Static Magnetic Therapy Does Not Decrease Pain or Opioid Requirements: A Randomized Double-Blind Trial

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A growing multibillion dollar industry markets magnetic necklaces, bracelets, bands, insoles, back braces, mattresses, etc., for pain relief, although there is little evidence for their efficacy. We sought to evaluate the effect of magnetic therapy on pain intensity and opioid requirements in patients with postoperative pain. We designed a randomized, double-blind, controlled trial. One-hundred-sixty-five patients older than 12 yr of age were randomized to magnetic ($n = 81$) or sham therapy ($n = 84$) upon reporting moderate-to-severe pain in the postanesthesia care unit. Devices were placed over the surgical incision and left in place for 2 h. Patients rated their pain intensity on a 0–10 scale every 10 min and received incremental doses of morphine until pain intensity was ≤4 of 10. Pain intensity levels were similar in both groups. The magnet group had on average 0.04 U more pain intensity (95% confidence interval, −0.4 to 0.5) than the sham group. Opioid requirements also were similar in both groups. The active magnet group required 1.5 mg more morphine (95% confidence interval, −1.8 to 4.0) than the sham magnet group. Magnetic therapy lacks efficacy in controlling acute postoperative pain intensity levels or opioid requirements and should not be recommended for pain relief in this setting.

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Magnetic therapy is increasingly used to alleviate pain. A growing multibillion dollar industry produces and markets magnetic necklaces, bracelets, bands, insoles, back braces, mattresses, etc., and claims almost miraculous powers for them (1). Drugstores, and even grocery stores, now carry many different magnetic therapy products that can cost anywhere from a few dollars to thousands of dollars, depending on the product (2).

Magnets appeal to patients because they promise a simple solution for pain relief; they are relatively safe, drug free, durable, and noninvasive. Patients are also swayed by celebrity testimonials for them (3). However, there are inconsistent results from a limited number of randomized, controlled trials (RCTs) testing the analgesic efficacy of magnet therapy (4).

The shortcomings of the available literature that evaluated magnetic therapy for pain relief are lack of adequate blinding, small sample sizes (median of 20 subjects exposed to magnetic therapy), and the fact that authors often analyze results only for patients who adhered to the treatment. These weaknesses could lead to an over-estimation of the efficacy of magnetic therapy because effective blinding protects against the positive effects of expectation and biased assessment (5); results from small studies may be distorted by the random play of chance, especially in pain studies (6), and patients who adhere to treatment regimens usually have better outcomes than those who do not or those lost to follow-up (7).

We believe that chronic pain syndromes are not the best models for the initial evaluation of the efficacy of magnetic therapy. First, these syndromes often lack a uniform pathophysiologic mechanism required to explain how a therapy works. Second, long-term follow-up in chronic patients may be problematic. Finally, maintaining long-term masking is challenging because patients can observe the magnetic properties of applied devices interacting with nearby ferrous material. The use of an acute pain model overcomes these limitations. Furthermore, findings in an acute postoperative pain model could be generalizable to pain syndromes that share "tissue injury" as the source of nociceptive input (8).

Because of the widespread marketing and use of magnetic therapy, despite a near total lack of scientific evidence supporting its use for pain relief, we sought to evaluate the effect of magnetic therapy on pain intensity levels and opioid requirements in patients with postoperative pain.

METHODS

We designed a double-blind RCT. The study was approved by the Javeriana University School of Medicine Review Board and registered at ClinicalTrials.gov;

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For allocation, we used a computer-generated random number program ("Ralloc" in STATA (9)). Ralloc provides a sequence of treatments randomly permuted in blocks, in which size and order are also random, to prevent the prediction of future treatment allocation based on past allocation patterns. The block sizes in our randomization varied from 2 to 10.

Because the intensity of the baseline pain is an important modifier of the response to pain therapies (10), we performed a stratified randomization: one for moderate and another for severe pain.

The operating room pharmacy regulated treatment assignment and distributed the corresponding devices to the nurses in charge of applying the devices.

