Effects of Reiki on Pain, Anxiety and Blood Pressure in Knee Replacement Patients

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Abstract

This blinded, controlled pilot study investigated the effects of Reiki on 46 patients undergoing knee replacement surgery. Of the three groups, Reiki, Sham Reiki, and Standard of Care, only the Reiki group showed significant reductions in pain, blood pressure, respiration rate and state anxiety, which provides solid evidence for a full-scale clinical study.

Key Words: Reiki, Pain, Anxiety, Knee surgery,

Introduction

Reiki is a Japanese stress reduction technique in which the practitioner's hands are used to induce a therapeutic effect in the human energy field, which in turn, encourages the body to heal itself (1). The National Center for Complementary and Integrative Health (2) classifies Reiki as a biofield therapy and indicates that working with energy moves the human system into a more relaxed state that is connected to health and healing. Reiki is becoming ever more popular in the U.S. as evidenced by a survey conducted in 2007 which indicates that 1.2 million adults and 161,000 children received one or more sessions the previous year in which Reiki, or a similar bioenergy therapeutic method, was used (3). NCCIH and other United States reports indicate that Reiki is now more frequently used by a growing number of Americans for relaxation, musculoskeletal conditions, pain management, anxiety and depression (3.4).

Use of Reiki in Hospitals

Hospitals and medical clinics are also adding Reiki to the list of services offered to patients. A *USA Today* article reported that in 2007 15% of U.S. hospitals (over 800) offered Reiki as a regular part of patient services (5). In many of these programs, physicians, nurses and other medical personnel with Reiki training are providing the sessions. Reiki began being used in hospital operating rooms as early as 1995 (6) and is now included in a holistic nursing "scope and standards of practice" publication as an accepted form of care (7).

Despite its widespread application, most reports about the efficacy of Reiki are still anecdotal. There is little research addressing potential mechanisms to explain the Reiki healing process or to support the use of Reiki therapy in patient care; however, research evidence is emerging, both on the general physiological effects of Reiki, as reviewed previously (8), and on those related specifically to control of pain and anxiety, as reviewed by Thrane and Cohen (9). More rigorous scientific studies are required to assess Reiki's value and usefulness as a scientific and evidence-based practice. The evidence is not strong regarding the efficacy of Reiki in reducing pain and improving anxiety management regarding hospitalized, surgical patients (8.10) but over the last several years, a body of work is emerging.

Significance to Nursing Practice

There is growing evidence that hospitals are exploring the usefulness of Complementary and Alternative Medicine (CAM) as an adjunct to pain management in response to

healthcare provider and consumer demands (1), and there is even regulatory influence from the Joint Commission on Hospital Accreditation (11), for provision of non-pharmacological approaches for inpatient pain management standards, especially surgical pain. In recent years, patients' perspective of hospital care has been collected and reported by many hospitals, using the Hospital Consumer Assessment and Healthcare Providers System (HCAHPS) Survey. HCAHPS data is publicly reported by the Centers for Medicare and Medicaid (CMS) and patients' perception of pain management during the hospital stay is a critical survey item (www.hcahpsonline.org)

To keep up with growing trends in practice and regulatory environments, more research into the effectiveness of Reiki as a supportive therapy in surgical and non-surgical pain management of hospital patients is warranted.

Purpose and Rationale

The purpose of this study was to measure how the use of Reiki, a means of gentle touch, influences pain, stress and anxiety levels in hospitalized patients undergoing total knee replacement surgery. An equally important goal of this pilot study was to assess the research protocol, including recruitment and enrollment of participants and the feasibility of achieving the data collection end points in an acute care setting in preparation for a multi-site clinical trial.

Materials and Methods

This study was approved by the Abington Memorial Hospital Institutional Review Board for Human Research Health Sciences. All participants were asked by a clinical research nurse to sign a consent form in order to enroll.

Participants

The population for this pilot study was male and female patients in the age range 50-85 who were admitted to an acute care hospital for a scheduled single knee replacement. Exclusion criteria included: (a) joint replacement surgery on an emergent basis and/or previous joint replacement revision, (b) patients who could not read or understand English, (c) patients with a history of emotional/psychological or anxiety-related diagnosis, (d) patients who received anti-anxiety or psychotropic medication within 2 weeks of the scheduled surgery, (e) patients whose surgery would be performed using anesthetic agents other than standard general anesthesia. Patients were invited to participate during their pre-operative office visit with Dr. Star.

