC, USA).

CHAPTER 4

RESULTS

4.1 Study population

Fifty-nine patients in the H1T2 group were treated with HTEMS during 1st phase intervention and 41 patients in the T1H2 group were treated with TENS (**Fig. 4.1**).

Both groups did not differ in their baseline characteristics (**Table 4.1**). All of them finished the 1st phase intervention, but four patients refused to start the 2nd intervention phase after crossover. Reasons for this were that one patient in the H1T2 group had tried TENS before without improvement of pain, two patients were free of pain after HTEMS intervention and one patient in the T1H2 group suffered from massive pain after TENS intervention. Therefore, 56 patients of the H1T2 group and 40 patients of the T1H2 group started with the 2nd intervention, but 2 patients dropped out because they did not agree with TENS. 54 patients of the H1T2 group and 40 patients in the T1H2 group finished both intervention phases.

4.1 Enrollment diagram

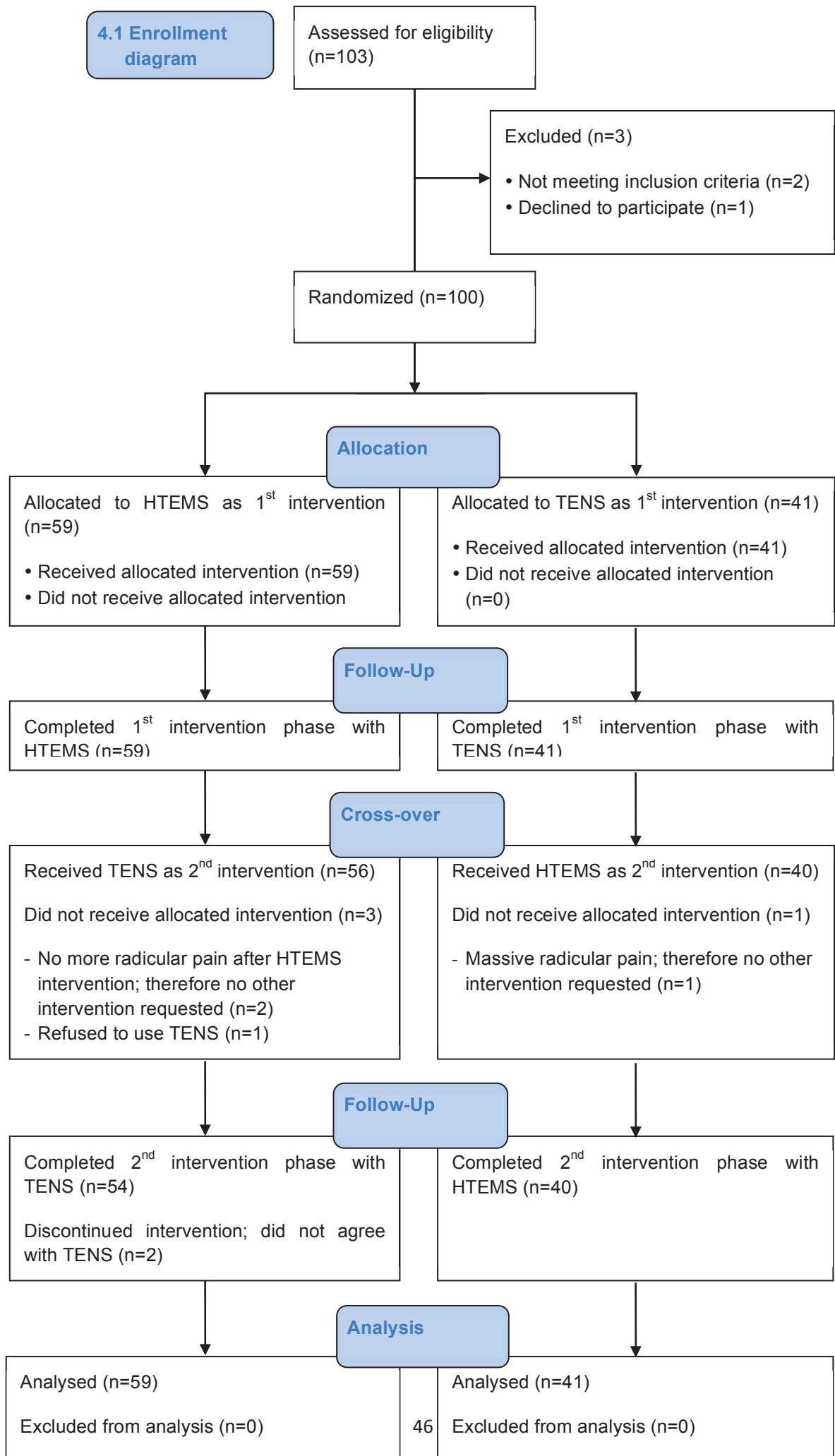


Table 4.1

	H1T2 (n=59)	T1H2 (n=41)
Sex (male/female) [n]	28 (47%) / 31 (53%)	14 (34%) / 27 (66%)
Age [years]	57 ± 14	57 ± 13
Low-back pain [n]	41 (71%)	25 (61%)
Ischialgia [n]	53 (90%)	40 (98%)
NPP [n]	26 (44%)	17 (41%)
Spinal canal stenosis [n]	10 (17%)	11 (27%)
Degenerative bone disease¹ [n]	34 (58%)	21 (51%)
Sakroiliopathy [n]	3 (5%)	-
Diabetes mellitus [n]	2 (3%) ²	4 (10%) ²
