PAIN MEDICINE
Volume 8 • Number 5 • 2007

Does Therapeutic Touch Ease the Discomfort or Distress of Patients Undergoing Stereotactic Core Breast Biopsy? A Randomized Clinical Trial

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ABSTRACT

Objective. To determine whether therapeutic touch administered at the time of stereotactic core biopsy of suspicious breast lesions results in a reduction in anxiety and pain.

Design. Randomized, patient-blinded, controlled trial of either Krieger–Kunz therapeutic touch administered by a trained practitioner or a sham intervention mimicking therapeutic touch delivered during core biopsy.

Setting. Stereotactic breast biopsy unit of a comprehensive breast center.

Patients. Women with mammographically detected, nonpalpable breast lesions requiring biopsy.

Outcome Measures. Changes in pain and anxiety measured by visual analog scales immediately before and after stereotactic core biopsy.

Results. A total of 82 patients were accrued: 42 received actual therapeutic touch and 40 sham therapeutic touch. No significant differences were found between the arms for age, ethnicity, educational background, or other demographic data. The sham arm had a preponderance of left breast biopsies (48% vs 58%; $P = 0.07$) and received a slightly higher volume of epinephrine-containing local anesthetic (6.5 ± 6.1 vs 4.5 ± 4.5 mL; $P = 0.09$). Therapeutic touch patients were more likely to have an upper breast lesion location (57% vs 53%; $P = 0.022$). No significant differences between the arms were seen regarding postbiopsy pain ($P = 0.95$), anxiety ($P = 0.66$), fearfulness, or physiological parameters. Similarly, no differences were seen between the arms when change in parameters from prebiopsy to postbiopsy was considered for any of the psychological or physiological variables measured. These findings persisted when confounding variables were controlled for.

Conclusions. Women undergoing stereotactic core breast biopsy received no significant benefit from therapeutic touch administered during the procedure. Therapeutic touch cannot be routinely recommended for patients in this setting.

Key Words. Therapeutic Touch; Pain; Percutaneous; Breast Biopsy; Anxiety

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Presented in part at the Comprehensive Cancer Care Symposium, Center for Mind-Body Medicine, Washington, DC, April 10, 2003, and the Annual Meeting of the American Society of Clinical Oncology, Chicago, IL, May 31–June 3, 2003.

Introduction

Major strides in reducing the mortality resulting from breast cancer have been made, with a large proportion of this gain attributable to enhanced compliance with breast cancer screening [1]. Current screening is rooted in annual breast mammography, complemented by clinical breast examination [2]. Abnormalities detected solely by

 1526-2375/07/$15.00/419 419–424 doi:10.1111/j.1526-4637.2006.00256.x

mammography (i.e., without a palpable lesion) require biopsy to confirm the presence of invasive or *in situ* carcinoma, or a benign histology, some of which confer an increased risk of breast cancer development and may require surgical intervention. The American Cancer Society estimates that over 210,000 women will be diagnosed with invasive breast cancer (and over 50,000 with *in situ* disease) in 2005 [3], but many more will require some form of invasive procedure to determine whether mammographically detected abnormalities are benign or malignant.

In recent years, the use of stereotactic core biopsy (SCB) techniques has simplified tissue sampling in patients who are found to have mammographic abnormalities without a palpable lesion [4]. Employing mammography for localization, these approaches allow for an accurate localization and core tissue biopsy of the lesion in a minimally invasive fashion without the need for general anesthesia. However, discomfort is experienced by most women that is not completely relieved or prevented by local anesthetic [4]. In addition, there is considerable anxiety surrounding the procedure, the result of unknown aspects of the biopsy, and the anticipation of the biopsy results expected some days later, compounded by the worry engendered by the news that a biopsy will be required as a result of an abnormal screening mammogram.

Therapeutic touch (TT), a contemporary and secularized version of ancient healing practices that can be classified as a group as the "laying-on of hands," was introduced into the nursing literature and advocated by Dr. Dolores Kriegler in 1975 as a method of "energy exchange" between clients and practitioners while avoiding the need for specific religious beliefs on the part of either practitioners or clients [5]. Laying-on of hands has been reported to improve wound healing in mice [6,7], to activate human enzymes and increase hemoglobin levels [8], and to change the rate of growth of plants [7].

