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Impact of Healing Touch on Pediatric Oncology Outpatients: Pilot Study

Kathi J. Kemper, MD, MPH, Nancy B. Fletcher, BSN, Craig A. Hamilton, PhD, Thomas W. McLean, MD

Healing Touch (HT) is a biofield therapy used to enhance well-being. We conducted a pilot study to assess its effects in pediatric oncology patients. We enrolled patients in the continuation or consolidation phase of therapy. Patients or their parent completed simple visual analogue scales (VASs; 0–10) for relaxation, vitality, overall well-being, stress, anxiety, and depression before and after a 20-minute period of rest and a standardized HT treatment. Patients’ heart rates were monitored and later analyzed for heart rate variability (HRV) characteristics. Of the nine patients, all completed VASs and six had usable HRV data. The average age was 9 years. VAS scores for stress decreased significantly more for HT treatment than for rest (HT: 4.4–1.7; rest: 2.3–2.3; p = .03). The HRV characteristic of total power was significantly lower during HT than for rest (HT: 599 ± 221; rest: 857 ± 155; p = .048), and sympathetic activity was somewhat but not significantly lower (HT: 312 ± 158; rest: 555 ± 193; p = .06). HT is associated with lowered stress and changes in HRV. Further studies are needed to understand the mechanisms of these effects in larger samples and to explore the impact on additional clinically relevant measures.

Key words: autonomic nervous system, Healing Touch, heart rate variability, oncology, pediatric, sound, stress

Cancer and its treatment are generally considered stressful. Oncology patients turn to complementary therapies to reduce stress and improve well-being. The US National Institutes of Health National Center for Complementary and Alternative Medicine (NIH NCCAM) has identified Healing Touch (HT) as a biofield therapy, and its use is increasing among adult patients. The extent to which HT is helpful for pediatric oncology outpatients is unknown.

Given developmental differences, parental reports are often used as proxies for the child’s symptoms, stress, and well-being. However, parent-proxy reports of health-related quality of life are only moderately correlated with child’s reports. As a result, objective measures would be useful to augment parental proxy reports of well-being.

HT is based on the theory that when biofield energy is present, balanced, and flowing properly, the patient experiences well-being. Furthermore, it is believed that the practitioner can sense this subtle energy and intervene to enhance it using their intention, presence, and hands. HT includes a variety of techniques, which may involve gentle touch, but tissue massage and joint manipulation are not involved. The mechanisms for the effects of HT remain speculative, but case reports and some clinical trials suggest that it may be useful in relieving pain and anxiety. For example, Wilkinson found lower levels of salivary cortisol among patients treated by an experienced HT practitioner. A small study of patients with spinal cord injuries also found an improvement in subjective well-being. Similarly, Weze and colleagues reported significantly lower stress levels among cancer patients treated with a closely related form of biofield healing.

HT is provided at numerous academic health centers, including Scripps Center for Integrative Medicine in California and New York-Presbyterian Hospital. National certification in HT practice requires approximately 5 years of training, including supervised practice and reporting on at least 100 treatment sessions. HT has been taught at our medical school and evaluated in a recent study of adult oncology patients at our institution. However, its effects on pediatric oncology patients have not been formally evaluated.

Improved well-being in response to therapies may be reflected in decreased sympathetic activity. Heart rate variability (HRV), the variability of the cardiac interbeat interval (IBI), is a noninvasive, sensitive measure of autonomic balance that has served as a physiologic measure of well-being. HRV parameters, such as the standard deviation of the normal-to-normal (NN) intervals, was significantly lower during HT compared to rest in the pilot sample.
deviation of the interbeat interval (SDNN), total power (TP), very low frequency (VLF), low frequency (LF), and high frequency (HF), have become widely used measures of autonomic function and balance. Decreases in LF values reflect decreased sympathetic activity and decreased stress.

Interpretation of HRV characteristics differs for acute and long-term recordings. For 24-hour recordings reflecting autonomic activity over a variety of activities, lower TP is generally associated with worse health or worse prognosis. However, HRV can also reflect acute changes in physiologic state. For example, meditation and restful sleep are associated with lower TP and lower LF values, reflecting a decrease in sympathetic activity.

