Clinical (Sleep, Pain and Atrial Fibrillation) and Hospital Stay Effects of Reiki and Manual Therapy after Open Heart Surgery

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Abstract

Objectives: Reiki is an energy-based healing therapy using light touch. Manual therapy is a technique using light effleurage. These complimentary healing services are utilized to promote relaxation, sleep, improve emotions, and decrease pain. After reviewing the Reiki research literature, more research is required since sample sizes were small, subjects were generally healthy (not hospitalized), and subjects had multiple medical backgrounds. Only 1 study focused on cardiac surgery patients. In the current research study, we aim to learn if Reiki and manual therapy enhances postoperative clinical outcomes for patients after first time coronary artery bypass graft (CABG) and/or cardiac valve surgery. *Design* and *Methods:* A randomized, controlled non-blinded study will be used. The sample size (272 total; 136 per group) was based on a power analysis using the primary outcome. The intervention group will receive usual care plus Reiki and manual therapy, with Reiki being delivered first. Hand placements include: head, chest, shoulders, hands, knees, and feet for 15 minutes. Manual therapy will consist of light effleurage to the head and feet for 5 minutes. Total therapies time is 20 minutes. Reiki and manual therapy will be delivered for 3 consecutive days beginning on the day after endotracheal tube removal. The usual care group will receive rest, which is part of usual postoperative care. There will not be a sham-treatment group, based on previous research findings when a sham group was used. *Outcome Measures*: depression and anxiety (*Brief Symptom Inventory*, 12-item self-administered tool); pain (self-reported and recorded in EPIC by staff nurses as part of usual care -- 0 [no pain] - 10 [worst pain] scale), highest (worst) and lowest (least) pain in the past 24 hours will be assessed; night time sleep (Richards-Campbell Sleep Questionnaire; 5 item self-administered tool)—to be measured at baseline and after the last Reiki/manual therapy treatment or 3 days of usual care. Hospital length of stay and all-cause 30-day hospital readmissions will be pulled from the billing database, narcotic drug burden (mean dose) use on postoperative days 3 and 4 will be obtained from electronic medical records, and data on patient characteristics, medical history, surgical procedure, new onset atrial fibrillation and other post-operative complications will be retrieved from the IRB-approved Cardiothoracic Surgery database.

Purpose and Research Questions

The purpose of this randomized, controlled study is to learn if Reiki and manual therapy lead to differences in patients' postoperative clinical outcomes after first time coronary artery bypass graft (CABG) and/or cardiac valve surgery.

Research questions:

Compared to usual postoperative care, does Reiki and manual therapy:

1. Reduce negative emotions (depression and anxiety)?
2. Improve sleep?
3. Reduce pain?
4. Decrease hospital length of stay?
5. Reduce new onset atrial fibrillation?
6. Reduce 30-day hospital readmissions?
7. Reduce total narcotic burden (mean dose)?

Review of Literature

In clinical practice, Reiki was studied by multiple investigators for its therapeutic effects. In a 2009 systematic review, 12 trials (that used placebo vs. treatment) were included, and in 9 of the 12, Reiki had a significant therapeutic effect (VanerVaart et al, 2009). Of the 12 trials, when assessed for quality, 11 of 12 ranked poor in quality (VanerVaart et al, 2009), making it difficult to determine the value of Reiki in clinical practice. In a 2008 systematic review of trails of Reiki that included placebo vs. treatment, researchers reported that outcomes varied dramatically between studies (Lee, Pittler and Ernst, 2008). For example, of the 9 papers, 3 had an outcome of depression, 1 had outcomes of pain and anxiety, 1 studied anxiety in pregnant women, 1 studied functional recovery after stroke, 1 studied pain in patients with diabetic neuropathy, 1 studied pain and anxiety in women undergoing breast biopsy and 1 paper had outcomes of stress and hopelessness. Researchers concluded that trials for any one condition were scarce and replication studies were not completed. Further, most studies had methodological flaws (small sample sizes, inadequate study design) and in one study, researchers failed to provide results between groups on depression, their primary outcome (Lee, Pittler and Ernst, 2008). In a final integrative review that included papers from 1980 to 2006, Vitale (2007) also found that outcomes and patient populations varied widely. Outcomes included both acute and chronic pain, stress/relaxation/depression, wound healing, biological factors (hematocrit and autonomic nervous system), and anxiety /wellbeing. Vitale (2007) found that there was not 1 consistent definition of Reiki and that 6 of 16 studies failed to meet primary endpoints.

