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A Critical Review of Randomized Controlled Trials of Static Magnets for Pain Relief

NYJON K. ECCLES, M.R.C.P., Ph.D.

ABSTRACT

Objective: The aim of this review was to establish whether there is evidence for or against the efficacy of static magnets to produce analgesia.

Methods: A systematic literature review was undertaken of studies that compared the use of static magnets with an appropriate control for the treatment of pain. Study methods, their quality, and outcome were also reviewed.

Results: Overall, 13 of the 21 studies reported a significant analgesic effect due to static magnets. Of the 18 better quality studies with 3 points or more on the quality assessment, 11 were positive and six were negative, and in one there was a non-significant trend towards a positive analgesic effect. In two of the negative studies, there are concerns over adequacy of magnet power for the type of pain, and in the other study of duration of exposure to the magnetic field. If these two studies are excluded on the grounds of inadequate treatment, then 11 out of 15 (73.3%) of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic, and postsurgical).

Conclusions: The weight of evidence from published, well-conducted controlled trials suggests that static magnetic fields are able to induce analgesia.

INTRODUCTION

IT HAS BEEN KNOWN for some time that the behavior of certain types of biological materials are influenced by magnetic fields.[1] Subtle magnetic fields can produce a physiological effect. For example, pico-tesla range electromagnetic fields have been shown to have significant effects on nerve regeneration.[2] Electrical activity exists in the body at all times (e.g., the beating heart). The heart generates the largest electromagnetic field in the body.[3] The mechanical loading of bone generates electrical currents. Deposits of magnetic material (magnetite) in the human brain have also been described.[4]

In the past, it was postulated by some that a pathological state may result from misalignment of submicroscopic magnetic fields from their natural state and that applying a magnet allows for a physiological reorientation of order and coherence in molecules.[5] We now know that the process of wound and hard tissue repair involves electric currents. Becker and Selden[6] proposed the existence of an electromagnetic system in the body that controlled tissue healing. When the electrical balance of the body is disturbed by an injury, an injury current is generated, with the resultant shift in the body's current triggering a set of biological repair systems. As healing progresses, the injury current diminishes to zero. It has been noted from space flight that deprivation of the electromagnetic wave between the earth's surface and the ionosphere leads to abnormal body functioning.[7]

The debate on physiologic influence of biomagnetism has been somewhat reawakened by more recent epidemiological studies[8,9] analyzing cancer deaths in relation to electromagnetic field (EMF) exposure. A small but significant relation between occupational EMF exposure and leukemia was reported,[10] and other studies have reported other health risks such as male breast cancer, chromosomal abnormalities, and several other health hazards.[11] A number of important studies have concluded a small but significant relation between childhood domestic EMF and leukemia.[12] The

The Chiron Clinic, London, United Kingdom.

general concordance of these results has led many investigators to revisit the EMF problem.

One of the prices that we pay as technology advances is an increase in electromagnetic pollution. Our environment of power lines, and ever-increasing mobile phones and computers has led to controversies over the effect of this electromagnetic pollution on our health. Geomagnetic storms are associated with an increase in the number of cases of myocardial infarction.[13,14] Small mammals and humans deprived of natural geomagnetic oscillations suffer ill health.[15] The dysregulation of these natural fields by technological devices emitting artificial fields and radiations have been reported to have adverse effects on health.[12,16,17] Electromagnetic fields have been shown to alter EEG signals, alter DNA synthesis, reduce melatonin synthesis, reduce immune response, increase messenger RNA transcription rate, alter enzyme activity, and influence the blood–brain barrier. Conversely, positive effects on health have been ascribed to magnetic fields of only a few hundred nanoTesla with frequencies in the range of 7–8 Hz.[18]

If indeed high-energy electromagnetic fields can disrupt human physiology, it should perhaps challenge us to investigate the possible beneficial effects of more subtle magnetic fields on human health that have been reported over the centuries.[5]

The public acceptance of magnet therapy (and complementary and alternative medicine [CAM] in general) far outweighs its acceptance by the medical community. The Japanese have used magnets for years to treat chronic fatigue syndrome, and have suggested that an increase in environmental electromagnetic pollution and/or progressive inability to be energized by the earth's magnetic field[18] is important in its etiology. The Yellow Emperor's Canon of Internal Medicine, some 4,000 years ago, also talks about stones, heat, and magnets working over acupuncture meridians. In the last two decades, the Japanese have been using magnets to relieve pain.

It has been established that oscillating electromagnetic fields can relieve pain and inflammation,[6] but static magnets are motionless magnetic fields, and until recently there have been very few studies of the efficacy of static magnetic fields in pain.

There are many anecdotal reports of effective pain relief from static magnets from users, including athletes[19] and physicians,[20] and many unpublished reports of increased healing and reduced pain by physicians.[21–23] In 1938, Hansen[24] reported pain relief on himself after application of a static magnet. Estimated worldwide profits from sales of static magnets exceed $5 billion annually. A quest for analgesia would appear to be a major part of these sales.

METHODS

A search was performed of scientific journals from 1966 to November 2004 of the following databases: MEDLINE® 1966–11/2004, EMBASE 1989–10/2004, LIFE SCIENCES 1990–10/2004, APPLIED & COMPLEMENTARY MEDICINE 1985–10/2004, SPORTS DISCUSSIONS 1830–10/2004. Search terms used were combinations of: *magnets, magnotherapy, pain, analgesia, blood flow,* and *circulation*. In addition Internet searches were performed in *Google* using the same terms. The search resulted in over 170 articles and two proceedings. These were all reviewed in detail, in particular the randomized double-blind trials. Original articles were obtained, and all references were scanned for further relevant articles.

The purpose of this article was to critically review the evidence for the efficacy of static magnetic fields in the treatment of pain.

Study selection

All articles were included that reported a randomized controlled trial in which subjects with pain were randomly allocated to either active treatment or placebo. No language restrictions were applied. Studies with no statistical comparisons were excluded. No exclusions were made for type of pain. For each study, trial design, randomization, blinding and handling of dropouts were recorded, inclusion and exclusion criteria were also noted, as were details of treatment and control procedures, main outcome measures, and study results.

