

Response of pain to static magnetic fields in postpolio patients: A double-blind pilot study.

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ABSTRACT:

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OBJECTIVE:

To determine if the chronic pain frequently presented by postpolio patients can be relieved by application of magnetic fields applied directly over an identified pain trigger point.

DESIGN:

Double-blind randomized clinical trial.

SETTING:

The postpolio clinic of a large rehabilitation hospital.

PATIENTS:

Fifty patients with diagnosed postpolio syndrome who reported muscular or arthritic-like pain.

INTERVENTION:

Application of active or placebo 300 to 500 Gauss magnetic devices to the affected area for 45 minutes.

MAIN OUTCOME MEASURE:

Score on the McGill Pain Questionnaire.

RESULTS:

Patients who received the active device experienced an average pain score decrease of 4.4 +/- 3.1 (p < .0001) on a 10-point scale. Those with the placebo devices experienced a decrease of 1.1 +/- 1.6 points (p < .005). The proportion of patients in the active-device group who reported a pain score decrease greater than the average placebo effect was 76%, compared with 19% in the placebo-device group (p < .0001).

CONCLUSIONS:

The application of a device delivering static magnetic fields of 300 to 500 Gauss over a pain trigger point results in significant and prompt relief of pain in postpolio subjects.

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POSTPOLIO SYNDROME is a well-recognized clinical entity which, since the early 1980s, has generated an abundant scientific literature (a Medline search found 88 references from 1981 to 1996; 24 of the publications included pain as a key word). The clinical manifestations are either very specific (eg, increasing muscle weakness on previously affected or unaffected muscles, muscle fasciculations) or somewhat unspecific (eg, fatigue, pain).

The pain reported by postpolio patients can generally be categorized as either (1) myofascial, which can be elicited in various muscle groups, or (2) arthritic, which is evident on active or passive mobilization of several joints. In the initial report about the postpolio syndrome by Halstead and coworkers, the prevalence of pain among polio survivors who responded to a questionnaire was 75.5%. Subsequent reports confirm that many types of pain are experienced by postpolio patients, but most include diffuse muscle and joint pain. In our experience with more than 1,000 patients diagnosed with postpolio

syndrome at postpolio clinic, pain is reported by almost all patients.

Pain in the joint is thought to result from degenerative arthritis caused by age and by longstanding asymmetrical load on the joints as a result of the asymmetrical skeletal muscle paresis or paralysis produced by poliomyelitis. The most common type of joint pain is referred to the low back, the cervical column, the sacroiliac joint. The last-named may be reported as diffuse low back pain but can be readily localized through palpation of a specific trigger point located above the sacroiliac joint. Hip and shoulder pain are also prevalent.

The muscular type of pain can be objectively elicited by palpation of the reported sore muscles and by identifying specific trigger points associated with the referred pain. The atlas of trigger points provided by Travell and Simons is of great aid in the search for such trigger points. Symptomatic cervical arthritis may be accompanied by a considerable degree of tightness of the neck muscles with trigger points in the sternocleidomastoid, scalenus, and trapezius areas.

Regardless of the type of pain, postpolio patients have increased sensitivity to nociceptive stimuli, and this may explain why they report pain so often. In spite of its prevalence the available treatment for it is limited. Currently, recommended modes of treatment are rest; traditional modalities of physical therapy (heat, cold, ultrasound, transcutaneous electrical neural stimulation (TENS); use of a support brace; or administration of muscle relaxants, analgesics, or anti-inflammatory agents. The effectiveness of pharmacologic agents is generally poor and in some instances (eg, use of aspirin or nonsteroidal antiinflammatory drugs) there are undesirable side effects. Other modalities of pain management such as meditation, yoga or hypnosis have not given our patients consistent relief.

The limited success in pain management prompted us to explore alternative methods of pain management. Static and fluctuating electromagnetic fields have been applied with apparent success for the management of pain in a variety of orthopedic conditions, most commonly traumatic bone fractures or surgical osteotomies. As early as 1938, Hansen reported the effectiveness of electromagnetic fields (which had a carrying power of from 8.5 to 14 kg) applied for 1 to 15 minutes. Twenty three of 26 patients with complaints of "sciatica," "lumbago" and "arthralgia" reported rapid and significant relief of their pain. The study was not double-blinded, but the author reported no pain reduction in two patients to whom the electromagnetic device was applied without the electricity being turned on. In osteoarthritis, double-blind, placebo-control studies have shown the efficacy of a pulsed electromagnetic field. Carpenter and Ayrapetyan provide an excellent overview of the biological effects of electromagnetic fields. The literature continues to grow from earlier reports, building on further efforts to scientifically document the impact of magnetic fields on biological systems. The safety of application of these electromagnetic fields is attested by the World Health Organization, which reported: "The available evidence indicates the absence of any adverse effects on human health due to exposure to static magnetic fields up to two Tesla" (2T = 20,000 Gauss).

