A Controlled Study of Minimal-Contact Thermal Biofeedback Treatment in Children With Migraine

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Objective: To evaluate the effectiveness of handwarming biofeedback (HWB) and stress management training in comparison to attention (handcooling, HCB) and wait-list control groups. Thermal biofeedback has been used in many pediatric migraine treatment studies and has demonstrated a consistent therapeutic effect. No published studies to date have compared this treatment modality with credible attention control using biofeedback technology.

Methods: Thirty-six children and adolescents (mean age: 12.8 years), as well as the mothers and fathers of these children enrolled in the study, were randomly assigned to the three groups. Thirty-four children completed treatment. Both treatment groups received four sessions of biofeedback training and a portable biofeedback device for home practice. Ratings of treatment credibility showed that the children rated the two treatments as equally credible. Assessment included anxiety and depression questionnaires for the children and both of their parents.

Results: Children who had been assigned to the HWB group were more likely to achieve clinical improvement in migraine after treatment than the children in the HCB group. Treatment gains were maintained up to 6 months after treatment. Home practice data reflected a general increase in temperature in the HWB group and a decrease in temperature for the HCB group.

Conclusions: The results of this study confirm the findings of earlier pediatric migraine biofeedback treatment studies and also provide support for the specific effect of treatments including stress management and HWB. Future studies with larger sample sizes will aid in delineating the appropriateness of HCB as a control treatment.

Key words: migraine; biofeedback; cognitive-behavioral treatment; children; adolescents; pediatric headache.

Pediatric migraine is a common problem, affecting 3% to 10% of the school-age population (Goodman & McGrath, 1999). Cognitive behavioral treatment studies for school-age children and adolescents have demonstrated good efficacy, although published studies often suffer from small sample sizes and a lack of control groups. A meta-analysis that examined the results of 17 behavioral treatment studies and 24 drug treatment studies of pedi-
iatric migraine (Hermann, Kim, & Blanchard, 1995) reported that thermal biofeedback, as well as progressive muscle relaxation training in combination with thermal biofeedback, had larger effect sizes than any other treatments examined. Adult studies of behavioral treatment for migraine have demonstrated similar findings. A meta-analytic review of adult studies concluded that thermal biofeedback, in combination with relaxation training, was as efficacious as a commonly used daily prophylactic medication (propranolol; Holroyd & Penzien, 1990). Biofeedback has been researched extensively as a treatment for migraine in both adults and children, and a recent review of empirically supported treatments in pediatric headache concluded that “some argument can be made that [thermal biofeedback] should be included as a ‘well-established treatment’ for migraine headache” (Holden, Deichmann, & Levy, 1999).

Because thermal biofeedback has demonstrated superior efficacy in comparison to other treatments, it deserves closer research examination. Initially, thermal biofeedback was regarded as being mostly nonspecific, or placebo (Onoda, 1983). Indeed, research in adults indicates that a sense of self-efficacy in mastering control over one’s body, as well as expectations of positive change, may be the strongest component of treatment (Barrios & Karoly, 1983; French et al., 2000). These elements alone may be all that is necessary to achieve a reduction in headache, and the contribution of training in specific biofeedback skills may be a minor or insignificant contribution to reports of symptom change. For example, studies have demonstrated that patients who receive “false” feedback that they are increasing their temperatures report similar reductions in headache compared to patients who actually learn to increase their temperatures (Mullinix, Norton, Hack, & Fishman, 1978).

Both specific and placebo effects of treatment may be quite different in children compared to adults, particularly because cognitive variables such as efficacy and expectancy are considered to have important placebo effects, and these variables may significantly change with cognitive development (Turner, Deyo, Loeser, Von Korff, & Fordyce, 1994). Placebo response may also be age-related, as children are more susceptible to suggestion than adults. The inclusion of control thermal biofeedback groups in pediatric treatment studies is necessary to determine the extent to which improvement is related to the specific effect (i.e., learning to increase one’s skin temperature), or the nonspecific effects of attention, suggestion, expectation, the technology involved, and changes in perception of control over one’s body (Furedy, 1985).