Number of subjects

Number of subjects in the key studies ranged from 14 to 259. Ten studies used 30 or fewer subjects, and four studies used 31–45 subjects. The remaining studies examined 50 or more subjects, with six studies testing 100 or more.

Quality assessment

The quality of the studies was assessed by the system of Jadad et al.[25]. Points were awarded in the following manner: study described as randomized, one point with an additional point for the appropriate method and a deduction of one point for an inappropriate randomization method; both subject and evaluator blinded to intervention, one point; description of withdrawals and dropouts, one point. A further point was deducted if the blinding procedure was described and inappropriate.

RESULTS

Description of studies

The searches revealed 28 possibly relevant studies, of which seven were excluded for the reasons given in Table 1.[26–32]

In the 21 remaining studies (Table 2),[33–51] subjects had the following types of pain: acute pain induced by heat, foot

Table 1. Reports of Studies of Static Magnet Therapy for Pain Retrieved from Literature Searches but Excluded from the Review for Reasons Indicated

Author (date)	*Reason for exclusion*
Nakagawa (1975)[26]	? Controlled or randomized, insufficient data
Shapiro (1987)[27]	Case reports only
Fisher (1988)[28]	Case reports only
Toysa (1998)[29]	Case reports only
Borsa and Ligget (1998)[30]	Single blind
Jacobson et al. (2001)[31]	Electromagnetic fields
Simoncini et al. (2001)[32]	Double-blind, no statistical analysis

pain from plantar fasciitis (two studies), postsurgical foot pain (included in Table 3 but excluded from conclusions due to absence of statistics), chronic shoulder and neck pain, post-polio pain, low back pain (in two studies), postsurgical wound pain, intractable neuropathic pain (two studies), chronic knee (two studies), and back pain, fibromyalgic pain, rheumatoid arthritic knee pain, osteoarthritic knee pain (two studies), chronic headache, wrist pain (from repetitive strain), carpal tunnel syndrome, chronic pelvic pain and monthly dysmenorrhea (two studies).

Subjects were recruited from various sources: a rehabilitation clinic,[41] healthy volunteers,[33,48] patients scheduled to undergo surgery,[32,38] clinical referral and media announcement through a university-based clinic,[43] recruitment from medical clinics,[35–37,39,42,44,49,50] medical centers combined with community-based clinics,[46,51] outpatient clinics combined with volunteers,[47] Media Press advertisement (Eccles, 2004, unpublished data), and volunteers of unspecified origin.[34,40]

Quality of studies

Five studies gained the maximum score of 5[41,43,47,49,51] seven studies scored 4 points,[34,36,39,45,46,48] six studies scored 3 points,[32,33,37,38,42,44] one study scored 2 (RSSL study, 2001, unpublished data), and the remaining two studies scored 1.[35,40] The procedure reported for randomization was only reported in 11 of the 21 studies (Table 2). Subject blinding was reported on in 20 of the 21 studies and assessor blinding was clearly reported in 16 of the 21, with five studies (one is the RSSL study, 2001, unpublished data) not clearly stating this.[32,35,37,40]

Outcomes

Overall, 13 of the 21 studies reported a significant analgesic effect due to static magnets. Of the 18 better quality studies with 3 points (Tables 2 and 3) or more on the quality assessment, 11 were positive and six were negative, and in one[44] there was a nonsignificant trend towards a positive analgesic effect. In two of the negative studies, there are major concerns over adequacy of magnet power for the type of pain (300 gauss for chronic back pain[41]), a query raised by the authors themselves, and duration of exposure (5 min[33]). The latter authors also failed to state the power of the magnet used in their study. If these two studies are excluded on the grounds of inadequate treatment together with the equivocal study,[44] then 11 out of 15 (73.3%) of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic, and post-surgical). Table 3 summarizes all the key studies in more detail, including the study designs, quality, number of subjects, methodology, endpoint measures, and results. Further detail of the reviewed studies is given below.

The positive studies

Wolsko et al.[51] recruited 26 subjects with idiopathic or post-traumatic osteoarthritis (OA) of the knee (American College of Rheumatology definition for idiopathic OA of the knee) with a rating of at least 3 of 10, modified daily activities, and need to take analgesics on at least 25 days of the month with radiological evidence of OA. Subjects were randomly allocated to receive either a magnetic device (designed to provide a field of 850 gauss) or placebo (a specially designed magnetic device designed to provide a field into the body of no more than 0.5 gauss). Pain assessment was made at 4 h, and 1 and 6 weeks. Subjects were asked to wear the devices at least 6 hours per day (preferentially at times when their pain was at its worst). Outcome measures were changes in WOMAC (Western Ontario & McMaster Universities Osteoarthritis Index) arthritis index for pain, stiffness, and physical function (Table 3). There were significant reductions in pain ratings ($p = 0.03$), global assessment of physical function ($p = 0.002$), favorable estimates of overall usefulness ($p = 0.003$), and willingness to make a recommendation to a friend ($p = 0.005$) in the active but not in the placebo group at 4 hours, but no difference between the groups in any of the outcome measures at 1 and 6 weeks, although compared to baseline there were significant changes in scores. The authors postulate that the very presence of a "magnetic" placebo may have a bearing on the 1- and 6-week results.

Eccles* studied 35 women with primary dysmenorrhoea. A telephone-based enquiry was performed before and after random allocation to use of either a specially designed unipolar, negative pole to skin, static magnet device (2700 gauss) or an identical weaker magnetic placebo (140 gauss).

*Eccles NK. A randomized, double-blinded, placebo-controlled pilot study to investigate the effectiveness of a static magnet to relieve dysmenorrhea. J Altern Complement Med 2005;in press.

