

The effect of distant reiki on pain in women after elective Caesarean section: a double-blinded randomised controlled trial

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ABSTRACT

Introduction: Approximately 25% of all babies in North America are delivered via Caesarean section (C-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 being sought. 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, the authors used distant reiki to assess its effectiveness in reducing pain following an elective C-section.

Methods: In this randomised, 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 1–3. Secondary measures included: the proportion of women who required opioid medications and 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 mm Hg vs 111.9±11.0 mm Hg, p=0.02) post surgery.

Conclusion: Distant reiki had no significant effect on pain following an elective C-section.

Clinical Trial Registration Number: ISRCTN79265996.

ARTICLE SUMMARY

Article focus

- This is the first randomised, double-blinded trial conducted on distant reiki.
- The focus is on distant reiki's effects on pain after Caesarean section.
- Special attention was paid to the methods of proper randomisation, patient allocation concealment and blinding.

Key messages

- Our trial suggests that distant reiki had no benefit in reducing patients' postpartum 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 maintained a high adherence to protocol, successful blinding of the research team, successful randomisation 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 h, 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.

Distant reiki for pain after elective C-section

INTRODUCTION

Approximately 25% of all babies in North America are delivered via Caesarean section (C-section)¹; alleviating pain early is important, as studies have shown that postoperative pain negatively affects a mother's ability to care for and breastfeed her infant.² To alleviate postoperative pain, opioids are commonly used after C-section.³ For example, codeine, a common opioid, is a prodrug, and it is the relative biotransformation of codeine into morphine by the highly polymorphic cytochrome P450 enzyme 2D6 (CYP2D6) that is the 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 no 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 6 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 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 practised 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 complementary and alternative medicine therapy for 2010.'¹¹ However, while it is commonly practised, 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 practised 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. Second, 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^{12–15}; 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 Jadad⁸; 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 owing 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 C-section, through a randomised double-blinded study.

METHODOLOGY

Study design

This was a double-blinded randomised 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 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 C-section were approached during a routine prenatal visit at the obstetrical clinic at St Michael's

Hospital between 1 September 2008 and 31 March 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 who 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 (SvdV) enrolled participants and then contacted the research assistant (YIG) at The Hospital for Sick Children with the participant's information (unique Hospital ID, date and time of C-section) for randomisation. YIG had previously generated the randomised number sequence in blocks of four or six. Participants were sequentially assigned (by YIG) to the random sequence, which was securely stored and password-protected on the Hospital for Sick Children 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 h). The intervention group received usual care plus three distant reiki sessions, one each morning. The first session was administered on the morning of the C-section, at least 30 min prior to surgery, and the second and third sessions were administered on the following mornings at approximately 08:00.

A single reiki master located over 100 km away, who was trained in the Usui line of reiki and has been practising reiki for over 10 years and regularly treats clients with distant reiki, administered the distant reiki interventions. Each distant reiki session lasted approximately 20 min, 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.

C-section, anaesthesia and analgesia protocol

All elective C-sections at St Michael's Hospital were performed using the Pfannenstiel protocol.¹⁹ Women who underwent elective C-sections received spinal anaesthesia with 0.75% bupivacaine, and 15 µg of fentanyl lasting 2–4 h followed by 100 µg of epidurally administered morphine, which typically lasts 12 h. Vital signs were checked, and pain and sedation scores were taken every 10 min for 2 h after the C-section. Following these 2 h, vital signs were taken every 12 h on the delivery ward.

The following analgesia protocol was administered immediately following the C-section:

1. Naproxen (500 mg) was given rectally and then orally every 12 h for 48 h.
2. For breakthrough pain: acetaminophen (300 mg) with codeine (30 mg) and caffeine (15 mg) (Tylenol

no 3, Johnson & Johnson, New Brunswick, New Jersey), 1–2 tabs orally, every 4 h, as needed.

