# The effect of distant Reiki on pain in women after elective caesarean section - a double blinded randomized controlled trial.

Sondra vanderVaart, HBSc, MBA[1,2], Howard Berger, MD[3], Carolyn Tam, HBSc [2,4] , Y Ingrid Goh, PhD[1,2], Violette MGJ Gijsen, MSc[2,5], Saskia N de Wildt, MD, PhD[5], Anna Taddio, PhD [2], Gideon Koren, MD, FRCPC, FACMT[1,2,6]

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**Corresponding Author's address:**

Dr. Gideon Koren,
Professor of Pediatrics, Pharmacology, Pharmacy, Medicine and Medical Genetics,
Clinician-Scientist,
Division of Clinical Pharmacology and Toxicology
The Hospital for Sick Children
555 University Ave
Toronto, Ontario, Canada
M5G 1X8
Phone: (416) 813-1500 Ext. 5781
Fax (416) 813-7562
Email: gideon.koren@sickkids.ca

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[1] Department of Pharmaceutical Sciences, University of Toronto, Toronto, Ontario, Canada.
[2] Division of Clinical Pharmacology and Toxicology, The Hospital for Sick Children, Toronto, Ontario, Canada.
[3] Department of Obstetrics and Gynecology, St. Michael's Hospital, Toronto, Ontario, Canada.
[4] Department of Pharmacology and Toxicology, Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
[5] Department of Pediatric Surgery, Erasmus MC Sophia Children's Hospital, Rotterdam, The Netherlands.
[6] Ivey Chair in Molecular Toxicology, Department of Medicine, University of Western Ontario, London, Ontario, Canada

## ABSTRACT

### Introduction

Approximately 25% of all babies in North America are delivered via caesarean section. Though a common surgical procedure, c-section recovery can be painful. Opioids, specifically codeine, are commonly used to ease pain; however, its active metabolite morphine passes into breast milk, and may produce unwanted side effects in neonates; therefore alternatives to opioids are sought out. Reiki is an ancient Japanese form of healing where practitioners transfer healing energy through light touch and positive healing intention. Although 1.2 million Americans use Reiki to reduce pain or depression, there is a lack of strong evidence supporting its effectiveness. A recent systematic review showed existing studies to be of poor methodological quality, with the common limitation of lack of blinding. To overcome this issue we used distant Reiki to assess its effectiveness in reducing pain following an elective C-section.

### Methods

In this randomized, double blinded study, women who underwent an elective C-section were allocated to either usual care (control, n=40) or three distant Reiki sessions in addition to usual care (n=40). Pain was assessed using a visual analogue scale (VAS). The primary endpoint was the Area Under the VAS-time Curve (AUC) for days 1 to 3. Secondary measures included: proportion of women who required opioid medications & dose consumed, rate of healing and vital signs.

### Results

AUC for pain was not significantly different in the distant Reiki and control groups (mean ± SD; 212.1 ± 104.7 vs. 223.1 ± 117.8; p=0.96). There were no significant differences in opioid consumption or rate of healing, however, the distant Reiki group had a significantly lower heart rate (74.3 ± 8.1 bpm vs. 79.8 ±7.9 bpm, p=0.003) and blood pressure (106.4 ± 9.7 mmHg vs. 111.9 ± 11.0 mmHg, p=0.02) post surgery.

### Conclusion

Distant Reiki had no significant effect on pain following an elective C-section.

**Trial registration number:** ISRCTN79265996.

ARTICLE SUMMARY

Article focus

- This is the first randomized, double-blinded trial conducted on distant Reiki.
- The focus in on distant Reiki's effects on pain after caesarean section.
- Special attention was paid to the methods of proper randomization, patient allocation concealment and blinding.

Key messages

- Our trial suggests that distant Reiki had no benefit in reducing patients' post partum pain over usual care for elective caesarean section.

Strengths and limitations of this study

We engaged a highly experienced Reiki Master to administer distant Reiki removing the placebo effect which was present in all other pain trials. In addition we had high adherence to protocol, successful blinding of the research team, successful randomization and patient allocation concealment and diligent data collection with extremely few data points missed. We had good credibility with research participants as all but 10 women refused to participate. We evaluated other aspects of healing after elective caesarean section, beyond patients' perceived pain levels, by including the previously developed and published Milestone Questionnaire.

A potential limitation was the magnitude of pain on which we were attempting to show an impact. Just as acetaminophen is not suitable as pain medication after caesarean section, distant Reiki may also not be suitable for this magnitude of pain. In addition, since some patients were discharged early, our complete dataset is limited to 48 hours, with gaps in data for 16 patients (20%) accounted for by carrying the last pain score forward. To ensure that this method did not distort the results, we also evaluated AUC for pain on day 1 and day 2 individually and found no differences between groups for both these time periods.