Study Design

This study was designed as a 3-armed (15 subjects per arm), randomized, blinded protocol and powered to detect trends (rather than statistically significant changes) that would support entry into a larger multi-centered study. The sample size was calculated using a 5% level of significance and effect sizes for the various parameters estimated using the means and standard deviations of earlier experiments. One group would receive three or four 30-min. Reiki treatments plus standard of care (SOC) throughout their

hospital stay; a second group would receive three or four 30-min. Sham Reiki sessions (placebo) plus SOC; a third group would receive three or four sessions of 'quiet time' plus SOC. For all groups, the first treatment/session would be one hour prior to surgery, with subsequent treatments/sessions 24, 48 and 72 hours (if not already discharged) post surgery. All treatments/sessions would be performed in the patient's room on the post-surgical floor, except for the pre-operative session that would be carried out in a private patient room in the pre-operative area.

Randomization of Participants

After each participant had consented to the study they completed a demographics form that was placed in an envelope. The clinical research nurse assigned a number to the envelope, in order of completion, and then randomly assigned the number (and hence patient) to one of the three groups, according to the throw of a die.

Reiki and Sham Reiki Providers: Reiki treatments were performed on each patient in the Reiki group by one of 3 expert (Master Level) Reiki practitioners. Each Reiki practitioner was provided with a detailed printed protocol describing the exact hand positions to be used, and in which order. Sham Reiki sessions were given to each patient in the Sham group by one of two people who were not trained in Reiki or any other touch therapy. The Sham practitioners were also given the printed protocol and placed their hands on the patients in the same positions as the Reiki practitioners. A member of the research team demonstrated and reviewed the Reiki protocol with both the Reiki and Sham practitioners, prior to the sessions on the patients, with return demonstrations to ensure

consistency. Reiki practitioners and Sham Reiki providers were all health care providers employed by Abington Hospital. Patients in both groups were each given sessions by the same practitioner/provider throughout their stay.

Outcome Parameters

The following data were collected from patients prior to and post all treatments/sessions: pain level (using the 0-10 visual analog numeric pain rating assessment scale used in Abington Hospital), blood pressure (BP) and respiration rate (RR) (using inpatient data monitors). Heart rate (inter-beat interval) was also recorded for 5 minutes prior to and post, all treatments/sessions, using the emWavePC (Institute of HeartMath, Boulder, CO) in order to calculate heart rate variability (HRV), a measure of sympathovagal balance that is an indicator of level of emotional stress at that moment. Unfortunately, inter-beat interval data from many of the patients were not usable due to a prevalence of cardiac arrhythmias in this group, and so this measure was discarded.

Patients completed a State Trait Anxiety Inventory (STAI) once before treatment on the day of surgery, and again after the last treatment. The STAI is designed to differentiate between the temporary condition of "state anxiety" and the more long-standing quality of "trait anxiety" in adults. The State Anxiety scale evaluates feelings of apprehension, tension, nervousness and worry, which increase in response to psychological stress at the time of stress. The Trait Anxiety Scale evaluates the same feelings over time. The STAI has adequate validity and reliability, with reliability coefficients ranging from 0.83 to 0.92 (12). Attempts were made initially to collect saliva samples for analysis of salivary

immunoglobulin A before surgery and on day of discharge, but this measure was soon abandoned due to difficulty collecting samples from these patients.

A qualitative component was initiated on the day of discharge after the last treatment/session. Each patient was asked: " which group do you think you were in?" The purpose of this question was to determine how well the study was blinded to participants. Additional data collected from the hospital records included: length of hospital stay post-surgery and usage of narcotics/analgesics post-surgery during length of stay. All data were de-identified and collected by trained data collectors.

Analysis of Pain Medication Use

Only subjects who completed all study interventions at 48 hours, who received scheduled Oxycontin (10 mg by mouth every 12 hrs) and who received a patient controlled analgesia pump in the immediate post-operative period (Morphine 2 mg dose; loading dose 0 mg; patient control 0.5 - 10 mg; lockout (minimum time between doses) 6 minutes; maximum limit 5-10 mg/hr) were included in this analysis (9 Reiki subjects, 6 Sham Reiki patients, 5 SOC patients). Oxycodone 5 mg/Acetamenophen 325 mg 1-2 tablets q 4 hrs PRN (when necessary) was available to patients for breakthrough pain. The number of dosages of this medication used by each patient per day was noted for analysis.