A few treatment studies have utilized attention control or educational treatment comparison groups with children with migraine or tension-type headache, and many of these have identified a clear advantage for the “active” treatment (e.g., Larson & Melin, 1986; Larsson, Melin, Lamminen, & Ullsted, 1987; McGrath et al., 1992; Richter et al., 1986). In contrast, two studies have found no advantage of active nonpharmacological treatment over a placebo control (Emmen & Passchier, 1988; McGrath et al., 1988). One study reported an advantage for the active treatment that appeared only at the 12-month follow-up (Bussone, Grazzi, D’Amico, & Andrasik, 1998). All of these studies used relaxation, EMG biofeedback, or a combination of nonpharmacological modalities as the active treatment. All of the attention control groups in the studies already mentioned received “supportive counseling” and/or education regarding headache, with the exception of Emmen and Passchier (1988), who used a control group trained in “concentration exercises” in contrast to an active progressive muscle relaxation group.

No published studies to date have compared thermal biofeedback to an attention control method involving biofeedback in children with migraine. This is surprising considering the evidence that this type of biofeedback may be the most effective treatment for pediatric migraine.

The purpose of this study was to evaluate the effectiveness of thermal biofeedback in comparison to attention and wait-list control groups. Children and adolescents assigned to the control group were instructed to cool their fingertip temperatures rather than to warm them. Handcooling attention control has been used in three studies of thermal biofeedback in adults with migraine. Two such studies have identified an advantage of handwarming over handcooling (Claghorn, Mathew, Largen, & Meyer, 1981; Marcus, Scharff, & Turk, 1995). However, these studies suffer from methodological flaws that make the results difficult to interpret, such as using samples of less than five (Gauthier, Bois, Alalai, & Drolet, 1981), or failing to assess patient perceptions of treatment credibility (Claghorn et al., 1981; Marcus et al., 1995). Also, none of the studies has used wait-list control groups, which would allow for the effects of self-monitoring and
regression to the mean to be taken into account. Nonetheless, the differential effects that have been demonstrated for handwarming and handcooling treatments in two previous studies indicate that handcooling may function well as a control for the specific effect of training in vasodilation, at least in adults.

**Method**

**Participants**

Both the University of Pittsburgh and the Children’s Hospital of Pittsburgh Institutional Review Boards approved the protocol for the study. The initial sample consisted of 36 children ages 7 to 17, with a mean age of 12.8 years ($SD = 2.4$) and their mothers and fathers. Children were referred from neurologists at Children’s Hospital of Pittsburgh if they (1) were between the ages of 7 and 17 years; (2) qualified for an International Headache Society (IHS; Headache Classification Committee of the International Headache Society, 1988) diagnosis of migraine with or without aura; (3) had no primary medical condition and a negative neurological exam; (4) were not taking daily preventative medication for headaches; and (5) reported an average of at least one migraine per week or 5 days per month with migraine. Information about the study was provided in a brochure given to the parents of potential study participants, and they were invited to call the primary investigator (LS) if they wished to join the research project. Consent from the parent and assent from the children were obtained during an assessment visit with the primary investigator.

The average migraine duration was 28.6 months ($SD = 25.4$), and 12 children (33.3% of the sample) met IHS criteria for co-existing tension-type headache. Three children (8.3%) described headaches in addition to migraine that did not meet full IHS criteria for tension-type headache. Two children dropped out of the study after the assessment was completed but before treatment was initiated (one had been assigned to the wait-list condition, and only completed 3 weeks of diaries; the other had been assigned to the handcooling group). The two dropouts did not differ from treatment completers in respect to age, psychological measures, or headache characteristics. Thirty of the 36 children (83.3%) reported use of abortive headache medications and were asked to note medication use as well as not to change the way they used medication or the type of medication they used throughout their participation in the study. All of the 30 children were using either ibuprofen or acetaminophen no more than an average of two times per week.