INTRODUCTION

Approximately 25% of all babies in North America are delivered via caesarean section (1); alleviating pain early is important, as studies have shown that post operative pain negatively affects a mother's ability to care for and breastfeed her infant (2). To alleviate post operative pain, opioids, are commonly used after c-section (3). For example, codeine, a common opioid, is a pro-drug, and it is the relative biotransformation of codeine into morphine by the highly polymorphic cytochrome P450 enzyme 2D6 (CYP2D6) that is single most important factor determining codeine analgesia in adults. Approximately 5-10% of ingested codeine is converted into morphine; however this percentage can increase dramatically in individuals who have multiple copies of the CYP2D6 allele (4).

We now know that morphine passes into breast milk. In 2005, a published study alerted the medical community to a case where a full term breast-fed baby died from a morphine overdose as a result of his mother taking Tylenol #3 with codeine to manage her pain; the mother had several copies of the CYP2D6 allele and had converted more than 10% of codeine into morphine (5, 6). Maternal breast milk is considered the optimal nutrition for infants, and the American Academy of Pediatrics recommends exclusive breastfeeding for the first six months of life (7). To ensure that all mothers who are recovering from c-sections and wish to breastfeed are able to do so safely, alternatives to opioids are sought.

Several complementary and alternative medicine (CAM) therapies are used to alleviate pain. In an attempt to reduce or eliminate the need for opioid pain medication, we sought to examine the effect of distant Reiki on pain. Reiki, an ancient Japanese form of hands-on healing, used to alleviate pain and depression(8), is classified as an Energy Medicine by the National Center for Complementary and Alternative Medicine (NCCAM)(9). Despite being an ancient Japanese practice, Reiki is practiced by over 1.5 million Americans and its popularity is growing (10). It was promoted by Dr. Oz, prominent cardiothoracic surgeon, host of the Dr. Oz Show and frequent Oprah guest as his "ultimate CAM therapy for 2010"(11). However, while it is commonly

practiced, there is no agreed-upon theory for how Reiki might work and its mechanism of action is still unknown(8).

Reiki practitioners believe that they can direct healing energy through their hands to their patients. To direct this energy, practitioners maintain a meditative presence and place their hands lightly over the person they are treating to aid in the patient's natural ability to heal. Reiki can be practiced either proximally, with the patient located beside the practitioner, or distally, with the patient and practitioner in separate locations. Both types of Reiki rely on the premise of a universal source of healing energy which a Reiki practitioner can direct through intention.

A distant Reiki treatment is like distant prayer, in that the practitioners are thinking of their patients from a distance. In distant Reiki, Reiki practitioners first undertake a specific protocol which allows them to send the healing energy to the patient. Secondly, practitioners mentally ask the person who is absent if he or she consents to treatment. Lastly, if practitioners do not hear a response or if they hear "yes" in their head, they follow the same procedure as for traditional Reiki but they place their hands on a substitute (eg. pillow) for the person being treated; if they hear "no", the session ends immediately.

Reiki may work. Several studies have found a reduction in pain when using Reiki (12)(13)(14)(15); furthermore, one of the studies found that women who received Reiki after hysterectomy reported less pain and requested fewer analgesics (12). While there were no studies which specifically evaluated distant Reiki for pain, one study found that distant Reiki was as effective as traditional Reiki in the management of depression and anxiety. The authors concluded that the distant Reiki was as efficacious as traditional Reiki and the healing power of Reiki was not due to placebo (16).

However, despite widespread and growing popularity, there is a dearth of well conducted published scientific literature supporting or refuting Reiki's efficacy. A recent systematic review of Reiki found that while

the vast majority of studies had positive therapeutic effects, all available studies scored poorly when methodological quality was measured using Jadad (8); thus definitive conclusions about efficacy could not be made. A common source of potential bias was the lack of blinding of participants and assessors when using traditional Reiki. Patient and medical-staff blinding to treatment allocation in a clinical trial is particularly important when the response criteria are subjective, such as alleviation of pain (17). To overcome this limitation, we employed distant Reiki in our trial.

Given the need for alternate pain control treatments for breastfeeding mothers due to the risk of morphine exposure in neonates, and the reduced pain observed in the women who received Reiki after hysterectomy, our objective was to determine if distant Reiki is effective in reducing pain after elective caesarean section, through a randomized double-blinded study.