Polyneuropathy [n]	2 (3%) ²	- ²
Treated with morphine [n]	41 (69%)	24 (59%)
Treated with Lyrica [n]	27 (46%)	21 (51%)

Table 4.1 Patients characteristics. H1T2, 1st intervention with high-tone external muscle stimulation (HTEMS), 2nd intervention with transcutaneous electrical nerve stimulation (TENS); T1H2, 1st intervention with TENS, 2nd intervention with HTEMS; 1 defined as osteochondrosis, spondyloarthritis, olisthesis, scoliosis; 2 missing data for n = 1.

4.2 Significant pain reduction during HTEMS intervention.

During the 1st phase of intervention mean pain intensity became significantly reduced from 5.6 ± 2.1 to 4.5 ± 2.1 in the H1T2 group ($p < 0.0001$), while no statistically significant improvement occurred in the T1H2 group (change from 5.9 ± 1.9 to 5.6 ± 1.9 ; **Fig.4.2**).

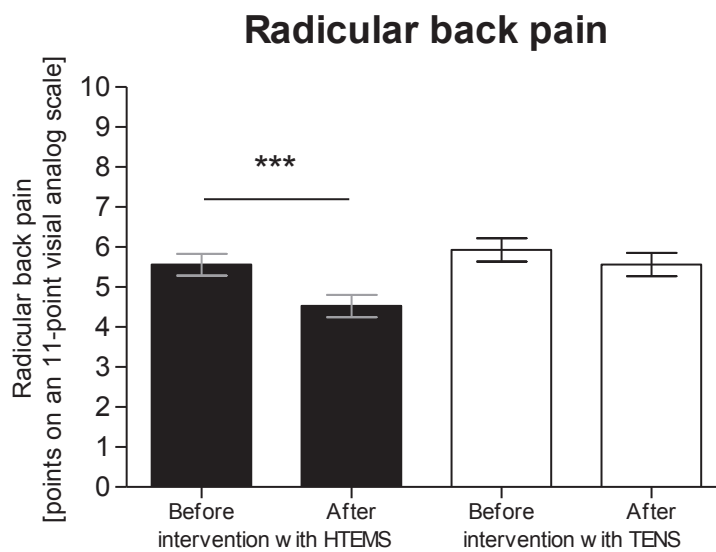


Fig. 4.2 Pain reduction after HTEMS/TENS

56% of participants in the H1T2 group reported a pain improvement of at least 1 au (arbitrary unit) in the VAS, while only 41% of the T1H2 group reported pain reduction ($p = 0.047$), thus the Odds ratio [95% confidence interval] was 1.83 [1.05-3.21] for HTEMS. In detail, pain intensity improved by 1.0 ± 1.7 au ($p < 0.0001$) during HTEMS treatment, while the intervention with TENS demonstrated a mean pain reduction of 0.4 ± 1.5 au during the 1st phase of treatment ($p = 0.046$ for difference between groups; **Fig.4.3**).