Only 1 paper was published of “healing touch” (definition was consistent with our definition of Reiki) in patients post CABG surgery (MacIntyre et al, 2008). Patients received usual care; visitors (distraction) therapy or healing touch during postoperative recovery and 6 outcomes were studied: postoperative length of stay, incidence of postoperative atrial fibrillation, use of anti-emetic medications, narcotic pain use, functional status and anxiety. Of outcomes, only anxiety was improved (decreased) among healing therapy subjects, compared to the other 2 groups. In sub-analysis, length of stay was reduced among outpatients who received healing touch, compared to placebo or visitor therapy, but there were no differences among groups for patients who were in-hospital on the day of surgery (MacIntyre et al, 2008). Finally, researchers assessed autonomic nervous system factors (heart rate, vagal tone, systolic, diastolic and mean blood pressures, breathing rate and cardiac sensitivity to baroreflex) among healthy volunteers. Of factors, only heart rate was different (lower) between Reiki and non-Reiki groups. Further, vagal tone trended to be lower in Reiki patients (and corresponded to lower heart rates) (Mackay, Hansen and McFarlane, 2004).

Thus, a review of the literature on Reiki therapy provided evidence that more research is needed. Most reports of comparative trials had small samples, used healthy subjects or patients with medical conditions that were different than our intended postoperative cardiac surgical population, or had methods that may have caused threats to internal validity of findings.

Integrative therapies have gained much support and interest in the literature as methods to help alleviate pain and anxiety (Anderson & Cutshall, 2007). However, very few studies revealed therapeutic benefits of massage therapy in patients post CABG surgery (Anderson & Cutshall 2007), including research conducted previously on this patient population at Cleveland Clinic (Albert et al., 2009) that include massage to arms, legs and back. Cardiac surgery patients undergo a long procedure, may experience back, shoulder, and neck pain, or generalized tension postoperatively (Anderson & Cutshall, 2007). In a pilot study (n=58), 1 session of 20 minutes of massage therapy offered between day 2 and 5 postoperatively reduced pain, anxiety and tension scores and patients provided positive feedback (Cutshall, et al, 2010). Although authors concluded that massage should be considered for the management of cardiovascular surgical postoperative healing and incorporated in post cardiac surgical units (Cutshall, et al, 2010), more research is needed, since it is not currently considered evidence-based therapy. In another study with a very small sample, researchers compared 15 minutes of hand massage to control care (hand holding) followed by 30 minutes of rest for 2-3 sessions in the first 24 hours following cardiac surgery. Patients who received hand massage had lower pain intensity, but vital signs were similar between groups (Boiter, et al, 2015). Although hand massage is a low-cost non- pharmacological intervention that can be safely completed at the bedside (Boitor, et al, 2015), the sample size was too small to provide generalizable evidence. Finally, in a randomized trial, pain and anxiety were assessed after 2 massage therapy or rest (usual care) sessions on day 3 or 4 and day 5 or 6 among 152 cardiac surgery patients (Braun, et al., 2012). The massage group demonstrated a reduction in both pain and anxiety. These studies demonstrate that massage therapy may play a significant role in supporting cardiac patients' wellbeing and healing and that it should be offered along with Reiki therapy to determine if the combination of therapies is more important than 1 complementary therapy alone.

Methodology

Design: Randomized, controlled non-blinded study

Study Groups: Adults who had first-time open heart or robotic-heart surgery involving coronary arteries, cardiac valves or aortic root (+ other procedures).

Inclusion criteria:

- Over 18 years of age
- Speaks English language and capable of reading and hearing.
- Up to 4 "To Come In" patients enrolled per day (2 standard care and 2 intervention group)
- Arrive for surgery from outpatient (home) environment.
- Scheduled for surgery (arrives in "To Come In" area) on Monday and Tuesday.
- Lives in one of 6 counties of Northeast Ohio, to ensure access post- discharge hospitalization.