## METHODOLOGY

### Study Design

This was a double blinded randomized clinical trial. The investigators, participants, and healthcare staff directly involved with the participants were unaware of the group assignments. The study was approved by the research ethics board (REB) at St. Michael's Hospital in Toronto and all participants provided written informed consent prior to participation.

### Participants

All pregnant women who were scheduled to have an elective caesarean section were approached during a routine prenatal visit at the obstetrical clinic at St. Michael's Hospital between September 1, 2008 and March 31, 2009. Criteria for exclusion included the following: having had previous experience with Reiki or not planning to use standard postoperative pain medication. Women were recruited in either English or Spanish,

and those that did speak other languages were approached if they had a translator with them, such as a husband or friend.

To ensure concealment of group assignment, the St. Michael's Hospital research associate (SV) enrolled participants and then contacted the research assistant (YIG) at The Hospital for Sick Children (HSC) with the participant's information (unique Hospital ID, date and time of c-section) for randomization. YIG had previously generated the randomized number sequence in blocks of 4 or 6. Participants were sequentially assigned (by YIG) to the random sequence which was securely stored and password protected on the HSC network. If the patient was assigned to the distant Reiki group, the research assistant (YIG) contacted the Reiki Master with the participant's information. If the patient was in the control group, no contact was made with the Reiki Master.

Intervention

Participants in the control group received usual medical and nursing care during their stay (typically 72 hours). The intervention group received usual care plus 3 distant Reiki sessions, one each morning. The first session was administered on the morning of the caesarean section, at least 30 minutes prior to surgery, and the second and third sessions were administered on the following mornings at approximately 8am.

A single Reiki Master located over 100 kilometres away, trained in the Usui line of Reiki and who has been practicing Reiki for over 10 years and regularly treats clients with distant Reiki administered the distant Reiki interventions. Each distant Reiki session lasted approximately 20 minutes and the Reiki Master followed the traditional Usui Reiki protocol for distant healing(18) . The unique Hospital ID was used as the identifier when sending distant Reiki to the participant.

*Cesarean Section, anesthesia and analgesia protocol*

All elective caesarean sections at St. Michael's Hospital were performed using the Pfannenstiel protocol(19). Women who underwent elective caesarean sections received a spinal anesthesia with 0.75% bupivicaine, and 15mcg fentanyl lasting 2-4 hours followed by 100 mcg of epidurally administered morphine,

which typically lasts 12 hours. Vital signs were checked and pain and sedation scores were taken every 10 minutes for two hours after caesarean section. Following these two hours, vital signs were taken every 12 hours on the delivery ward.

The following analgesia protocol was administered immediately following the cesarean section:

1. Naproxen (500 mg) was given rectally and then orally every 12 hours for 48 hours.
2. For breakthrough pain: acetaminophen (300 mg) with codeine (30 mg) and caffeine (15 mg) (Tylenol no.# 3 ®, Johnson & Johnson) , 1 - 2 tabs orally, every 4 hours, as needed;
    a. patients that could not tolerate acetaminophen with codeine were given either acetaminophen (325 mg) with oxycodone (5 mg) (Percocet®, Endo Pharmaceuticals) or oral morphine (5 mg)
3. For mild to moderate pain: acetaminophen, 500 mg (Tylenol Extra Strength®, Johnson & Johnson), 1 - 2 tabs orally, every 4 hours, as needed.
4. Forty-eight hours after the caesarean section, the women received a self-medication package. This package included:
    a. Acetaminophen, 325 mg (Tylenol®, Johnson & Johnson), 1 - 2 tabs orally, every 4 to 6 hours, as needed for mild pain control;
    b. Ibuprofen, 200 mg (Advil ®, Wyeth Consumer Healthcare), 1 - 2 tabs orally, every 4 to 6 hours, as needed for moderate pain control;
    c. Docusate sodium, 100 mg (Colace®, Purdue Pharma), 1 capsule orally, twice a day, as needed for constipation;
    d. Zinc sulfate monohydrate (0.5%) with hydrocortisone (0.5%) (Anusol HC Ointment®, Pfizer Consumer Healthcare) applied to the anal area for hemorrhoids, if applicable.
5. Upon discharge, women were also given a prescription for acetaminophen 300 mg with 30 mg codeine and 15 mg caffeine, which they could fill at their local pharmacy if required.

Outcome Measures

A research associate collected baseline ethno demographic and pain history data, while a nurse measured baseline vital signs prior to surgery and prior to first distant Reiki treatment. All personal patient information was de-identified by a numeric code to protect patient confidentiality.

