

Neuromagnetic treatment of pain in refractory carpal tunnel syndrome: An electrophysiological and placebo analysis

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Objective: To evaluate the neurobiological effect of constant, subthreshold magnetic field exposure on symptomatic median nerve compression symptoms, neurophysiology and assess the role of placebo.

Background: Conservative treatment of moderate and severe CTS has been variable and often results in surgical decompression at the wrist.

Design/methods: Eight moderately symptomatic and intractable CTS hands constantly wore identical Elastomag wrist support wraps (unmagnetized vs. magnetized 350 gauss) for one month intervals. Identical wraps were then switched at the second month. Baseline assessments included the neurological exam, VAS scores for burning, numbness and tingling twice a day on a 10 point ordinal scale. CMAP/SNAP was determined at baseline and monthly intervals. Clinical follow-up at end of fourth and eighth weeks was compared to baseline.

Results: The mean pain scores improved in four patients (57%) which also correlated with clinical benefit. Improvement in Tinel and Phalen sign as well as sensory changes was similarly noted. Placebo effect was detected in one patient (13%). Electrophysiological improvement in distal latencies in 5/8 hands using magnetic treatment was noted compared to no change or worsening in all placebo cases.

Conclusions: Percutaneous magnetic stimulation induced palliative pain relief, presumably via modulation of the unmyelinated C-fibers. Prior studies have suggested an influence on K⁺ inward rectification excitability. These observations suggest that wearing magnetized wrist wraps appears

to be a novel therapeutic agent. However, the underlying neuropathology tends to be progressive.

1. Introduction

Carpal tunnel syndrome (CTS) is the most common condition causing sensory and motor disturbances in the hand. Entrapment of the median nerve has been estimated to affect over 10 million Americans. It consequently represents a formidable medical challenge. While conservative therapies, i.e. hand splinting, Vitamin B6, steroid injections or oral preparations, etc., are the cornerstone of effective management in mild cases, recurrences are common. As the condition advances in severity, with persistent and unrelenting neuropathic burning, tingling and pain, most conventional medical treatment approaches are unsatisfactory and ultimately surgical decompression and neurolysis is warranted. While usually successful, a troublesome complication rate of 7–30% [1,2] has been reported! Given the limitations of the available therapies, new approaches that are safe and directed at slowing or halting the process are worthy of pursuit. In this regard, the public perception that magnetic devices play an effective role in healing and pain reduction, has led to worldwide sales of \$5 billion despite an absence of scientific validation. In 1975 Nakagawa [3] reported a decrease of neck and shoulder pain utilizing a loosely fitted magnetically active necklace. In 1982 Hong and co-workers [4] were unable to reproduce those results. Valbona and co-workers [5] demonstrated significant pain relief with the application of static magnetic devices over painful trigger points in post-polio patients. Recently Collacott and co-workers [12] failed to improve chronic sufferers of low back pain with bipolar magnets. In view of the limitations and shortcomings of current conventional approaches in CTS, a rigorous exploratory study utilizing a commercially available, tightly fitting wrist wrap

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with randomized placebo controls and electrophysiological parameters was created to determine if magnetic bio-stimulation was effective in moderately advanced CTS.

2. Methods

2.1. Study design

This pilot study was designed to determine whether cumulative subthreshold magnetic field exposure was an effective treatment for symptomatic and intractable carpal tunnel neuropathic pain symptoms. The primary outcome measure were the VAS scores tabulated twice daily during the morning and evening hours. Secondary endpoints were electrodiagnostic distal latencies, i.e., compound muscle action potentials (CMAP) and sensory nerve action potentials (SNAP) and tabulation of placebo responses. This is a single blind, placebo-controlled trial in patients with refractory symptoms from CTS. The protocol was approved by the Phelps Hospital Investigational Review Board (IRB). After a complete description of the study to the patients, written informed consent was obtained prior to enrollment. No new analgesics were allowed, however, patients could remain on their current regimens.

2.2. Subjects

There were six patients recruited from the neurologic practice of the author. Two had bilateral refractory symptoms of carpal tunnel syndrome. Thus, a total of eight hands with moderately severe CTS were enrolled. There were four females (avg. age 62.5 years) and four males (avg. 75 years) (Table 1). The duration of symptoms were from 3–108 months (average 37 months). All cases previously received several standardized medical treatments and were considered refractory without successful pain relief, and were considered refractory. These included wearing splints, Vitamin B6, oral and injectable steroids, analgesics, hand therapy, laser stimulation, etc. Their last treatment was six weeks before entry into study. Baseline pain scores (Table 1) using a validated VAS scale 0–10, averaged 6.6. Numbness and tingling of the fingers was present in 8/8 and nocturnal discomfort altering sleep was present in 7/8 (88%). Hand burning complaints were noted in 2/8 (25%). The clinical examination with median nerve hypalgesia was positive 7/8 (88%) with Tinel/Phalen sign present in 5/8 (63%). No atrophy was present but weakness was