**Procedure**

Evaluation included a semi-structured diagnostic interview, the Anxiety Disorders Interview Schedule for Children (ADIS-C; Silverman & Nelles, 1988), which was administered to the children and their parents and was developed to assign DSM-III-R diagnoses for children and adolescents (the majority of data were collected before the publication of the ADIS-C based on the DSM-IV). Questionnaires including the Child Depression Inventory (CDI; Kovacs, 1992) and the State-Trait Anxiety Inventory for Children (STAIC; Spielberger, 1973) were completed by the children. Both parents were asked to complete the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and the State-Trait Anxiety Inventory-Trait Scale (STAI; Spielberger, 1970). The child measures were chosen because of their wide use in other pediatric migraine populations, which would allow for comparisons to other research studies utilizing the same population. The adult measures are also widely used in a variety of populations.

The children completed 2 weeks of baseline headache recording where pain was rated on a 0 to 4 scale four times a day before the initiation of treatment. At the assessment visit children were randomized into three groups using a randomization table that was stratified by two age groups (ages 7 to 12 and ages 13 to 17). The handwarming biofeedback group (HWB, $n = 13$) received four 1-hour sessions within 6 weeks consisting of cognitive-behavioral stress management training and 30 minutes of thermal biofeedback training, as well as progressive muscle relaxation, imagery training of warm places and vasodilation, and instruction in deep breathing techniques. Specific stress management training techniques varied with the child’s age. Younger children (under 13 years) were taught thought stopping and positive self-statements. They learned to identify stressful situations (e.g., tests at school) and thoughts (e.g., “I can’t do this!”) that may trigger migraine, stop themselves, and substitute a coping statement (e.g., “I can do this!”). Older children were trained to identify stressful thoughts that triggered migraine episodes, test the logic of
their thoughts in a more formal manner (e.g., “What evidence do I have that I can’t do this?”), and come to conclusions based on the logic testing, (e.g., “I have no evidence to support that I can’t do this, and a lot to say that I can do this. I’ve done well on tests before, and I know this stuff.”).

The handcooling biofeedback group (HCB, \(n = 12\)) received four 1-hour sessions within 6 weeks consisting of 30 minutes of thermal biofeedback training. These children and adolescents were trained in handcooling strategies such as imagery of cold places and peripheral vasoconstriction. An additional 30 minutes of each session consisted of general discussion regarding their lives and headaches in order to control for the time and attention of the investigator that was spent on stress management with the HWB group. The children were asked about the previous week including what they did and how they felt, and the investigator listened without providing specific instructions or suggestions regarding stress management or pain coping.

A wait-list control (WLC, \(n = 12\)) maintained the same headache diaries as the treatment groups for 8 weeks before starting treatment. The CDI and STAIC were repeated at the end of the wait-list period to compare to the posttreatment scores of the children in the HWB and HCB groups, and the last 2 weeks of waitlist diaries were compared to the posttreatment diaries of the treated children. The WLC children were then treated with the HWB treatment protocol, and were followed up after treatment at 3-, 6-, and 12-month periods. Information from the follow-up diaries was combined with that of the HWB group because they had received the same treatment.

Both treatment groups were provided with the rationale that blood vessel constriction followed by dilation were associated with migraine pain. The HWB group was given the instruction that they were to use the techniques they would learn to dilate blood vessels during the constriction phase, and the HCB group was given the instruction that they were to use their training to constrict blood vessels during the dilation phase. Before treatment was initiated and after the last treatment session, the children and adolescents were asked to rate perceived treatment credibility, as well as efficacy and expectancy, on a 0 to 4 ordinal scale with the following questions: How logical does this type of treatment seem to you? How confident would you be that this treatment would be successful in reducing headaches? How confident would you be in recommending this treatment to someone who has headaches? How confident would you be that children could learn this technique? Younger children were provided with a verbal description of each item (i.e., for the question regarding logic, “How much sense does it make to use this treatment?”).

