

Research article

Clinical Outcome of specific therapy using high intensity electromagnetic field in Patients with Carpal Tunnel Syndrome

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Abstract: Background: Carpal tunnel syndrome(CTS) is a compressive mononeuropathy affecting approximately 3-6% of the adult population, having a strong physical, psychological, and economic impact on the patient. The high intensity electromagnetic field applied with Super Inductive System (SIS) therapy has effects on pain relief, myorelaxation or miostimulation. The objective of this study is to assess the clinical outcome of patients with CTS after SIS therapy. Material and method: An observational prospective study was conducted between 2021-2022 on a cohort of 56 patients admitted to the Balneal and Rehabilitation Techirghiol Sanatorium for 2 weeks, with specific symptoms of CTS. The patients underwent treatment for two weeks at the sanatorium, receiving three SIS therapy sessions per week with the BTL-6000 device, and also other daily physical therapies. Results: There was a statistically significant difference in the proportion of patients who experienced pain and paresthesia before treatment and the proportion of patients who experienced the same symptoms after treatment $p<0.05$ respectively $p<0.01$. Conclusion: The high intensity electromagnetic field using SIS therapy has been proven to be effective and safe in treating patients with CTS, bringing important benefits to patients by relieving pain, and paraesthesia, and improving the quality of life of patients.

Keywords: carpal tunnel syndrome, mononeuropathy, Super Inductive System, pain, paresthesia, quality of life.

1. Introduction

Carpal tunnel syndrome (CTS) is the most common compressive mononeuropathy affecting the median nerve at its passage through the carpal tunnel. Although the median nerve is compressed over a relatively small surface area, the resulting symptoms affect the patient both physically and mentally, as well as economically[1]. This condition affects approximately 3-6% of the adult population, but there has been a significant increase in its prevalence and incidence in recent decades due to the increasingly common use of digital devices[2]. The highest prevalence is among women and individuals aged 45-64[3].

To understand the pathophysiology and constellation of symptoms encountered in carpal tunnel syndrome, we need to briefly review the anatomy of the structures involved at this level. The carpal tunnel is a narrow and rigid passage through which both the median nerve and the 9 tendons of the flexors pass, with a width of 20-25 mm. The

segment of the median nerve that passes through the carpal tunnel between the distal flexion crease of the wrist and the proximal metaphysis is at high risk of compression and injury. The median nerve is composed of fascicles originating from the medial and lateral cords of the brachial plexus. At the elbow, the median nerve innervates a considerable number of muscles: the pronator teres, the radial wrist flexor, the palmaris longus, and the superficial digital flexor. Later on, the anterior interosseous nerve branches off, innervating the flexor digitorum profundus I and II, the long thumb flexor, and the pronator quadratus muscles. Although there are several places where the median nerve can be compressed, most commonly this occurs at the carpal tunnel level. The palmar cutaneous branch of the median nerve runs through the fascia, providing cutaneous sensitivity to the proximal palm. The other fascicles of the median nerve reach the wrist between the tendons of the radial wrist flexor and the palmaris longus and enter the carpal tunnel. The terminal branches of the median nerve are partly sensory, providing cutaneous sensitivity to the palmar surface of the thumb, index, third finger, and radial part of the fourth finger, as well as the dorsal aspect of the distal phalanges of these fingers, and a motor nerve called the recurrent or thenar nerve, which innervates the abductor pollicis brevis, the superficial head of the flexor pollicis brevis, and the opponens pollicis muscles[4-7].

Most often, carpal tunnel syndrome occurs due to compression and ischemia of the median nerve segment within the carpal tunnel. Normally, the pressure in the carpal tunnel is less than 5 mmHg in a neutral position of the joint. Pressure increases as a result of activities that involve prolonged flexion and extension - for example, in a patient who frequently uses a computer mouse, the pressure can reach values of 20-30 mmHg. At this pressure, the nerve's blood supply is affected, initially resulting in demyelination of the sensory branches, followed by demyelination of the motor branch, and ultimately axonal destruction⁷. In addition, nerve compression can also occur following trauma or as a result of a chronic joint condition. In these situations, the volume of the contents within the carpal tunnel increases, and compression of the median nerve occurs.