The primary endpoint for the study was the Area Under The Curve (AUC) for pain (in movement) for days 1-3 using the Visual Analogue Scale (VAS)(20, 21), corresponding to a person's total pain. The VAS is a 10 cm line with an anchor at each end. Under the anchor on the left hand side is "0: no pain", and under the anchor on the right hand side is "10: worst pain". A research assistant collected two sets of pain scores three times each day (7:30-9:30am; 12noon-2:30pm; and 5:30-8:00pm). The two sets of pain scores corresponded to: the amount of pain felt at that moment in rest, and the amount of pain felt when moving. In addition, each morning, participants were asked to indicate the worst level of pain felt during the night.

Secondary endpoints included the following ten measures: AUC for pain in motion for days 1, 2 and 3 separately; the mean VAS (in motion) from days 1-3; the mean VAS (in rest) from days 1-3; the number of patients in need of opioid pain medication; the dose of codeine equivalent consumed per kilogram of body weight; the number of adverse events to opioids such as constipation or itchiness; mother's respiratory rate, heart rate, and blood pressure (systolic and diastolic); and the time-to-first activity (first hunger, first spontaneous voiding, first eating solid foods, first walk, etc) using a Milestone Questionnaire. The Milestone Questionnaire was previously used on women post elective caesarean section to evaluate their rate of healing (22). As Reiki is used not only for pain, but also to send "healing energy to where the body needs it most"(23), this activity milestone questionnaire was used to capture additional healing that could have taken place

Statistical Analysis

Reporting adhered to the CONSORT statement for reports of parallel-group randomized designs (24). Area Under the VAS-time Curve was calculated by plotting the VAS scores on the time scale and dividing the curve into a series of trapezoids (Figure 2). Opioid medications were converted to codeine equivalents (60 mg oral

codeine was considered equivalent to 10mg oral morphine and 6.7 mg oxycodone)(25)(26). All analyses were performed by intention-to-treat. We calculated that 40 participants per group would be required for the study to have 80% power to show a clinically significant 25% mean reduction in pain with distant Reiki as compared to placebo. A 25% mean pain reduction was determined *a priori* to be clinically relevant by our expert clinicians as the literature concludes that 20-33% reduction is considered clinically significant (27-29). For power analysis, we used a standard deviation in pain of 56% in the normal postoperative caesarean section population (30). Baseline demographic and outcome variables were compared using the Student's t-test, Mann-Whitney U test or Fisher's Exact test where appropriate. For missing data, we used the last-observation-carried-forward method in the analysis of AUC and mean pain scores.

RESULTS

One hundred and thirty women were eligible for participation in this study, 47 women were excluded (did not meet inclusion criteria, refused or did not speak English/Spanish) and 83 women were enrolled (Figure 1). A total of 42 women were randomized to receive distant Reiki and 41 women were randomized into the control group. Three women were withdrawn from the study after randomization: one woman (control group) was withdrawn as she suffered a severe hemorrhage during surgery and remained in the ICU for several days, leaving researchers unable to collect her pain score data; two participants were withdrawn from the distant Reiki group as they received general anesthesia instead of spinal anesthesia (thus, they no longer met inclusion criteria). This left a total of 40 women randomized into each group.

No patients mentally refused the distant Reiki intervention and the two groups did not differ significantly in baseline measures or demographic characteristics (Table 1) except for birth weight of newborns ($p<0.001$); differences between groups in maternal age approached significance ($p=0.06$).

