Bipolar Permanent Magnets for the Treatment of Chronic Low Back Pain
A Pilot Study

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Context Chronic low back pain is one of the most prevalent and costly medical conditions in the United States. Permanent magnets have become a popular treatment for various musculoskeletal conditions, including low back pain, despite little scientific support for therapeutic benefit.

Objective To compare the effectiveness of 1 type of therapeutic magnet, a bipolar permanent magnet, with a matching placebo device for patients with chronic low back pain.

Design Randomized, double-blind, placebo-controlled, crossover pilot study conducted from February 1998 to May 1999.

Setting An ambulatory care physical medicine and rehabilitation clinic at a Veterans Affairs hospital.

Patients Nineteen men and 1 woman with stable low back pain of a mean of 19 years' duration, with no past use of magnet therapy for low back pain. Twenty patients were determined to provide 80% power in the study at $P<.05$ to detect a difference of 2 points (the difference believed to be clinically significant) on a visual analog scale (VAS).

Interventions For each patient, real and sham bipolar permanent magnets were applied, on alternate weeks, for 6 hours per day, 3 days per week for 1 week, with a 1-week washout period between the 2 treatment weeks.

Main Outcome Measures Pretreatment and posttreatment pain intensity on a VAS; sensory and affective components of pain on the Pain Rating Index (PRI) of the McGill Pain Questionnaire; and range of motion (ROM) measurements of the lumbosacral spine, compared by real vs sham treatment.

Results Mean VAS scores declined by 0.49 (SD, 0.96) points for real magnet treatment and by 0.44 (SD, 1.4) points for sham treatment ($P = .90$). No statistically significant differences were noted in the effect between real and sham magnets with any of the other outcome measures (ROM, $P = .66$; PRI, $P = .55$).

Conclusions Application of 1 variety of permanent magnet had no effect on our small group of subjects with chronic low back pain.

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Low back pain is a disabling, costly condition that is difficult to treat effectively. It is estimated that 85% of all people will have back pain during their lifetime. Annual prevalence reports range from 15% to 45%.[1] Currently more than 5 million Americans are disabled with low back pain.[2] The direct cost of treating low back pain is estimated at $15 billion, with indirect costs as high as $100 billion annually.[3] According to one recent study, 75% of patients who visit a physician for an acute episode of low back pain are still symptomatic 1 year later.[4] In view of the significant risks of some conventional treatments, there has been renewed interest in alternative methods[5] for a variety of conditions. In the United States there has been a dramatic increase in visits to practitioners of alternative medicine, with expenditures in the range of $21.2 billion in 1997.[6]

There currently exists a media campaign promoting the use of permanent magnets for the treatment of pain,[7-9] which has resulted in large profits: worldwide sales of $5 billion have been reported.[10] Four reports of the use of permanent magnets for the treatment of pain have been published, only 1 of which used a double-blind randomized design.[10-13] Vallbona and colleagues[12] used active and placebo permanent magnets in a single 45-minute application to treat muscle pain in patients with postpolio syndrome. A statistically significant improvement was reported with the active magnets. Weintraub[11] reported a statistically significant reduction in neuropathic pain in patients with diabetic polyneuropathy using magnetic foot pads for a total of 12 weeks. Because of public interest, and a lack of adequate scientific docu-

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mentation, there has been a call for further clinical trials.[14]

Two types of permanent magnet therapy are popular: unipolar and bipolar. The terms *unipolar* and *bipolar* refer to the magnetic poles facing the patient's skin. Unipolar magnet therapy usually uses several discrete, individual magnets aligned with the same magnetic pole toward the skin. Usually the pole facing the patient is the biomagnetic north pole or negative pole (hence the term *unipolar*). The so-called biomagnetic south pole then faces away from the skin.

Bipolar magnet therapy usually uses a flexible plastalloy (flexible plastic containing barium ferrite) sheet of magnetic material that has impressed upon it an alternating spatial pattern of north and south magnetic domains. Popular patterns in some bipolar magnetic designs are stripes, concentric circles, squares, and triangles. In each case, the adjacent shape is of the opposite magnetic polarity relative to its contiguous neighbor. Bipolar magnet therapy thus uses magnetic material arranged in an alternating pattern, so that both north and south poles face the skin.

The length of time the magnets must be worn to obtain maximum pain relief has not been established. Vallbona et al[12] reported pain relief from a 45-minute application while Weintraub[10] suggested continuous treatment.

Therapeutic permanent magnets are popular for a variety of musculoskeletal complaints.[7-9] Low back pain was selected for study because it is 1 of the most common problems for which magnets are used. The objective of this study was to evaluate the effectiveness of a commonly used bipolar magnet, used repetitively for a fixed period, in the treatment of chronic low back pain.