Method of Data Analysis

Pain level, BP and RR were first compared among four time points (pre and post intervention at pre-surgery and 24 hr post surgery) within each group, using Friedman Repeated Measures ANOVA on ranks. If there was a significant difference between the time points, pair-wise multiple comparison procedures were performed with an overall significance level set at 0.05 (Holm-Sidak Method). Due to attrition at later time points, data from 48 hrs post-surgery were treated separately using paired t-test (or signed rank test if data distribution was not normal), comparing only with the pre-intervention, pre-surgery data obtained from patients who were discharged at 48 hrs or more post-surgery. The state anxiety data were treated similarly. It was hypothesized that Reiki plus SOC, but not the other two treatments, would reduce pain, BP, RR and anxiety at all time points.

A between group t-test was performed on the post surgery, post last intervention data to determine whether the Reiki plus SOC group showed less pain and anxiety on discharge compared to the other two groups. Another between group t-test was performed to determine whether there was a differential usage of post-operative analgesics, and length of hospital stay according to patient group assignment. It was hypothesized that there would be reduced usage of post-operative analgesics and a shorter length of hospital stay for the patients who received Reiki, compared to those in the other two groups.

Results

Participant Enrollment

The record of participant enrollment and attrition is shown in Table 1. Sample sizes for the Sham Reiki and SOC groups were below the desired value of 15, but the size of the Reiki group exceeded this value.

Pain Level

When comparing pain levels assessed pre-surgery with those at 24 hrs post-intervention, post-surgery, there was a trend of pain reduction in the Reiki group (4.25 ± 0.62 (SEM) vs 2.62 ± 0.42 (n=18)) that was not seen in the Sham Reiki (3.21 ± 0.61 (SEM) vs 3.54 ± 0.58 (n=12)) or the SOC groups (5.85 ± 1.09 (SEM) vs 5.70 ± 0.75 (n=10) (Figure 1).

In comparisons of measurements taken pre-surgery, pre-intervention with those at 48-hrs post-surgery, post-intervention, only baseline data from those patients still within the study 48 hrs post-surgery were included in the analysis. For this reason, the baseline results listed below are slightly different from those that appear in Figure 1. The Reiki group showed significant pain reduction 48 hrs post-surgery, post-intervention compared to baseline (from 4.11 ± 0.72 (SEM) to 1.40 ± 0.40, n=16, p=0.003). The large reduction in pain score was of sufficient magnitude to provide adequate statistical power (power = 0.9) for this comparison. The corresponding results for the Sham Reiki and SOC groups were: from 2.96 ± 0.60 (SEM) to 2.77 ± 0.45, (n=11) (NS), and from 5.43 ± 0.37 (SEM) to 5.71 ± 0.56 (n=7) (NS). The smaller sample sizes for the Sham Reiki and SOC groups resulted in lower statistical powers than for the Reiki group and for that reason a

statistically valid intergroup comparison could not be made. However, only the Reiki group showed a large percentage reduction in pain, 48 hr post-surgery (Figure 1).

Blood Pressure

Only the Reiki group showed a significant difference among the 4 blood pressure readings taken pre and post-intervention, pre and 24 hrs post-surgery. Both systolic and diastolic blood pressures were significantly reduced when comparing pre-treatment, pre-surgery vs post-treatment, post-surgery (systolic: 141.4 ± 3.7 (SEM) mmHg vs 116.2 ± 3.6, n=18, $p<0.001$ power=0.99; diastolic: 73.6 ± 1.9 (SEM) mmHg vs 59.3 ± 2.4, $p<0.001$, power=1.0).

Comparing measurements taken pre-surgery, pre-intervention to those at 48-hrs post-surgery, post-intervention, only the Reiki group showed significantly reduced systolic (143.1 ± 3.9 (SEM) mmHg vs 115.2 ± 5.9, n=16, $p<0.001$, power=0.99) and diastolic blood pressures (74.3 ± 2.1 (SEM) mmHg vs 60.4 ± 2.8, $p<0.001$, power=1.0). The decrease in systolic blood pressure was a desirable response in the patients because mean systolic blood pressure was bordering onto hypertension pre-surgery. The Sham Reiki group showed significantly reduced systolic pressure (147.6 ± 3.2 (SEM) mmHg vs 131.0 ± 5.2, n=11, p=0.01, power = 0.78), but diastolic pressure was not significantly changed (76.9 ± 3.0 mmHg vs 68.6 ± 2.4, NS). The SOC group showed a trend for reduction of systolic blood pressure (143.0 ± 4.8 (SEM) mmHg vs 130.7 ± 7.6, n=7, NS) but little change for diastolic pressure (79.4 ± 4.6 (SEM) mmHg vs 74.3 ± 4.2, NS). Based on observed trends, it is possible that if the sample sizes for the Sham Reiki and SOC alone

groups had matched that of the Reiki group, there may have been significant reductions in blood pressure for these groups as well, suggesting that this effect may not be mediated by Reiki treatment per se.

