Electromagnetic Treatment of Shoulder Periarthritis: A Randomized Controlled Trial of the Efficiency and Tolerance of Magnetotherapy

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ABSTRACT. Leclaire R, Bourgouin J: Electromagnetic treatment of shoulder periarthritis: randomized controlled trial of efficiency and tolerance of magnetotherapy. Arch Phys Med Rehabil 1991;72:284–7.

• The potential benefit of magnetotherapy was investigated in 47 consecutive outpatients with periarthritis of the shoulder. Using a controlled triple-blind study design, one group of patients received hot pack applications and passive manual stretching and pulley exercises; the other group received the same therapy plus magnetotherapy. Treatment was administered three times a week. For a maximum of three months, a standardized treatment protocol was used. There was no significant improvement in pain reduction or in range of motion with electromagnetic field therapy. After 12 weeks of therapy, the patients who received magnetotherapy showed mean pain scores of 1.5(±.61 SD) at rest, 2.2 (±.76 SD) on movement, and 1.9 (±.94 SD), on lying, compared to scores for the control group of 1.4 (±.65 SD), 2.2 (±.7 SD), and 1.9 (±.95 SD), respectively. Linear pain scale scores improved from 71 to 21 for both groups. At 12 weeks the gain in range of motion was $\bar{x}$ 109° ±46.8 in patients receiving electromagnetic field therapy, compared to 122°±33.4 for the controls (not significant). At entry, the functional handicap score was 53.5 for both groups. At 12 weeks, it was 24 for the magnetotherapy group and 17 for the control group (difference not significant). In conclusion, this study showed no benefit from magnetotherapy in the pain score, range of motion, or improvement of functional status in patients with periarthritis of the shoulder.

KEY WORDS: Electromagnetics; Periarthritis; Shoulder; Therapy

Magnetic field therapy has been used in clinical practice but its value has not been substantiated by clinical studies in patients with periarthritis of the shoulder.[1] The study of the magnetic effect is hypothesized to act by increasing membrane potentials of erythrocytes, increasing oxygen content of tissue, vasodilatating blood vessels, or relieving pain without increasing local temperature.[1-5] Previous clinical studies have shown that magnetic field therapy may increase and accelerate callus formation in delayed union fractures,[6] accelerate wound healing,[7-11] and reduce inflammation.[12]

The effects of static magnetic field on conduction velocity of isolated nerves remain controversial.[13] Sandler and coworkers[14] reported no gross histologic alterations of the large motor neurons exposed to electromagnetic fields. Reite and Zimmerman[15] concluded that the ultimate worth of magnetic recording in the central nervous system is unproven. In tissue culture, controlled studies demonstrated no significant effect of magnetic fields on growth.[16,17] For musculoskeletal disorders, there is no convincing evidence that this form of therapy is clinically useful[18,19] because the literature is contradictory.[20] The purpose of this study, using a triple-blind experimental design, was to demonstrate that magnetic field therapy reduces pain, increases the range of motion, and improves the functional status in patients with periarthritis of the shoulder.

METHODS

Subjects

The initial assessment included patient age, duration of primary disease, secondary diagnosis, previous treatment, and personal history. A complete physical examination was performed, as were clinical and hematologic examinations and shoulder x-rays, to assess joint calcification. Inclusion criteria were (1) shoulder pain for more than two months, (2) limited active and passive shoulder movement, and (3) pain on resisted abduction, internal or external rotation, and impaired glenohumeral joint motion. To be eligible, subjects had to have a decreased passive range of motion of 20% or more, in at least three movements, according to the American Medical Association guide for the evaluation of permanent impairment,[21] ie, flexion <144°, extension <32°, abduction <120°, adduction <24°, external rotation <72°, and internal rotation <32°. Subjects with arthritis, bone or neurologic disease, unstable heart disease, or hemostatic disorder were excluded. Subjects with rotator cuff rupture, x-ray calcification >2mm, or severe adhesive capsulitis defined as limitation of flexion to 100°, abduction to 90°, or global rotations by 20° or more were excluded. Finally, patients receiving anticoagulants or anti-inflammatory drugs, or who had received steroid injection in the shoulder were excluded.

Procedure

Consenting subjects were then randomized. Forty-seven patients (22 in the magnetotherapy group and 25 in the control

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Submitted for publication February 10, 1989. Accepted in revised form February 9, 1990.

No commercial party having a direct or indirect interest in the subject matter of this article has conferred or will confer a benefit upon the authors or upon any organization with which the authors are associated.

Presented at the 10th International Congress of Physical Medicine and Rehabilitation, Toronto, Canada, April 11–15, 1988.