Table 2. Jadad Scoring System to Measure Methodological Quality

	Harper and Wright, 1977[33]	*Hong et al., 1982*[34]	*Caselli et al., 1997*[35]	*Vallbona et al., 1999*[36]	*Kanai et al., 1998*[37]	*Man et al., 1999*[38]	*Weintraub, 1999*[39]	*Brown et al., 2000*[40]	*Collacott et al., 2000*[41]	*Holcomb et al., 2000*[42]	*Alfano et al., 2001*[43]	*Kim, 2001*[44]	*Segal et al., 2001*[45]	*RSSL study, 2001, unpublished*	*Carter et al., 2002*[46]	*Hinman et al., 2002*[47]	*Pope and McNally, 2002*[48]	*Weintraub et al., 2003*[49]	*Winemiller et al., 2003*[50]	*Wolsko et al., 2004*[51]	*Eccles, 2005,*[a]
Study described as randomized (includes use of words such as random, randomly and randomized)	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1
Study described as double-blinded	1	1	0	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1
Description of withdrawls and dropouts	0	0	0	1	0	0	1	0	1	0	1	0	0	0	0	1	0	1	1	1	1
Method to generate sequence of randomization described	0	1	0	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	1	1	1
Method of double-blinding described and appropriate (identical placebo, active placebo, dummy)	1	1	0	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1
Method to generate sequence of randomization described and inappropriate (patients were allocated alternately or according to their date of birth or hospital number)																					
Method of double blinding described and inappropriate of (e.g., comparison tablet with injection etc)																			−1		
Total: maximum of 5	3	4	1	4	3	3	4	1	5	3	5	3	4	2	4	5	4	3	4	5	5

[a]Eccles NK. A randomized, double-blinded, placebo-controlled pilot study to investigate the effectiveness of a static magnet to relieve dysmehorrhea. J Altern Complement Med 2005, in press.

Subjects were mailed a randomly selected device with clear instructions on how to attach the device. They were asked to apply the device 1–2 days before their anticipated next menses. Assessment was made by telephone before and after a complete menstrual cycle. Baseline levels of pain were recorded as their usual experience of menstrual pain. None of the participants were examined or seen face to face. Level of pain was assessed using the McGill Pain and Visual Analogue Scales (VAS). There was a significant reduction ($p < 0.02$) in pain in the magnet group compared to the placebo group. Pain score differences (McGill pain score before/pain score after device) were −17 (−53, 13) (median and interquartile ranges) in the magnet group and −5.0 (−29, 27) in the placebo group. A reduction in irritability symptoms in the magnet group approached statistical significance ($p = 0.056$).

Weintraub et al.[49] performed a multicenter (48 centers in 27 U.S. states) to examine whether 450-gauss multipolar magnetic insoles could reduce the pain associated with diabetic peripheral neuropathy. Three hundred and seventy five (375) subjects with symptomatic symmetrical sensory and motor neuropathy were randomly assigned to wear either magnetic or placebo insoles for 4 months (worn 24 hours a day). Symptoms had to be constant and present at least 6 months and refractory to various medications. Daily VAS for numbness, tingling and burning were logged. Nerve conduction was measured. An assessment of bias and masking was also made, and it was determined that there was no significant association between the actual treatment received and the belief about the treatment received from both subjects and investigators. There was a statistically significant decrease in the 3rd and 4th months in burning $p < 0.05$), numbness and tingling ($p < 0.05$), and exercise-induced foot pain ($p < 0.05$). Fifty percent (50%) of subjects with magnets had at least a 30% reduction in severe numbness and tingling compared to 25% of patients with the sham devices ($p < 0.05$). The authors stated that this magnitude of the reductions of burning, numbness, and exercise-induced pain, especially in the severe cases, was comparable to that observed with gabapentin, tramadol, and lamotrigine and that no side-effects were reported. There was also a nonsignificant trend for less sleep disturbance in the magnet group from months 2 to 4.

Hinman et al.[47] reported on 47 subjects with chronic knee pain resulting from degenerative disease (physician confirmed, mean duration of 11.5 years) in one or both knee joints (when both knees were affected, subjects were asked to wear the device over the more painful sides). The WOMAC index was used to assess pain and functional status. Pain was rated in five areas (walking, stair climbing, nocturnal, rest, and weight bearing) using an 11-point VAS. Difficulty performing 17 daily activities was rated using a 5-point Likert scale. A 15-meter walk test was used to assess subject's gait speed. Magnetic devices were 4 × unipolar neodymium-iron-boron discs yielding an approximate surface power of 1600 gauss each. After 2 weeks, subjects wearing magnets demonstrated greater improvements (60%) in pain ($p = 0.002$), 45% increase in physical function ($p = 0.01$), and 10% improvement in gait speed ($p = 0.042$) compared with placebo.

Segal et al.[45] studied 64 patients with rheumatoid arthritis who despite medications had persistent knee pain by taping either static magnets (190 millitesla [mT], 1900 gauss) or placebos (one steep field as opposed to four steep field gradients in the active treatment group) to the knee for 1 week. Control devices looked identical except that they contained only one instead of four magnets (72 mT, 720 gauss). Subjects had to meet the 1987 criteria of the American Rheumatism Association classification of rheumatoid arthritis and had to have a baseline pain score of at least 40/100 on a VAS. Assessments of disease activity, ESR, CRP, range of motion, examination for tenderness and swelling, patients' assessment of physical function and the The Modified Health Assessment Questionnaire (MHAQ) for difficulty with activities of daily living were also assessed. These assessments were made at 1 h, 1 day, and 1 week after placing the devices in situ. Each subject was also give a pain diary and asked to log their pain scores in the morning and evening each day. Baseline pain scores in treatment and control groups were similar (61/100 and 63/100, respectively). A greater reduction in reported pain was sustained through the 1-week follow-up (40.4% and 25.9%) and corroborated with the diary pain scores ($p < 0.0001$ for each versus baseline). However, comparison between the two groups demonstrated a statistically insignificant difference ($p < 0.23$). They found a significant reduction in pain in the magnet group ($p < 0.0001$). Subjects in the active treatment group also reported a reduction in global disease activity of 33% as compared with a 2% decline in the control group ($p < 0.01$). After 1 week, 68% of the treatment group reported feeling much better, compared with 27% of the control group. No significant differences were measured in serum inflammatory markers. In this study both test and placebo magnets were active magnets, which may have contributed to the lack of statistical difference despite the occurrence of significant pain reduction compared to controls without magnets. A 3-month follow-up questionnaire indicated even greater improvement. The authors admit to a dose-comparative study rather than a placebo-controlled study.