A Radicular back pain reduction

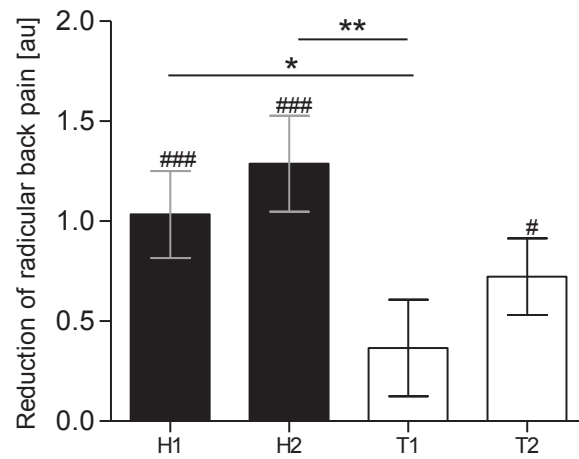


Fig. 4.3

After the cross over, a reduction of 1.3 ± 1.5 au ($p < 0.0001$) was achieved with HTEMS treatment and of 0.7 ± 1.4 au ($p = 0.0015$) with TENS. In the T1H2 group the pain reduction during 2nd phase intervention with HTEMS induced a significant higher pain reduction than 1st phase treatment with TENS ($p = 0.0075$). No statistically significant difference had been observed between groups for the sum of back pain reduction during their 1st and 2nd phase of intervention, indicating no carry over effect during crossover (**Fig.4.4**)

B Sum of radicular back pain reduction

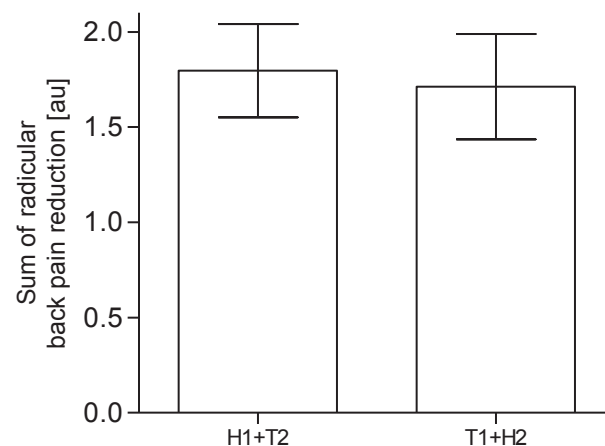


Fig. 4.4

Conclusion: The difference of radicular pain reduction demonstrated a higher pain improving potential of HTEMS vs. TENS ($p=0.011$; **Fig.4.5**).

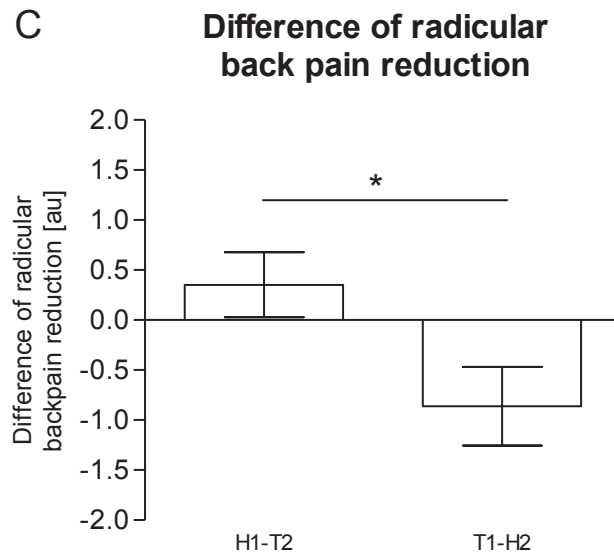


Fig. 4.5

CHAPTER 5

DISCUSSION

HTEMS was introduced in this study for the first time as a new therapy method in treating sciatic pain. My main purpose was to provide a basis for separating treatment effects from period effects that's why i determined and measured the treatment effects separately in two sequence groups formed via randomization. It was vey essential to me to guard against carryover effects.