reported in 4/6 patients (67%). Baseline electrophysiological studies were performed on the median nerve CMAP/SNAP and are noted in Table 2. Criteria for abnormality was CMAP distal latency ($dl > 4.0$ m/sec) and SNAP (> 3.7 m/sec) [6]. Advanced or severely symptomatic was defined as refractory and progressive symptoms with clinical abnormalities interfering with quality of life and significantly prolonged distal latencies. One subject had a normal CMAP (3.7 msec) but abnormal SNAP and F-wave distal latency. All 7 other patients had abnormal conductions and one displayed denervation. Patients were blinded and were randomly assigned to wear identical commercially available wrist wraps that were either magnetized or placebo for 24 hr. periods. Daily VAS pain scores were tabulated for burning, numbness and tingling twice a day on a 10 point ordinal scale. At the end of four and eight weeks, repeat electrophysiological analysis was performed.

2.3. Masking

The author was not blinded. All patients were informed of the placebo nature of the trial and were encouraged not to test and break the code in these identically-appearing wrist wraps.

3. Magnetic design

Patients wore commercially available identical neoprene wrist support wraps (Elastomag) that were either magnetized or placebo. The magnetized device contained a permanent 350 gauss steep field gradient with a geometric multi-polar triangular arrangement that produces a static sub-maximal magnetic field. Penetration of this field is 4 cm (1.75"). Since magnetic field strength drops off significantly with distance, subjects were instructed to keep constant contact during the day and night. Thus, 24 hours of direct continual contact was established in this two month trial. These Elastomag wrist wraps are commercially available (Nikken, Inc., Irvine, California).

4. Statistical analyses

Categorical variables were analyzed by using the Binomial test (1-tailed) to compare paired continuous variables (CMAP/SNAP). The Binomial test (1-tailed) was also utilized to compare VAS pain scores serially. Values of $p < 0.05$ were considered significant.

Table 1

Cohort	4 females 4 males
	Avg. age 62.5 yrs. Avg. age 75 yrs.
Symptom duration	3–108 months (avg. 37 months)
Baseline pain	6.6 avg.
Clinical	Numbness and tingling 8/8 (100%)
	Nocturnal discomfort altering sleep 7/8 (88%)
	Burning hand 2/8 (25%)
	Clinical examination (hypalgesia in median nerve distribution 7/8 (88%)
	Tinel/Phalen 5/8 (63%)
	Baseline Nerve Conduction Velocity CMAP/SSEP/F-wave dl – abnormal 8/8 (100%)
	Delayed CMAP 7/8
	Normal CMAP 1/8
	Delayed SNAP 7/8
	Absent SNAP 1/8
	F wave delay 8/8
	Denervation 1/8

5. Funding

There was no funding for this study. Devices were manufactured and supplied gratis by NuMagnetics, Inc., Port Jefferson, NY). The authors had complete independence regarding study design, data analysis and manuscript preparation.

6. Results

The mean neuropathic pain scores (numbness and tingling) in the treatment group improved in 4/7 patients (57%) and was significantly different from the placebo response rate (1/8 or 13%) using the binomial test (1-tailed), $p = 0.046$. This relief was considered significant but rarely persisted for more than 24 hours. This relief lead individuals to perform increased activities, i.e., shopping, gardening, etc., which would provoke symptoms. Burning symptoms were significantly reduced in one patient within two weeks of wearing the magnetic wrap and lasted throughout the active phase but slowly increased less than baseline value, during the placebo phase. Sleep improved in 4 patients. The clinical examination displayed improved hand sensation to pin prick stimulation, yet symptoms could be precipitated by protracted hand angulation positions, i.e., Phalen maneuver. A placebo response was noted in 1/8 patients (13%). Electrophysiological parameters for CMAP revealed that 5 out of 8 hands (63%) demonstrated improvement while during placebo no hands showed improvement. The Binomial test demonstrated a statistical difference between placebo and magnetic treatment ($P = 0.00$). Sensory latencies deteriorated in three cases with development of conduction block. Table 2 identifies the specific baseline latencies.

7. Discussion

Neuropathic pain is difficult to manage and remains a clinical challenge. Thus, this pilot data is provocative demonstrating that significant pain relief could be obtained in 57% (4/7 patients) with constant application of static magnetic devices. The possibility exists that wearing magnetic wrist wraps in some CTS patients may obviate surgery if treatment is begun in milder stages of the disorder. Additionally, the possibility of combined oral analgesia with wearing magnetic wraps could potentially produce augmentation analgesia and this issue needs to be further explored.