Table 1: Demographic and Baseline Characteristics of the Participants

| Characteristics - number (%) | Reiki n=40 | Control n=40 | Difference mean (95% CI) | p value |
|---|---|---|---|---|
| Maternal Age (years) | | | | |
| mean ± sd | 35.1 ± 5 | 32.9 ± 6 | 2.2 (-0.3 to 4.7) | 0.06 |
| range | 21-44 | 19-44 | | |
| Number of Previous C-sections** | | | | |
| median | 1 | 1 | n/a* | 0.90 |
| range | 0-3 | 0-3 | | |
| Ethnicity* | | | | |
| Caucasian | 19 (47.5%) | 16 (40%) | n/a* | 0.51 |
| Asian | 12 (30%) | 14 (35%) | n/a* | |
| Hispanic | 3 (7.5%) | 7 (17.5%) | n/a* | |
| Afro Carribbean | 5 (12.5%) | 3 (7.5%) | n/a* | |
| Other (Iranian) | 1 (2.5%) | 0 | n/a* | |
| Self-reported pain tolerance: scale (1-10) | | | | |
| mean ± sd | 6.2 ± 2.1 | 6.6 ± 1.6 | -0.4 (-1.2 to 0.4) | 0.40 |
| range | 1-10 | 2-10 | | |
| Weight of Mom (kg) | | | | |
| mean ± sd | 83 ± 12.6 | 79 ± 15.5 | 4 (-2.3 to 10.3) | 0.22 |
| range | 54-111 | 54-145 | | |
| Previous Pregnancies | | | | |
| first time pregnancy* | 4 (10%) | 6 (10%) | | |
| >4 pregnancies* | 3 (7.5%) | 4 (10%) | | |
| mean ± sd | 2.8 ± 1.2 | 2.6 ± 1.2 | 0.2 (-0.3 to 0.7) | 0.40 |
| range | 1-6 | 1-6 | | |
| Number of children living** | | | | |
| median | 1 | 1 | n/a* | 0.94 |
| range | 0-4 | 0-3 | | |
| Duration of cesearean section surgery (minutes) | | | | |
| mean ± sd | 41.9 ± 11.9 | 45.3 ± 19.2 | -34 (-10.5 to 3.7) | 0.35 |
| range | 23-70 | 28-146 | | |
| Baby APGAR scores (1-10) | | | | |
| 1 minute (mean) ± sd | 8.7 ± 0.6 | 8.7 ±0.7 | 0 (-0.3 to 0.3) | 0.88 |
| 5 minutes (mean) ± sd | 9.1 ± 0.5 | 9.3 ± 0.5 | -0.2 (-0.4 to 0) | 0.15 |
| Weight of Newborn Babies (grms) | | | | |
| mean ± sd | 3579 ± 469 | 3228 ± 424 | 351 (152 to 550) | <0.001*** |
| range | 2745-5315 | 2625-4332 | | |
| no. of babies over 4000 grms | 5 (12.5%) | 4 (10%) | | |
| Gestational Age of babies (weeks) | | | | |
| mean ± sd | 38.5 ± 0.7 | 38.3 ± 0.6 | 0.2 (-0.1 to 0.5) | 0.08 |
| range | 37.5-40.5 | 37-39.5 | | |

* P values for ethnicity and number of pregnancies was determined by Fisher's exact test.
All other comparisons were determined using an unpaired t-test unless noted;
** denotes Mann Whitney U test for non-parametric data.
Self-reported pain tolerance scores were taken before the c-section. A score of "1" was low pain tolerance, while a score of "10" was high pain tolerance.
n/a* Not applicable to median or proportion calculations
***significance ($p<0.05$)

During days 1 and 2, a total of three pain scores, which represented less than 1% of the data, were not collected because the patients were sleeping during the time to record their level of pain; all other data for patients were captured (pain medication consumption, physiological measures and time to first activity) on these days. However on day 3, a total of 16 patients (20%), 8 from the distant Reiki group and 8 from the control group, were discharged early (after 48 hours instead of after 72 hours in hospital) resulting in 20% missing data (pain scores, pain medication consumption and time to first activity). AUC pain data was not compared between distant Reiki and control groups for day 3 alone due to the large amount of missing data.

No significant difference was seen between groups in the primary outcome of overall pain from days 1-3. The mean (±SD) AUC for pain for days 1-3 in the distant Reiki and control group were 212±104 and 223±118 respectively ($p = 0.96$). There were no significant differences between groups in AUC for pain for day 1 or day 2, mean VAS pain scores (in rest or in motion), use of opioids, dose (mg/kg body weight) of opioid medication consumed or time to first activity (Table 2). The main outcome and most secondary outcomes were normally distributed, with the notable exception of pain medication consumption and adverse events which were not normally distributed.