Table 1: Characteristics of Study Patients

	Active Magnetized Device	Inactive Device
No. of subjects	29	21
Age (mean+-SD)	51.5 +- 9.6	55.9 +- 9.7
Sex (F:M)	24:5	15:6
Race-ethnicity (W, B, H, A)*	22, 1, 6, 0	18, 2, 0, 1
Weight (mean +- SD)	151.59 +- 31.05	151.79 +- 34.76
Age at onset of poliomyelitis (mean yrs +- SD)	6.34 +- 5.72	7.17 +- 6.79
Age at onset of postpolio syndrom (mean yrs +- SD)	42.84 +- 7.44	44.41 +- 7.10
Type of treated pain (M/A)†	52%/48%	43%/57%

*W, White; B, African-American; H, Hispanic; A, Asian, †M, Muscular; A, Arthritic.

Static magnetic fields can be delivered by placing magnets of different field strengths on the skin over the affected areas. These magnets usually vary in strength from 300 to 5,000 Gauss. The magnets can be kept in place with adhesive tape. A variety of magnets are commercially available. Frequently, significant pain relief has been observed less than 30 minutes after placement of the magnets. Anecdotal reports of the benefits of permanently magnetized devices abound (even in postpolio patients who had reported pain relief to us before our study). Nakagawa, in a technical bulletin, reported a decrease of neck and shoulder pain after use of a loosely fitted magnetically active necklace. However, Hong and associates did a double-blind study of the long-term effect of a similar device on some physiologic parameters (nerve conduction velocity and excitation threshold) in a group of 101 volunteers, but did not find any significant pain relief in the 52 who had reported chronic neck or shoulder pain before the study when compared with the 48 who had not reported pain.

To our knowledge, static magnetic fields (electromagnetic or permanently magnetized devices) have not been scientifically tested on postpolio survivors. Consequently, we completed a double-blind pilot study on patients at our clinic who reported significant muscular or arthritic-type pain.

METHOD

Subjects

We recruited 50 patients with postpolio syndrome who reported muscular or arthritic pain and who consented to participate in the study. The diagnosis of the postpolio syndrome was made according to well-established criteria.

The patients selected for the study had significant pain for at least 4 weeks, had not taken an analgesic or similar drug for at least 3 hours before the study, had a trigger point or a circumscribed painful region by palpation, and had body weight less than 140% of predicted for age and height. Patients were required remain in the clinic for 1 hour after the scheduled visit with the postpolio team. Only five of the patients invited to participate refused; four could not stay at the clinic for the additional required time and one refused because of concern about side effects.

The consent form given to the patients stated the purpose of the research. No explanations were given as to expected responses, but patients were told that the level of pain would be assessed by palpation of a trigger point before and after application of the device.

Table 1 summarizes the characteristics of these patients according to the group to which they were randomized (magnetic treatment or placebo).

Treatment Intervention

The specific devices used were the BIOflex® magnets with a pattern of concentrically arranged circles of alternating magnet polarity. The company made available to us 8 discs 40mm in diameter, 1.5mm thick; 18 discs 90mm in diameter, 1.5mm thick; 20 credit-card-sized pads, 83 X 53mm, 1.5mm thick; and 24 strips, 175 X 50mm, 1.5mm thick. The magnetic field intensity of the active devices was rated at 500 Gauss at the device surface for the 40-mm disc and the strips. The 90-mm discs and the credit-card pads were rated as 300 Gauss at the surface of the device. The manufacturer supplied us with an equal number of the active and placebo devices of identical size and shape. Each device was placed in a number-coded envelope, and all devices were delivered to us in four separate boxes according to device shape. The code numbers identifying active and placebo devices were not broken until all patients completed the study.