- a. patients who could not tolerate acetaminophen with codeine were given either acetaminophen (325 mg) with oxycodone (5 mg) (Percocet, Endo Pharmaceuticals, Chadds Ford, Pennsylvania) 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 h, as needed.
 4. Forty-eight hours after the C-section, the women received a self-medication package. This package included:
 - a. acetaminophen, 325 mg (Tylenol, Johnson & Johnson), 1–2 tabs orally, every 4–6 h, as needed for mild pain control;
 - b. ibuprofen, 200 mg (Advil, Wyeth Consumer Healthcare, Richmond, Virginia), 1–2 tabs orally, every 4–6 h, as needed for moderate pain control;
 - c. docusate sodium, 100 mg (Colace, Purdue Pharma, Stamford, Connecticut), 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, Morris Plains, New Jersey) applied to the anal area for haemorrhoids, if applicable.
 5. Upon discharge, women were also given a prescription for 300 mg of acetaminophen with 30 mg of codeine and 15 mg of caffeine, which they could complete at their local pharmacy if required.

Outcome measures

A research associate collected baseline ethnographic 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 deidentified 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 (07:30–09:30; 12:00–14:30; and 17:30–20:00). 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 10 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

Distant reiki for pain after elective C-section

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 the Milestone Questionnaire. The Milestone Questionnaire was previously used on women post elective C-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 Consolidated Standards of Reporting Trials statement for reports of parallel-group randomised designs.²⁴ The Area Under the VAS-Time Curve was calculated by plotting the VAS scores on the timescale and dividing the curve into a series of trapezoids (figure 1). Opioid medications were converted to codeine equivalents (60 mg of oral codeine was considered equivalent to 10 mg of oral morphine and 6.7 mg of 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 with placebo. A 25% mean pain reduction was determined a priori to be clinically relevant by our expert clinicians, since the literature concludes that 20–33% reduction is considered clinically significant.^{27–29} For power analysis, we used an SD in pain of 56% in the normal postoperative

C-section population.³⁰ Baseline demographic and outcome variables were compared using the Student t test, Mann–Whitney U test or Fisher 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 2). A total of 42 women were randomised to receive distant reiki, and 41 women were randomised into the control group. Three women were withdrawn from the study after randomisation: one woman (control group) was withdrawn, as she suffered a severe haemorrhage 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 anaesthesia instead of spinal anaesthesia (thus, they no longer met inclusion criteria). This left a total of 40 women randomised into each group.

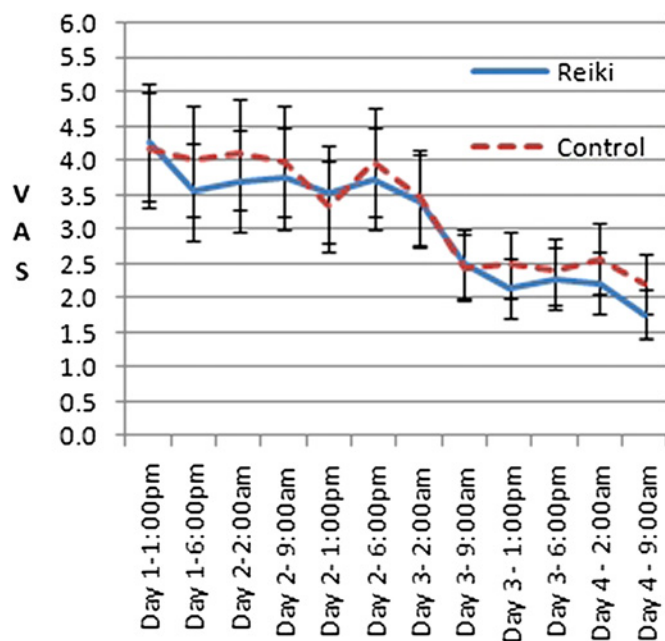


Figure 1 Visual analogue scores (VAS) for pain in movement after Caesarean section for women receiving distant reiki (Reiki) and usual care (control). Values are means (n=40)±SD.