Wording of these questions was changed in the posttreatment questionnaire to reflect past tense. All of the questions were rated with “0” as no credibility/confidence, and “4” as a great deal of credibility/confidence. Total scores, ranging from 0 to 16, were compared between the treatment groups.

All sessions were conducted in a room equipped with a recliner, a computerized J&J I-330 biofeedback system with a 15-inch monitor for biofeedback viewing. Each biofeedback session consisted of a 4-minute habituation phase (with no feedback), 20 minutes of biofeedback, followed by 6 minutes of return to baseline with no feedback. The children were instructed to practice for at least 15 minutes every day and were provided with a portable biofeedback monitor (SC-90, Biomedical Instruments, Inc.). Home practice of biofeedback was recorded on a daily monitoring sheet. Children recorded the day of practice, how many minutes they practiced, minutes of biofeedback, followed by 6 minutes of return to baseline with no feedback. The children were instructed to practice for at least 15 minutes every day and were provided with a portable biofeedback monitor (SC-90, Biomedical Instruments, Inc.). Home practice of biofeedback was recorded on a daily monitoring sheet. Children recorded the day of practice, how many minutes they practiced, minutes of biofeedback, followed by 6 minutes of return to baseline with no feedback. The children were instructed to practice for at least 15 minutes every day and were provided with a portable biofeedback monitor (SC-90, Biomedical Instruments, Inc.). Home practice of biofeedback was recorded on a daily monitoring sheet. Children recorded the day of practice, how many minutes they practiced, minutes of biofeedback, followed by 6 minutes of return to baseline with no feedback. The children were instructed to practice for at least 15 minutes every day and were provided with a portable biofeedback monitor (SC-90, Biomedical Instruments, Inc.). Home practice of biofeedback was recorded on a daily monitoring sheet. Children recorded the day of practice, how many minutes they practiced, minutes of biofeedback, followed by 6 minutes of return to baseline with no feedback.

The children continued monitoring their headaches until 2 weeks after treatment was completed. A headache index (HI) was calculated as the mean headache intensity value for a 2-week period. HI is a general measure of headache activity that has been used in several published studies of treatment outcome in children and adolescents (i.e., Barry & von Baeyer, 1997; Labbe, 1995). Headache indices were calculated before and after treatment. Treatment outcome was assessed by calculating percentage reduction in HI using the pre- and posttreatment diaries with the following formula:

\[
\text{Percent HI change} = \frac{\text{Pretreatment HI} - \text{Posttreatment HI}}{\text{Pretreatment HI}} \times 100
\]

It is widely accepted that a clinically significant degree of change in headache is a 50% or greater reduction in HI (Blanchard & Schwarz, 1988). Thus, percentage change was used to compare clinically significant improvement in the groups.

Follow-up was conducted at 3, 6, and 12 months following treatment, and all children were again asked to complete 2 weeks of diaries and the depres-
tion and anxiety questionnaires at that time. Children who had completed the HCB treatment and did not experience at least a 50% reduction in headache were offered the HWB treatment at the 3-month follow-up.

Results

Participant Characteristics

Demographic and psychological questionnaire information for all the children and adolescents who participated in the study is provided in Table I. There were no differences in age, headache duration, HI, DSM III-R diagnosis, or questionnaire scores between the three groups. A total of 11 children (30.6% of the sample) qualified for a DSM III-R diagnosis, with no children reporting more than mild to moderate interference with life because of this diagnosis. Five children qualified for a diagnosis of generalized anxiety disorder, three for dysthymia, and one each for separation anxiety disorder, adjustment disorder, and attention deficit hyperactivity disorder (this child was currently receiving medication treatment [Ritalin] and met criteria for this disorder by history only).