Alfano et al.[43] studied the effects of magnetic and placebo mattresses on the pain of fibromyalgia. All 119 subjects met the 1990 American College of Rheumatology criteria for fibromyalgia. The subjects were divided randomly into four groups. Subjects in Functional group A were exposed to a mattress of 3,950 gauss with the magnets arranged in a unipolar and uniform manner, whereas those in Functional group B were exposed to a mattress of 750 gauss with the magnets arranged with varied space and varied polarity. Subjects in the two sham groups used mattresses that were identical in appearance and texture to the functional pads except that they contained inactive magnets. Subjects in the usual care group continued with their established treatment

Table 3. Randomized Controlled Trials of Static Magnets in the Treatment of Pain: Study Characteristics and Results

Author	*Design*	*Study quality[a] (x/5)*	*Diagnosis duration*	*Treatment n*	*Method*	*Control n*	*Method*	*Endpoint measure*	*Follow-up*	*Result*
Harper and Wright, 1977[33]	Double-blinded	3	Pain thresholds to radiant heat applied to back of hand of healthy volunteers	8	Magnetic bracelet applied for 5 mins prior to pain stimulus application. Each subject tested 5 times with and without bracelet.	8	Placebo bracelet applied in a similar manner to active bracelet for 5 mins. Each subject tested 5 times with and without bracelet.	Pain quantification not described	No	T test (level not stated) showed no difference between the 2 groups in pain thresholds
Hong et al., 1982[34]	Randomized double-blinded	4	Chronic neck and shoulder pain more than 1 year.	52	Magnetic necklace of 1300 gauss and non-magnetic necklaces randomly assigned to subjects with and without pain for 24 hr wear for 3 weeks.	49	Non-magnetic necklaces applied similarly. All subjects told they were receiving magnetic devices.	VAS of 0 to 4 used for subjective pain. Frequency and intensity of pain noted. Nerve conduction times at baseline and 3 weeks.	No	Significant placebo effect noted in reduced intensity and frequency of pain. 52% magnet group, 44% placebo group. Proximal conduction time in ulnar nerve reduced in non pain subjects.
Caselli et al., 1997[35]	Randomized double-blinded	1	Plantar fasciitis of the heel. Duration not specified.	19	Magnetic foil insoles of uncertain magnetic power worn for 4 weeks	15	Non-magnetic insoles worn for the same duration.	VAS for pain and and foot function.	No	No significant difference found between the 2 groups (see text).
Vallbona et al., 1997[36]	Randomized double-blinded	4	Post polio pain syndrome. Significant pain for at least 4 weeks	29	300-500 gauss magnetic pads applied to site of pain. Pain reassessed after 45 min magnet application by palpation of trigger points.	21	Non-magnetised identical pads applied.	Pain assessed by McGill pain Q and VAS 0-10 for trigger points	No	Active group average pain decrease of 4.4 $\pm$3.1 ($p < 0.001$). Placebo devices decrease of pain scores of 1.1 $\pm$ 1.6 ($p < 0.005$). 76% active group reported greater than placebo effect on pain ($p < 0.0001$)
Kanai et al., 1998[37]	Randomized double-blinded	3	Patients with low back pain. Duration not specified. Pain confirmed by thermal imaging.	85	180mT (180 gauss applied to painful region for 3 weeks. Pain assessed at 1, 2 and 3 weeks by VAS and thermal imaging	22	Dummy magnet of 10mT (100 gauss) applied.	Pain assessment by VAS and thermal imaging at weekly intervals over 3 weeks.	Yes	Significant improvement after 1 week in active magnet group. Increased warming seen on thermal images at 2 and 3 weeks in active group.

Man et al., 1999[38]	Randomized double-blinded	3	Post operative pain studied for 14 days	10	Suction lipectomy patients. Same surgeon. Magnetic patches (150 to 400 gauss) immediate post-op. Negative pole to skin. Pain by VAS assessed at days 1, 2, 3, 4, 7 and 14. Same observer.	10	Sham patches identical without magnetic power.	Pain by VAS, oedema, discoloration	No	Significant ($p < 0.05$), decrease in pain at days 1, 2, 3, 4 and 7 compared with control group. Day 14- $p < 0.09$. Decreased consumption of analgesics noted in magnet group.
Weintraub, 1999[39]	Randomized double-blinded crossover	4	Painful peripheral neuropathy. 10 with stage 2 and 3 refractory diabetic, DPN, and 9 with non-DPN	19	4 phases. Active 475 gauss magnet insole in 1 foot. VAS twice a day over 4 months. Sham magnet in other foot. Application for 24 hours a day.	19	Phase 2 sham and control feet switched after 30 days. Phase 3 and 4 after 30 days 2 new active insoles both feet. Placebo response monitored first 2 months.	Pain levels as assessed by VAS scores. Secondary outcome measures-serial comparisons of neurological examination and electrodiagnostic studies.	8 weeks	90% diabetic group had significant reduction in pain cf 33% in N-DPN group.
Brown et al., 2000[40]	Double-blinded	1	Chronic pelvic pain of non-specified duration.	14	500 gauss magnets worn 24 hr per day. 2 week double blinded, 2-week single blinded extension.	Unclear	Dummy magnets applied as per active group.	Pain as assessed by McGill pain Q and Pain disability index	No	60% of magnet group cf 33% of placebo group had 50% reduction in pain.
Collacott et al., 2000[41]	Randomized double-blinded crossover	5	Stable low back pain mean duration 19 years	20	Real (300 gauss) and sham magnets applied alternate weeks, 6 hours per day, 3 days per week for 1 week.	20	As for treatment group. One week washout period between the 2 treatments	Pain VAS McGill questionnaire. Range of motion measurements of lumbo-sacral spine	No	No significant differences between groups in VAS ($p = 0.9$) and ROM ($p = 0.66$) and McGill ($p = 0.55$)
Holcomb[42] et al., 2000	Randomized double-blinded crossover	3	Chronic low back or knee pain from 3 months to 30 years.	41 back pain (30 muscu-loskeletal, 11 neuro-pathic) 13 treated for knee pain	2 centres. Pain assessment by VAS and VRS (verbal rating scale) at 1, 3 and 24 hours. 200mT magnet (2000 gauss)	As per treatment group	Sham magnets applied in same way and pain assessed at same times post application	Pain level as as determined by VAS and VRS at 1, 3, and 24 hours	No	Significant reduction of pain in magnet group at 1 and 24 hours ($p = 0.032$ and 0.03 respectively)