CTS may be idiopathic or secondary, the latter being caused by a series of factors including structural changes of the carpal canal, dynamic changes or vibration exposure[8-11]. The characteristic histological appearance in CTS is non-inflammatory fibrosis and thickening of the synovial connective tissue[12].

The most common risk factors in the development of CTS are as follows: female gender - the hypothesis proposed for this factor is represented by the fact that women have a smaller cross-sectional area at the level of the carpal canal than men - 9.0 compared to 11.3[13] - and therefore women are more susceptible to developing compression phenomena at the level of the median nerve. Another element that incriminates the female gender is the occupational nature, by the fact that the ratio of job positions that predispose to this condition is in favor of women[14]; pre-existing inflammatory diseases such as rheumatoid arthritis lead to synovial hypertrophy, which implies a larger space at the level of the carpal canal and compression of the median nerve[15]; pregnancy - due to fluid retention during pregnancy, pressure in the carpal canal increases. Furthermore, during pregnancy, hormonal levels change, including insulin-altered glucose metabolism being associated with the development of CTS[16]; diabetes mellitus - prolonged hyperglycemia causes enzymatic and non-enzymatic glycosylation of collagen and inflammation, which hinders the gliding of tendon fibers and leads to their stiffening; Hypertension produces small vessel vascular disease and implicitly of the vessels tributary to the median nerve[17]; obesity - although the mechanism by which obesity is a risk factor in the development of CTS has not been established, it has been demonstrated that this condition increases the relative risk of CTS by 2 times compared to the general population[18]

The clinical manifestations of CTS are extremely important as they represent the gold standard for diagnosis, keeping in mind the exclusion of other possible causes. CTS is initially characterized by nocturnal paraesthesias and dysesthesias that increase in intensity throughout the day. Afterward, there may be sensory loss in the distribution of the median nerve, pain, and numbness, followed by muscle wasting in the thenar eminence due to axonal degeneration[19]. These manifestations are characteristic of CTS and are rarely encountered in other pathologies. Symptoms are generally localized to the hand, but in advanced cases, they can extend to the forearm, arm, and even shoulder.

The most common clinical manifestations of CTS are pain and paresthesia, which include burning, tingling, and numbness. These symptoms are initially intermittent but gradually become more constant, with periods of relief becoming shorter. Symptoms are often exacerbated after activities that involve prolonged flexion and extension. Patients have also reported the sensation of a swollen hand and weakness associated with thenar atrophy[20,21].

The diagnosis of CTS is mainly based on clinical manifestations, which are the gold standard of diagnosis. However, there are a series of paraclinical investigations that are useful in establishing the diagnosis, such as electrodiagnostic studies (electromyography and nerve conduction studies) and ultrasound[22]. The patient's history and clinical examination are indispensable for diagnosing CTS. The most useful clinical elements are Flick's sign, Phalen's maneuver, nerve compression test, Tinel's sign, and the presence of thenar atrophy, all of which have high sensitivity and specificity[23].

Electrophysiological studies can detect changes in nerve conduction in the median nerve, and electromyography can show changes in muscle function due to altered nerve conduction, especially in the abductor pollicis brevis muscle. The importance of these investigations lies in the fact that they can exclude other pathologies with similar clinical manifestations, such as polyneuropathies and radiculopathies, and can establish the severity of CTS [24,25].

Ultrasonography provides important information regarding the dimensions of the median nerve on the longitudinal section and the cross-sectional area of the median nerve, which is correlated with the severity of CTS and can exclude the diagnosis of tendinopathy, tenosynovitis, or space-occupying processes [26,27].

Treatment for CTS includes surgical and conservative methods. Conservative methods that have proven to be effective include joint immobilization, local corticosteroid injections, oral corticosteroid therapy, laser therapy, physiotherapy, and electrotherapy, but there is currently no consensus on the management of patients with CTS[1-3].