Sham devices were constructed by opening the plastic cases of the original magnets, removing the magnets, and replacing them with lead; as a result, active magnet and sham magnets looked alike and also had similar weight (17.1 g). In each case, different persons placed the devices and performed the evaluations.

We used commercially available magnets (MagnaBloc®) that were affixed to each patient using double-sided adhesive pads. There was no opportunity for the patient to observe any magnetic attraction to nearby ferrous material.

The MagnaBloc® is a quadrapolar static magnetic device 3.5 cm in diameter with 4 permanent magnets arrayed with alternating polarity. It has a magnetic flux return ring that maximizes the flux to the treatment side. We chose this magnet because it has been reported to produce magnetic fields with the high tissue penetration (11), which, in theory, may augment pain alleviation.

We included hospitalized or ambulatory patients older than 12 yr of age, subjected to surgical procedures under general anesthesia, who reported at least moderate pain. We started recruitment in November 2004 and finished 9 mo later.

We excluded subjects with operations lasting longer than 3 h, multiple surgical incisions, back or craniofacial surgeries, or surgeries that required cast placement, bulky dressing, or the implantation of metallic or other devices. We also excluded subjects with chronic exposure to opioids and patients who did not understand the pain scales we used (see below).

Informed consent was obtained before surgery. For subjects 17 yr old or younger, both the child and the parent signed an informed consent.

No limitations were placed upon the technique of general anesthesia. However, the administration of nonsteroidal antiinflammatory drugs was not permitted during anesthesia, nor was the administration of fentanyl within 30 min before the end of the procedure. Fentanyl was the only intraoperative opioid allowed.

Upon arrival in the postanesthesia care unit, patients were asked to describe their pain intensity on a 4-point verbal scale (none, mild, moderate, or severe pain). Once pain intensity was at least moderate, patients were randomized to receive either magnet therapy or sham therapy.

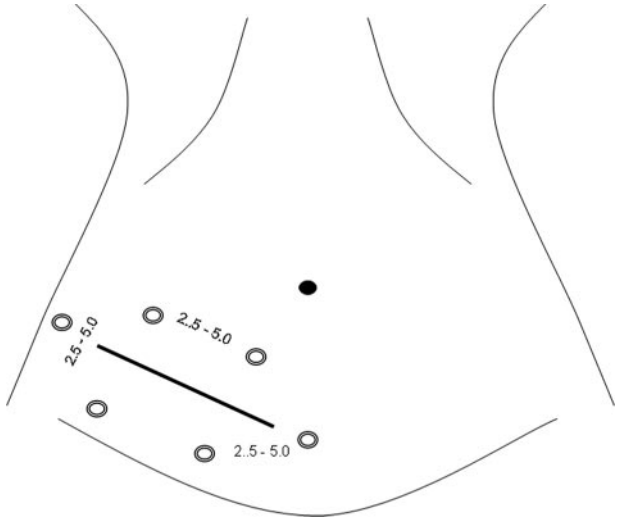

Figure 1. Placement of magnets around the surgical wound.

Magnets were placed at each end of the incision and around it. The minimal separation between the magnets was 2.5 cm and the maximal 5 cm. All the devices (active and sham magnets) were aligned according to the manufacturer's instructions (Fig. 1). The devices (active or sham magnets) were left in place for 2 h.

Upon postanesthesia care unit arrival and every 10 min thereafter, we asked patients to rate their pain intensity on a 0–10 numerical rating scale, where 0 represents no pain and 10 the worst pain imaginable. Research nurses masked to patient group allocation administered the initial loading doses of morphine every 10 min until pain intensity was ≤4 of 10. Adult patients younger than 65 yr old received 2.5 mg of morphine per initial dose; patients 65 yr or older received initial doses of 1.5 mg, and children younger than 15 yr received initial doses of 0.04 mg/kg of morphine.

Patients older than 65 yr received smaller doses because of increased susceptibility to opioid side effects than younger patients (12); in children, the doses were prescribed in milligrams per kilograms to avoid overmedication.

We documented the number of rescue doses of morphine required in each group during the 2 h of the study. We also asked patients to describe the presence and severity of sedation, nausea, vomiting, pruritus, and dizziness using a 4-point verbal rating scale for each (none, mild, moderate, or severe).