The STAIC and CDI scores were comparable to previously published assessment and treatment studies of children with migraine or chronic headache (e.g., Andrasik et al., 1988; Bussone et al., 1998; Cooper, Bawden, Camfield, & Camfield, 1987; Labbe, Delaney, Olson, & Hickman, 1993).

Treatment Outcome

Treatment Credibility. The pre- and posttreatment ratings of the credibility questionnaire were compared between the two treatment groups via a Kruscal-Wallis test, as the ratings were not normally distributed. There were no group differences on any of the credibility items among the treatment groups, in both pretreatment and posttreatment analyses. The HWB and HCB groups rated their treatment as equally logical and perceived the treatments as equally successful in reducing pain at posttreatment.

Headache Changes. Headache change from preto posttreatment was assessed with both multivariate and nonparametric analyses. The multivariate analysis allowed for the examination of change in each specific dependent variable, and the nonparametric analysis allowed for an examination of the clinical significance of headache change, or what percentage of the children reported a decrease in the HI by at least 50% (Blanchard & Schwarz, 1988). A chi-square analysis was conducted to compare the degree of clinical improvement in all three groups. None of the 11 children and adolescents in the WLC group had demonstrated significant im-

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Table I. Demographics

<table>
<thead>
<tr>
<th></th>
<th>HWB group</th>
<th>HCB group</th>
<th>Wait-list controls</th>
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<tbody>
<tr>
<td></td>
<td>(n = 13)</td>
<td>(n = 11)</td>
<td>(n = 12)</td>
</tr>
<tr>
<td>Mean age</td>
<td>13.3 (2.5)</td>
<td>13.2 (2.0)</td>
<td>12.0 (2.7)</td>
</tr>
<tr>
<td>Girls/boys</td>
<td>9/4</td>
<td>5/6</td>
<td>10/2</td>
</tr>
<tr>
<td>Mean pretreatment headache variables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration (months)</td>
<td>31.8 (25.6)</td>
<td>29.8 (26.9)</td>
<td>28.3 (25.1)</td>
</tr>
<tr>
<td>Days with headache</td>
<td>11.3 (3.0)</td>
<td>9.5 (4.7)</td>
<td>12.0 (3.2)</td>
</tr>
<tr>
<td>Highest headache rating</td>
<td>3.6 (0.8)</td>
<td>3.4 (1.0)</td>
<td>3.4 (1.0)</td>
</tr>
<tr>
<td>Headache index</td>
<td>1.5 (0.8)</td>
<td>1.8 (1.3)</td>
<td>1.8 (0.9)</td>
</tr>
<tr>
<td>Coexisting other headache (%)</td>
<td>6 (46.2%)</td>
<td>4 (36.4%)</td>
<td>5 (41.7%)</td>
</tr>
<tr>
<td>Child questionnaire scores*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretreatment CDI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 12)</td>
<td>8.2 (7.2)</td>
<td>9.1 (9.4)</td>
<td>6.2 (1.9)</td>
</tr>
<tr>
<td>Pretreatment STAIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 12)</td>
<td>32.2 (12.2)</td>
<td>34.6 (8.5)</td>
<td>37.7 (10.6)</td>
</tr>
<tr>
<td>Parent questionnaire scores*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Father: BDI</td>
<td>(n = 9)</td>
<td>2.9 (5.4)</td>
<td></td>
</tr>
<tr>
<td>(n = 6)</td>
<td>1.2 (1.8)</td>
<td>(n = 9)</td>
<td>7.7 (6.5)</td>
</tr>
<tr>
<td>Father: STAI</td>
<td>(n = 9)</td>
<td>33.4 (12.5)</td>
<td></td>
</tr>
<tr>
<td>(n = 6)</td>
<td>26.5 (2.2)</td>
<td>(n = 9)</td>
<td>33.3 (11.4)</td>
</tr>
<tr>
<td>Mother: BDI</td>
<td>(n = 13)</td>
<td>6.0 (5.2)</td>
<td></td>
</tr>
<tr>
<td>(n = 10)</td>
<td>7.5 (6.1)</td>
<td>(n = 11)</td>
<td>7.0 (6.26)</td>
</tr>
<tr>
<td>Mother: STAI</td>
<td>(n = 13)</td>
<td>38.2 (10.1)</td>
<td></td>
</tr>
<tr>
<td>(n = 10)</td>
<td>36.5 (11.8)</td>
<td>(n = 11)</td>
<td>37.5 (11.5)</td>
</tr>
</tbody>
</table>