Physiotherapy using high intensity electromagnetic field with Super Inductive System (SIS) therapy has effects on pain relief, myorelaxation, miostimulation, and joint mobilization. SIS targets the neuromuscular tissue, and the interactions between the electromagnetic field and the muscular tissue result in a controlled and repetitive muscular contraction, which leads to the release of joint blockages, increased circulation and tissue metabolism, and muscle toning. In recent decades, a considerable number of specialized studies have been published analyzing various conservative methods, but further research is needed, which is the subject of the present study[28].

2. Results

This study included 56 patients, 44 women, and 12 men. Table 1. The age group distribution is shown in Fig.2, the most common being between 50 and 60 years.

Age (years)		Frequency	Percent
Valid	[35-50)	6	10.71
	[50-60)	24	42.86
	[60-70)	18	32.14
	[70-80)	8	14.29
	Total	56	100.00

Table 1. The distribution of the patients by age group

The age group distribution is shown in Table 2, the most common being between 50 and 60 years.

Sex		Frequency	Percent
Valid	M	12	21.43
	F	44	78.57
	Total	56	100.00

Table 2. The distribution of the patients by sex

The monitorized parameters were:

- 1) gasping/holding objects
- 2) personal hygiene
- 3) dressing
- 4) nutrition

Before treatment, 46% of patients were able to grasp/lift objects with great difficulty, but after treatment, 32% of patients were able to perform the same activity without any difficulty, and 68% with much lower difficulty compared to the initial evaluation (Figure 1).

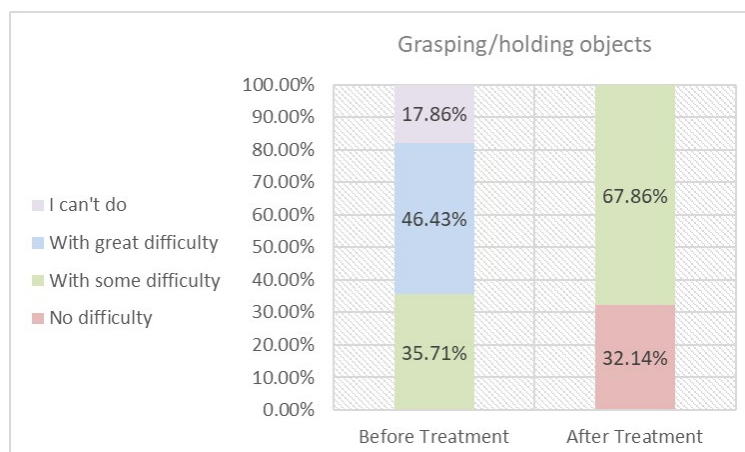


Figure 1. Grasping/holding objects

The following graph shows that half of the patients perform personal hygiene activities with great difficulty, while after treatment, 50% of them perform the activities without any difficulty (Figure 2).

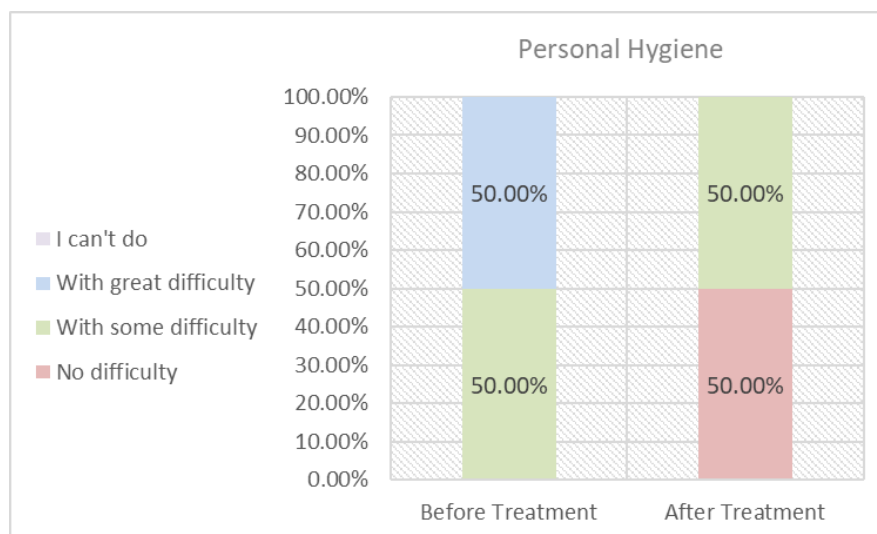


Figure 2. Personal Hygiene

The same trend is observed in the case of dressing/undressing activities, with 50% of patients performing these activities with great difficulty before treatment while after treatment, half of them perform the activities without any difficulty (Figure 3).