Patients were observed for 2 h after placement of the devices. Pain intensity at rest was the primary outcome, and opioid requirement was the secondary outcome.

Sample size calculations were based on pain intensity levels. We have previously shown that a decrease of one unit on a scale from 0 to 10 is the minimum decrease in pain intensity that patients can discern

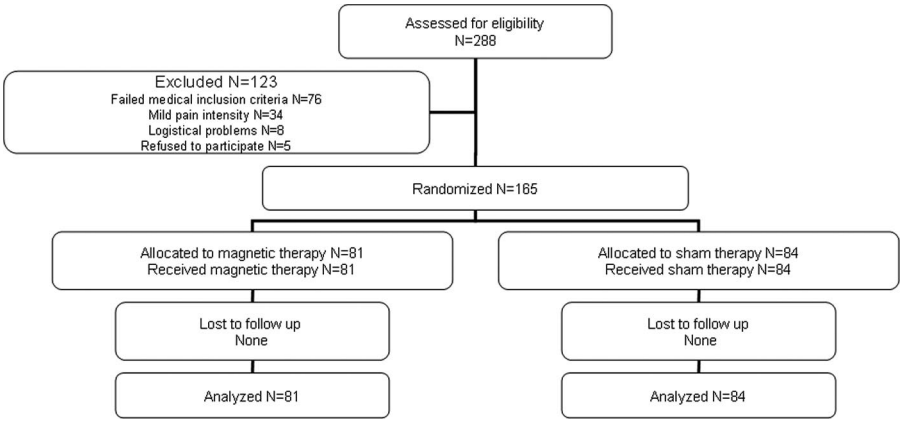

Figure 2. Flow diagram of the phases of the study.

(10). To detect such a difference between groups with 90% power and an α error of 0.05, assuming that the baseline pain intensity in our patients was on average 7.9 ± 2.0 (13), we estimated the need for 80 patients per group.

The analyses were based on all randomized patients (intent-to-treat analysis). To analyze the effect of the treatment on pain intensity, we used an analysis of repeated measures using the method of generalized estimating equations. This method was applied to adjust the values for the standard errors because each patient had multiple evaluations (until the pain intensity was 4 of 10 or less), and these measures were not independent (14,15). The outcome variable was the numerical rating pain score, and the explanatory variables were treatment group and time. We assumed that the correlation among measurements was constant. We also estimated the proportion of subjects who achieved at least 50% of pain relief at the end of the follow-up in each group.

To analyze the effect of magnet therapy on opioid requirements, we estimated the total dose of morphine that patients required in each group and used a robust regression to determine if there was a difference between groups caused by the presence of outliers (patients with unusually high requirements). Robust regression does not assume normality and minimizes the impact of influential observations. It assigns less weight to observations that have larger residuals or observations that are very influential (16,17) and thus provides a "robust estimate" that is not distorted by any particular observation. This technique has been used in the analysis of analgesic studies (18,19).

We also estimated 95% confidence intervals (CI) for the difference in opioid requirements, pain intensity, and the proportion of subjects with at least 50% of pain relief.

To compare the incidence of side effects between groups, we estimated the proportion of subjects with specific side effects and used a χ^2 analysis to determine if there was a difference between groups.

In all the analyses, we considered P values <0.05 to be statistically significant. All statistical tests were performed with STATA® statistical software version 9.1 SE.

RESULTS

We randomized 165 patients. Eighty-one subjects were allocated to active magnets and 84 to sham magnets. There were no protocol violations, and all patients were included in the analyses. The number of subjects screened and enrolled is shown in Figure 2.

Demographic characteristics, duration and type of surgery, intraoperative fentanyl dosage, and baseline pain intensity were similar in both groups. Seventy-five percent of patients had severe pain, and the mean baseline pain intensity of the subjects included was 8.4 (Table 1). Surgeries included were cholecystectomies, hysterectomies, herniorrhaphies, appendectomies, and lipoma excision.

Pain intensity levels were similar in both groups during the duration of the study. The magnet group had on average 0.04 U higher pain intensity (95% CI, −0.4 to 0.5) than the sham magnet group (Fig. 3).