The premise behind TT is the proposition that humans are surrounded by "energy fields" that, in the healthy state, are abundant and balanced, while in illness are blocked, depleted, and/or unbalanced. This postulate has been described by Rogers in a conceptual framework often referred to as the "science of unitary human beings" [5,9]. TT, according to proponents, results in "replenishment" and "re-balancing" of these fields through purposeful hand movements and conscious intent on the part of the practitioner (belief on the part of the patient is not required), yielding a "re-patterned" energy flow.

Therapeutic touch has been the subject of a number of published reports, few of them involving the treatment of pain, and even fewer randomized [10]. These studies have been challenged by small sample size, inconsistent or uncertain TT methodology, and variable approaches to the control arm (sham TT mimicking TT practice but without intent on the part of the practitioner, no treatment or a standard medical intervention) [10,11]. Examples include a 60-patient study that reported significant reduction in headache pain that was maintained for 4 hours with TT compared with sham TT [12]. In contrast, a 108-patient study evaluating postoperative pain yielded negative results for the primary endpoint of pain relief, but with a possible effect on subsequent analgesic needs [13], and a randomized trial of 99 burn patients demonstrated reductions in some pain rating scales without change in analgesic intake [14]. Other studies have found reduction in anxiety with the use of TT [14–16]. While studies have yielded mixed results, Spence and Olsen, in a published review of TT, concluded that there was evidence for TT and reduction of pain and anxiety [10].

Stereotactic core biopsy is a minimally invasive procedure that causes self-limited discomfort in the context of anxiety, surrounding not only the procedure itself but also the patient's circumstances—a possible breast cancer diagnosis—making it an interesting setting in which to test whether TT can be effective. Consequently, we set out to determine whether TT alters patient perceptions of pain, anxiety, and other psychologically oriented outcomes such as nervousness and fear, as well as physiological parameters, when delivered during breast SCB.

Methods

Patients were eligible for this study if they were recommended for SCB for a nonpalpable lesion found on mammography; potential subjects were approached regarding participation prior to the day scheduled for SCB. All participating subjects gave study-specific informed consent and signed a consent form reviewed and approved by the institutional review board (IRB) of Baystate Medical Center.

Kriegler–Kunz TT was provided by four trained practitioners (all of whom have completed both basic [12 hours] and intermediate [14 hours]

level courses in Kriegler and Kunz Therapeutic Touch[SM], have taken continuing education classes, and have practiced TT for at least 3 years). Sham TT employed the approach of Quinn [16]—practitioners having no conscious intent to help and counting backward by "serial 7s" silently during "treatment"—was administered by providers neither trained nor experienced in actual TT delivery but who completed two 3-hour training sessions instructing them only on hand movements simulating TT. In this way, variables such as support from another person not involved with the procedure and patient distraction during SCB can be controlled for. The IRB-approved consent form contained the following description of TT or sham TT delivered in the context of the study:

> While undergoing stereotactic core breast biopsy, you will receive a 10-minute treatment of either therapeutic touch (TT), a complementary medicine practice that may relieve pain, decrease anxiety, and/or promote a sense of well being, or a placebo treatment that appears to be therapeutic touch. . . . By agreeing to participate in the study, you acknowledge that you may receive actual therapeutic touch or a placebo treatment that looks like therapeutic touch. In order to evaluate the effectiveness of therapeutic touch, you will not know if you are receiving TT or a placebo treatment.
>
> During the biopsy, you will receive a 10-minute treatment of either therapeutic touch or a placebo. During the treatment, practitioners will use slow, sweeping motions of their hands, 2 to 6 inches above your body. There is no physical contact between you and the practitioner.