(*continued*)

Table 3. Randomized Controlled Trials of Static Magnets in the Treatment of Pain: Study Characteristics and Results (*Continued*)

Alfano et al., 2001[43]	Randomized double-blinded	5	Fibromyalgia patients. Pain for at least 3 months and pain on palpation of at least 11 of 18 specified sites	67	2 treatment groups, 1 using 4000 gauss magnetic mattresses with magnets uniformly arranged with negative pole to the skin. Second group varied spacial and varied polarity of 750 gauss. Pain intensity to standard pressure over tender points assessed. Pain scores summed for all sites.	44	2 placebo groups inactivated magnets in identical arrangement to corresponding magnet groups. 5th group was usual care with no change to treatment over the study period.	Pain by 11 point numeric rating scale of number of tender points and total summated tender point scores. 3 and 6 month assessment. Functional status also assessed	No	Significant reduction of pain at 6 months in treatment group 1 ($p = 0.03$) and significant reduction in pain in treatment group 2 at 3 months ($p = 0.01$)
Kim et al., 1994[44]	Randomized double-blinded	3	Chronic headache for a mean of 15.4 yrs (range 7 months to 57 yrs)	6	Headband with 2 ceramic magnetic discs (850–1100 gauss) worn for 30 mins daily at set time for 4 weeks	8	Headband worn without magnets. No description of placebo given.	VAS scores at 5 time points over 8 weeks measured.	No	A non-significant trend towards greater improvement in headache (61%) cf placebo (48%) and a trend towards reduction in analgesic use in the magnet group.
Segal et al., 2001[45]	Randomized double-blinded	4	Active Rheumatoid arthritis of knee with minimum VAS pain scores of 40/100	38	MagnaBloc 4 steep field magnets 4 × 190mT (1900 gauss) alternating polarity taped to knee for 1 week	26	MagnaBloc with 1 steep field magnet in situ and 3 aluminum blanks. Estimated field strength 72mT (720 gauss)	VAS pain assessment ESR, CRP, ROM, assessment of tenderness and physical function. RGADA, SGADA, MHAQ	No	Significant reduction in pain scores cf baseline in both treatment and control groups ($p < 0.01$). Difference between 2 groups not significant ($p < 0.23$).
Simoncini et al., 2001[32]	Randomized double-blinded Excluded from analysis because of absence of statistics.	3	Hallux pain after bilateral surgery	20	Post surgery 2× flexible bar magnets, 100–150 gauss, inserted inside the dressing of the right foot.	20	Placebo, two flexible, non-magnetic equivalents placed in the dressing of the left foot.	Pain assessment by VAS and oedema by circumferential measurements.	No	Reduced oedema but not pain at 2 days on the magnet side. Reduction of pain but not oedema at 1 and 2 months on the magnet side.
RSSL study, 2001, unpublished	Randomized double-blinded	2	Regular dysmenorrhoea	50	Application of device to pelvis at onset of pain.	50	Application identical to control group	5-point pain assessment scale completed 3 times a day during menses.	No	Small but significant reduction in pain on days 2 and 3 compared with placebo group.
Carter et al., 2002[46]	Randomized double-blinded	4	Carpal Tunnel Syndrome (CTS) Diagnosis duration not described.	15	1,000 gauss magnetic disc secured by velco over CTS area for 45 mins.	15	Placebo. Metal disc, non-magnetic in same location.	Pain assessed by VAS.	2 weeks	Significant decrease in pain at 45 mins and at 2 weeks in both magnet and placebo group.

Hinman et al., 2002[47]	Randomized double-blinded	5	Arthritic knee pain of average 11.5 yrs duration.	18	Pad with 4 × 1.08 Tesla (approx 1600 gauss surface power) magnets worn over the painful knee joint with negative pole towards the skin.	25	Pad with 4 × non-magnetic discs. Non-specified material.	Self-rating of pain and WOMAC and 15 m walking speed at 2 weeks.	No	Significant improvements in the magnet group ($p = 0.002$) in pain, function and walking speed.
Pope and McNally, 2002[48]	Randomized double-blinded	4	Wrist pain on typing (RSI) of non-specified duration.	14	Pain (by VAS) and typing speed assessed pre and post 30 min application of 2450 gauss magnetic wrist bracelet	16	Non-magnetic wrist strap applied as per active device	VAS (1–7) after 30 min treatment. Number of words typed in 4 mins also assessed.	No	Mean pain improvement of 2.3 in sham and 2.4 in the magnet group ($p > 0.05$).
Weintraub et al., 2003[49]	Randomized double-blinded	5	Pain from Diabetic peripheral neuropathy (DPN) stage II or III of at least 6 months duration.	141	450 gauss magnetic insoles worn 24 hours a day	118	Non-magnetic insoles.	VAS scores for pain, tingling and numbness at 2 and 4 months.	No	Significant reduction at 3 and 4 months in burning, tingling and numbness in the magnet group.
Winemiller et al., 2003[50]	Randomized double-blinded	4	Plantar heel fasciitis for at least 30 days	56	Bipolar magnets of 192 gauss worn as insoles for at least 4 hours a day, 4 days a week for 8 weeks.	44	Metallic non-magnetic insoles	VAS pain scores at 4 and 8 weeks.	No	No difference in pain scores between magnet and sham groups at 4 and 8 weeks.
Wolsko et al., 2004[51]	Randomized double-blinded	5	Osteoarthritis for at least 3 months verified clinically and by X-ray	13	Knee sleeves with magnetic field up to 850 gauss	13	Magnetic devices of same power but designed to emit filed away from the skin (estimated 0.5 gauss)	Change in WOMAC (Western Ontario MacMaster questionnaire) Osteoarthritis Index	No	Significant analgesic and functional improvement at 4 hours in the magnet group. Differences not present at 1 and 6 weeks.
Eccles, 2005[b], 2005	Randomized double-blinded	5	Women with regular dysmenorrhoea (most since menarche)	17	Specially designed magnets of 2000 gauss with directional plate attached anteriorly to the underwear overlying the pelvis/uterine region.	18	Same device with attenuated magnetic power of 150 gauss.	Pain assessed by VAS and McGill questionnaire after device application 2 days prior to menses. Associated symptoms and effects on function also assessed.	No	There was a significant reduction ($p < 0.02$) in pain in the magnet group compared to the placebo group.

