A Randomized, Double-Blinded, Placebo-Controlled Pilot Study to Investigate the Effectiveness of a Static Magnet to Relieve Dysmenorrhea

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ABSTRACT

Objectives: The aim of this study was to investigate the hypothesis that a specially designed, static magnet of 2700 gauss, attached over the pelvic area, could relieve menstrual pain.

Design: This was a randomized, double-blind, placebo-controlled, postal questionnaire study.

Setting: The study was conducted in a primary care, single center.

Participants: Sixty-five (65) women (mean age 29.1 ± 1.52 years) were recruited from an advertisement in a London newspaper. The entry criterion was regular dysmenorrhea. The exclusion criterion was known secondary dysmenorrhea. Of the 65 women who were enrolled, 35 completed the study.

Interventions: A questionnaire-based assessment was completed by each subject and checked by telephone before and after random allocation to use of either the static magnet device (2700 gauss) or an identical, weaker magnetic placebo device (140 gauss). Assessment was made by telephone before and after a complete menstrual cycle. None of the participants was examined or seen face-to-face.

Main outcome measures: The main outcome measures were level of pain, using the McGill Pain and Visual Analogue Scales, and ratings of associated symptoms such as irritability, restriction of usual activities, and painkiller consumption.

Results: 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 use of device) were −17 (−53, 13) (median and interquartile ranges) in the magnet group and −5.0 (−29, 27) in the placebo group. The 95% Mann-Whitney confidence intervals for the median difference between the magnet and placebo groups (magnet − placebo) were −53.0 to 23.38. A reduction in irritability symptoms in the magnet group approached statistical significance (p = 0.056).

Conclusions: Despite the small number of participants, the level of significance reached in the reduction of pain merits reporting. This is a pilot study to a much larger study of the same device as an analgesic in women with primary dysmenorrhea.

INTRODUCTION

On a worldwide basis, dysmenorrhea affects 40%–70% of women of reproductive age and their daily activities. Some investigators have estimated prevalence rates to be as high as 90%. In the United States approximately 40% of adult women have menstrual pain, and 10% are incapacitated for 1–3 days each month and may result in absence from school or work. Menstrual pain is the most common reason the women miss work. Dysmenorrhea is a leading cause of absenteeism for women younger than 30 years. A recent critical review of randomized control trials of static magnets for pain relief revealed that 73.3% of 21 studies reported statistically significant analgesic effect across

MATERIALS AND METHODS

Seventy (70) women responded to an advertisement in the newspaper to take part in this double-blind controlled study of menstrual pain. These respondents were screened by telephone and excluded if they did not experience pain every menstrual cycle or if they had been diagnosed with secondary dysmenorrhea (endometriosis, fibroids, or pelvic inflammatory disease). The remaining 65 women were sent detailed information by mail about the study, a consent form confirming their understanding of the nature of the study and their agreement to take part, and a home McGill questionnaire with instructions on how to fill this in. They were told over the phone that they would receive a coded device and that neither they nor the assessor would know whether it was a live device or a placebo. Furthermore they were informed verbally and in the literature sent to them that this was a study involving a metallic device and that they should continue their usual treatment for menstrual pain if necessary. Magnetic devices (LadyCare,® Magnopulse, Bristol, UK) were neodymium magnets of 2700 gauss (surface measurement made by the manufacturer at the body surface of the magnet using a gauss meter) with patented directional plate designed to allow high gauss rating in proportion to small size (Fig. 1), whereas placebo devices were low-power magnets of approximately 140 gauss. The two devices were identical in appearance and designed to be self-secured to the underwear by magnetic force between two parts of the device applied on either side of the underwear material anterior to the pubis. The magnetic force of the placebo device was powerful enough to hold the device in place securely and without comparison with a live device so that subjects would not know that this was a weaker device. None of the subjects enrolled in the study knew each other.

Both placebo and live devices were applied in an identical manner. After returning a completed consent form, each woman received either a live or placebo device that had been selected randomly by computer (randomization generated by the supplier of the devices) from a batch of mixed live and placebo devices, each bearing a 3-digit code. Sequences and codes were concealed by the manufacturer until after the study was completed and only revealed after the all measurements of pain and associated symptoms had been made. Women were asked to apply the device 2 days before their anticipated start of next menses and to leave the device in place except during bathing until the end of menses. After 4–5 weeks the volunteers were contacted by telephone and their detailed inventory, including a McGill pain questionnaire, was confirmed with them over the telephone. This was done to optimize data gathering and the researcher was blinded to the type of device that the subject had used. Subjects were asked to rate their experience of pain throughout their menstrual periods comparing the experience after wearing the device to their usual experience. They were then asked to send in their home McGill questionnaires as part of their assessment.