The proportion of patients who achieved at least 50% of pain relief at the end of the 2 h was similar in both groups. Eighty-three percent (67 of 81) of patients in the magnet group achieved at least 50% of pain relief compared with 88% (74 of 84) of patients in the sham group (95% CI, −16% to 5%).

Opioid requirements were similar in both groups. The magnet group required 15.8 ± 9.0 mg of morphine, and the sham group required 14.6 ± 8.4 mg. The magnet group required 1.5 mg more morphine (95% CI, −1.8 to 4.0) than the sham group.

Sedation was the most frequent side effect in both groups. The incidence of side effects was similar in both treatment groups (Table 2).

DISCUSSION

For thousands of years, wonder and magic have surrounded the forces exerted by magnets (1). The use of magnets for therapeutic purposes is not new and may be traced back at least to Paracelsus (1493–1543), a physician and alchemist who reasoned that because magnets have the power to attract iron, perhaps they could also attract diseases and therefore remove them from the body (1). In the 19th century, magnet therapy

Table 1. Baseline Characteristics by Treatment Group

	Magnetic therapy	Sham therapy
Number of subjects	81	84
Females (%)	50 (61.7)	51 (60.7)
Age (yr) (mean ± SD)	37.5 ± 14.4	37.7 ± 16.2
Number of subjects ≤18 yr old	5	7
Weight (kg) (mean ± SD)	63.0 ± 13.0	61.9 ± 13.1
Duration of surgery (min) (mean ± SD)	75.5 ± 38.8	71.1 ± 39.0
Intraoperative fentanyl (μg) (mean ± SD)	169.2 ± 52.7	168.3 ± 55.0
Moderate pain (%)	21 (25)	21 (25)
Severe pain (%)	60 (75)	63 (75)
Baseline pain intensity (0–10) (mean ± SD)	8.3 ± 1.6	8.6 ± 1.5
Type of surgery		
Upper abdominal surgery (%)	24 (29.6)	20 (23.8)
Lower abdominal surgery (%)	51 (63.0)	61 (72.6)
Soft tissue surgery (%)	6 (7.4)	3 (3.6)

was considered to be quack medicine; but more recently, magnet therapy has had a rebirth. Drugstore shelves now have many lines of magnet products for sale, despite a lack of rigorous scientific evaluation. Estimated worldwide profits from sales of static magnets exceed 5 billion dollars annually, and most of these sales are for analgesia (20).

Our study shows that magnetic therapy does not decrease postoperative pain intensity or opioid requirements. The scientific rigor of the study design and execution and the precision of the estimates permit us to confidently conclude that magnetic therapy should not be used for treatment of postoperative acute pain or other pain syndromes in which the source of nociception is tissue injury.

Pain intensity levels upon enrollment were almost identical in the subjects allocated to active or sham magnets, and the CIs for the difference in pain intensity between the groups eliminate any statistical or clinical difference. The minimal decline in pain intensity that patients can discern is a 1-U decrease (10,21); the difference observed in the present study was 0.04 U. Likewise, opioid requirements were similar in the active and sham magnet groups.

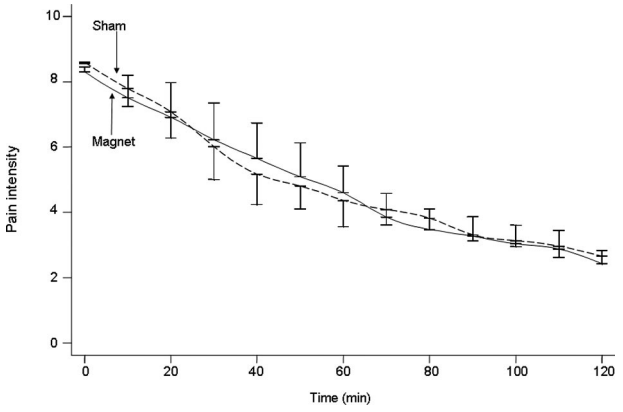

Figure 3. Pain intensity through the 2-h observation of the magnet and sham groups. Mean pain intensity and its standard deviation are plotted at each time of observation. Active and sham magnet groups exhibited similar levels of pain throughout the duration of the study.