We conducted this pilot study to begin to evaluate the impact of HT for pediatric oncology patients. The null hypothesis was that the HT would have no significant effect. We planned to use any observed differences as the basis for sample size calculations for future studies.

Methods
As part of an ongoing study on the effects of music on pediatric oncology patients, we asked a subset of patients who had completed that study if they would be willing to participate in a pilot project to begin to evaluate the effects of a standardized HT treatment on well-being.

Design and Setting
We conducted a prospective cohort pilot study at the pediatric oncology unit of Brenner Children's Hospital (BCH) in North Carolina between October 2006 and May 2007. Each patient served as his or her own control.

Subjects
Subjects were eligible if they had been diagnosed with acute lymphoblastic leukemia, received their primary oncology care at BCH, were in remission, had completed the induction phase of therapy, had an English-speaking parent, and had participated in the study on the effects of music on well-being. In the larger study, owing to slower than expected patient accrual, eligibility criteria were expanded to include any pediatric oncology patient who was not undergoing induction therapy. Patient age, gender, diagnosis, and treatment information were extracted from the medical records and verified by the pediatric oncologist.

Procedure
At two routine clinic visits, patients participated in 40-minute monitoring sessions: visit 1, (usual care plus rest in a quiet room, and visit 2, usual care plus rest in a quiet room while receiving a standard HT treatment for 20 minutes. All patients had previously received a rest visit and participated in a study in which they listened to music while they were monitored. Thus, they were familiar with the procedure of being part of a study, completing a visual analogue scale (VAS), and wearing an HRV monitor; for the current study, no music was played during the intervention. At the beginning and end of each study session, the child's parent completed 0- to 10-point VASs with numeric and verbal anchors; typically, the parent asked the child to help complete these questionnaires. The VAS surveys assessed three positive and three negative states: relaxation, well-being, and vitality/energy (scored from 0 to 10, with 10 being best) and anxiety, stress, and depression (scored from 0 to 10, with 10 being the worst). Patients received a $10 gift certificate at each visit as an incentive and thanks for their participation.

Intervention
The HT practitioner for this study was a registered nurse who was a certified HT practitioner who had practiced for 5 years; she was not on the hospital staff, was not involved in the patients' care, and was not previously known to the patients. She oriented the pediatric oncology nursing staff prior to the study to familiarize them with the process by providing several in-service training sessions, giving an overview and providing demonstrations. For the study, she used a standard HT protocol involving light touch for 2 minutes each at the ankles, knees, hips, abdomen, midsternum, shoulders, elbows, wrists, neck, and head. Although typical HT sessions allow the practitioner to use a variety of techniques to meet individual patient needs, for this study, the intervention was standardized to determine whether standardization was feasible for the practitioner and had any effect on patients.

HRV Data Collection
During the intervention, subjects wore a MiniMitter 2000 monitoring unit (Mini-Mitter Co, Inc., Bend, OR). This unit consisted of two electrocardiograph electrodes placed on the anterior chest wall and attached to a transmitter unit, which was belted around the participant's chest. A wireless receiver collected telemetric HRV data.

HRV was measured by several parameters. The SDNN is the most widely used measure of HRV. Power spectrum analyses included TP, HF oscillations (0.15–0.4 Hz), LF oscillations (0.04–0.15 Hz), and VLF oscillations (0.0033–0.04 Hz). Coherence is a measure that reflects a peak in LF compared with the TP spectral analysis and is thought to reflect an optimal physiologic state associated with a sense of well-being; higher values reflect better well-being.
Data Management

Data files for each individual session were stored in a secure location and electronically transferred for analysis. We picked the central 15 minutes to reduce artifacts from motion during monitor placement and removal. Data were filtered prior to analysis by identifying and excluding IBI outliers if any lay outside a range of half to twice the mean IBI for that individual. Any session in which more than 20% of IBIs were identified as outliers was omitted from further HRV analysis. Power spectrum calculations were performed using the Lomb periodogram, the source code for which was obtained from the PhysioNet archives with 500 frequency points over the range 0.0033 to 0.4 Hz.