[a]Ref 25.
[b]Eccles NK. A randomized double-blinded, placebo-controlled pilot study to investigate the effectiveness of a static magnet to relieve dysmenorrhea. J Altern Complement Med 2005; in press.

regimens. Primary outcome measures were the change in pain scores (on an 11-point VAS scale) at 3 and 6 months in functional status (fibromyalgia impact questionnaire), pain intensity ratings and a tender point pain intensity score (summation of pain ratings from palpation of tender points, tender point count). A single physician performed the tender point assessment and was blinded to all treatment group assignments. There was a significant difference among groups in pain intensity ratings ($p = 0.03$) with Functional pad A showing the greatest reduction from baseline at 6 months. All four groups showed a decline in the number of tender points, but the difference in this decline among the groups was not quite statistically significant ($p = 0.072$). Whilst there was a significant reduction in pain intensity in Functional group A, the trend for improvement in functional improvement in the active treatment groups was not significant ($p = 0.23$).

A randomized double-blind crossover study[42] compared the effect of a quadripolar static magnet device, 200 mT (2000 gauss), against an identical nonmagnetic placebo on 54 patients with chronic back and knee pain. Diagnosis was based on physical and radiographic findings. All patients underwent x-rays of the lumbar spine to demonstrate evidence of degenerative disc or joint disease. Patients with knee pain also received x-rays of the affected knee. All 13 patients with knee pain in the study had confirmed osteoarthritis. Patients were randomly assigned to one of two treatments; either magnet or placebo and then these treatments were reversed after a 7-day washout period and 24-h reassessment of pain scores. Outcome measures were pain scores as determined by VAS and a verbal rating scale (VRS). Pain assessments were made after 1, 3, and 24 h after the device application. The magnet group was found to have a significant reduction of pain scores compared with the placebo group ($p = 0.030$).

A 4-week application of a 500-gauss unidirectional static magnets to trigger points for 24 h a day in 14 women with chronic pelvic pain of nonspecified duration. This was conducted as a 2-week double-blinded study with a 2-week single-blinded extension. Pain was assessed by McGill pain inventory and the Pain disability index. The study demonstrated a 50% reduction in the level of pain in 60% of subjects after 4 weeks compared with a 33% reduction in the level of pain after 2 weeks. This study indicates that duration of exposure, as well as field strength may be important considerations in the study of chronic pain syndromes.[40]

A randomized double-blind placebo controlled crossover study on 19 subjects with Diabetic painful peripheral neuropathy using multipolar magnetic foot pads (475 gauss) was conducted over a period of 4 months by Weintraub.[39] All patients had failed to improve with conventional pharmacological treatments (e.g., analgesics, NSAIDs, anticonvulsants, tricyclics). Acupuncture had also been tried in a few individuals. Ten subjects had diabetic peripheral neuropathy, and nine had nondiabetic peripheral neuropathy. The study design entailed four phases. After initial neurologic and electrodiagnostic evaluation, patients randomly received an active magnetic foot insole for 1 foot and a similar appearing sham insole on the other foot. Subjects scored their pain in both feet by a VAS twice a day. After 30 days, the sides of the active and sham insoles were switched for an additional 4 weeks. At the end of this month, the subjects received two new active magnetic insoles (475 gauss) and continued for a further 8 weeks rating their pain level twice daily. No new pharmacologic interventions were allowed. Patients were evaluated on a monthly basis by the same assessor. Motor, sensory, and reflex functions were also assessed. Nerve-conduction velocities were also investigated in the common peroneal and posterior tibial nerves. Improvement in the magnetic group was significantly more pronounced in the diabetic cohort (90%) versus placebo (33%) at the end of 4 months ($p < 0.02$). Severe axonal damage was demonstrated in the diabetic cohort compared with only mild demyelinating changes in the nondiabetic group and these differences seemed to be predictive of clinical success and responsiveness.

Man et al.[38] looked at the effect of unidirectional (negative pole against the skin) static ceramic magnet patches of 150–400 gauss over a 14-day period in 20 patients who had undergone surgical liposuction. The same surgeon performed all the procedures. The devices were applied immediately postoperatively overlying the areas that had been suctioned and left in place for 14 days. The treated areas were assessed at day 1, 2, 3, 4, 7, and 14 postsurgery by the same blinded observer. Discoloration and edema were assessed on a scale of 1 to 10, and pain was assessed by a VAS. Several observations were made including significantly less discoloration at days 1, 2, and 3 and significantly less edema at days 1–4 in the magnet group compared to controls. There was significantly less pain between days 1 and 7 (37%–65% reduction) compared with the control group and this was confirmed by the consumption of less analgesics in the magnet group.

Kanai et al.[37] studied 85 patients with low-back pain (duration not specified; the pain being confirmed by thermal imaging) and 22 controls. The 180-mT (1800 gauss) small samarium-cobalt magnets were applied to painful regions for 3 weeks. Dummy magnets of 10 mT (100 gauss) applied to the control subjects in the same region. Pain was assessed at 1, 2, and 3 weeks by VAS and by thermal imaging. Magnets compared with dummy magnets (10 mT) improved low back pain significantly after 1 week. This improvement was associated with a significant increase in the lowest temperatures on thermographic images at 2 and 3 weeks. The authors suggested that the reduction in pain correlated with a gradual increase in blood flow.

Vallbona et al.'s study[36] recruited 50 patients with post-polio syndrome (pain syndrome notoriously difficult to treat, associated with diffuse muscle and joint pains in 76% of sufferers and increased susceptibility to nociceptive stimuli) who reported muscular and arthritic pain. All patients had significant pain for at least 4 weeks. Assessment of pain was made by palpation of trigger points before and after appli-

cation of the device. Magnetic devices were multipolar and had 300–500 gauss power. Placebos were identical but with inactive magnets. Baseline pain levels were also assessed by the McGill Pain Inventory. Only one area of reported pain, that being most sensitive to palpation, was evaluated, although multiple sites may have been present. An active trigger point associated with the site of pain was elicited by pressure with a blunt object. Patients were asked to rate their pain on palpation on a scale of 1–10. A randomly chosen device was then taped over the area for 45 min; thereafter, it was removed and pain reassessed at the trigger point. Patients who received the active device experienced an average pain score decrease of 4.4 ± 3.1 ($p < 0.0001$) on the 10-point scale. Those with the placebo devices experienced a decrease of 1.1 ± 1.6 ($p < 0.005$). 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 ($p < 0.0001$).