**Table 2: Outcomes for Days 1-3 (combined), Day 1 and Day 2 .**

| | Reiki Group (n=40) mean ± std dev[2] | Control Group (n=40) mean ± std dev[2] | Difference mean (95% CI) | Significance p |
|---|---|---|---|---|
| Area Under the Curve Pain Scores (in movement)[1] | | | | |
| Days 1-3 combined | 212.1 ± 104.7 | 223.1 ± 117.8 | -11 (-60.6 to 38.6) | 0.96 |
| Day 1 | 74.2 ± 39.6 | 79.7 ± 42.9 | -5.5 (-23.9 to 12.9) | 0.55 |
| Day 2 | 82.9 ± 41.5 | 84.5 ± 45.7 | -1.6 (-21.0 to 17.8) | 0.87 |
| Mean Pain Scores (centimenters) | | | | |
| Days 1-3 (in movement) | 3.1 ± 1.5 | 3.3 ± 1.7 | -0.2 (-0.9 to 0.5) | 0.61 |
| [2] Days 1-3 (in rest) (median, IQR) | 1.1 (0.4, 1.7) | 1.4 (0.6, 2.1) | n/a* | 0.32 * |
| Pain Medication Consumption (mg codeine equivalent/kg body weight[2] ) | | | | ? |
| Day 1 (median, IQR) | 0.7 (0,1.4) | 1.1 (0,2.0) | n/a* | 0.35 * |
| Day 2 (median, IQR) | 0.5 (0, 1.7) | 0.6 (0, 1.5) | n/a* | 0.36 ?* |
| Days 1-3 (median, IQR) | 1.7 (0, 3.12) | 1.7 (0, 4.4) | n/a* | 0.87 ?* |
| Patients on Opioids : number (percentage) | | | | |
| Day 1 | 24 (60) | 26 (65) | n/a* | 0.56 ** |
| Day 2 | 23 (58) | 21 (53) | n/a* | 0.56 ?** |
| Number of adverse events to codeine | | | | ? |
| Day 1 (median, IQR) | 0 (0,0) | 0 (0,1) | n/a* | 0.36 * |
| Day 2 (median, IQR) | 0 (0,0) | 0 (0,0) | n/a* | 0.84 ?* |
| Activity Milestone (hours) | | | | ? |
| Time to first hunger | 15.5 ± 18.9 | 10.9 ± 13.0 | 4.6 (-2.6 to 11.8) | 0.15 * |
| Time to first eating solid food | 23.6 ± 12.1 | 23.9 ± 12.3 | -0.3 (-5.7 to 5.1) | 0.88 |
| Time to first flatus | 19.8 ± 12.8 | 20.1 ± 12.4 | -0.3 (-5.9 to 5.3) | 0.92 |
| Time to first bowel movement | 57.7 ± 15.6 | 57.9 ± 16.7 | -0.2 (-7.4 to 7.0) | 0.95 |
| Time to first spontaneous voiding | 17.0 ± 5.5 | 17.7 ± 5.0 | -0.7 (-3.0 to 1.6) | 0.6 |
| Time to first ambulation | 16.9 ± 5.3 | 17.2 ± 5.2 | -0.3 (-2.6 to 2.0) | 0.82 |

| Physiology Measures | Reiki Group (n=40) mean ± std dev[2] | Control Group (n=40) mean ± std dev[2] | Difference mean (95% CI) | Significance p |
|---|---|---|---|---|
| Heart Rate (per minute) | | | | |
| Baseline - prior to surgery | 84.4 ± 9.4 | 84.8 ± 10.6 | -0.4 (-4.9 to 4.1) | 0.88 |
| Day 1 ( 4 hours post surgery) | 74.3 ± 8.1 | 79.8 ± 7.9 | -5.5 (-9.1 to -1.9) | 0.003*[3] |
| Difference btw Baseline to Day 1 (4 hrs post) | 10 ± 11.3 | 4.9 ± 11.5 | 5.1 (0.1 to 10.2) | 0.04*[3] |
| Day 1 - 8pm | 79.0 ± 7.8 | 79.6 ± 7.7 | -0.6 (-4.0 to 2.8) | 0.72 |
| Day 2 - 8 am | 80.5 ± 8.1 | 80.8 ± 7.8 | -0.3 (-3.8 to 3.2) | 0.84 |
| Day 2 - 8 pm | 81.3 ± 7.0 | 80.8 ± 6.1 | 0.5 (-2.4 to 3.4) | 0.73 |
| Day 3 - 8 am | 76.5 ± 8.7 | 77.6 ± 8.0 | -1.1 (-4.8 to 2.6) | 0.54 |
| Respiratory Rate (per min) | | | | |
| Baseline - prior to surgery | 18.3 ± 1.2 | 18.6 ± 0.8 | -0.3 (-0.8 to 0.2) | 0.19 |
| Day 1 ( 4 hours post surgery) | 19.0 ± 1.3 | 20.0 ± 4.6 | -1 (-2.5 to 0.5) | 0.17 |
| Day 1 - 8pm | 19.2 ± 0.9 | 20.0 ± 3.0 | -0.8 (-1.8 to 0.2) | 0.14 |
| Day 2 - 8 am | 19.4 ± 1.0 | 20.3 ± 6.5 | -0.9 (3.0 to 1.2) | 0.39 |
| Day 2 - 8 pm | 19.4 ± 1.0 | 20.1 ± 4.6 | -0.7 (-2.2 to 0.8) | 0.35 |
| Day 3 - 8 am | 19.5 ± 1.5 | 20.4 ± 5.5 | -0.9 (-2.7 to 0.9) | 0.35 |
| Diastolic Blood Pressure (mmHG) | | | | |
| Baseline - prior to surgery | 71.2 ± 8.6 | 71.3 ± 9.6 | -0.1 (-4.2 to 4.0) | 0.94 |
| Day 1 ( 4 hours post surgery) | 66.9 ± 8.2 | 67.3 ± 8.2 | -0.4 (-4.0 to 3.2) | 0.82 |
| Day 1 - 8pm | 65.8 ± 6.9 | 65.9 ± 8.9 | -0.1 (-3.6 to 3.4) | 0.94 |
| Day 2 - 8 am | 64.5 ± 7.2 | 65.8 ± 8.3 | -1.3 (-4.8 to 2.2) | 0.43 |
| Day 2 - 8 pm | 66.8 ± 8.6 | 64.6 ± 7.1 | 2.2 (-1.3 to 5.7) | 0.21 |
| Day 3 - 8 am | 64.9 ± 7.6 | 67.7 ± 7.8 | -2.8 (-6.2 to 0.6) | 0.09 |
| Systolic Blood Pressure (mmHG) | | | | |
| Baseline - prior to surgery | 120.1 ± 11.7 | 118.1 ± 15.7 | 2 (-4.2 to 8.2) | 0.52 |
| Day 1 ( 4 hours post surgery) | 107.8 ± 10.9 | 109.4 ± 12.1 | -1.6 (-6.7 to 3.5) | 0.54 |
| Day 1 - 8pm | 107.8 ± 9.7 | 107.3 ± 12.9 | 0.5 (-4.6 to 5.6) | 0.85 |
| Day 2 - 8 am | 104.0 ± 10.3 | 106.9 ± 10.3 | -2.9 (-7.5 to 1.7) | 0.21 |
| Day 2 - 8 pm | 110.3 ± 11.3 | 106.0 ± 10.8 | 4.3 (-0.6 to 9.2) | 0.08 |
| Day 3 - 8 am | 106.4 ± 9.7 | 111.9 ± 11.0 | -5.5 (-10.1 to -0.9) | 0.02*[3] |
| Difference: baseline to Day 3 @8am | 13.7 ± 14.4 | 6.2 ± 13.3 | 7.5 (1.3 to 13.7) | 0.02*[3] |