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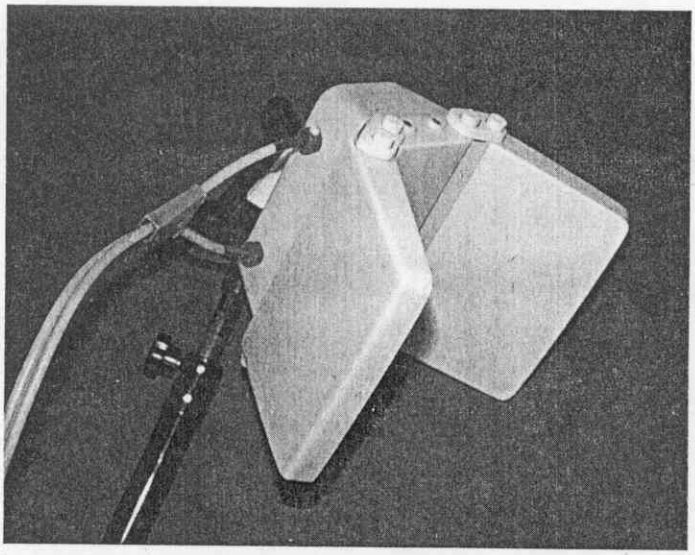

Tridimensional transmitter.

group) fulfilled the inclusion and exclusion criteria, and all completed the study according to the protocol. There were 18 men and 29 women with a mean age of 58 ± 6.9 years (SD) and weight of 69 ± 14.4kg (SD). The duration of primary illness was 17 ± 4.1 weeks (SD). The mean number of treatments administered were 32 ± 7.0 (SD) for the magnetotherapy group and 30 ± 7.0 (SD) for the control group.

The study used a triple-blind parallel group design. Subjects received either (1) electromagnetic therapy or sham therapy. A magnetic field treatment unit[a] was used with a concealed switch for either presence or absence of magnetic waves when activated by the patient's attendant. A tridimensional applicator (fig) was placed on the affected shoulder using the parameters indicated in table 1.

The patient, therapist, and investigator were blind to the procedure. A separate individual was provided the randomization code and controlled the concealed switch.

Treatment was administered three times a week, up to a maximum of 12 weeks or to complete remission of signs and symptoms. With the exception of aspirin (up to 1200mg/day) for pain, no concomitant medication was permitted during the study.

For all patients, physical treatment included hot pack applications (20 minutes), passive glenohumeral joint stretching exercises to the patients' tolerance (five minutes), standardized pulley exercises (actively assisted exercises for ten minutes), and Active nonassisted exercises using a wooden stick (20 minutes/day) were done everyday by the patients at home, excepting the three days patients received physical treatment.[22,23]

Measurements of movement amplitude were recorded at baseline and monthly thereafter. Pain intensity for the affected joint at rest, on motion, and lying down was rated at baseline and weekly thereafter using a semiquantitative ordinal scale: (1) absence of pain, (2) light pain, (3) moderate pain, and (4) severe pain. In addition, a linear visual analog scale (0 to 100mm)[24,25] was used to evaluate pain. A similar linear scale was used for assessing interference with daily activities.

Adverse events were noted weekly, and the severity and degree of relationship of adverse effects to the study treatment were assessed by the one investigator.

Table 1: Schedule for Electromagnetic Treatments

Intensity	Frequency	Duration	Sequence of sessions
30 Gauss	10HZ	30 min	Sessions 1 to 6
40 Gauss	15HZ	30 min	Sessions 7 to 16
60 Gauss	30Hz	30 min	Sessions 17 and beyond

Statistical Analysis

Mean and standard deviations of the mean were calculated for descriptive purposes. The baseline values were compared, using an analysis of variance (ANOVA) for parallel groups. Comparisons between treatments during the study were performed with ANOVA and covariance using baseline values as covariates when appropriate.[26]

Evaluation of treatment over time within each group was assessed, using ANOVA for repeated measurements and the Dunnett *t*-test for comparison of each time point to baseline.

Noncontinuous data were analyzed using the chi-square test with Yates continuity correction of the Fisher exact probability test. The level of Type 1 error was fixed at 5%.

RESULTS

At entry, the mean pain intensity at rest, on movement, and on lying was 1.9 ± .96 (SD), 3.7 ± 0.55 (SD), and 3.1 ± 1.03 (SD), respectively, indicating moderate to severe symptoms. The analog self-rating mean disability scale score averaged 55 ± 24.0 (SD) for functional handicap and 69 ± 19.9 (SD) for pain. The mean joint amplitude was clinically decreased for the four following movements: flexion, abduction, external rotation, and internal rotation (table 2). No significant differences were observed between the two groups at baseline for any of these variables.

The mean pain score at rest was significantly improved for the placebo group at weeks 11 and 12 compared to baseline, whereas it was significantly worse at week three for the magnetotherapy group. Also, patients on placebo showed significantly less pain than those receiving magnetotherapy at weeks four and five. Pain on movement was significantly improved over baseline for both groups from week one on, except for the magnetotherapy group at week two. Pain on lying was significantly better from weeks three and four on, for both groups (table 3).