Three systematic reviews of RCTs evaluated magnetic therapy for pain relief. One included only heel pain, and found no evidence to support the use of insoles with magnetic foil (22). The other 2 described 21 studies for pain relief in general (4,20), but no conclusion could be drawn because the studies reported conflicting results. The included studies assessed patients with strain injury of the wrist, carpal tunnel syndrome, headache, chronic back pain, chronic shoulder and neck pain, chronic arthritis, chronic pelvic pain, fibromyalgia, musculoskeletal pain secondary to polio, dysmenorrhea, and postoperative pain.

Our findings are in opposition to the only study that evaluated, in patients after lipectomy, the analgesic effect of magnets upon postoperative pain (23). This study reported that the group receiving active magnetic therapy ($n = 10$) had substantially less pain (a difference of 2.8 points on a 0–10 scale) than the placebo group ($n = 10$). A decline of this magnitude is comparable to

Table 2. Incidence (%) and Severity of Side Effects by Group

	Magnetic therapy ($n = 81$)	Sham therapy ($n = 84$)	*P*-value
Sedation			0.54
Absent	5	2.4	
Mild	35	42.8	
Moderate	38.7	39.3	
Severe	21.3	15.5	
Nausea			0.06
Absent	61.2	67.9	
Mild	22.5	10.7	
Moderate	12.5	9.5	
Severe	3.7	11.9	
Pruritus			0.45
Absent	86.2	90.5	
Mild	12.5	7.14	
Moderate	1.25	2.4	
Dizziness			0.95
Absent	46.2	47.6	
Mild	26.2	23.8	
Moderate	20	19	
Severe	7.5	9.5	
Vomiting	2.5	4.8	0.44

the one observed after an IV dose of morphine of 0.1 mg/kg (24). The magnetic devices used in that study were patches that varied in size from 5 × 15 cm to 20 × 30 cm and were placed on the skin that had been suctioned. The strength of those devices ranged from 150 to 400 gauss. Each of the magnets used in the present study had a strength of 1900 gauss (11). Therefore, one cannot attribute the negative results of the present study to weaker magnet strength. Differences in baseline pain intensity between the groups (baseline pain data were not reported) in the study by Man et al. (23), the small size of the study, or both could explain the large treatment effect seen in that study (6,25).

Unconventional treatments or complementary therapies should be evaluated with the same scientific rigor as any medications or interventions, and the present study emphasizes this. The variety of operations included in the present trial facilitates the generalizability of the findings without affecting their validity. One could think that including diverse types of operations or anesthetics would be problematic because of different pain intensity levels. However, by using a stratified randomization, we assured that a similar number of patients with moderate or severe pain were equally distributed in both groups. Because the exclusion of children or elders is heavily criticized (26), in this trial, we also included subjects of all ages to facilitate the generalizability of our findings.

The duration of observation in our study was short, but theory suggests that the effect of static magnetic therapy should be almost immediate (27). It is believed that magnetic therapy creates an electric field that affects ion movement through cellular membranes, affecting the conductive properties of afferent nerve fibers, which, in turn, decreases neuronal excitability in the spinal cord. Because the changes in membrane conductance are seen immediately after changes in ion flow, the onset of action of static magnetic therapy is expected to be rapid. In addition, the manufacturer of the magnets states that "laboratory tests are demonstrating that MagnaBloc® works in as little as four minutes," and Eccles (20), in his systematic review, found that studies that demonstrated relief from magnets used a minimum exposure of 45 minutes. A delayed onset (longer than one hour) can also be excluded because the difference in pain intensity levels between the active and sham magnet groups did not vary across time.

In summary, bipolar static magnetic therapy lacks efficacy, and its use is not recommended for acute pain relief.