After the patients gave their written consent, they were asked to complete a McGill Pain Questionnaire to provide a subjective evaluation of their general pain experience. In this study, only one area of reported pain was evaluated, even though multiple sites may have been present. An active trigger point associated with the site of referred pain was grossly elicited first by finger palpation and then identified by firm application of a blunt object approximately 1cm in diameter, which in nonpainful areas produces a sensation of pressure but no pain. The subject was asked to subjectively grade the pain at the trigger point on a scale from 1 to 10 (with 1 being the least and 10 being the maximum). When patients reported

pain in more than one area, the area most sensitive to palpation was selected.

The pain scale used in this study had been previously validated and is particularly applicable to patients with disabilities. Depending on the area involved, we used either a disc, a credit-card-sized pad, or a strip-shaped device. An envelope containing a device of the appropriate shape was randomly selected from a box and applied to the skin with adhesive tape. Each patient was then asked to remain in the clinic or immediate clinic area, to keep the device in place for the next 45 minutes, and assume whatever position was most comfortable, including walking. After 45 minutes, the device was removed, and the patient was asked to report whatever sensations were felt after the application of the device. Again, the patient was asked to assess the intensity of the pain felt on palpation of the active trigger point associated with the referred pain site. The same scale of 1 to 10 was used. Although we did not measure the exact pressure exerted by the blunt object at the trigger point before and after the study, the investigators tried to be as consistent as possible on the amount of applied pressure. There was no systematic follow-up of patients after the application of the device, but in many cases we obtained information at the time of the patients next visit to our clinic.

RESULTS

Table 1 shows the characteristics of the study participants. There was no significant difference in any of the variables that described the two groups. There was a much greater proportion of women than men in both groups (the women-to-men ratio of the participants in the study is slightly higher than the ratio for our clinics population). The race-ethnicity distribution of the participants parallels that of the postpolio clinic patients. The age of onset of poliomyelitis and the age of onset of the postpolio syndrome were almost identical in both groups. Since the time of onset of the postpolio syndrome cannot always be clearly established, the data in the table should be considered estimates only. The classification of the type of pain as predominantly muscular or predominantly arthritic is somewhat arbitrary because arthritic changes are often accompanied by muscular spasm with clearly distinguishable trigger points. An analysis of the frequency distribution of the location of pain where the active or inactive magnetic devices were applied did not show any significant difference between the two groups. The sacroiliac joint was the most common location for both groups (41% of those who received the magnetized device and 33% of those who received the inactive device).

Table 2 shows the mean and standard deviation of the pain scores before and after application of the device in the two groups of subjects. The pretreatment score was almost identical in both groups of subjects, but there was a highly significant difference between pre-treatment and posttreatment scores in the two groups. Those who received the active device reported much less pain than those who had the inactive device.

It is of interest to examine the proportion of patients in each group who reported improvement in pain intensity. Since the average decrease of pain score was 1.1 (+-1.6) in the subjects who received the inactive device, we decided to dichotomize changes in pain scores as "improved" if the score decreased by 3 points or more and "not improved" if the decrease was less than 3 points. As shown in table 3, 22 patients (76%) in the active-device group showed improvement, compared with only 4 (19%) in the inactive-device group. This difference is highly significant ($p < .0001$). Also, the average score decrease in the four patients who had a placebo effect was 4 points versus 7 for those who had a treatment effect.

Table 2: Pretreatment and Posttreatment Pain scores

	Active Magnetized Device	Inactive Device	Significance
No. of Subjects	29	21	
Pretreatment Pain Score (mean +- SD)	9.6 +- 0.7	9.5 +- 0.8	NS
Posttreatment Pain Score (mean +- SD)	4.4 +- 3.1	8.4 +- 1.8	$p < .0001$
Change in Pain score (mean +- SD)	5.2 +- 3.2	1.1 +- 1.6	$p < .0001$

Table 3: Proportion of Subjects Reporting Pain Improvement by Magnetic Activity of the Treatment Device

	Active Magnetized Device (n=29)	Inactive Device (n=21)
Pain Improved	n=22 (76%)	n=04 (19%)
Pain not Improved	n=07 (24%)	n=17 (81%)

$\chi^2 (1 \text{ df}) = 20.6 (p < .0001)$.