Statistical methods

Results were analyzed by an independent university-based statistician. To compare pain score differences and all other outcomes between the magnet and placebo groups, the Mann-Whitney test (nonparametric test) was used, as the distribution of the pain scores differences and other data in both groups did not appear to be symmetric (that is, normally distributed). For all hypothesis tests a 5% significance level ($p < 0.05$) and two-tailed tests were used. Ninety-five percent (95%) Mann-Whitney confidence intervals (CI) for the median differences between the magnet and placebo groups were determined. Where improvement versus no improvement was compared the $\chi^2$ test was used.

This analysis was on an intention-to-treat basis insofar as data for the participants were analyzed within the group to which the patients were allocated. However dropout and missing data were not explored and this analysis was of those individuals who completed the study.

This was unlikely to cause bias unless the reason for data being missing was different in the two arms of the study.

RESULTS

The advertisement was placed in July 2002 and 35 women had completed the study by April 2003. Because of poor follow-through with initially expressed interest the advertise-
ment was placed in February 2003 to recruit more volunteers for the study. Eighteen (18) women had received placebo devices and 17 had received the test magnetic device. Thirty (30) women declined for the reasons shown in Table 1.

Both groups were well matched for age; mean age was 29.1 ± 1.52 years in the placebo group and 30.4 ± 1.37 years in the magnet group (p = 0.531).

The usual level of menstrual pain experienced was rated similarly in both groups (placebo group 7.6, magnet group 7.2, p = 0.468). Figure 2 illustrates the rating of menstrual pain in relation to the worst of other types of pain ever experienced by the women. The majority of women in both groups (70% of the placebo group, 53% of the magnet group) described an onset of pain since the commencement of menstruation. Mean duration of menstruation was 5.25 days in the placebo group and 5.41 days in the magnet group (p = 0.518) and mean pain duration was 3.08 days and 3.56 days in the placebo and magnet groups, respectively. Menstrual flow, rated on an analog scale of 1–3 (1 = light and 3 = heavy), was rated as a mean of 2.1 in the placebo and 2.5 in the magnet group.

Days taken off work because of menstrual pain appeared to be greater in the magnet group but did not reach statistical significance (p = 0.384). A significant proportion of women in both groups described restriction across a broad range of activities because of menstrual pain (Fig. 2). The commonly associated symptoms (Fig. 3) were experienced to the same degree in both groups. Regarding consultations with a professional for dysmenorrhea, 73% of all women had consulted their own doctors about menstrual pain. There was no difference in consultation rate between the magnet and placebo groups (p = 0.188). Fourteen (14) of the 35 women (39%) had consulted a specialist (gynaecologist) about menstrual pain and again there was no difference in consultation rate between the magnet and placebo groups (p = 0.589). Seven (7) of the 35 women (21%) had consulted a complementary and alternative medicine practitioner about menstrual pain.

Seven of the 35 (21%) had taken prescribed medicine for period pain (five of 17 of the magnet group and two of 18 of the placebo group, p = 0.153). Prescribed medicines included the oral contraceptive pill and the nonsteroidal anti-inflammatory drugs, mefenamic acid, and naproxen. Only six of the 35 women (18%), took painkillers preventively before the anticipated onset of pain. There was no significant difference between the two groups in this respect (p = 0.642). Ten (10) of the 35 women (29%) had tried herbal or natural medicines for menstrual pain (seven in the placebo group and three in the magnet group, p = 0.182). Only nine (26%) had obtained complete pain relief with various combinations of therapies (over-the-counter preparations plus painkillers, painkillers alone, a combination of painkillers with hot water bottle, Chinese herbal medicine). Twenty-nine (29) of the 35 (82%) said that they would be very much interested in a natural alternative to treat menstrual pain.

Static magnets versus placebo

Pain score differences (McGill pain score before – McGill pain score after device) were, in median with interquartile ranges, 17.0 (−53.0, 13.0) in the magnet group.