Figure 3. Dressing

Nutrition-related activities are performed with great difficulty by 53% of patients, while after treatment, 36% of them perform the same activities without any difficulty (Figure 4).

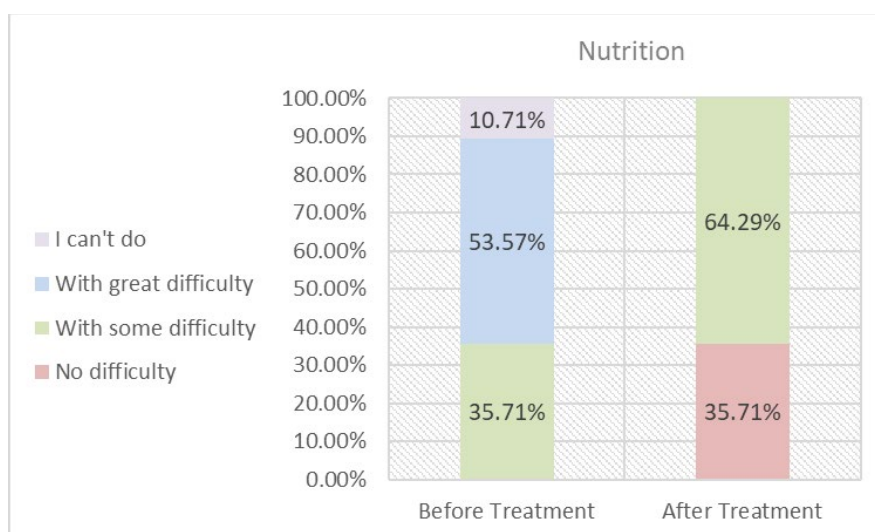


Figure 4. Nutrition

There was no statistically significant difference between the proportion of patients who presented with hypotrophy of thenar muscles before treatment (10 out of 56) - 17.86% and the proportion of patients who presented with hypotrophy of thenar muscles after treatment (8 out of 56) - 14.29%. The p-value obtained was 0.317. The evaluation of hypothenar muscles did not show a statistically significant difference before and after treatment. Muscle hypotrophy was evaluated clinically.

There was a statistically significant difference in the proportion of patients who experienced paresthesia before treatment (22 out of 56) - 39.29% and the proportion of patients who experienced paresthesia after treatment (12 out of 56) - 21.43%, with a p-value of $0.025 < \alpha = 0.05$. There is a statistically significant difference between the number of patients who reported pain before treatment and after treatment, patients being evaluated by the VAS scale (46 out of 56; 82.14% reported no pain after treatment), and the number of patients who did not report pain before treatment but reported pain after treatment (0; 0.00%), and this difference cannot be attributed to chance (McNemar's test). VAS scale There are significant differences between the median values of the VAS score recorded before and after treatment ($z = -4.662$, $p < 0.001$, Wilcoxon Signed Ranks Test)(Figure 5).