I compared HTEMS with a currently recognised method in treating radicular leg pain, which is TENS, and through demonstrating my results; HTEMS was proven to be an equivalent to TENS in reducing radicular leg pain, even with more potent analgesic effect. This is undoubtedly very valuable as currently there is a growing need to find alternative conservative therapy measures for management radicular leg pain because the current methods available mostly are considered insufficient and are associated with delayed recovery.

Sciatica is mostly difficult to treat and needs a multidisciplinary approach. If there are no red flag signs then a conservative therapy trial is almost indicated according to the spine guidelines for at least the first six weeks.

Conservative care provided by general practitioners, including health information, medication and physiotherapy initially led to an increase of radicular pain in sciatica patients (n = 142), and a minor improvement of 0.5 au after 8 weeks of prolonged treatment was achieved. (43)(44) While physiotherapy and isometric exercise in patients suffering from sciatica (n = 28) reported an improvement of 1.9 au on the VAS after 6 weeks. (43)(44)

Using invasive non-surgical procedures as by using transforaminal (n = 15) or interspinous epidural corticosteroid injections (n = 16) with pain reduction of 4.4 and 3.0 au, respectively, after 6 days. (44) It is considered invasive procedure and cannot be applied by patients, receiving anticoagulation medications. Usually the effect does not last long und

there is not enough evidence that it does really help, still it is considered as a common practice by sciatica patients. Klenerman et al. reported pain reduction of 1.8 au 10 days after injection of depomedrone (n = 16) and of 1.9 au after bupivacaine injection (n = 19) while placebo injection (n = 16) and acupuncture (n = 12) reduced back pain by 2.6 and 2.0 au, respectively. Three weeks after injection of methylprednisolone (n = 77) or placebo (n = 80) pain became reduced by 2.1 or 1.2 au in sciatica patients. Epidural steroid injection for sciatica patients with lumbar disc herniation patients (n = 50) reduced pain about 2.3 au after 1–3 month. Injections also have side effects like infection, bleeding or nerve injury. (16, 45, 46 & 47)

If red flag signs occur or if the pain persists over six weeks and the patient cannot tolerate it then surgery may be favoured despite there is not any sensorimotor deficit. Early surgery in sciatica patients (n = 141) reduced their back pain by 1.9 au after 8 weeks (48)(49)(50). Using a combination of microdisectomy and physiotherapeutic instructions or disectomy alone the studies of Osterman et al. (n = 28) and Buttermann et al. (10) (n = 50) demonstrated an improvement of about 3.2 au after 1–3 month in lumbar disc herniation patients. (54)(55)(56)

We introduced HTEMES for the first time in treating the radicular leg pain as a promising therapy method in both the conservative therapy regime and even as a part of the postoperative regime like in failed back surgery syndrome. This is in the sum the first randomized controlled cross-over trial that compares short-term effects of HTEMES vs. TENS on pain relief in patients with lumbar radicular pain.

HTEMES was proven to be an equivalent to TENS with a more potent analgesic effect. It is easy to use; the patient can use at home and adjust the usage frequency according to his own needs and in case the pain re-occurs then it could be re-applied again. HTEMES is non-invasive therapy method. It is cost-efficient and does not have any known side effects.

The results of HTEMES treatment with an improvement of 1.0 ± 1.7 au had been directly visible after five applications. The effect of TENS with a mean pain reduction of 0.4 ± 1.5 au is less beneficial. This might be an enormous advantage compared to pharmaceutical therapies or invasive methods such as injections and surgery.