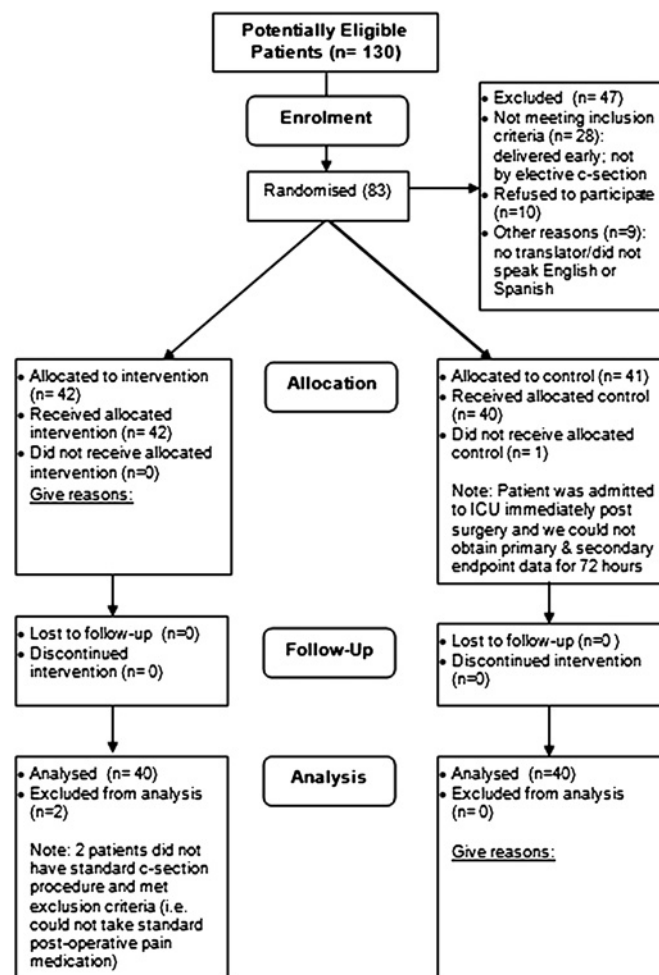


Figure 2 Patient recruitment and analysis: the Consolidated Standards of Reporting Trials E-flow chart.

Table 1 Demographic and baseline characteristics of the participants

Characteristics; no (%)	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 to 44	19 to 44		
No of previous C-sections†				
Median	1	1	NA	0.90
Range	0 to 3	0 to 3		
Ethnicity*				
Caucasian	19 (47.5%)	16 (40%)	NA	0.51
Asian	12 (30%)	14 (35%)	NA	
Hispanic	3 (7.5%)	7 (17.5%)	NA	
Afro Carribean	5 (12.5%)	3 (7.5%)	NA	
Other (Iranian)	1 (2.5%)	0	NA	
Self-reported pain-tolerance score: scale (1 to 10)				
Mean±SD	6.2±2.1	6.6±1.6	−0.4 (−1.2 to 0.4)	0.40
Range	1 to 10	2 to 10		
Weight of mother (kg)				
Mean±SD	83±12.6	79±15.5	4 (−2.3 to 10.3)	0.22
Range	54 to 111	54 to 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 to 6	1 to 6		
No of children living‡				
Median	1	1	NA	0.94
Range	0 to 4	0 to 3		
Duration of Caesarean section surgery (min)				
Mean±SD	41.9±11.9	45.3±19.2	−34 (−10.5 to 3.7)	0.35
Range	23 to 70	28 to 146		
Baby Apgar scores (1 to 10)				
1 min (mean)±SD	8.7±0.6	8.7±0.7	0 (−0.3 to 0.3)	0.88
5 min (mean)±SD	9.1±0.5	9.3±0.5	−0.2 (−0.4 to 0)	0.15
Weight of newborn babies (g)				
Mean±SD	3579±469	3228±424	351 (152 to 550)	<0.001‡
Range	2745 to 5315	2625 to 4332		
No of babies over 4000 g	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 to 40.5	37 to 39.5		

*p Values for comparisons of ethnicity and number of pregnancies was determined by Fisher exact test. All other comparisons were determined using an unpaired t test unless noted.

†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.

‡Significance (p<0.05).

NA, not applicable to median or proportion calculations.

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).