Exclusion criteria:

- EPIC history of dementia, cognitive decline, Down's syndrome or other neurologic, psychological or congenital deficiency that impacts ability to make decisions about enrollment. EPIC assessment will occur during the process prior to approaching patients.
- Severe sight and hearing impairment despite assistive devices
- Cardiac surgery on a Wednesday, Thursday or Friday.
- Was not admitted to the hospitals for surgery via To Come In status on the morning of surgery.
- Prolonged intubation (over 48 hours), or reinsertion of an endotracheal tube during or before the intervention is initiated (will result in intervention withdrawal).
- Sedated due to new onset delirium.

Intervention

Reiki is a Japanese energy-based healing technique that has been utilized in the United States since the 1940's. The English translation of Reiki is universal vital energy that flows throughout and encompasses all living forms (Rand, 1991). Reiki is delivered by gentle hand placement either on or slightly above the body by certified Reiki practitioners. In this study, Reiki will be delivered first, for 15 minutes and will involve light placement of hands-on patients' head, chest, shoulders, hands, knees, and feet (~ 3 minutes to each body part).

Manual therapy techniques include light effleurage to head and feet (for 5 minutes; ~ 2.5 minutes to each body part) by the Reiki practitioner who delivered the Reiki therapy. For this research study, manual therapy techniques are defined as light effleurage without pressure.

Reiki and manual therapy will be delivered for 3 consecutive days beginning on the day after endotracheal tube removal. A holistic environment will be provided for healing to both groups.

- Rooms will be quiet, and doors will be closed during the 20 minutes of rest (usual care) or intervention, unless patients are in an ICU setting; in ICU, curtains will be drawn.
- Patients will lie down in bed in supine position or sit in recliner, inhaling through their nose and exhaling through their mouth with their eyes closed.
- Duration of Reiki service will be 15 minutes followed by manual therapy for 5 minutes.
- The intervention is completed after the 3rd Reiki + manual therapy sessions are completed.

Reiki and manual therapy will be delivered by 4 Reiki practitioners with training at a Level 2+. The 4 Reiki practitioners are part of this study's research team. Intervention patients may receive different practitioners during the intervention period. To assure that both groups receive 20 uninterrupted minutes of rest (control) or intervention, practitioners will place a sign on the door or ICU curtain stating, "Please do not disturb the patient when this sign is posted". All practitioners will use a systematic approach when delivering both Reiki and manual therapy. Prior to study initiation, all practitioners

will receive an in-service and understand the sequence of service delivery during the intervention. The in-service will include a mock demonstration of all steps, including placing the sign on the room door.

To assure quality and integrity of the intervention, the study PI (SZ) will observe all 4 practitioners deliver the intervention at least 1 time pre-study (on patients who agree to receive it) and will share any issues or discrepancies observed. If there is divergence among practitioners, SZ will lead a group discussion of expectations for the study and will observe all 4 practitioners complete the intervention until there is conformity in actions.

We believe a sham group is not needed, based on (a) massage therapy research results that showed the benefits of massage on pain and anxiety compared to usual care subjects who received rest (as we will) and (b) 1 Reiki study in which investigators had 3 groups-- usual care, a sham group that involved a person without Reiki training mimicking Reiki therapy and a treatment group who received Reiki therapy by an experienced Reiki practitioner. Reiki had effects on the autonomic nervous system (reduced heart rate and diastolic blood pressure), but the sham and placebo groups did not experience any benefit (MacIntyre et al., 2008).

Usual Care

All usual care provided pre- and post-operative management will continue, uninterrupted; including the 20 minute rest period. The only non-usual care component will be placement of a sign on the door to discourage visitors and providers from entering the room and disturbing the rest period.