Numbers in parentheses are standard deviations.

*CDI is the Child Depression Inventory; STAIC is the State Trait Anxiety Inventory for Children.

*BDI is the Beck Depression Inventory, STAI is the State Trait Anxiety Inventory.
Improvement by the end of the monitoring period. In contrast, one child in the HCB group (10%) and seven in the HWB group (53.8%) achieved a clinically significant degree of improvement. The chi-square test ($\chi^2 [2] = 12.65, p < .002$) indicated a significant difference in the proportion of each group that had improved over the course of treatment.

A repeated measures MANOVA was used to compare the pre- and posttreatment HI, the highest recorded intensity for the 2-week period, and the number of days with headache by group assignment. The MANOVA revealed significant main effects for both time (Pillai's trace $= .267, F[3, 29] = 3.53, p < .03$), and treatment group (Pillai's trace $= .36, F[6, 60] = 2.21, p < .05$). Univariate ANOVAs revealed that all three dependent variables demonstrated significant change over time (HI, $p < .005$, highest intensity rating, $p < .01$, number of headaches recorded, $p < .02$). Figures 1 through 3 illustrate the changes in each of these variables. Due to inconsistent recording, medication use changes could not be assessed.

Follow-up tests of between-subjects effects yielded no significant treatment group differences for any one of the dependent variables; however, number of headaches reported within the 2-week assessment period demonstrated a trend, $F(2) = 3.02, p < .06$. Power was low for these contrasts, ranging from .13 for highest headache rating to .54 for number of headaches. Tukey LSD contrasts for number of headaches revealed significant differences between the WLC group and the HWB group ($p < .05$) and the WLC group and the HCB group ($p < .05$).

**Psychological Questionnaire Changes.** A repeated measures MANOVA was also conducted with the pre and post CDI and STAIC scores. No significant difference in questionnaire score change was identified.

**Temperature Change**

**In-Session Temperature Change.** Consecutive 2-minute averages were calculated for each 30-minute biofeedback session. Temperature change was then calculated for each 2-minute interval by subtracting the mean temperature from the last 2 minutes of the habituation (baseline) phase. Mean temperature change was compared by treatment group via a repeated measures general linear model analysis to determine if the patterns of temperature change during the treatment sessions were significantly different by group assignment. Data from the initial training session were not used for this analysis, to ensure that the children had the opportunity to practice the skill. Thus, each mean represented the mean temperature change for an individual across three treatment sessions. Data collected from the WLC while they were going through the HWB protocol were combined with the original HWB group. The results revealed a significant effect of time (Pillia's trace $= .44, F[12, 69] = 4.44, p < .001$). There
Data from the WLC group were not evaluated. The remaining 29 records reported that the average number of practice sessions was 5.3 times a week (SD = 0.9). There were no differences in the number of home practices between treatment groups. Each home practice session was assigned to one of three categories: (1) decreased temperature (with a decrease of 2 degrees Fahrenheit or more); (2) increased temperature (with an increase of 2 degrees Fahrenheit or more); or (3) no significant change in temperature, within 2 degrees of recorded baseline.

Chi-square tests were performed for each of the 6 weeks of home practice, and all six were significant, demonstrating a significant difference between the two treatment groups ($p = .11$), and the power for this contrast was low ($1 - \beta = .36$).