Statistical Analysis

Statistical analyses included simple descriptive statistics. To test the effect of HT on changes in VAS score, only data from those children with both pre and post VAS scores at both the baseline and HT sessions were used. Pre and post change scores were calculated. To test the effect of music on HRV parameters, only data from those children with usable HRV data from both the baseline and HT sessions were used. Differences were compared for the rest and HT visits using a paired t-test.

Human Subjects

This study was approved by the Wake Forest University School of Medicine Institutional Review Board. Informed consent was obtained from the parents of all children enrolled.

Results

During the study period, 15 patients were eligible, 12 were approached, and 9 enrolled, all of whom completed baseline and outcome VASs for both sessions. Of these, six had usable HRV data for both sessions. The six with usable data were demographically similar to the total group (Table 1). The mean age of the children was approximately 9 years, and about half were male; most had acute lymphocytic leukemia, were in the consolidation phase of treatment, and had received doxorubicin, a potentially cardiotoxic medication (see Table 1).

VAS Results

Scores for the VASs for subjective well-being were similar at baseline for the rest and HT visits; average positive scores ranged from 5.7 to 6.9 (generally positive), whereas average negative scores ranged from 1.0 to 4.4 (not very distressed) (Table 2). The positive state VAS parameters generally improved more with HT than with rest, but none of these differences were statistically significantly different. The VAS score for stress remained the same prior to and following the rest visit but improved from 4.4 to 1.7 with HT (p = .03). The change in the average negative state score was better for HT than rest (HT from 3.1 to 1.7; rest: 2.1 to 2.0; p = .03).

HRV Results

The values for HRV parameters for both rest and HT visits are shown in Table 3. The most common reason for nonusable HRV data was movement artifact. TP was significantly

<table>
<thead>
<tr>
<th>Table 1. Patient Description</th>
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<tr>
<td></td>
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<tr>
<td>Mean age (yr) ± SD</td>
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<tr>
<td>Male gender, n</td>
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<tr>
<td>Race</td>
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<tr>
<td>Caucasian</td>
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<tr>
<td>African American</td>
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<tr>
<td>Type of cancer</td>
</tr>
<tr>
<td>ALL</td>
</tr>
<tr>
<td>Other: neuroblastoma, AML</td>
</tr>
<tr>
<td>Treatment stage: consolidation</td>
</tr>
<tr>
<td>Continuation</td>
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<tr>
<td>Significant comorbidity (1 Down syndrome; 1 relapsed disease)</td>
</tr>
<tr>
<td>Received doxorubicin</td>
</tr>
</tbody>
</table>

ALL = acute lymphoblastic leukemia; AML = acute myelogenous leukemia; HRV = heart rate variability; VAS = visual analogue scale.
Table 2. Change in VAS Scores before and after 20 Minutes of Rest versus Healing Touch

<table>
<thead>
<tr>
<th></th>
<th>Rest</th>
<th>Healing Touch</th>
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<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Relaxation</td>
<td>6.9 (5.7)</td>
<td>7.3 (5.7)</td>
</tr>
<tr>
<td>Vitality</td>
<td>5.7 (5.8)</td>
<td>5.9 (6.3)</td>
</tr>
<tr>
<td>Overall well-being</td>
<td>5.9 (5.3)</td>
<td>5.8 (6.3)</td>
</tr>
<tr>
<td>Average positive state</td>
<td>6.2 (2.3)</td>
<td>6.2 (4.4)</td>
</tr>
<tr>
<td>Stress*</td>
<td>2.3 (1.0)</td>
<td>1.1 (2.1)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.0 (2.9)</td>
<td>1.1 (3.1)</td>
</tr>
<tr>
<td>Depression</td>
<td>2.9 (2.6)</td>
<td>2.0 (3.1)</td>
</tr>
<tr>
<td>Average negative state*</td>
<td>2.1 (2.0)</td>
<td>1.7 (2.1)</td>
</tr>
</tbody>
</table>

VAS = visual analogue scale.