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%), eight

from the distant reiki group and eight from the control group, were discharged early (after 48 h instead of after 72 h in hospital) resulting in 20% missing data (pain scores, pain medication consumption and time to first activity). AUC pain data were not compared between distant reiki and control groups for day 3 alone, owing 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) AUCs 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,

Distant reiki for pain after elective C-section

Table 2 Outcomes for days 1–3 (combined), day 1 and day 2

	Reiki group (n=40) Mean±SD†	Control group (n=40) Mean±SD†	Difference mean (95% CI)	Significance§ p value
Area Under the Curve Pain Scores (in movement)*				
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 (cm)				
Days 1–3 (in movement)	3.1±1.5	3.3±1.7	–0.2 (–0.9 to 0.5)	0.61
Days 1–3 (in rest) (median, IQR)‡	1.1 (0.4 to 1.7)	1.4 (0.6 to 2.1)	NA	0.32* §
Pain medication consumption (mg of codeine equivalent/kg body weight¶)				
Day 1 (median, IQR)	0.7 (0 to 1.4)	1.1 (0 to 2.0)	NA	0.35* §
Day 2 (median, IQR)	0.5 (0 to 1.7)	0.6 (0 to 1.5)	NA	0.36* §
Days 1–3 (median, IQR)	1.7 (0 to 3.12)	1.7 (0 to 4.4)	NA	0.87* §
Patients on opioids: no (%)				
Day 1	24 (60)	26 (65)	NA	0.56** §
Day 2	23 (58)	21 (53)	NA	0.56** §
No of adverse events to codeine				
Day 1 (median, IQR)	0 (0 to 0)	0 (0 to 1)	NA	0.36* §
Day 2 (median, IQR)	0 (0 to 0)	0 (0 to 0)	NA	0.84* §
Activity milestone (h)				
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)	0.60
Time to first ambulation	16.9±5.3	17.2±5.2	–0.3 (–2.6 to 2.0)	0.82
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 h post surgery)	74.3±8.1	79.8±7.9	–5.5 (–9.1 to –1.9)	0.003‡
Difference between baseline and day 1 (4 h post)	10±11.3	4.9±11.5	5.1 (0.1 to 10.2)	0.04‡
Day 1—20:00	79.0±7.8	79.6±7.7	–0.6 (–4.0 to 2.8)	0.72
Day 2—08:00	80.5±8.1	80.8±7.8	–0.3 (–3.8 to 3.2)	0.84
Day 2—20:00	81.3±7.0	80.8±6.1	0.5 (–2.4 to 3.4)	0.73
Day 3—08:00	76.5±8.7	77.6±8.0	–1.1 (–4.8 to 2.6)	0.54
Diastolic blood pressure (mm Hg)				
Baseline—prior to surgery	71.2±8.6	71.3±9.6	–0.1 (–4.2 to 4.0)	0.94
Day 1 (4 h post surgery)	66.9±8.2	67.3±8.2	–0.4 (–4.0 to 3.2)	0.82
Day 1—20:00	65.8±6.9	65.9±8.9	–0.1 (–3.6 to 3.4)	0.94
Day 2—08:00	64.5±7.2	65.8±8.3	–1.3 (–4.8 to 2.2)	0.43
Day 2—20:00	66.8±8.6	64.6±7.1	2.2 (–1.3 to 5.7)	0.21
Day 3—08:00	64.9±7.6	67.7±7.8	–2.8 (–6.2 to 0.6)	0.09
Systolic blood pressure (mm Hg)				
Baseline—prior to surgery	120.1±11.7	118.1±15.7	2 (–4.2 to 8.2)	0.52
Day 1 (4 h post surgery)	107.8±10.9	109.4±12.1	–1.6 (–6.7 to 3.5)	0.54
Day 1—20:00	107.8±9.7	107.3±12.9	0.5 (–4.6 to 5.6)	0.85
Day 2—08:00	104.0±10.3	106.9±10.3	–2.9 (–7.5 to 1.7)	0.21
Day 2—20:00	110.3±11.3	106.0±10.8	4.3 (–0.6 to 9.2)	0.08
Day 3—08:00	106.4±9.7	111.9±11.0	–5.5 (–10.1 to –0.9)	0.02‡
Difference: baseline to day 3 at 08:00	13.7±14.4	6.2±13.3	7.5 (1.3 to 13.7)	0.02‡

*Area Under the Curve pain scores were calculated by taking the trapezoidal area after measuring pain scores from the VAS 10.0 cm scale.

†Values are means±SD unless otherwise noted. Values were calculated based on 40 participants in each group.

‡Significance defined as $p < 0.05$.

§Significance tests measured using Student t test unless noted: Mann–Whitney test (*) or Fisher exact test (**).