Outcomes

Depression and *anxiety*: Depression and anxiety will be assessed using the *Brief Symptom Inventory,* a 12-item survey that provides subscales severity indexes for depression and anxiety. The *Brief Symptom Inventory* was internally consistent (reliable); in patients with ischemic heart disease (Doering, et al., 2010). The *Brief Symptom Inventory* has been used to assess depression and anxiety in multiple patient populations, including cardiac diseases, and results were found to predict mortality (Doering, et al., 2010). The survey uses simple statements and a 5-level Likert-type response set, ranging from 0, *not at all* to 4, *extremely*.

Pain: Pain is a subjective symptom best measured by self-report. Pain will be measured in 2 ways. (1) Pain intensity will be measured on a scale of 0-10 with a score of 0 for no pain and 10 for worst pain, as part of usual care. (2) Highest (worst) and lowest (least) pain in the past 24 hours will be assessed via pain scores recorded in EPIC.

Sleep: The Richards-Campbell Sleep Questionnaire (RCSQ) was developed in 2000 to overcome issues with other sleep questionnaires used in an acute or ICU setting. Permission was previously given to the mentor of this study (NMA) to use the tool unconditionally. This tool has 5 domains: sleep depth, falling asleep, number of awakenings, percent of time awake, and overall quality of sleep. It uses a visual analog

scale to measure domains of sleep and the composite score range is 0 to 100 (to reflect 0 to 100 mm). The RCSQ is calculated by dividing the sum of the total length in millimeters of the visual analog scale lines by 5. It is reliable with a Cronbach's alpha of .90 in 70 critically ill subjects (Richards, O'Sullivan & Phillips, 2000). It is short, simple, and easy to administer and analyze. This tool will take approximately 1 minute to complete.

Hospital length of stay: Data will be collected by analysts using EPSi administrative database.

New onset atrial fibrillation: Data will be retrieved from the Cardiothoracic Surgery database, led and managed by HVI Institute. It is IRB approved and data are collected on every open-heart surgery as part of the Society of Thoracic Surgery data collection, that Cleveland Clinic participates in. Data will be received in an excel file and encounter record numbers will be matched to questionnaire data for analysis.

All cause 30-day hospital readmission: Data will be collected by analysts using EPSi administrative database.

Narcotic drug burden (mean dose) on postoperative days 3 and 4: Data will be collected via an electronic medical record pull, using our Pharmacy's database. Of oral narcotics, Percocet (acetaminophen and oxycodone) is most commonly used; however, if another oral agent or IV agents are used (for example, fentanyl or dilaudid [hydromorphone]) we will create a drug dose equivalency table so that data are analyzed based on equivalent doses of different agents used.

Patient and medical characteristics: Data will be retrieved from the Cardiothoracic Surgery database, led and managed by HVI Institute. It is IRB approved and data are collected on every open-heart surgery as part of the Society of Thoracic Surgery data collection (version 2.81, effective, 04-23-2015; www.STS.org), that Cleveland Clinic participates in. Data will be received in an excel file and encounter record numbers will be matched to questionnaire data for analysis. This data will be used to compare groups for symmetry. Data collection will include the factors highlighted on the Appendix form; attached and marital status, from the EPSi (billing) database.

Reiki/manual therapy practitioners: Number of practitioners who applied Reiki/manual therapy during the intervention.

Data Collection Procedures

From the "To Come In" (TCI) list for first time cardiac surgery patients, data collectors will retrieve names and interview patients that meet criteria for research and offer the study to patients while they are in the TCI area for surgeries that are planned for upcoming Monday's and Tuesday's, so that consent is given prior to their surgery date. Alternately, we will enroll potential patients in the pre-cath area of J2 when they are in for a cardiac catheterization as part of their upcoming survey.

Written consent will be acquired by patients before initiation of the research study. Research nurses or research coordinators, who are not involved in the intervention or in clinical patient care will administer the questionnaire packets preoperatively (in TCI) and after the last Reiki treatment or usual care day of the research intervention for the following data: anxiety and depression and sleep. After preoperative data collection, patients will be randomized to the usual care or intervention group: using envelopes with assignments (136 control subjects 136 experimental subjects); based on groups of 20. Packets will be created by a nurse from the Office of Research and Innovation and envelope assignments will not be shared with any researcher. Research nurses or research coordinators can assist patients with completion of baseline and post-intervention questionnaires, as desired.