Respiration Rate

The four respiration rates (pre and post-treatment, pre and 24 hrs post-surgery) were significantly different from each other within the Reiki group, but not within the other two groups. For the Reiki group there was a trend towards reduced respiration rate when comparing pre-treatment, pre-surgery vs post-treatment, 24 hrs post-surgery. This trend became statistically significant when data obtained from the Reiki group pre-treatment, pre-surgery were compared with those taken post-treatment, 48 hrs post-surgery (20.1 ± 0.5 (SEM) br/min vs 17.7 ± 0.5, $p=0.008$).

Anxiety State

Comparing measurements taken pre-surgery, pre-intervention with those discharged at 48 or 72-hrs post-surgery, post-intervention, only the Reiki group demonstrated significantly reduced state anxiety scores at discharge compared with intake (39.1 ± 3.3 vs 32.1 ± 2.7, $n=14$, $p=0.004$, power=0.88). The 7 patients who were discharged at 72 hrs post-surgery had very similar state anxiety levels to those who were discharged 48 hrs post-surgery. The corresponding results for the Sham Reiki and SOC groups were: 42.2 ± 3.3 (SEM) vs 37.4 ± 2.4, $n=10$ (NS), and 42.6 ± 3.6 (SEM) vs 40.3 ± 4.5 ($n=6$) (NS). The majority of the Sham Reiki (8/10) and SOC patients (4/6) were discharged 72 hrs post-surgery. Since the sample sizes for the Sham Reiki and SOC groups were smaller than for the Reiki

group, leading to inadequate statistical powers, a statistically valid intergroup comparison could not be made. There was a trend of reduced anxiety after Sham Reiki that may have shown significance if the sample size had been larger. However, the Reiki group showed the largest reduction in state anxiety, 48 hr post-surgery (Figure 2).

Pain Medication Usage

The Reiki group used the lowest number of doses of PRN pain medication (22 doses or 2.4 doses/patient) compared to the Sham Reiki group (36 doses or 6 doses /patient) and the SOC group (29 doses or 5.5 doses/patient).

Retention in Study

The Reiki group had the highest percentage retention rate in the study up to, and including, the 48-hr post-surgery time-point, whereas the SOC group had significant drop-offs between 24 and 48-hrs post-surgery (Table 1 and Figure 3).

Hospital Stay

The Reiki group had the highest percentage of discharges at 48 hrs rather than at 72 hrs (Figure 4), implying fewer complications leading to later discharge.

Believed Group Assignment

Blinding of Groups 1 and 2 (Reiki and Sham Reiki, respectively) was assessed by asking patients on discharge to guess to which group they had been assigned. Group 3 subjects, receiving SOC only, were not blinded as to their assignment. For Group 1, 15/16 subjects

correctly guessed their assignments, many mentioning that they felt relaxed, less stressed, and fell asleep during their sessions. These comments suggest that there are noticeable effects of Reiki treatment in otherwise naïve subjects. It is unlikely that this skewed result was the effect of compromised blinding because the results from the Sham Reiki group (Group 2) were highly supportive of the quality of blinding. Here, 6 of the 10 respondents mistakenly believed they were assigned to the Reiki group and 4 guessed otherwise.

Results Summary

This blinded, sham-controlled pilot study has shown, for the first time, that Reiki significantly reduces pain, stress (as reflected by blood pressure and respiration rate) and anxiety levels in hospitalized patients undergoing total knee replacement surgery. In addition, Reiki treatments, given pre and post-operatively, along with a pharmacologic pain management protocol, enhanced post-operative pain management and resulted in less use of narcotic pain medication than Sham Reiki or SOC alone. Overall, Reiki exceeded Sham Reiki, and SOC, in the improvement and/or quality of all 7 of the parameters measured (see Table 2).