Figure 4 illustrates the average temperature changes from baseline throughout the training sessions, representing the averages of sessions 2 through 4. Although no statistical differences were identified, the HWB group generally achieved higher temperatures compared to baseline during the treatment session, and the HCB group generally achieved lower temperatures compared to baseline.

**Home Practice Changes.** Three subjects from the HWB group and two subjects from the HCB group failed to maintain adequate home practice records. Data from the WLC group were not evaluated. The remaining 29 records reported that the average number of practice sessions was 5.3 times a week ($SD = 0.9$). There were no differences in the number of home practices between treatment groups.

Each home practice session was assigned to one of three categories: (1) decreased temperature (with a decrease of 2 degrees Fahrenheit or more); (2) increased temperature (with an increase of 2 degrees Fahrenheit or more); or (3) no significant change in temperature, within 2 degrees of recorded baseline. Chi-square tests were performed for each of the 6 weeks of home practice, and all six were significant, demonstrating a significant difference between
groups in temperature change. The HWB group was more likely to report that their temperatures increased than the HCB group ($p < .01$ for all comparisons).

**Maintenance of Change at Follow-Up.** Figures 1 through 3 illustrate the follow-up information for both treatment groups. One child in the HCB group, who did not achieve a 50% reduction in migraine, accepted the offer of training in the HWB condition during the 3-month follow-up and was dropped from future follow-ups.

To increase power for the follow-up contrasts, we combined information from the WLC after they had completed the HWB protocol with the original HWB group. The return rate for follow-ups was 86.1% ($n = 31$) at the 3-month follow-up, 61.1% ($n = 22$) at the 6-month follow-up, and 38.8% ($n = 14$) at the 12-month follow-up. Thus, only data up to the 6-month follow-up were included in the analysis. A MANOVA identical to the pretreatment/posttreatment comparison was used to examine all three of the dependent variables between the two treatment groups.

The follow-up results up to six months after treatment demonstrated a significant effect for time (Pillia’s trace $= .81$, $F[9, 12] = 5.62$, $p < .01$), and a trend for treatment group (Pillia’s trace $= .32$, $F[3, 18] = 2.80$, $p = .07$). Both HI and number of headaches recorded significantly changed over time (HI, $p < .001$, number of headaches $p < .01$). Between-subjects univariate contrasts revealed a trend for HI, $F(1) = 34.32$, $p = .08$.

At the 3-month follow-up, 72.2% of those that had completed the HWB protocol and 33.3% of the HCB group returned diaries reflecting a significant improvement in migraine compared to pretreatment ($\chi^2 [1] = 3.76$, $p < .05$), and at the 6-month follow-up, 100% of the HWB group compared to 62.5% of the HCB group demonstrated clinical improvement ($\chi^2 [1] = 4.50$, $p < .05$).

**Discussion**

The findings of this study support previous studies, as well as the conclusions drawn from the meta-analysis conducted by Hermann, Kim, and Blanchard (1995), in finding that thermal biofeedback is an effective treatment for pediatric migraine. The findings also support the supposition that there are nonspecific effects of this treatment modality, as evidenced by the decrease in migraine reported by the children and adolescents in the HCB group. The HCB group was designed to include all of these nonspecific effects, including the use of biofeedback instrumentation and investigator time and attention, without the specific effects of training in vasodilation and stress management. Because both biofeedback and stress management training were used for the active treatment, differences between the treat-
ment groups cannot be attributed to the specific effect of handwarming, but rather to the treatment package as a whole.

Although the majority of the study participants tended to report fewer migraines in their treatment diaries regardless of treatment group assignment, the HWB treatment was associated with a greater degree of clinical improvement than the HCB treatment. These results were also maintained over time, with a trend for treatment group difference up to the 6-month follow-up. Thus, the “active” treatment package may have contained a component that had a stronger effect on migraine in both the short and long term. Whether this component was the handwarming training or the stress management training, or the fact that both were used in combination, is a question for further study.