METHODS

This was a randomized, double-blind, placebo-controlled, crossover pilot study. The trial was carried out in the physical medicine and rehabilitation outpatient facility of a Veterans Affairs hospital in Prescott, Ariz. The institutional review board of the Veterans Affairs hospital approved the study and all subjects gave written informed consent prior to participation. Randomization of devices was achieved using a computer-generated list of random numbers. The order of treatment (magnet first and placebo second or vice versa) also was randomized.

Study Population

Participants were recruited from the primary care and physical medicine and rehabilitation clinics of a Veterans Affairs hospital. Participants were recruited from February 1998 through March 1999. A total of 24 individuals met the study criteria. Two individuals did not wish to participate and 2 of the remaining 22 failed to complete the protocol because of time conflicts, leaving 20 subjects who completed the study. Their general characteristics are given in TABLE 1.

All patients were examined by the same investigator (E.A.C.). Evaluations included radiography of the lumbosacral spine for all subjects. All imaging studies were consistent with spondylosis and some studies revealed additional diagnoses (Table 1). However, the source of subjects' existing back pain was thought to be degeneration of the "3-joint complex"[15] (intervertebral disks and facet joints) in all cases. Subjects were required to have stable low back pain of at least 6 months' duration. None had a new neurological deficit. Exclusion criteria were past use of magnet therapy for low back pain; secondary gain issues such as recent application for disability or ongoing litigation; pregnancy; cardiac pacemaker; skin lesions over the site of pain; and difficulty understanding the directions.

Outcome Measures

The visual analog scale (VAS) was chosen as the primary outcome measure and used to quantify pain intensity. The VAS, shown to be a reliable and valid measure,[16,17] consists of a standard 10-cm line with verbal anchors indicating "none" at one end (0) and "severe" at the other (10). Participants were told to estimate their current level of pain by an appropriate mark on the line, with severe indicating the worse imaginable pain. The McGill Pain Questionnaire was used to measure the affective component of pain.[18] The Pain Rating Index (PRI) of the McGill Pain Questionnaire was the sole measure analyzed rather than the subscales.[19,20] The PRI uses 20 category scales of verbal descriptors to demonstrate the sensory and affective components of pain, with a minimum score of 0 and a maximum score (most severe pain) of 78. Lacking a reliable measure of the physical response to pain, formal measurements of the range of motion (ROM) of the lumbosacral spine were obtained for all subjects by the same investigator (D.W.W.). The degree of flexion/extension of the lumbosacral spine was obtained using the 2-inclinometer method.[21]

Table 1. Baseline Characteristics of Study Participants (N = 20)

Characteristic	No. of Subjects*
Age, mean (SD), y	60 (12)
Sex	
Men	19
Women	1
Duration of pain, mean (SD), y	19 (15)
Work status	
Employed	3
Disabled	11
Retired	6
Type of pain	
Low back	7
Low back and leg	13
Diagnosis	
Spondylosis	20
Herniated nucleus pulposus	2
Radiculopathy	4
Spinal stenosis	2
Spondylolisthesis	1
History of laminectomy	3
Ankylosing spondylitis	1
Fibromyalgia	1
Baseline outcome measures†	
Visual analog scale, mean (SD), cm	4.8 (2.2)
Pain Rating Index, median (range)	14.5 (3-49)
Range of motion, mean (SD)	37° (23°)

*Age, duration of pain, and baseline outcome measures are presented as mean (SD) or median (range).
†Details of these instruments and their scoring are provided in the "Outcome Measures" section in the text.

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Study Design

The trial lasted from February 9, 1998, to May 21, 1999. All subjects followed the treatment protocol for 2 weeks: 1 week with the magnets and 1 week with the sham devices. There was a 1-week washout period between the 2 treatment weeks. The protocol consisted of application of the devices 6 h/d, 3 d/wk (Monday, Wednesday, and Friday of each treatment week). Therefore, all participants were exposed to a total of 18 hours of treatment for both real and sham devices.

Both the real and sham devices consisted of a flexible rubberlike compound. The real devices were impregnated with active magnetic material; sham devices were identical, but had been demagnetized using a magnetizer/demagnetizer (Master Magnetics, Colorado Springs, Colo). After demagnetization the sham devices showed no detectable magnetism by gaussmeter. The magnetic strength measured on the cloth surface of the real devices approximated 300 G (range, 282-330 G). The devices were trapezoid in shape (19 × 11.5 × 14 cm) and about 2 mm thick. The surface applied to the participant's skin was covered with cloth fabric, while the outer surface was covered with smooth gold foil. The magnets were of the bipolar variety, with a magnetic design of multiple triangles of alternating north and south magnetic polarity. An abdominal binder, connected via Velcro straps, held the device in place. Subjects were advised not to manipulate the devices.