DISCUSSION

The results of this randomized pilot clinical trial show that static magnetic fields of an intensity of 300 to 500 Gauss are effective in the control of pain in patients with the postpolio syndrome. Whether the pain was of a myofascial or arthritic nature, it seemed to respond equally well to the static magnetic field and the effect was noticed within 45 minutes from the onset of the application.

We must point out that we studied the effect of the static magnetic fields in one painful area only on each subject and we did not attempt to quantify the potential impact of such field on other painful areas that may have been present on the same patient. Interestingly, some patients recorded benefit derived from the magnetic field in other areas. This effect was reported mostly in the patients who had pain in both sacroiliac joints, in which case we always applied the device on the one that was most sensitive to palpation.

The intensity of the applied magnetic fields was rather low in relation to that applied in other studies, and we did not attempt to assess a dose-response effect. It is likely that the level of penetration of the magnetic field is related not only to the magnets intensity, but also to the distance between the superficial area to which the device is applied and the site of the trigger point that lies on the fascial plane of a muscle, tendon, or joint. Because of this, we excluded from the study very obese patients or those who had a significant amount of subcutaneous fat overlying the trigger point associated with the painful area. The fact that Hong did not find evidence of effect in his double-blind study of a loose magnet necklace may be due to the small delivered magnetic intensity of the device which was not directly applied over specific pain trigger points.

We cannot explain the significant and quick pain relief reported by our study patients. The effect could result from a local or direct change in pain receptors, but it is also possible that there was an indirect central response in pain perception at the cerebral cortical or subcortical areas, or a change in the release of enkephalins at the reticular system. If the magnetic fields have an impact on the subcortical level of the brain, it is possible that the application of one magnetic device in one painful area may benefit to a greater or lesser extent the pain elicited in other trigger points. This is an issue that requires further study. Bruno and colleagues have pointed out the existence of lesions in various areas of the brain of poliomyelitis survivors, and they believe that these lesions may explain the hypersensitive response to painful stimuli that they have observed in postpolio patients. This should not be interpreted to mean that the relief of pain produced by magnetic fields that we observed was specific for postpolio patients because similar responses to magnetic fields have been reported in patients without known lesions of the central nervous system. Even so, our understanding of pain and pain relief is far from complete.

Insofar as we can determine from the literature, this double blind placebo-controlled study using permanent magnets in a bipolar configuration directly applied to trigger points may be the first reported. This study coincides with mounting evidence that magnetic fields interact in significant ways with biological tissues. The exact mechanisms of the interaction of magnetic fields with biological tissues resulting in functional changes are unknown. This is particularly true for our understanding of the pain relief associated with the application of a magnetic field to trigger points as demonstrated in this study. Much progress, however, is being made in the field of bioelectromagnetics, in both the experimental studies and theoretical concepts. Several of these concepts (some old and some new) appear to be

promising; certainly, they are ultimately testable.

We are interested in the possible role of water in the pain mechanism, and attempts will be made to evaluate the physical basis of this idea using magnetic resonance technology. It is now clear that water is organized in space and time, and in a human study conducted by one of us (C.H.) subjective pain relief was associated with a shift of T-cells into the S-phase. Beall and colleagues demonstrated cyclical changes in the physical state(s) of water with the water being most organized in the S-phase. That water plays a major role in explaining the therapeutic effects of magnetic fields has also been proposed by others.

The fact that none of our patients reported any discomfort resulting from the use of magnetic devices and that no complications have been reported in the literature supports the notion that low-intensity magnetic fields produced by permanent magnets or electromagnetic devices are biologically safe.

CONCLUSIONS

The delivery of static magnetic fields through a magnetized device directly applied to a pain trigger point or to a localized painful area results in significant relief of pain within a short period of time (less than 45 minutes in our study) and with no apparent side effects. Based on the results of this study and reports in the literature of the effect on people with arthritis, it appears that magnetic field energy may be useful in the management of pain in individuals with other types of impairments that are commonly treated in primary care settings.

Specific issues that need to be explored through new studies are: (1) dose-response to pain relief; (2) duration of the effect after applying a static permanent magnetic field; (3) identification of the local and central effects of magnetic fields on the same pain area; (4) effect of the simultaneous application of magnets on several pain trigger areas; (5) possible difference of effect of various sizes and shapes of a magnetized device; and (6) cost effectiveness of pain management with magnetic fields versus traditional pharmacologic or physical therapy modalities.

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Supplier

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