Both TT practitioners and sham TT providers begin by introducing themselves to the patient while in the biopsy suite and stating that they will be providing the "study intervention." They then begin mentally counting backward by sevens while standing still beside the patient for 1 minute. Sham practitioners make four passes over the patient's body, the first (lasting 1 minute) consisting of sweeping motions of the hands 2–6 inches (5–15 cm) above the body, beginning at the head and working caudally toward the feet. The second is similar to the first but with a wider sweeping pattern; during both of these phases, the sham practitioner continues to count backward mentally by sevens. The third pass begins at the head, but at the torso, a series of gentle sweeping motions is undertaken over this area for 5–6 minutes while counting backward silently from 400. The fourth and final pass repeats the first. TT practitioners begin similarly but intend to provide "energy repatterning" hand movements over parts of the patient's anatomy (often the torso) where energy field abnormalities are detected by the practitioner and do not engage in silent counting. Both practitioner groups continued "treatment" for approximately 10 minutes, beginning before SCB and continuing through and beyond the actual procedure.

A permuted block randomization process was employed; scheduled SCB slots were assigned to active TT or sham TT practitioners; patients, as well as breast center clinical and scheduling staff and study coordinators, were blinded to TT assignment and to actual TT or sham provider status. Prior to SCB, patients completed a medication history, as well as baseline visual analog scale (VAS) assessment of pain and anxiety, nervousness, fearfulness, restlessness, tension, and fright [17]. Pulse and blood pressure were also measured. Data including patient age and ethnic background, history of pain experience, duration of TT, duration of procedure, number of biopsies performed, location of biopsies, amount of local anesthesia administered, and radiologist performing the procedure were collected. Immediately after SCB, VAS assessments were repeated. All data were collected by breast center nursing staff, who were blinded to the patient's study arm assignment; data were then entered into a computer database and analyzed by clinical trial office staff, who were also blinded.

Continuous variables were analyzed by *t*-tests or Pearson correlation; categorical variables or outcomes were compared by contingency table analysis (chi-square or Fisher exact tests), Spearman correlation, or simple logistic regression. Analysis was assisted by computer programs (JMP Version 5.0.1a, SAS, Cary, NC; MedCalc, Brussels, Belgium); all *P* values reported are two-sided.

An accrual target of 50 patients per arm was based on an ability to detect a 10-mm difference (with an assumed standard deviation (SD) of 10 in the control arm and 20 in the treatment arm) between treatment arms in change in pain based on VAS ($\alpha = 0.05$, $\beta = 0.1$). A blinded analysis after 80 patients were accrued was planned to determine whether these assumptions were correct, and to establish whether additional patient accrual was warranted.

Results

A total of 82 patients were enrolled; patient characteristics are listed in Table 1. No significant differences were seen between the groups with regard to demographics or pretreatment characteristics or VAS findings. Similar distributions of ethnic background ($P = 0.67$) and greatest educa-

Table 1 Patient characteristics

Factors	TT (N = 42) Mean ± SD	Sham TT (N = 40) Mean ± SD	*P* value
Age (years)	51.5 ± 11.6	53.0 ± 10.5	0.62
Number of biopsy cores	13.6 ± 6.0	13.9 ± 5.9	0.96
Volume of lidocaine (mL)	4.2 ± 1.1	4.4 ± 2.0	0.58
Volume of epinephrine/ lidocaine (mL)	5.2 ± 4.5	6.5 ± 6.12	0.09
Biopsy time (minute)	17.0 ± 6.8	16.8 ± 7.3	0.94
Pulse (per minute)	79.1 ± 11.4	80.0 ± 9.3	0.98
Systolic BP (Torr)	122.6 ± 17.7	127.5 ± 16.1	0.23
Diastolic BP (Torr)	77.0 ± 7.5	76.7 ± 8.5	0.89
Pre-SCB pain (mm)	10.4 ± 20.4	14.3 ± 27.6	0.49
Pre-SCB nervousness (mm)	69.9 ± 42.6	67.1 ± 34.8	0.76
Pre-SCB tense (mm)	66.1 ± 33.4	69.2 ± 36.7	0.71
Pre-SCB fearful (mm)	60.6 ± 43.8	67.7 ± 46.1	0.86

BP = blood pressure; SCB = stereotactic core biopsy; TT = therapeutic touch.

tional achievement (χ^2 for trend, $P = 0.14$), left or right breast ($P = 0.2$), and radiologist performing procedure ($P = 0.16$) were also noted. Similar proportions of patients in both arms experienced preprocedure pain (20% for the TT arm vs 28% for the mimicked arm, $P = 0.4$). A trend for higher volumes of combination lidocaine/epinephrine administered to patients receiving mimicked TT was seen ($P = 0.09$). Both arms received similar mean durations of TT (actual TT 10.1 minutes vs 9.95 minutes for the mimicked arm, $P = 0.18$). Pain VAS increased significantly from pre- to post-SCB measurements ($P = 0.0047$). In contrast, post-SCB scales decreased compared with pre-SCB levels for scared, nervous, tension, fearful, and restlessness (all $P < 0.0001$).