Data retrieved from administrative, EPIC and cardiothoracic surgery databases will be requested using usual procedures, after patients have completed the study. The cardiothoracic surgery database is IRB approved.

Sample Size

Depression and anxiety are the primary outcomes. In a study of healing touch among hospital patients recovering from cardiac surgery (MacIntyre et al, 2008), those who received healing touch had a 71% greater change in “anxiety” score, compared to control subjects (mean decreases: healing touch, 6.3 [2.0, 10.6] and control group, 1.8 [-2.6, 6.2], p=0.01). For this research study, we are hypothesizing that Reiki and manual therapy will result in a *30% greater reduction of depression and anxiety* compared to patients in the usual care group. A rate of 30% was selected based on previous research findings: In a cohort of patients who received surgical procedures, postoperative anxiety BSI had a mean of 0.51 and a standard deviation of 0.56, and depression BSI had a mean of 0.42 and a standard deviation of 0.56 (Mackay, Hansen, & McFarlane, 2004). Given the skewed nature of these data, a lognormal distribution was assumed, with a coefficient of variation (standard deviation/mean) of 1.35, based on the depression BSI results above. We believe that a 30% reduction in mean depression and anxiety scores would be clinically important. Based on use of a two-sided two-sample t-test with significance level of 0.05, with adjustment for use of analysis of covariance based on an assumed small positive correlation between baseline and follow-up (ρ=0.25) as described by Borm et al. (2007), a sample size of 123 per group would provide 80% power to detect this difference. To account for loss-to-follow-up, recruitment was increased by 10%, creating a sample size of 136 patients per group (272 patients in total). Sample size calculations were performed using SAS software (version 9.4; Cary, NC) by Jim Bena MS of QHS.

Data Analysis

Patient characteristics will be summarized using frequencies and percentages for categorical measures, and means and standard deviations or medians and quartiles, as dictated by the distribution of these measures.

Anxiety, depression and sleep analyses: an analysis of covariance models will be fit, using the follow-up score as the response and patient group and baseline levels of the outcome measure as predictors by using the Brief Symptom Inventory (BSI).

Pain, LOS and other continuous factors: will be compared between groups using analysis of variance models. In each of the models, normality of the outcomes will be evaluated and, if necessary, data will be transformed prior to analysis. Results will be back-transformed for presentation of mean differences with 95% confidence intervals.

Reduced new onset of atrial fibrillation and reduced 30-day hospital readmission are binary outcomes that will be evaluated using Pearson chi-square tests or Fisher exact tests, in the case of rare outcomes.

Exploratory analyses will evaluate the relationship between patient characteristics and outcomes and adjust treatment group differences for these factors using similar methodology. An analysis will be performed using SAS software (version 9.4; Cary, NC). A significance level of 0.05 will be assumed for all outcomes.

Feasibility

The facility has sufficient trained Reiki certified practitioners to provide these modalities safely and accommodate the sample size. Hand placements and manual therapy specific for this study will be conducive for this patient population and will not put the patient at risk. The facility does at least ten cardiac surgeries Monday through Friday specific for this study to meet criteria for sample size.

Limitations and Anticipated Problems

Patients may be off the floor, busy with another service, sleeping or too sick (worsening status, readmitted to the ICU, intubated and sedated) or nauseated to be approached to carry out the Reiki intervention, even after enrollment. Not all patients will receive 3 sessions. To make up for possible attrition, 10% will be added to the minimum sample size. Patients may refuse therapy (a rare occurrence) or may not complete questionnaire tools. Administrative and cardiovascular registry data will be used to collect most variables. If there is a delay in data collection or entry into the database, we may be delayed with analysis.

Human Subjects Protection

Risks to patients are low since our Reiki intervention consists of light touch and light rhythmic effleurage with no applied pressure. Patients could develop fatigue when completing tools, although unlikely as both are very short (BSI: 12 items and sleep scale: 5 items). Study coordinators will administer the tools after the 4th session is provided. Sandi Zampino, RN, Principal Investigator will maintain collected paper data in a secure file in her office and she will also be responsible for entering data in the database. The office door is locked when not in use. Shredder will destroy written surveys after 1 year of filing. In the informed consent letter, participants will receive the name and phone number of Sandi Zampino so that any questions or concerns can be addressed. No adverse events are anticipated.