The self-rating scale showed improvement from week two on, for both groups. The disability score improved from week four on, for both groups. The mean range of motion improved significantly in flexion, abduction, and external and internal rotations from weeks four to twelve for both groups (table 2). No significant difference between treatments was observed for any of these variables. The total dosage of aspirin taken by all the patients during the study was minimal: 45 subjects required no medication, one took a total of 1600mg and the other 650mg. We have not observed any side effects related to electromagnetic field therapy.

DISCUSSION

The hypothesis of this study, using a triple-blind experimental design, was rejected because the study failed to dem-

Table 2: Range of Motion (Means and SD)

Time	Flexion	Extension	Abduction	Adduction	External Rotation	Internal Rotation
Baseline						
Magnetotherapy	133°(12.4)	40°(1.1)	99°(10.2)	30°(1.3)	40°(15.9)	26°(9.3)
Control	137°(10.9)	40°(2.0)	101°(8.4)	30°(3.0)	46°(16.0)	29°(12.4)
4 Weeks						
Magnetotherapy	149°(15.4)*	40°(0)	115°(17.3)*	30°(0)	57°(22.4)*	33°(10.3)*
Control	154°(9.8)*	40°(0)	120°(13.2)*	30°(0)	62°(16.8)*	36°(10.0)*
8 Weeks						
Magnetotherapy	159°(18.9)*	40°(0)	130°(22.0)*	30°(0)	64°(22.6)*	37°(10.4)*
Control	167°(13.3)*	40°(0)	136°(15.3)*	30°(0)	74°(15.9)*	39°(6.8)*
12 Weeks						
Magnetotherapy	163°(17.1)*	40°(0)	135°(19.8)*	30°(0)	71°(20.3)*	38°(9.9)*
Control	171°(11.9)*	40°(0)	142°(13.1)*	30°(0)	80°(14.5)*	40°(4.0)*

*Dunnett t-test compared to baseline, $p < .05$

onstrate that magnetic field therapy reduces pain, increases the range of motion, and improves the functional status in patients with periarthritis of the shoulder when compared to a control group receiving a standardized treatment of physical therapy. Both groups showed a similar improvement with therapy.

Based on the hypothesis that magnetic field therapy could ither reduce inflammation,[12] accelerate the healing process,[7-11] reduce pain,[1,2] we investigated whether magnetic field therapy could improve different outcomes in a population of patients having periarthritis of the shoulder. We believe that the different outcomes used were appropriate, because they are always present, can be easily measured, and are the targets of treatment in patients with periarthritis of the shoulder. This belief is reinforced by the fact that these outcomes had also shown an improvement with therapy in both groups of patients in the study.

Having found no difference in these outcomes in a group receiving electromagnetic field therapy and a control group, we concluded that electromagnetic therapy has no positive influence on patients receiving this form of therapy.

We demonstrated no significant difference between the two study groups for any variable at entry, which suggests that the randomization of our 47 patients was successful. At no point in the trial was there any evidence of a significant benefit that favored electromagnetic treatment over sham treatment. Our results are applicable to the general population of patients with shoulder periarthritis, because range of motion could be precisely measured, and the pain scales used in the study are widely accepted measures of analgesic effect. Most importantly, since improving the total range of motion is the primary objective in the treatment of shoulder periarthritis, the power of this study was 90% to show a change of 37° in mean total range of motion recorded for the placebo group.

Electromagnetic field therapy is interesting to study in an experimental trial because a patient receiving this therapy feels nothing, as there is no perceptible heating effect. By using a third party to manipulate a concealed switch, both the therapist and the patient can be kept completely blind to the procedure. It is very rare that such effective blinding can be achieved in studies of physical therapy.

To our knowledge this is the first controlled study of electromagnetic field therapy in periarthritis of the shoulder. Like other studies,[22,23] we found that a standardized treatment of physical therapy for shoulder periarthritis produced a gradual improvement in range of motion in a 12-week treatment period. There was also a significant decrease in the pain score and functional handicap scores by the 12th week.

This clinical study reaches the same conclusion as other studies[18,19] on musculoskeletal diseases: there is no convincing evidence that electromagnetic therapy is of benefit in these musculoskeletal disorders.

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Table 3: Results of Pain Index at Baseline and 12 Weeks

	Baseline*				12 weeks*			
	Magnetotherapy		Control		Magnetotherapy		Control	
Pain index	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Rest	1.9	.80	1.8	1.05	1.5	.61	1.4	.65
Movement	3.7	.56	3.8	0.55	2.2	.76	2.2	.70
Lying	3.2	.98	2.9	1.05	1.9	.94	1.9	.95

*p-value not significant (ANOVA)

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Supplier

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