Relatively little is known about the neurobiology of subthreshold magnetic bio-stimulation [6–8]. Based upon experimental studies, magnetic strength as well as steep magnetic field gradient are known to produce translational and torsional forces on magnetically susceptible materials, i.e. lipoproteins within neuronal membranes. Also, conformational changes arise which presumably effect ionic potentials and voltage sensitive sodium and potassium channels involved in the generation of action potentials [13]. In experimental studies, this multi-polar magnetic design with steep field gradient was more effective in blocking action potentials in over 70% of neurons tested as compared to unipolar magnetic design with a shallow gradient [9].

The sustained decline in neuropathic symptoms suggest a preferential influence on sensory afferents. The fact that the underlying pathophysiology (A fiber conduction) worsens or is unchanged in all cases indicates that modulation of C-fiber membrane potentials is the most likely explanation of pain relief. Despite clinical improvement, however, the pathological process progresses and that is disturbing. Weintraub noted a

Table 2A

Baseline		Placebo (4 wk)				Magnet (8 wk)			
FC	VAS	=	4.5	VAS	=	4.2	VAS	=	4.2
	RCMAP	=	6.4	RCMAP	=	8.96	RCMAP	=	8.9
	RSNAP	=	6.2	RSNAP	=	7.3	RSNAP	=	8.3
FP	VAS	=	10.0	VAS	=	10.0	VAS	=	10.0
	RCMAP	=	5.0	RCMAP	=	5.4	RCMAP	=	6.6
	RSNAP	=	5.9	RSNAP	=	Absent	RSNAP	=	Absent
FP	VAS	=	10.0	VAS	=	10.0	VAS	=	10.0
	LCMAP	=	5.3	LCMAP	=	6.2	LCMAP	=	6.4
	LSNAP	=	5.7	LSNAP	=	Absent	LSNAP	=	Absent
PS	VAS	=	5.0	VAS	=	1.3* (Placebo responder)	VAS	=	4.8
	LCMAP	=	4.4	LCMAP	=	5.2	LCMAP	=	5.1
	LSNAP	=	3.9	LSNAP	=	4.9	LSNAP	=	5.0
CC	VAS	=	5.7	VAS	=	5.6	VAS	=	3.8* Significant
	RCMAP	=	4.2	RCMAP	=	5.0	RCMAP	=	3.4
	RSNAP	=	4.2	RSNAP	=	4.3	RSNAP	=	3.3
CC	VAS	=	3.8	VAS	=	3.6	VAS	=	2.7* Significant
	LCMAP	=	3.7	LCMAP	=	4.2	LCMAP	=	3.8
	LSNAP	=	4.0	LSNAP	=	4.1	LSNAP	=	3.2

Table 2B

Baseline		Magnets				Placebo			
AG	VAS (wrist)	=	8	VAS (wrist)	=	0* Significant	VAS (wrist)	=	8.5
	VAS (hand)	=	8	VAS (hand)	=	5* Significant	VAS (hand)	=	8.5
	RCMAP	=	5.0	RCMAP	=	4.6	RCMAP	=	4.8
	RSNAP	=	Absent	RSNAP	=	Absent	RSNAP	=	Absent
				Feels worse					
JS	VAS (burning)	=	5.0	VAS (burning)	=	1.3* Significant	VAS (burning)	=	2.3*
	VAS (N/T)	=	5.0	VAS (N/T)	=	2.0* Significant	VAS (N/T)	=	3.4*
	RCMAP	=	7.2	RCMAP	=	7.1	RCMAP	=	8.2
	RSNAP	=	5.8	RSNAP	=	5.8	RSNAP	=	Absent*

similar hypothesis and conclusion in two prior studies in diabetic peripheral neuropathic pain [10,11]. These results suggest that once carpal tunnel syndrome becomes established and advanced neurophysiologically, it is largely progressive.

Several questions are legitimately raised from this provocative pilot data. Could more subjects improve if a stronger magnet with greater steep field penetration was available? Would quantitative sensory testing provide further insight into mechanism of action? Future randomized, placebo-controlled studies with larger cohorts are required to determine if this provocative pilot data can be validated.

From a clinical perspective, Once CTS is established, it is often a progressive disorder both clinically and electrophysiologically. Rehabilitative efforts to prevent chronicity and disability may be significantly impacted by magnetic biostimulation.

In conclusion, this novel treatment has the potential to positively influence mild cases of acroparesthesias of hands secondary to carpal tunnel syndrome and 57% of moderately advanced cases. If this observation can be

validated by a larger, randomized, placebo-controlled study, it represents an important advance in our therapeutic armamentarium to control one of the most disabling symptoms in hands of CTS.

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