*Differences in pre/post session change in the VAS between rest and Healing Touch were significant at p < .05 for stress and average negative state by paired t-test. Scores ranged from 0 to 10, with higher scores being better for positive states and lower scores being better for negative states.

lower during HT than rest visits (p = .048), and LF power was lower, but not significantly so (p = .06).

Discussion

This pilot study shows that it is feasible to recruit pediatric oncology patients and provide standardized HT treatment. Although the sample was small, the patients did not report high stress levels, and the HT practitioner was previously unknown to the patients, there was a significant decrease in reported stress with HT treatment. HT treatments were also associated with changes in HRV consistent with less stress and less sympathetic activation. These results are consistent with other studies of biofield therapies, suggesting lower stress levels with treatment.\textsuperscript{30,41}

For this pilot study, we analyzed patients as their own controls to reduce the impact of the between patient variability. Previous studies have shown that HRV values increase with age in pediatrics, peaking in late adolescence/early adulthood.\textsuperscript{32-44} Values for the HRV parameters in this study were similar to those in an earlier study of HRV in pediatric oncology patients.\textsuperscript{19} To bolster sample size, we included a broad age range of patients, many of whom had received cardiotoxic medications that might affect HRV. Using patients as their own controls protects against confounding by these factors.

We were surprised to find any statistically significant differences with HT versus rest treatments given the small sample size in this pilot study and the relatively positive sense of well-being and minimal stress at baseline. We planned to use any observed differences as the basis for sample size calculations for larger, more highly powered studies. Given an average standard deviation in VAS values of 2.1, a future study would require complete data on 11 patients who undergo both conditions to have 80% power to detect a statistically significant (p < .05) difference of at least 2 points on the VASs between rest and HT treatments. Similarly, to have 80% power to detect a statistically significant (p < .05) fall of 200 units in the LF HRV parameter with a standard deviation of 175, 9 patients with complete, usable HRV data would be needed.

There are several potential reasons for not finding a greater effect on subjective well-being in this pilot project in addition to the small sample size. Parental proxy may not be sensitive to subtle changes in a child's subjective sense of well-being.\textsuperscript{7,8} The extent to which parents asked their children for help completing the scales was not documented. Longer questionnaires may be more sensitive than the VAS in detecting subtle differences; on the other hand, the VAS correlates well with longer instruments for pain and quality of life in pediatric patients.\textsuperscript{45} Patients who can provide self-report and who have greater baseline distress may show more improvement than patients who are doing well. However, such studies will not provide insight into the impact of HT on well-being in younger or less distressed patients, who comprise a substantial portion of the pediatric oncology population.

Limitations

As with any pilot study, this one had several important limitations. We did not address the effects of individualized, multiple, or longer treatments or provide HT in combination with guided imagery, music, or other complementary...
therapies. Clinicians seeking a significant clinical impact may use individualized approaches developed collaboratively with patients and families. Such choices would be expected to have greater impact on subjective well-being and would be more clinically appropriate. Furthermore, although patients were familiar with the study routine, the pilot research design was not counterbalanced in terms of rest/HT treatment order; the greater reduction observed in stress levels in the HT treatment may be due to higher stress levels at the beginning of HT compared with rest visits.

Conclusions and Suggestions for Future Research

Despite its limitations, this study demonstrates that it is possible to assess both subjective and objective measures of well-being with standardized HT treatment in pediatric oncology patients. Like this one, future studies in pediatric oncology patients would benefit from using patients as their own controls unless the sample size is quite large given the heterogeneity in this population. Future studies and clinicians may compare the effects of standardized versus individualized treatments, different “doses” of treatments, or HT treatments alone or in combination with other therapies. Future studies should balance the order of interventions to control for the possibility that patients might become more relaxed and comfortable over time as they become more used to the HT procedure.

These data provide important and useful information for sample size calculations for future studies.

In a pediatric oncology outpatient population experiencing low to moderate levels of stress and normal HRV values, the specific HT treatment provided in this study decreased stress and sympathetic arousal. These results and additional hypotheses warrant additional study.

Acknowledgments

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