¶Opioid conversion described in Methodology section.

NA, not applicable to median and IQR.

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.

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 a 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 days 1–3. 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, 4 h after C-section (see figure 3 for timeline), whereby the mean (\pm SD) heart rate in the distant reiki group was 74.3 ± 8.1 bpm compared with 79.8 ± 7.9 bpm in the control group ($p=0.003$). Systolic blood pressure on day 3 at 08:00 was also significantly lower in the distant reiki group (106.4 ± 9.7 mm Hg) compared with the control group (111.9 ± 11.0 mm Hg) ($p=0.02$). Otherwise, there were no significant differences between groups in the physiological measures.

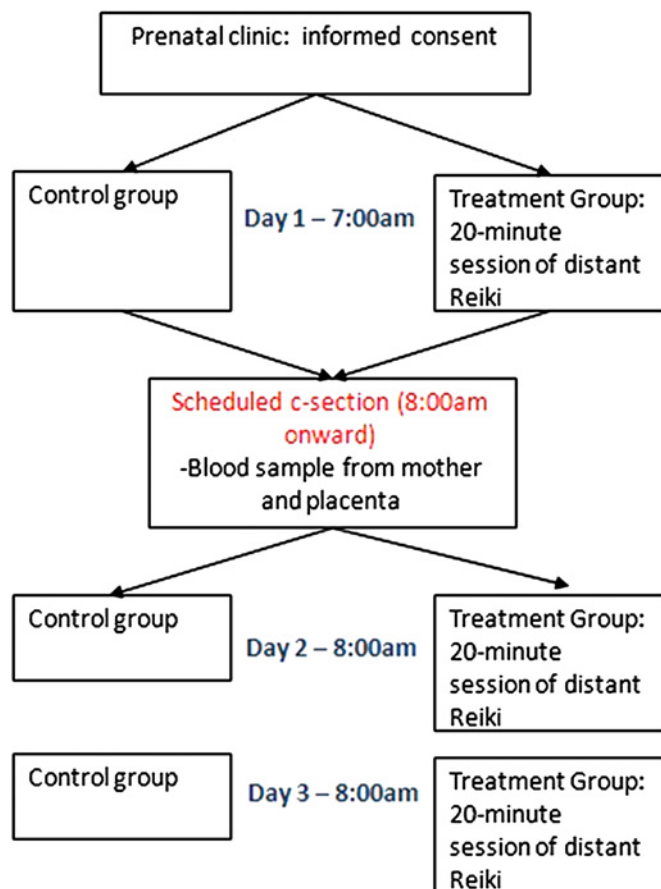


Figure 3 Timeline for surgery, first distant reiki treatment and vital measures time.

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 3 days in hospital, while they recovered from an elective C-section. We found no beneficial effect of distant reiki over usual care for pain reduction up to 3 days after elective C-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 randomised 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 C-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 centres) 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 biological⁴⁶ detectors. However, the intensity of these fields fades rapidly with distance, and thus cannot explain the effect of distant reiki.

One author⁴⁷ 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 neurological⁴⁸ and immunological functions⁴⁹ at the cellular level. However, the idea that reiki energy works through quantum fields is highly controversial,

Distant reiki for pain after elective C-section

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 2530 patients (1265 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 of 10 h 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 randomisation, 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 h after C-section and systolic blood pressure taken on day 3 at 08:00 (table 2) were significantly lower in the distant reiki group compared with the control group. This is consistent with three studies,¹³ two of which^{52 53} specifically examined the physiological changes as a result of 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 generalisability 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 that in a published 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 3 days after elective C-section. It is not recommended as a method of primary pain relief for women undergoing an elective C-section.

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Competing interests SvdV is a reiki practitioner.

Ethics approval This study was approved by the Review Ethics Board (REB) at St Michael's Hospital in Toronto, Ontario.

Contributors SvdV and GK conceived the study. SvdV, HB, VMGJG, SNdW, AT and GK designed the study. SvdV, CT, YIG and VNGJG acquired the data. SvdV and GK analysed the data. SvdV drafted the article. All authors interpreted the data, revised the article critically for important intellectual content and approved the final version. GK had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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The effect of distant reiki on pain in women after elective Caesarean section: a double-blinded randomised controlled trial

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