**Table 1. Reasons Given by Volunteers for Not Completing the Study**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not respond to 3 or 4 telephone messages</td>
<td>19</td>
</tr>
<tr>
<td>Chose not to take part</td>
<td>2</td>
</tr>
<tr>
<td>Out of the country</td>
<td>2</td>
</tr>
<tr>
<td>Too ill (not specified)</td>
<td>1</td>
</tr>
<tr>
<td>Irregular period or period not started</td>
<td>1</td>
</tr>
<tr>
<td>Bereavement</td>
<td>1</td>
</tr>
<tr>
<td>Epileptic</td>
<td>1</td>
</tr>
<tr>
<td>Told not to use (by nurse)</td>
<td>1</td>
</tr>
<tr>
<td>Pregnant</td>
<td>1</td>
</tr>
<tr>
<td>Unsure of what to do</td>
<td>1</td>
</tr>
</tbody>
</table>
and 5.0 (−29.0, 27.0) in the placebo group (Fig. 4). This difference was statistically significant ($p < 0.02$) and represents an average of 53% reduction in pain in the magnet group compared to an average of 15% reduction in pain in the placebo group. Seventy percent (70%) of the subjects in the magnet group had at least a 50% reduction in pain, 47% of whom had a >75% reduction in pain (Fig. 5). Fifty percent (50%) of the placebo group had a reduction in pain but this was <25% in magnitude. The median difference in total number of painkillers consumed during the course of menses (painkillers before — painkillers after using the magnet) was $0.0 \pm -8.0$, $32$ (interquartile range) for the placebo group, $n = 8$, and $-5.0 \pm -14.0$, 0 for the magnet group ($n = 5$). This reduction in painkiller consumption in the magnet group did not reach significance ($p < 0.071$). The numbers were small here because of missing or unreliable recording of these data by volunteers. It would seem on enquiry that this was primarily caused by the volunteers being unclear as to the instructions given on this matter.

Ten (10; 57%) women in the magnet group reported a reduced tendency to be awakened by pain compared to five (28%) in the placebo group. This apparent difference approached statistical significance ($p = 0.093$). One woman in the magnet group reported more sleep disturbance.

**Associated symptoms**

In all, 71.5% of the magnet group reported a decrease in irritability compared to 32.5% of the placebo group. Figure 3 illustrates the high proportion of women that reported this as an associated symptom (91% of the magnet and 89% of the placebo group). This difference did not reach statistical significance ($p = 0.056$). There was no significant difference between the magnet and placebo groups in reported breast tenderness ($p = 0.800$), water retention and bloating ($p = 0.180$), nausea or vomiting ($p = 0.228$), or loss of appetite.

**Side-effects**

Six (6) women in the placebo group reported unusual symptoms after wearing the device compared to two women in the magnet group. In the placebo group these symptoms were listed as more painful menstrual periods (two women), heavier periods (one), nausea (one), rumbling stomach (one), and diarrhea (one). In the magnet group these were listed as nausea (one) and “fuzzy-headedness” (one).

**Role of the funding source**

The study sponsor Magnopulse provided the live and placebo devices in coded form. The magnetic devices are commercially sold under the brand name of LadyCare (Fig. 1). The manufacturer had no role in the design of the study.
FIG. 4. Comparison of the analgesic effect of static magnet against placebo for dysmenorrhea. Pain score differences (McGill pain score before − McGill 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. This represents an average of 53% reduction in pain in the magnet group compared to an average of 15% reduction in pain in the placebo group. This difference was statistically significant, \( p < 0.02 \). The 95% Mann-Whitney confidence interval (CI) for the median difference between the magnet and placebo groups (magnet − placebo) were −53.0 to 23.38. LadyCare® (Magnopulse, Bristol, UK).

FIG. 5. Degree of pain relief achieved. In all, 70% of subjects in the magnet group had at least a 50% reduction in pain, 47% of whom had a greater than 75% reduction in pain. A total of 50% in the placebo group had a reduction in pain, but this was less than 25% in magnitude. LadyCare® (Magnopulse, Bristol, UK).