A double-blinded study crossover trial on a sample of 107 women, 18–45 years old, with regular menstrually related pelvic pain was conducted with an outcome measure of a 5-point pain assessment scale completed three times a day during menses. This study showed a small but significant reduction ($p < 0.05$) in pain compared with placebo on days 2 and 3 of the menses after application of a specially designed neodymium magnet (2000 gauss) was applied to the pubic region at the time of onset of pain (RSSL study, 2001, unpublished data). The same device was tested more recently as a randomized double blind investigation (Eccles, 2005).[*]

The negative studies

Winemiller et al.[50] randomly assigned 101 subjects with plantar fasciitis to receive cushioned insoles with active magnets (192-gauss surface measurement) or placebo insoles. Active or sham insoles were worn for at least 4 hours a day for 4 days a week for 8 weeks. Pain was logged daily by VAS and assessed at 4 and 8 weeks. Impact on work performance and enjoyment was also measured. Effectiveness of blinding was confirmed at 4 and 8 weeks. No significant difference was found in any of the outcome measures between the two groups. Both groups reported a significant reduction in morning foot pain intensity. In most studies reviewed here that demonstrate a positive effect analgesic effect, magnetic strengths of at least 400 gauss were used, so the magnetic power of 192 gauss used in this study may have had a bearing on the outcome. In this study, insoles were picked randomly out of a box but given the mixture of magnetic and nonmagnetic insoles, no comment was made as to how possible magnetic adherence may have affected the process of randomization.

Pope and McNally[46] investigated the effects of magnets on self-identified repetitive strain injury of the wrist in college students. Thirty subjects were randomly assigned to receive magnetic bracelets (single disc magnet of 2450 gauss, no surface power given), sham bracelets (with magnets removed) or no-treatment controls. Assessment was made of number of words typed from a standard text in 4 min and pain rating before and after a 30-minute period of treatment. Both magnet and placebo groups had similar significantly greater improvement than the no-treatment group both in pain reduction and in number of words typed. There were no comments by the authors as to whether pain was always present on typing, of chronicity of pain in the subjects or whether the baseline level of pain was the same in both groups. Thirty minutes was a relatively short time for treatment exposure and may have influenced the results.

Thirty patients with pain attributable to carpal tunnel syndrome were randomly allocated to 1000-gauss magnets applied over the region of pain or sham non-metallic devices. Exclusions were made if painkillers had been taken within 4 h of the test or if no pain was present at the time of treatment. Pain was scored using VAS and McGill pain questionnaire at 45 min and then after a 2-week period. Both groups had a significant reduction in pain at 45 min compared with baseline levels, and this difference persisted at 2 weeks.[46]

Kim[44] investigated the efficacy of magnetic headbands for the treatment of chronic primary headache. Nineteen (19) patients with chronic primary headache (54% experienced headache 3–6 times a week with each episode lasting at least 4 hours). Patients were randomized to magnets (six patients) or placebo (eight patients) or their standard treatment. Pain was assessed by VAS at five time points at weekly intervals. The magnet group received a headband containing two ceramic magnetic discs each of 850–1100 gauss (surface measurement). No description is given of the placebo. The devices were worn for 30 minutes daily for 4 weeks at a regular time (and therefore not necessarily at the time of pain). No description is given of headache frequency. Although the subjects in the magnet group experienced the highest improvement in their headache (60.2%) compared to placebo (47.9%), this apparent difference was not statistically significant. There was a reduction in analgesic consumption in the magnet group 36.1% compared with an increase in consumption in the placebo group, +9.6%. The study employed particularly small numbers and despite the lack of statistical significance showed some positive trends in favor of magnet-induced analgesia.

Collacott et al.[41] used a randomized placebo control procedure to compare the effect of a 300-gauss bipolar magnets with an identical sham magnet. Twenty (20) patients were studied with chronic back pain due to degenerative disease and this was confirmed radiographically beforehand. Their pain was assessed using a VAS and the McGill pain inventory. Range of motion of the lumbosacral spine was also assessed by the same observer. All subjects followed the treatment protocol for 2 weeks: 1 week with magnets and 1 week with sham devices, with a 1-week washout period between the two treatment weeks. Devices were applied for 6 hours per day, 3 days a week. Assessments were made after the first day of treatment and then after each week. The

researchers were unable to demonstrate a statistically significant effect of magnets compared to sham treatments on any of the outcome measures.

Caselli et al.[35] studied 40 patients with plantar fasciitis pain of the foot. Subjects were randomly assigned to receive magnetic insoles or nonmetallic shams. Six patients were lost to follow-up (five from the placebo group and one from the magnet group) but the reasons are not specified. VAS was measured at baseline and at 4 weeks, with the subjects being asked to indicate the level of pain experience in the preceding week. The study was not clearly double-blinded, nor was there a description of magnet power. Eleven (11) of 19 patients with magnets had improvement in foot function measurements at 4 weeks compared to nine of 15 with the nonmagnetic insole. There are several concerns over this study's methodology (Table 2).

Hong et al.[34] studied the effects of magnetic necklaces of 1300 gauss power on 101 volunteers, 46 males and 55 females. Forty-nine of the subjects were without pain, but 52 had chronic neck and shoulder pain periodically or consistently for more than 1 year. They were divided into four groups (with pain versus without pain matched with either magnetic or nonmagnetic necklaces). Necklaces were worn for 24 hours per day for 3 weeks. All subjects were told that they would receive a treatment with a magnetic necklace for 3 weeks. Subjective evaluation of pain was performed before and at the end of 3 weeks. Results did not reveal a significant analgesic effect of the magnetic necklace (52% improvement) compared with placebo (44% improvement). The significant placebo effect was commented on by the authors who found that almost all their subjects believed that their necklaces were magnetized. Interestingly, proximal conduction times in the ulnar nerve were significantly reduced in subjects without pain but were unchanged in subjects with pain. The authors suggested that this differential effect may represent an action on healthy (without pain) compared with diseased (patients with pain) nerves.