The clinical improvement rate of 53.8% for the HWB group is somewhat low compared to previous thermal biofeedback treatment studies. However, it appears to be the norm for a four-session format. Hermann, Blanchard, and Flor (1997) reported that 68.8% of children who enrolled in a four-session home-based treatment were significantly improved by the end of treatment. Guarnieri and Blanchard (1990) reported that 33% of children enrolled in a four-session thermal biofeedback treatment experienced clinically significant improvement in symptoms. Our findings are consistent with these results. Future research to predict which children would benefit from minimal or home-based treatment formats, such as the one used here, will be useful considering the cost-effectiveness of these approaches.

The multivariate analyses for treatment outcome revealed a significant effect for treatment group, but no one specific dependent variable was found to significantly differ in the between-group follow-up analysis. This was likely due to the small number of participants in the study. Thus, low power limited the extent to which group differences could be observed. In contrast, the chi-square comparison of posttreatment clinical improvement did show a treatment group difference, with the HWB group demonstrating a significantly higher proportion of children and adolescents with a 50% or greater reduction in HI than the HCB group. This group difference was significant at the 3- and 6-month follow-ups as well. Considering that most studies of pediatric populations incorporate small groups, and that few of these studies report or consider power analysis, an important point can be made based on these results. Although the multivariate analysis yielded findings that conflicted with the univariate follow-up contrasts, the nonparametric results yielded a clear group treatment effect.

One issue that needs to be taken into account is that although many researchers use HI as a succinct overall measure of headache activity as well as to increase the power of contrasts, it is difficult to assess the exact nature of headache change when HI changes. HI change does provide a useful indicator of potential overall clinical improvement in individual patients, but it may be a variable of interest in future studies investigating prediction of outcomes in children and adolescents with migraine. However, results of studies using HI as a variable do need to be interpreted with caution, until it is clear exactly what HI reflects.

Treatment integrity appeared to be maintained in that the chi-square comparison of reports of home-practice temperature change did show a significant difference, suggesting that the children adhered to the home-practice instructions. The HWB group tended to report temperature increases, and the HCB group tended to report temperature decreases. The in-session temperature change repeated measures analysis did not demonstrate significant differences between the treatment groups and was inconsistent with the home-practice reports; the reason for this is unclear. The in-session temperature changes were in general less dramatic than the home-practice reports of temperature change (i.e., the less than a mean of 1 degree change as presented in Figure 4 compared with reports of changes of 2 degrees or more in home practice). This may reflect more familiarity and less distraction in the home-practice setting.

A major limitation of this study, aside from the small sample, lies in the fact that a single investigator conducted all evaluation, treatment, and follow-up sessions. There were no treatment integrity checks, and drift may have occurred. The fact that the in-session biofeedback recording, as well as the patients’ homework, demonstrates that skin temperatures generally corresponded with treatment assignment does provide some evidence that treatment integrity was maintained. However, it would have been more desirable for another investigator to monitor treatment sessions and for separate investigators to conduct the assessment and treatment sessions. In addition, it would have been beneficial to add a behavioral observation component, to examine if the children and adolescents in the HCB group were engaging in relaxation despite
the lack of instruction in this strategy. Finally, a longer-term follow-up would have yielded useful information. Adequate follow-up information for this sample was available only for up to 6 months after treatment.

Further research incorporating larger groups with stringent treatment integrity checks such as audio or videotapes to be viewed by a co-investigator is called for to determine the strength of thermal biofeedback’s specific effects. A larger sample size would also allow for investigation into the specific effect of cognitive-behavioral strategies such as stress management by administering this treatment component to the control group as well as the HWB group. This study was limited by low statistical power, yet it did lend support for handcooling as an adequate “placebo” control in thermal biofeedback. A larger scale study is clearly indicated, given the results reported here.

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