DISCUSSION

Primary dysmenorrhea is by far the most common gynecologic problem in menstruating women. A recent prospective study of college students, based on diaries kept for 1 year, found that 72% of monitored menstrual periods were painful, most commonly during the first day of menses. Sixty percent (60%) of the women studied reported at least one episode of severe pain. Dysmenorrhea is a common cause of absenteeism and reduced quality of life in women. In an earlier study, dysmenorrhea accounted for 600 million lost work hours and $2 billion in lost productivity on an annual basis. The problem of absenteeism from school or work is also underappreciated. Dysmenorrhea is often underdiagnosed and undertreated. Nonsteroidal anti-inflammatory medications are the mainstay of treatment, with the addition of oral contraceptive pills when necessary. Approximately 10% of affected women do not respond to these measures. A relative lack of physician awareness of the very high rates of prevalence and the substantial morbidity of dysmenorrhea often leads to inadequate treatment of this problem. With the widespread availability of over-the-counter nonsteroidal anti-inflammatory drugs, it is often assumed that women are treating their symptoms to an adequate extent. Unfortunately, this is not always the case. The significant impact of primary dysmenorrhea on women was confirmed in this study (Fig. 2), with significant proportions of women in both groups describing restriction across a broad range of daily activities. A high percentage of women in the study (82%) expressed interest in the concept of a natural alternative for menstrual pain relief.

Only 26% of women in this study had obtained complete pain relief with various combinations of prescribed and nonprescribed therapies. This finding, together with the data on absenteeism, would support the conclusions from other studies (cited at the beginning of this discussion) that many women may not be obtaining adequate treatment for their dysmenorrhea and makes the findings of the current study all the more interesting and relevant.
The relative lack of compliance (50% of the 70 women who had expressed an initial interest in taking part in the study) was one of the reasons that data collecting ceased after 1 month. Despite this, the results obtained were believed to be of sufficient importance to warrant publication. A larger study over several menstrual cycles is proposed.

Both the magnet and placebo groups were well matched demographically for age, pain severity and duration, degree of associated symptoms, and doctor or specialist consultations. Both devices were identical in appearance and were held in place by their magnetic force on the underwear. It was not possible therefore for the women to determine whether they had a therapeutic or a placebo device. One of the difficulties raised in other double-blind studies using magnets lies in masking the obvious interaction of the magnet with metallic objects. It was therefore decided to use a static magnet of relatively low power (140 gauss) as a control compared to the active device (2700 gauss). It was anticipated that this would provide effective masking without effective therapeutic power. However, it is still possible that some of the reported analgesic effect in the placebo group was in fact a magnetic effect even at this low magnetic power.

Consistent with the finding of significant analgesia with the magnet was the trend, although not statistically significant, for a reduction in usual painkiller consumption in the magnet group (p = 0.071). Some women had not responded or had not completed the question on painkillers used on the home questionnaire, which reduced the statistical power of the analysis on painkiller consumption. The tendency for a reduction in irritability (p = 0.056) is perhaps likely to be secondary to the reduction in pain as opposed to a specific anxiolytic effect of the magnetic field.

A limitation of the study is the small size of the study and also that the effects were only determined over one menstrual cycle. In a recent survey of 193 women with primary dysmenorrhea (randomly selected from the manufacturer’s customer database) (average duration, 11.6 years), all of whom were using the same magnetic device as in this study. This survey found a highly statistically significant reduction in pain (p < 0.0001), consumption in painkillers (p < 0.0001), and a 54% reduction in days taken off work (p < 0.0001). Long-term persistence of the analgesic effect of these magnets to relieve menstrual pain was suggested by 90% of the women using them for > 1 year and still having pain relief. Furthermore, these long-term users noted no side-effects.

This double blinded trial also provides preliminary pilot evidence for the analgesic properties of static magnetic fields in the treatment of dysmenorrhea. This requires large-scale verification, perhaps with crossover, but the potential impact on what would seem to be for most inadequately treated dysmenorrhea is exciting. These findings also add to the growing weight of evidence from well-controlled trials that static magnets can elicit analgesia. A very recent publication in the British Medical Journal demonstrated that magnetic bracelets relieved the pain of osteoarthritis of the hip and knee, and a recent critical review of randomized control trials of static magnets for pain relief revealed that 73.3% of 21 studies reported a statistically significant analgesic effect across a broad range of different types of pain.

ACKNOWLEDGMENTS

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CONFLICT OF INTEREST

Part of the funding included remuneration for the author’s time involved in conducting and writing up the project. The author was approached by the company on the basis of his interest and research in the field of magnotherapy. This has become known to them by way of a comment on magnets made in the National Press.

REFERENCES