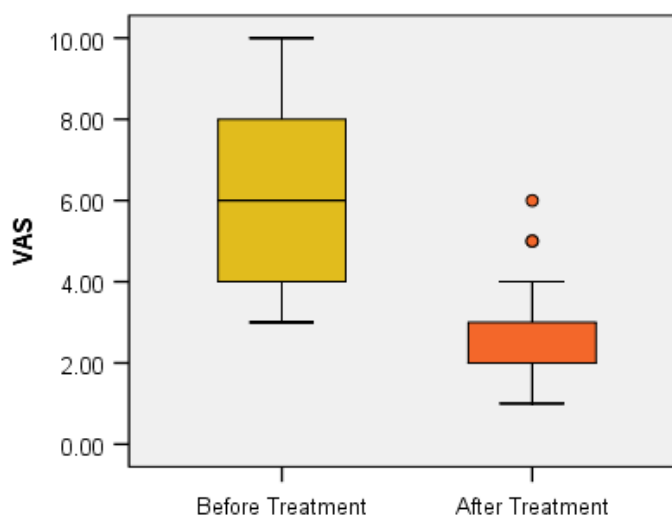


Figure 5. Box Plot graphic representation of VAS score before and after treatment

A statistically significant correlation was not established based on the ultrasound measurements of the median nerve - cross-sectional area of the median nerve - before and after treatment, with a p-value of 0.071.

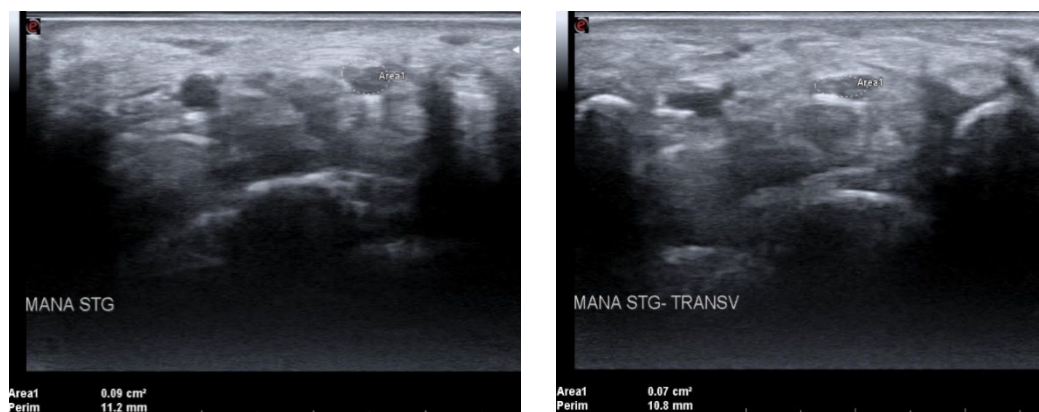


Figure 6. Median nerve area before and after treatment (personal archive)

3. Discussion

Although we evaluated a relatively small number of patients suffering from carpal tunnel syndrome, this pathology has a high incidence and prevalence worldwide[7]. In this study, the first working hypothesis was confirmed, namely that SIS is safe and effective for patients, improving their quality of life, reducing pain intensity and bringing benefits to their daily activities. The second working hypothesis was not confirmed, as no significant statistical correlation was established in the measurements of the cross-sectional area of the median nerve before and after treatment.

Although no significant statistical difference was obtained, considerable improvements were observed in some patients.

In the last decade, significant progress has been made in the clinical evolution of patients with carpal tunnel syndrome (STC) due to the appearance on the market of various devices that improve the quality of life of patients after treatment. From the point of view of the studies published so far, there is a vast collection of articles that study conservative, non-surgical methods of treating STC[2,3,7].

To date, no extensive studies have been published on the benefits of high intensity electromagnetic therapy in patients with STC, and we find it necessary to publish the data obtained and increase the sample size in future studies.

The advantages of this study are that it addresses a current issue and evaluates a relatively new treatment method, analyzes variables in patients with STC, has a design similar to recent studies in this field, and as far as we know, is the only one that evaluates this method of treatment. The major disadvantage, although remediable through continued study, is that the patient samples are small and patients have not been evaluated in the long term, but we intend to continue this work and hope that this study will bring a major benefit to patients. Another weak point is the fact that the patients did not receive only electromagnetic therapy with SIS but also mud baths and physical therapy.

Based on the studies published so far, there is a vast collection of articles that investigate conservative, non-surgical methods for the treatment of CTS.

Sevim et al. published an article studying the effect of joint immobilization compared to local corticosteroid injections, with results in favor of joint immobilization[29].