Post-SCB variables were found to be statistically similar between the active TT and sham TT groups, including pain measurement (21.4 ± 5.1 [SE] mm for those in the TT group vs 25.7 ± 4.8 mm in the sham group, $P = 0.53$), nervousness (26.3 ± 5.7 mm vs 26.5 ± 5.3 mm, $P = 0.99$), restlessness (23.9 ± 5.0 mm vs 23.0 ± 5.3 mm, $P = 0.90$), systolic (119.6 ± 3.1 Torr vs 125.5 ± 2.9 Torr, $P = 0.17$) and diastolic blood pressure (75.7 ± 1.4 Torr vs 76.3 ± 1.5 Torr, $P = 0.75$), and pulse (80.2 ± 1.8 per minute vs 82.7 ± 1.7 per minute, $P = 0.33$). Change in factors from pre- to post-SCB (Table 2) yielded comparable results; once again, no difference was seen between the TT and sham TT groups. The same results were found when other variables (practitioner, volume of local anesthetic, pain reported prior to SCB, age, duration of SCB procedure, and number of biopsy cores obtained) were controlled for in a multivariate model.

The change in pain on VAS from pre- to post-SCB was positively associated with the number of biopsy cores taken (r_s 0.24, $P = 0.032$) and the duration of the SCB procedure (r_s 0.22, $P = 0.046$), but not with age ($P = 0.11$), nor with the volume of lidocaine ($P = 0.16$), nor with the lidocaine/epinephrine ($P = 0.15$) used during the procedure. The duration of TT or sham TT similarly were not associated with pain. Those patients who noted that they had pain prior to the procedure (N = 18) experienced a decrease in pain compared with pre-SCB levels, while others experienced a mean increase in pain (–11.2 ± 38.9 [SD] mm vs 17.2 ± 27.3 mm, $P = 0.0007$).

Assessment of these results revealed that the initial estimate of needed patient accrual was low, largely due to an underestimation of the variability of pain experienced by patients and reported using the VAS after SCB (change in pain VAS scores: sham TT 11.5 ± 31.0 [SD] mm; TT 10.3 ± 36.3 mm) and the unexpectedly small difference (1.2 mm) found between the study arms. Based on the experience with the initial 82 patients, an accrual of 240 patients per arm would be required in order to achieve the original planned power of the study to find the originally proposed 10-mm difference between the treatment arms. Consequently, a clinically important difference would not likely be determined with the additional accrual of patients to the original planned accrual target (50 patients per arm), and the study was closed.

Discussion

In 1998, Rosa and colleagues published a provocative and controversial report describing the inability of TT practitioners to detect "energy fields" surrounding an unseen hand, accompanied by a detailed and critical assessment of the TT

Table 2 Change in factors from pre- to posttreatment (means ± standard error) between treatment groups*

Factor	TT	Sham TT	*P* value
Pain (mm)	10.3 ± 5.7	11.5 ± 5.3	0.95
Systolic BP (Torr)	–3.2 ± 2.2	–2.1 ± 2.2	0.71
Diastolic BP (Torr)	–1.3 ± 1.4	–0.4 ± 1.3	0.65
Pulse (per minute)	0.3 ± 1.9	2.8 ± 1.7	0.35
Restlessness (mm)	–29.6 ± 7.9	–28.9 ± 7.4	0.95
Tense (mm)	–40.0 ± 6.8	–37.0 ± 6.4	0.80
Nervousness (mm)	–40.7 ± 6.8	–43.5 ± 6.4	0.77
Scared (mm)	–43.1 ± 6.9	–40.7 ± 6.5	0.80
Fearful (mm)	–35.3 ± 7.4	–43.4 ± 6.9	0.43

* Negative results denote decrease in value from pre-SCB to post-SCB.
BP = blood pressure; SCB = stereotactic core biopsy; TT = therapeutic touch.

literature and claims of TT proponents published to date [11]. Their conclusion that these results drew the underlying hypothesis supporting TT and related complementary approaches into question generated substantial criticism from TT proponents and practitioners, some of whom felt that discrediting the "energy field" postulate underlying TT did not inform regarding the clinical efficacy of the technique [18,19], including "the full and unhurried attention of a caregiver" [20]. For this reason, we decided to pursue further clinical studies of TT in a controlled and, in our view, clinically relevant setting.