Participants completed VAS measurements before and after each treatment (ie, before and after either the real or sham device was applied). Measurements for ROM and PRI were obtained before and after the first day's treatment and at the end of each week. The same examiner (D.W.W.) applied all the devices and obtained all ROM measurements. Subjects were advised to avoid new treatments during the time of the study, and they were instructed not to alter their usual pattern of medication use.

Statistical Analysis

Statistical analysis of the data was performed using SigmaStat software (San Rafael, Calif). A 2-point difference in the VAS scores was selected as a clinically significant reduction in pain intensity. The power calculation was performed for the primary outcome measure (VAS). Analysis showed that enrolling 20 patients would provide an adequate sample size to achieve a power of 80%, assuming an SD of 1.5. The difference between baseline (preapplication) and posttreatment VAS scores and ROM measurements was analyzed using repeated measures analysis of variance and paired *t* test, respectively. The difference between baseline and posttreatment PRI scores (nonparametric) was analyzed and compared between treatments using the Wilcoxon signed rank test. Statistical significance was set at $P < .05$.

RESULTS

The mean (SD) cumulative baseline VAS score for all participants was 4.8 (2.2). The mean cumulative baseline score for the sham treatment was 5.0 (2.4) and for the magnet treatment, 4.7 (2.9). TABLE 2 shows the difference between baseline and posttreatment VAS scores, by day, for magnet and sham treatments. TABLE 3 shows the difference between baseline and posttreatment ROM and PRI measures for day 1. TABLE 4 compares cumulative change from baseline (day 1 vs posttreatment day 3) for VAS, ROM, and PRI. No statistically significant differences between magnet and sham treatment were found with any outcome measure. No adverse effects were reported by any of the participants.

Table 2. Baseline and Change in Visual Analog Scale (VAS) Scores After Treatment, by Day

	Mean (SD) VAS Score				
	Baseline		Change After Treatment		
Day	Sham	Magnet	Sham	Magnet	*P* Value
Monday	5.2 (2.3)	4.7 (2.8)	−0.58 (2.4)	−0.41 (1.3)	.80
Wednesday	5.2 (2.5)	4.8 (2.8)	−0.75 (1.1)	−0.80 (1.1)	.90
Friday	4.5 (2.5)	4.6 (3.1)	0.36 (1.5)	−0.31 (1.4)	.17
Overall	5.0 (2.4)	4.7 (2.9)	−0.44 (1.4)	−0.49 (0.96)	.90

Table 3. Baseline and Change in Outcome Measures After 1 Day of Treatment

	Baseline		Change After Treatment		
Measure	Sham	Magnet	Sham	Magnet	*P* Value*
Range of motion, mean (SD)	37° (19°)	34° (19°)	−0.25° (14°)	0.40° (12°)	.87
Pain Rating Index, median score	12	11	−2.5	−1.5	.30

*See "Statistical Methods" section for complete description of methods used.

Table 4. Change in Outcome Measures: Baseline vs Posttreatment Day 3

	Change From Baseline		
Measure	Sham	Magnet	*P* Value*
Visual analog scale, mean (SD), cm	−0.40 (1.8)	−0.49 (1.6)	.86
Range of motion, mean (SD)	0.85° (11°)	2.8° (11°)	.66
Pain Rating Index score, median	−2	−0.5	.55

*See "Statistical Methods" section for complete description of methods used.

COMMENT

This study found no immediate or cumulative difference in the outcome measures of low back pain comparing real with demagnetized (sham) therapeutic magnets. Neither magnet nor sham treatment achieved the prospectively determined reduction in pain intensity (2-point reduction in the VAS score). To our knowledge, this is the only randomized, double-blind, placebo-controlled study reporting the use of permanent magnets on more than a single occasion and for more than 45 minutes. Our pro-

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tocol treatment was 3 times a week for a total of 18 hours for both treatments. This was a pilot study and was not intended to prove or disprove the effectiveness of magnet therapy in general. Additional studies using different magnets (unipolar and bipolar), treatment times, and patient populations are needed.

A stronger magnet may be necessary to penetrate to the source of chronic low back pain. Expanding the treatment time in an ambulatory setting would require manipulation of the devices by the subjects, which would increase the chances of detecting whether the magnet/sham was magnetized. If a device with opposite polarity or of a certain design was found to be ineffective, it could serve as a placebo.

Our study population was small and had special requirements. The subjects had to travel to the clinic twice daily at specific times, conditions that eliminated many employed and younger individuals. Other potential subjects lived too far away or had no transportation. Since we recruited from the Veterans Affairs clinic population there were too few women. Thus, it is difficult to generalize these results to the population at large with chronic low back pain.

Our results did not support the findings of Vallbona et al[12] and Weintraub.[10] However, there were considerable differences in the study designs and populations, including the cause of pain. The patients of Vallbona and colleagues had muscle pain while Weintraub's subjects had neuropathic pain. The source of pain in our participants would appear to be deeper than that of the former, and may explain the lack of beneficial effect from the magnets used (300 G).

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