A small study to assess pain thresholds to heat in the back of the hands of 16 healthy volunteers, before and after application of a wrist magnet was performed by Harper and Wright.[33] The magnetic power of the bracelet was not noted. Each volunteer acted as his or her own control, being tested five times with and without the bracelet. The order in which the bracelets were worn was randomized. They were unable to demonstrate a significant change in pain threshold resulting from use of the magnetic device.

DISCUSSION

In general the methodological quality of the studies, as assessed by the three criteria of the modified Jadad score for clinical trials was good with 18 of the 21 trials scoring 3 or more out of the possible 5. The 21 key trials are outlined above in Table 3.

Magnets were applied as necklaces, footpads, mattresses, patches, or straps. Magnet power, where clearly stated, varied from 150 to 3950 gauss.

Pain relief was generally reported at gauss ratings of 400 and above. Duration of exposure ranged from 45 minutes to prolonged wear for 6 months. Studies demonstrating significant relief used a minimum exposure of 45 min. Two studies in which no significant relief was observed used exposure times of 6 hours per day for 3 days on alternate weeks[41] and 4 hours per day for 4 days in the other.[50] The former study used a magnet of 300 gauss power for treating chronic back pain. The latter study used 192-gauss magnets to treat plantar fasciitis pain. In both studies too low a magnetic power may be an important consideration in the lack of effect. It is also possible that the intermittent exposure protocols may also have affected the efficacy. Another two studies showing no effect on pain used short exposure times of 5 minutes[33] and 30 min[48] to the magnet.

One of the problems with static magnet studies is in identifying the power of the magnet to use. Very few studies, in fact, none of the studies reviewed here, gave an estimate of the magnetic field penetration. Quoted magnetic power of commercial magnets tends to be grossly overestimated.[52] There is, therefore, a need to identify accurately magnet power measurement both in terms of the magnet surface power and also field penetration. From the current studies, it would appear that pain relief was achieved by static magnet power of at least 400 gauss.

It is difficult to perform a truly double blind study using magnets because of the obvious interaction of the magnet with metallic objects. This makes masking of the placebo difficult. As reported by Hong et al.[34] most of their subjects believed that they were being given a magnetic necklace and the authors suggest that this fact alone accounted for the 44% improvement observed in the placebo group. It may be a better approach, when performing magnet studies, to give no clue that magnets are being used at all and that the study is designed to test a "metallic device." One study on rheumatoid arthritic knee pain tried to circumvent this by using a magnet of 25% strength of the test magnet (i.e., 500 compared to 2000 gauss) as placebo.[45] The "placebo" also produced significant relief to the degree that there was no significant difference between placebo and control. There was, however, a significant difference between magnet and nonmagnetic controls. Several of the research groups in this review attempted to circumvent this problem by asking subjects to sign an agreement that they would not try to elicit the nature of their device against metallic objects.

FURTHER CONSIDERATIONS

Most commercial static magnets have powers of less than 1000 gauss (0.1 Tesla). Moreover, gauss readings are often found to be much lower than manufacturers' claims

(less than 20% of the claimed power in some cases).[52] Also, the surface of a magnet usually has non-uniform gauss readings.

Field flux density is often greater at the edges compared with the centre of the magnet.[52] The field strength is proportional to the square of the distance from the magnetic source. The strength falls off rapidly from the body surface. This makes it difficult to assess penetrability. A nonuniform field results in tissues after application to the skin surface.[53] Devices that utilise a directional plate can be used to increase magnetic field penetration. The degree of subdermal decay also varies with different magnetic alloys.[52]

The polarity of the magnet that faces the skin may have a differential effect,[7] but there is still debate over whether application of north or south poles determines the nature of the effect. Most of the double blind studies cited in this review have employed the south (negative) pole of the magnet adjacent to the skin. According to Vallbona,[36] both bipolar (alternating north and south poles in concentric pattern or a grid) and unipolar (one pole at the surface applied to the skin) magnets are effective in pain relief. Some have hypothesized that multipolar magnets may generate deeper field gradient penetration than either unipolar or bipolar magnets,[20] although as stated above a directional plate can be used with a unipolar magnet.

SAFETY

The evidence that certain electric and magnetic fields augment DNA synthesis has been met with concern about cancer risk. This concern is largely directed at pulsed electromagnetic fields and, in particular, continuous exposure to high voltages, for example, overhead power lines and electric blankets.[54] No adverse effects on human health have been observed with static magnets up to 2 Tesla or 20,000 Gauss.[36,55] Magnetic fields of 2 and 7 Tesla produced no teratogenic effects in pregnant mice.[56] However, some studies have reported effects on young animals. It therefore seems prudent to avoid magnets in pregnancy and young children less than 3 months.[57] It is also recommended that magnets should be avoided in pacemaker wearers, and patients who have metal implants or who wear insulin syringe drivers.

Some researchers have reported the possibility that magnetic fields can enhance conventional drug treatments, necessitating a dose reduction in the latter.[58] There is however a paucity of research in this area, and clearly more research needs to be done to validate this claim.

As part of future experimental design, researchers need to consider carefully magnetic power, magnetic field penetration (and perhaps in this context, magnet polarity), duration of exposure, type and location of pain, and adequacy of placebo masking. Future research should also address the important question of whether static magnetic fields have any influence on concurrent medications.

CONCLUSIONS

The majority, 11 of 15, of the better quality randomized control studies (73.3%) demonstrate an analgesic effect of static magnets. Analgesia seemed to be elicited across a broad variety of types of pain, including neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic, and postsurgical pain. None of the studies reported any side effects with magnets. The weight of evidence from this critical review suggests that static magnetic fields can elicit an analgesic effect.

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Address reprint requests to:
Nyjon Eccles, M.R.C.P., Ph.D.
The Chiron Clinic
121 Harley Street
London W1G 6AX
United Kingdom

E-mail: drnyjon@hotmail.com