REFERENCES

1. Livingston JD. Magnetic therapy: plausible attraction? Skeptical Inquirer 1998;22:25–30.
2. Carroll RT. Magnet therapy: the skeptic's dictionary. http://skepdic.com/magnetic.html. Accessed November 4, 2005.
3. Colburn D. Little scientific basis for magnets' pain relief. Washington Post May 15, 2000.
4. Ratterman R, Secrest J, Norwood B, Ch'ien AP. Magnet therapy: what's the attraction? J Am Acad Nurse Pract 2002;14:347–53.
5. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med 2001;134:663–94.
6. Moore RA, Gavaghan D, Tramer MR, et al. Size is everything–large amounts of information are needed to overcome random effects in estimating direction and magnitude of treatment effects. Pain 1998;78:209–16.
7. Anonymous. Influence of adherence to treatment and response of cholesterol on mortality in the coronary drug project. N Engl J Med 1980;303:1038–41.
8. Woolf CJ, Bennett GJ, Doherty M, et al. Towards a mechanism-based classification of pain. Pain 1998;77:227–9.
9. Ryan P. Ralloc: Stata module to design randomized controlled trials. http://econpapers.repec.org/software/bocbocode/s319901.htm. Accessed November 4, 2005.
10. Cepeda MS, Africano JM, Polo R, et al. What decline in pain intensity is meaningful to patients with acute pain? Pain 2003;105:151–7.
11. Segal NA, Toda Y, Huston J, et al. Two configurations of static magnetic fields for treating rheumatoid arthritis of the knee: a double-blind clinical trial. Arch Phys Med Rehabil 2001;82:1453–60.
12. Cepeda MS, Farrar JT, Baumgarten M, et al. Side effects of opioids during short-term administration: effect of age, gender, and race. Clin Pharmacol Ther 2003;74:102–12.
13. Cepeda MS, Alvarez H, Morales O, Carr DB. Addition of ultralow dose naloxone to postoperative morphine PCA: unchanged analgesia and opioid requirement but decreased incidence of opioid side effects. Pain 2004;107:41–6.
14. Zeger SL, Liang KY, Albert PS. Models for longitudinal data: a generalized estimating equation approach. Biometrics 1988;44:1049–60.
15. White H. Maximum likelihood estimation of misspecified models. Econometrica 1982;50:1–25.
16. Mosteller F, Tukey JW. A class of mechanisms for fitting. In: Mosteller F, Tukey JW, eds. Data analysis and regression. Reading: Addison-Wesley, 1997:333–80.
17. Fox J. Outlying and influential data. In: Lewis-Beck MS, ed. Regression diagnostics. Newbury Park: Sage University Papers, 1991:21–39.
18. Akerman N, Saxena S, Wilson R, et al. Effect of intrathecal diamorphine on block height during spinal anaesthesia for Caesarean section with bupivacaine. Br J Anaesth 2005;94:843–7.
19. Cepeda MS, Carr DB. Women experience more pain and require more morphine than men to achieve a similar degree of postoperative analgesia. Anesth Analg 2003;97:1464–8.
20. Eccles NK. A critical review of randomized controlled trials of static magnets for pain relief. J Altern Complement Med 2005;11:495–509.
21. Cepeda MS, Africano JM, Polo R, et al. Agreement between percentage pain reductions calculated from numeric rating scores of pain intensity and those reported by patients. Pain 2003;106:439–42.
22. Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev 2003;CD000416.
23. Man D, Man B, Plosker H. The influence of permanent magnetic field therapy on wound healing in suction lipectomy patients: a double-blind study. Plast Reconstr Surg 1999;104:2261–6.
24. Cepeda MS, Carr DB, Miranda N, et al. Comparison of morphine, ketorolac, and their combination for postoperative pain: results from a large, randomized, double-blind trial. Anesthesiology 2005;103:1225–32.
25. Ioannidis JP, Lau J. The impact of high-risk patients on the results of clinical trials. J Clin Epidemiol 1997;50:1089–98.
26. Gender and the inclusion of minorities and children. http://ninr.nih.gov/ninr/research/dea/genderminority.pdf. Accessed November 4, 2005.
27. Vallbona C, Hazlewood CF, Jurida G. Response of pain to static magnetic fields in postpolio patients: a double-blind pilot study. Arch Phys Med Rehabil 1997;78:1200–3.