References

Albert, N. M., Gillinov, A. M,, Lytle, B. W., Feng, J., Cwynar, R., & Blackstone, E. H. (2009). A randomized trial of massage therapy after heart surgery. *Heart & Lung*, *38*(6), 480-90.

Anderson P.G., Cutshall S.M. (2007). Massage therapy: A comfort intervention for cardiac surgery patients. *Clinical Nurse Specialist, 21(3),* 161-65.

Boiter, M., Martorella, G., Arbour, C., Michaud, C., & Gélinas, C. (2015). Evaluation of the preliminary effectiveness of hand massage therapy on postoperative pain of adults in the intensive care unit after cardiac surgery: a pilot randomized controlled trial. *Pain Management Nursing, 16(3)*, 354-66.

Borm, G.F., Fransen, J., & Lemmens, WA. (2007). A simple sample size formula for analysis of covariance in randomized clinical trials Journal of Clinical Epidemiology*, 60(12),* 1234-38.

Braun, L. A., Stanguts, C., Casanelia, L., Spizer, O., Paul, E., Vardaxis, N. J., & Rosenfeldt, F. (2012). Massage therapy for cardiac surgery patients--a randomized trial. *Journal Thoracic Cardiovascular Surgery, 144(6),* 1453-9.

Cutshall S. M., Wentworth L. J., Engen D., Sundt T.M., Kelly R. F., & Bauer B. A. (2010). Effect of massage therapy on pain, anxiety, and tension in cardiac surgical patients: pilot study. *Complimentary Therapy Clinical Practice, 16(2), 92-5.*

Doering, L. V., Moser, D. K., Riegel, B., McKinley, S., Davidson, P., Baker, H., Dracup, K. (2010). Persistent comorbid symptoms of depression and anxiety predict mortality in heart disease. *International Journal of Cardiology, 145(2)*, 188-92.

Gordon, D.B., Polomono, R.C. Pellino, T.A., Turl, D.C.., McCracken, L.M., and et al. (2010). American pain society patient outcome questionnaire for quality improvement of pain management in hospitalized adults: Preliminary psychometric evaluation: *The Journal of Pain, 11(11),* 1172-86.

Lee, M.S., Pittler, M.H., Ernst, E. (2008). Effects of reiki in clinical practice: A systematic review of randomized clinical trials. *International Journal of Clinical Practice, 62(6),* 947-54.

MacIntyre, B., Hamilton, J., Frickle, T., Wenjun, M., Mehle, S., Michel, M. (2008). The efficacy of healing touch in coronary artery bypass surgery recovery: A randomized clinical trial. *Alternative Therapies, 14(4)*, 24-32.

Mackay, N., Hansen, S., McFarlane, O. (2004). Autonomic nervous system changes during reiki treatment: A preliminary study. *The Journal of Alternative and Complementary Medicine, 10(6)*, 1077-81.

Rand W. (1991). The Healing Touch. First and Second Degree Manual. Vision Publication: Southfield, MI.

Richards, K.C., O'Sullivan, P., Phillips, R.L. (2000). Measurement of sleep in critically ill patients. *Journal of Nursing Measurement, 8(2),* 131-44.

Society of Thoracic Surgeons. The Society of Thoracic Surgeons Adult Cardiac Surgery Database data collection form version 2.81, April 23, 2015. Society of Thoracic Surgeons, www.sts.org. Accessed 09-12-2016.

VanderVaart, S., Gijsen,V., De Wildt, S., Koren, G. (2009). A systematic review of the therapeutic effects of reiki: The journal of alternative and complementary medicine, *15(11),* 1157-69.

Vitale, A. (2007). An integrative review of reiki touch therapy research. *Holistic Nursing Practice, 21(4),* 167-79.

Timetable

Data collection and placement in database	8 months
Data cleaning	2 weeks
Data analysis	3 months
Data dissemination	6 months
Research translation	To be determined