No significant differences were found between the treatment groups in terms of demographics, preprocedure pain, or other VAS findings. A trend for higher volumes of lidocaine/epinephrine given to patients receiving sham TT was found, but this was not associated with the number of cores taken or with pretreatment pain. While VAS pain scores tended to be higher after than before the procedure, and other parameters such as anxiety, restlessness, tension, and fearfulness declined, no differences were seen for the changes from the pre- to the postprocedure measurements between the TT and sham TT groups. It is probable that decreases in anxiety and other psychological endpoints are due to patient relief that the procedure is complete, and may be also related to "the full and unhurried attention of a caregiver" present during the procedure.

This study does suffer from a relatively small sample size, a result of an underestimate of the variability of pain experienced by patients prior to the procedure, and the lack of efficacy of TT in the initial sample. While this trial can be criticized for limited power to detect a difference, no difference was seen that could be construed to be clinically meaningful, and consequently no further accrual was pursued, as a very large trial would be required. Given our findings of a very small absolute difference between the study arms, we do not recommend that further TT research in this setting be pursued.

We did not collect data from patients concerning their opinion as to which study arm they were assigned to, and consequently we cannot state how effectively the mimicked TT worked as a placebo. While this can be considered a weakness of the study, it would seem unlikely that patients receiving mimicked TT would feel more rather than less relief if they suspected that they were assigned to the inactive arm. The intent of the mimicked TT arm was not only to provide a placebo for patients but also to remove the "therapeutic intent" of the practitioners, a key tenet of Kriegler–Kunz TT. The lack of differences between the arms on measured study parameters, even if mimicked or active TT was suspected by all patients in their respective arms, suggests that TT practitioners were unable to effect improvement in the patient's condition.

Randomized studies of TT have yielded variable results, often of questionable clinical importance. In one study, burn patients were randomized to TT or sham TT by a coin toss resulting in an extreme imbalance (62 allocated to TT, 37 to sham TT) between the arms [13]. Additionally, 99 patients were described in the report, but no further information is available on the 115 patients who were initially accrued to the study but either did not remain on the study for 3 days or otherwise failed to meet the study criteria. Pain VAS did not yield differences in decreases in pain (measured from baseline to 1 day beyond TT or sham TT to a maximum of 6 days), although two scales on the McGill Pain Questionnaire (pain rating index and number of words chosen) did demonstrate some differences [21]. No difference in analgesic intake was seen between the study arms. A study of TT in postoperative pain [13] randomized 108 consenting patients requiring a narcotic analgesic during the time of data collection (employing VAS) to TT, sham TT, or standard "as needed" analgesic medication. Pain medication was most effective in reducing pain, as expected, but TT posttreatment results were superior to sham TT. However, the authors felt that the described 13% decrease in pain was not clinically significant. In contrast, another trial, a randomized study of 60 patients suffering from tension headache, found lower levels of pain on all three McGill Pain Questionnaire scales in the TT-treated group that persisted for 4 hours [12].

Our study differs from other TT pain studies in that the intervention was intended to reduce pain caused relatively suddenly through the use of local anesthesia and the introduction of the core biopsy needle while TT is being delivered, in contrast to acute or chronic established pain that has characterized patients in other studies [10,22]. We were unable to find any effect of TT on pain or other parameters, such as anxiety or nervousness—distressing symptoms that were experienced by our patients prior to the procedure. While TT may be shown to be effective in other clinical settings, we do not feel—given these results—that

TT is an effective intervention to reduce pain and other forms of distress resulting from acute percutaneous procedures, such as SCB performed on conscious patients.

Acknowledgments

This research was supported by a grant from Rays of Hope, a Walk towards the Cure of Breast Cancer, Springfield, MA.

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