Since we intended to analyse the effects of HTEMS and TENS on immediate pain reduction with 5 applications within 10 days we could not speculate on long-term effects. For such an analysis patients would have to be continuously treated after their in-house stay. Moreover, one might argue that we could not exactly distinguish between effects of electrotherapy and analgesic medication. However, treatment with morphine and lyrica have been started a while before begin of electrotherapy and the doses had not been changed during the study. Therefore, we might exclude pharmaceutical influence on the reported pain reduction. Strength of our study is that compared to most interventions in literature we included a relatively large number of 100 study participants.

The effectiveness of HTEMS might be based on neurophysiologic and neurochemical mechanisms that are stimulated by the electrotherapy. (12) Although the exact mechanisms are unknown so far it was postulated that HTEMS enhance the release of endogenous analgesics. Additionally, it might enhance vasodilatation, leading to enhanced microcirculation and increased endoneural blood flow. Also an inhibition of sympathetic afferent activity was suggested which decreases the pain transmission to brain. Compared to TENS in HTEMS, both, the amplitude and the frequency are modulated simultaneously and thus through increasing the frequency, the energy introduced will be accordingly increased. The different frequencies applied might activate structures of different size and might increase distribution of pain and inflammation mediators. Also positive effects on the transport of nutritive and waste substances are hypothesized, which positively influence the cell metabolism and increase the wash of waste and toxic materials.

Our results demonstrate that an intervention with HTEMS has the potential to immediately reduce sciatica with a significantly stronger analgesic effect than TENS. These results show the potential of a new therapeutic strategy in management of lumbar radicular pain due to nerve compression. With a clear and statistically significant statement our study delineates the potential of HTEMS in the treatment of sciatica due to nerve root compression. HTEMS was proven to be an equivalent to TENS with a more potent analgesic effect. It is easy to use; the patient can use at home and adjust the usage frequency according to his own needs and in case the pain re-occurs then it could be re-applied again. HTEMS is non-invasive therapy method. It is cost-efficient and does not have any known side effects.

Tab. 5.1 Improvement reported on VAS under different therapy measures on sciatic pain

• Physiotherapie & isometric exercise	1.9 au (43)(44)
• Transforaminal & epidural corticosteroid injections	4.4 & 3.0 au respectively (45)(46)(47)
• Microdisectomy	3.2 au (48)(49)
• TENS	0.4 ± 1.5 au (through our statistical analysis)
• HTEMS	1.0 ± 1.7 au (through our statistical analysis)

CHAPTER 6

CONCLUSION

In sum, this is the first randomized controlled crossover trial that analysed the effect of HTEMS on immediate pain relief in radicular back pain patients. Sciatica affects not only the patient but also the whole society as it does have a big negative impact on the whole society through impairing the quality of life and decreasing the ability to work with a high rate of sick leave. This entails the vital need to find alternative methods to treat radicular leg pain and improve the quality of life. That's why in this study we aimed to offer a new therapy regime through introducing HTEMS in treating sciatic pain. It is easy to use; the patient can use at home and adjust the usage frequency according to his own needs, cost-efficient, practical and does not have any known side effects.

The results demonstrated that a short-term intervention with HTEMS significantly reduced radicular pain and the effects were significantly stronger compared to TENS therapy. These findings might offer new therapeutic strategies in spinal disorders management for treatment of patients with chronic lumbar radiculopathies and thus provides a hope and a chance for sciatica patients to overcome the pain without a need to an invasive intervention. What from our point of view still has to be studied is the long-term effect of HTEMS on lumbar radicular pain.

Conflict of Interest Statement

The author declares no conflict of interest.

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Eidesstattliche Versicherung

Ich versichere an Eides statt, dass die Dissertation selbständig und ohne unzulässige fremde Hilfe erstellt worden ist und die hier vorgelegte Dissertation nicht von einer anderen medizinischen Fakultät abgelehnt worden ist.

09.01.2017



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