[1] Area Under the Curve (AUC) pain scores were calculated by taking the trapezoidal area after measuring pain scores from the VAS 10.0cm scale.
[2] Values are means ± standard deviation unless otherwise noted. Values were calculated based on 40 participants in each group.
[3] Signficance defined as $p<0.05$
Significance tests measured using student's t-test unless noted: Mann-Whitney test (*) or Fisher's Exact Test (**).
? All Opioid Medication equivalized to mg Codeine as described in the Methods section.
n/a* Not applicable to median and interquartile range

To determine if the two variables which varied between the two groups (baby birth weight and mother's age) affected the primary outcome, we performed multivariate regression analysis with three independent variables; mother's age, baby's birth weight, and group allocation were regressed against the dependent variable: AUC of pain for days1-3. Both baby's birth weight and mother's age were found to be significant (p=0.013, p=0.046 respectively), while the distant Reiki group allocation was still not significant (p=0.558).

There was a small but significant difference in heart rate on day 1, four hours after C-section (see Figure 3 for timeline), whereby the mean (±SD) heart rate in the distant Reiki group was 74.3±8.1 bpm compared to 79.8±7.9 bpm in the control group (p = 0.003). Systolic blood pressure on day 3 at 8am was also significantly lower in the distant Reiki group (106.4±9.7 mmHg) compared to the control group (111.9±11.0 mmHg) (p = 0.02). Otherwise, there were no significant differences between groups in the physiological measures.

There were no significant differences in the rates of adverse events between the two groups.

## DISCUSSION

This study measured perceived pain and healing in women over their three days in hospital, while they recovered from elective caesarean section. We found no beneficial effect of distant Reiki over usual care for pain reduction up to three days after elective caesarean section.

The lack of an observed benefit of distant Reiki for all pain outcome measures at all points in time is in contrast to most (12-15), but not all (31), earlier Reiki pain studies. However, unlike all earlier published studies, our study differed in two key regards: firstly, ours was the only randomized and double-blinded trial. In addition to the patients not knowing their group assignment, the investigators and outcome assessors were unaware of the intervention assignment. This suggests that the therapeutic benefit of Reiki for pain observed in previous, non-blinded studies was a placebo effect or that the magnitude of pain from an elective caesarean section is too great for distant Reiki to make an impact.