Naeser M.A. et al. concluded in a 2002 article that laser therapy and electrotherapy at the joint level benefit the patient in terms of pain intensity, but they mention that further studies are necessary[30,31].

Another study from 2010 concludes that magnetotherapy does not provide benefits in terms of clinical manifestations for patients with CTS after treatment[32].

4. Materials and Methods

An observational prospective study was conducted between 2021-2022 on a cohort of 56 patients admitted to Balneal and Rehabilitation Techirghiol Sanatorium for 2 weeks, with specific symptoms of CTS.

The first hypothesis of this study is the correlation between SIS therapy and improvement in patient's quality of life by monitoring specific parameters, and the second is if there are ultrasonographic differences in measurements of the median nerves.

The patients underwent treatment for two weeks at the sanatorium, receiving three SIS sessions per week with the BTL-6000 device – using the program A0011[33]. Patients were evaluated through questionnaires regarding clinical manifestations and quality of life and ultrasound examination before and after treatment. The monitored parameters in questionnaires were the ability to grasp/hold objects, the capacity to perform activities related to personal hygiene, dressing and nutrition. Ultrasound measurements were taken of the cross-sectional area and longitudinal diameter of the median nerve, measurements being performed using an Essaote Mylab X6 device[28]. In terms of quality of life, patients were analyzed using the VAS (Visual Analog Scale), the adapted HAQ score, and were clinically examined for determining thenar and hypothenar muscle atrophy.

Inclusion criteria for this study were informed consent from the patient for treatment, patients with specific carpal tunnel syndrome symptoms, and patients who refused or had contraindications for surgical intervention. Exclusion criteria for this study were patients with cardiac pacemakers/mechanical implants, patients with coagulation disorders/anticoagulant treatment, patients with active infections/fever/cutaneous lesions in the joints, pregnant patients, oncologic patients, and patients with respiratory insufficiency.

Statistical analysis was performed using IBM SPSS software version 25. Data are presented as mean and standard deviation (SD) for continuous variables with a symmetric distribution, median and IQR (Interquartile range P75-P25) for variable data with an asymmetric distribution, and as a percentage for categories of variables. The distribution of continuous data was estimated with the Shapiro-Wilk Tests of Normality. Parametric and non-parametric tests were used to test the hypothesis: T-test, Wilcoxon Signed Ranks Test, and McNemar test. The level of clinical significance was set at $p=0.05$.

5. Conclusions

The main advantage of physiotherapy in the management of mild or moderate cases of carpal tunnel syndrome is that provides a non-invasive treatment option for CTS, avoiding the need for surgical intervention[34]. Physiotherapy interventions such as manual therapy, therapeutic exercises, and modalities like ultrasound or laser therapy can

help alleviate pain associated with CTS. These techniques aim to reduce inflammation, promote tissue healing, and enhance pain modulation[35].

Another conservative treatment are nerve mobilization techniques, which involve specific movements to mobilize and free the median nerve from any adhesions or restrictions within the carpal tunnel. These techniques can help improve nerve gliding and reduce nerve compression, leading to symptom relief[36].

Physiotherapists can also provide education on ergonomic principles and recommend modifications in the workplace or daily activities to reduce excessive strain on the wrist and hand. This can include adjusting workstation setup, promoting proper posture, and providing advice on activity modification[37].

SIS therapy has been proven to be effective and safe in treating patients with CTS, bringing important benefits to patients by relieving pain, and paraesthesia, and improving the quality of life of patients. Although nominal improvements have been observed in terms of the cross-sectional area of the median nerve before and after treatment, a statistically significant correlation between measurements before and after treatment could not be demonstrated.

Supplementary Materials: The technical books of used devices can be downloaded at:
https://eifu.esaote.com/fileadmin/Manuals/F100100/english/MyLabX6_MyLabX7_GettingStarted_E_R11.pdf
https://files.btlnet.com/cor/documents/af40969e-4070-4864-bf4e-b84545dfed99/BTL-6000_SIS_CAT_ELITE_EN103_preview_1473426747_original.pdf

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