Discussion

The most striking result of this study was that Reiki reduced pain scores in subjects undergoing single knee replacement surgery, a procedure that is quite painful and that usually involves powerful pain management protocols. In the field of Reiki clinical research, no other clinical study has been reported in peer-reviewed literature using three groups: Reiki plus SOC, Sham Reiki Plus SOC, and SOC alone. The inclusion of Sham

Reiki controls for the effects of attention, caring and touch on pain levels. Treatment of patients with Reiki is controversial because many people consider it is nothing but a placebo effect; however, this study shows that Reiki goes above and beyond a placebo effect. The fact that Reiki is effective in reducing pain is highly relevant to the medical field because pain medication is the second largest market in the world of pharmaceuticals, behind cancer, and thus the financial aspect is very important. The reduction of patients' pain in the hospital environment can enhance the patient experience and satisfaction with care and pain management, influencing data being collected by hospitals for quality and regulatory compliance. Moreover, reduction of post-operative pain will promote early mobility, begin the rehabilitation phase faster and minimize complications.

Another strength of the study was the fact that patients were blinded regarding whether they were included in the Reiki or the Sham Reiki group. The effectiveness of the blinding was verified by asking the participants at discharge to which group they thought they had been assigned. The majority of patients in the Sham Reiki group thought that they had been placed in the Reiki group, indicating that the blinding was convincing, leading to the conclusion that the reported pain assessment differences were well-corrected for the placebo effect.

Study Limitations and Benefits

Problems with the study were linked to the fact that this was an exploratory pilot study, one aim of which was to assess the research protocol, including recruitment and

enrolment of participants and the feasibility of achieving the data collection end points in an acute care setting in preparation for a multi-site clinical trial. Issues that were encountered included: low efficiency of recruitment of participants; difficulty obtaining usable measures of heart rate variability from many patients; and trouble collecting sufficient saliva from patients.

The recruitment problem stemmed from the fact that we relied on a single point of enrollment and a single clinical site to perform all recruitment procedures. This single point of enrollment was a bottleneck that could be corrected in a larger study by including multiple centers. In addition, there were patient flow considerations arising from scheduling problems due to the limited capacity of a single center to process subjects accounting for surgeon availability and enrollment officer schedules. All of these situations could be handled effectively by including multiple sites.

The HRV recording as a measure of sympathovagal balance was not useful as a primary endpoint in this case because many patients presented with arrhythmias. Recordings can be corrected for occasional ectopic beats and arrhythmic events by omitting those RR intervals and interpolating the data (13). However, when too many RR intervals are interpolated as a percentage of the total number of intervals recorded, this leads to inaccurate results.

Salivary IgA was not a suitable clinical endpoint in this case because the amount of saliva the patients could produce pre-surgery was limited since they were instructed to abstain

from taking solids or liquids for a certain time prior to admission. This is valuable information because it serves to eliminate saliva-based testing of this patient population.

On the other hand, the pain scale and state anxiety score parameters were very useful, as were the simple and inexpensive measurements of time to discharge and PRN pain medication usage. This is extremely valuable information in that a clear advantage of Reiki can be observed with cost-effective measures that can be performed by any clinical center.

Implications for Further Research and Nursing Practice

The next step is to perform a multi-center clinical study with 50 patients per group, in which we focus on the measurements that were informative, such as pain scores, state anxiety, blood pressure, on-time discharge, less PRN pain medication use, fewer readmissions or trips back to the ICU, and increased patient satisfaction and pain management HCAHPS scores.

The opportunity to differentiate between hospitals on the basis of patient outcomes, patient satisfaction and readmission rates, for such a low-cost offering as Reiki, should be of significant financial impact to insurers, patients and providers. In addition, positioning Reiki as an *adjunct* to SOC should promote a more generalized adoption and acceptance. Reiki is additive and may increase patient compliance while allowing on-time discharge and fewer complications.

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Figure Legends

Figure 1: Effects of Reiki or Sham Reiki on pain score. Only the Reiki group showed a significant reduction in pain score 24 and 48 hours post-surgery. Note: As stated in the Results section, due to attrition the number of patients who contributed to the 48 hr post-surgery data was lower than for the other data points. This discrepancy was accounted for in the statistical analysis.

Figure 2: Effects of Reiki or Sham Reiki on state anxiety score at discharge. Only the Reiki group showed a significant reduction in state anxiety at discharge.

Figure 3: Effects of group assignment on percentage retention in study. The Reiki group showed the highest percentage rate of retention in the study up to, and including, the time-point 48 hours post-surgery, after which half of the patients were discharged.

Figure 4: Effects of group assignment on percentage of patients discharged at various times. The term ‘other’ refers to the percentage of patients who were taken off the study prior to 48 hrs post-surgery due to complications, such as the need to return to the ICU. The Reiki group had the highest percentage of discharges at 48 hrs.

Table Legends

Table 1: Record of patient enrollment and attrition.

Table 2: Summary of relative effects of the three treatments on all seven parameters measured (1=best, 3=worst).