Secondly, we employed distant Reiki and not traditional hands-on Reiki as our intervention. In considering the physiological effects of Reiki, one of the basic teachings of healing with Reiki is that we are more than our physical bodies. We also have an energy body made up of our aura (energy fields), the chakras (energy centers) and the meridians (energy pathways.) Because Reiki healers believe that Reiki energy is not limited by time and distance, distant Reiki healings can also be given without the client being present (18). Reiki practitioners assert that a distant Reiki intervention works by directing healing energy which engages the body by generating biological reactions such as pain reduction.

It is well accepted that many constituents of living systems communicate with each other via electromagnetic signals. A number of studies have demonstrated that weak electromagnetic fields (EMF) are capable of eliciting in vivo and in vitro effects from different biological systems. Endogenous electromagnetic and magnetic fields are associated with many basic physiological processes ranging from ion binding and molecular conformation in the cell membrane to the macroscopic mechanical properties of tissues (32-41).

In an attempt to validate energy therapies such as Reiki, researchers have been measuring classical electromagnetic (EM) fields emitted by the body using both physical (42-45) and biologic (46) detectors. However, the intensity of these fields fade rapidly with distance, and thus cannot explain the effect of distant Reiki.

One author (47) has proposed that in addition to classical EM fields, the body generates non-classical and quantum fields, which do not fade with distance. Several studies have shown that quantum fields can influence neurological (48) and immunological functions (49) at the cellular level. However, the idea that Reiki energy works through quantum fields is highly controversial and more scientific trials need to be conducted in this area.

Another possible explanation for the lack of observed effect is the study's sample size. Based on our calculations, the distant Reiki would have had needed to have an effect size of 0.55; however, based on the AUC for pain, distant Reiki had an effect size of 0.1 which is considered to be very small. Using this effect size, a total of 2,530 patients (1,265 per group) would have been needed to see a significant difference between

groups. It is unlikely that the failure to find significant differences is due to selection bias as only 10 women (12.5%) refused to participate in the study.

The Milestone Questionnaire which recorded time-to-first activity also showed no differences between groups. We evaluated these responses against the measures obtained by Roseag and colleagues (22) and found all rates of healing to be similar to their published results, except for time-to-first eating solid foods, where our study showed an average 10 hours longer for both groups. This could be due to the fact that St. Michael's Hospital does not routinely allow women to eat solid foods until after they have passed gas, regardless of whether or not they are hungry.

Despite randomization, there was a statistically significant difference between the two groups in birth weight; differences in maternal age approached significance. Our finding that a mother's perceived pain decreases with maternal age is consistent with previous studies (50, 51). However, we could not find any literature to support or refute the finding that larger babies born via elective c-section caused more pain. The increase in mothers' pain could be due to larger uteri which housed larger babies, thereby resulting in more pain as they contracted back to normal. In addition, lifting heavier babies post surgery could result in more pain for a recovering mother.

Heart rate taken approximately 4 hours after caesarean section and systolic blood pressure taken on day 3 at 8am (Table 2) were significantly lower in the distant Reiki group compared to the control group. This is consistent with three studies (13), two of which (52)(53) specifically examined the physiological changes as a result of distant Reiki. However, given that distant Reiki's method of action is unknown, there is the possibility that our findings are simply due to chance given the number of secondary measures evaluated. The small but statistically significant benefits of lower heart rate and blood pressure levels are unlikely to be clinically significant, but may be interesting to future researchers who are searching for a mechanism of action for distant Reiki.

The generalizability of our study may be limited given that one Reiki Master performed all of the distant Reiki treatments; in addition given the absence of information about the mechanism of action of distant Reiki,

we chose the same dosage as a published pain trial using traditional Reiki (12). Outcomes may differ given other Reiki practitioners and other dosage regimes.

## CONCLUSION

In conclusion our trial showed no significant benefit of distant Reiki (administered once per day) over usual care for pain management in the first three days after elective caesarean section. It is not recommended as a method of primary pain relief for women undergoing elective caesarean section.

## CONTRIBUTION & ACKNOWLEDGEMENTS

SV and GK conceived the study. SV, HB, VMGJG, SNdW, AT and GK designed the study. SV, CT, YIG and VNGJG acquired the data. SV and GK analysed the data. SV drafted the article. All authors interpreted the data, revised the article critically for important intellectual content, and approved the final version.

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## COMPETING INTERESTS

SV is a Reiki practitioner. All other authors have nothing to declare.

## ETHICS APPROVAL

This study was approved by the Review Ethics Board (REB) at St. Michael's Hospital in Toronto, Ontario. Approval was given on May 12, 2008 and the reference number is REB08-030.

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