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Samantha L. Ciaccia

Philadelphia College of Osteopathic Medicine, samanthaci@pcom.edu

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**Does Reiki therapy decrease pain during chemotherapy and radiation
treatment in patients with gynecological and breast cancer?**

Samantha L. Ciaccia, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not Reiki therapy decreases pain during chemotherapy and radiation treatment in patients with gynecological and breast cancer.

Study Design: Review of two randomized control trials and one randomized prospective cross-over study published in 2003, 2004, and 2011.

Data Sources: One double blind randomized control trial, one 2-arm single blind randomized control trial and one randomized, prospective, 2-period crossover intervention study comparing Reiki therapy to placebo. Articles were found using PubMed and Medline.

Outcomes Measured: Pain by BPI (brief pain inventory linear analog scale), SF-36 questionnaire, daily log of medication use, HTCQ linear scale, and Well-being analog scale.

Results: The study by Caitlin et al showed a slight increase in physical comfort in patients who received Reiki therapy verses those who received standard care during chemotherapy. However, sham Reiki therapy showed a statistically significant increase in physical comfort from an attentive presence of a designated nurse at the bedside. According to Cook et al, Reiki therapy showed a statistically significant decrease in a patient's pain level verses a patient receiving standard care for radiation therapy. In addition, Reiki and Massage therapy was more effective at reducing pain in one 45-minute intervention (short-term relief) than a patient who received standard care shown in a study conducted by Post-white et al.

Conclusions: Results from the three studies showed a decrease in pain when Reiki therapy is administered during radiation and chemotherapy. However, one study concluded there is no statistical difference in pain management when comparing Reiki therapy and sham Reiki. Another study discovered both Reiki and Massage therapy decreased pain when compared to standard care. In conclusion, there is no convincing evidence that Reiki therapy alone relieves pain, however, human touch with or without energy transfer showed positive benefits. Thus, further studies with adequate sample sizes, non-biased participants, and a greater variety of subjects from different treatment centers should be considered to determine if this alternative approach reduces pain.

Key Words: Reiki therapy + gynecological cancer + pain reduction

INTRODUCTION

Reiki therapy is an alternative approach to healing by lying on hands and transferring unseen life force energy to another person, promoting health and pain relief. The Japanese word Reiki stands for, spiritually guided life force energy.¹ If the patient's life force energy is low, they are more likely to feel stressed or get sick. On the contrary, if their energy is high, they are likely to be healthier and happy. This paper evaluates one double blind, one single blind randomized control trials and one randomized prospective, 2-period, cross over intervention study comparing the efficacy of Reiki therapy in relieving pain in women who suffered from gynecological or breast cancer.

Female gynecological including breast cancer is the most common cancer in American women after skin cancer and the second leading cause of death in women.² Majority of women are treated with chemotherapy and radiation to eradicate the cancer cells. Even though the traditional approach to eliminating cancer is effective, side effects such as pain become an issue and interfere with the patient's life and well being. Knowledge of alternative therapies for pain relief is of importance to Physician Assistants because patients who are unable, or choose not take the traditional route (narcotics) will ask for another approach. Data showed that 1-year health care cost per patient diagnosed with breast cancer was \$42,401, which included 12%, 86%, and 2% of the total for inpatient, outpatient, and prescription use.³ The exact number of healthcare visits each year is unknown. However, in 2008, 210,203 women in the United States were diagnosed with breast cancer.⁴ Knowledge of these findings are important to the Physician Assistant as they will encounter many breast and gynecological cancer patients.

Symptoms of breast cancer are palpable mass in the breast during a self breast exam, dimpling or change in skin appearance of the breast and nipple. The cause of female

gynecological and breast cancer is a combination of genetics and environmental factors. However, only 5-10% of breast cancer diagnoses are from a genetic predisposition. Tumor suppressor gene p53, BRCA-1 and BRCA-2 have been identified and thought to increase the incidence of breast cancer.⁵ Specifically, germline mutations in BRCA-1 and BRCA-2 have a 60-80% chance of developing breast cancer and 33% for ovarian cancer in their lifetime.⁵ However, majority of the breast cancer cases are sporadic and incidence increases with age. 53% of breast cancer diagnosis have the p53 mutation.⁵ In addition, over expression of the oncogene erbB2 (HER/2 neu) is present in 25% of breast cancer cases.⁵ It is evident that genetics plays a role in the development of breast cancer but is not the only factor to consider. Major risk factors such as age of first menarche, nulliparity, poor diet, obesity, age of menopause, and long term use of hormonal therapy also play a role in development of breast cancer. Women who have menarche at 16 years only have 50-60% of the breast cancer risk of a woman having menarche at 12 years.⁵ In addition, women who experience menopause 10 years before the median age of 52 years, have a decrease in breast cancer incidence by 35%.⁵ These facts are based on the increased exposure time to estrogen and progesterone throughout a woman's life. Studies have shown that prolonged use of hormonal replacement therapy (HRT) greatly increases the risk of developing breast cancer. Data from the Women's Health Initiative (WHI) suggests women on HRT for 6 to 7 years doubles the risk of breast cancer.⁵

Treatment for breast cancer is based on the staging: TNM (primary tumor, regional nodes, and metastasis). The first approach is to decide whether the woman is a candidate for breast conservation surgery (lumpectomy) or mastectomy. Generally tumors greater than 5cm, history of collagen vascular disease, tumors involving the nipple areola complex or with extensive intraductal disease involving multiple quadrants of the breast, and for women who do

not wish to have a lumpectomy are medically advised to undergo a mastectomy. Currently, one-third of women in the United States are managed by lumpectomy.⁵ Following surgery, chemotherapy adjuvant with hormonal therapy and radiation is recommended. Studies have shown that the use of systemic therapy after local management significantly improves survival.⁵ For example, premenopausal women are recommended to have multidrug chemotherapy such as anthracycline or paclitaxel, along with tamoxifen if the tumor is ER-positive and trastuzumab in HER2/neu-positive tumors regardless of their lymph node status, and tumor size.⁵ Similarly, postmenopausal women with lymph node involvement and an ER-positive tumor are recommended to take systemic chemotherapy followed by an aromatase inhibitor and tamoxifen.⁵

Despite the suggested treatment options, the patient may experience pain whether it is from the cancer itself or the administered treatment (chemotherapy and/or radiation therapy). Instead of continual use of NSAIDs or opiates, which have long term side effects such as ulcers, constipation, addiction and inadequate pain control, Reiki therapy is an alternative suggestion to relieve pain and increase the patient's quality of life.

OBJECTIVE

The objective of this systematic review is to determine whether or not Reiki therapy decreases pain during chemotherapy and radiation treatment in patients with gynecological and breast cancer.

METHODS

Specific selection criteria for these randomized control trials (RCT) and cross-over studies were used for this review. The population chosen was women diagnosed with gynecological or breast cancer undergoing chemotherapy and/or radiation therapy. The

interventions utilized in each study were Reiki therapy (healing touch). Comparisons were made between Reiki therapy to a placebo^{6,7} and/or Massage therapy and standard care⁸. Outcomes measured were based on patient oriented evidence that matters (POEMs) specifically, the efficacy of Reiki therapy in reducing pain. Pain was measured by a well-being analog scale, daily log for pain medication use, BPI (brief pain inventory linear analog scale), HRQoL and SF-36 questionnaire. The study types included one double blind, one single blind randomized control trials and one randomized prospective, 2-period, cross over intervention study.

Key words used in the searches were “Reiki therapy”, “gynecological cancer”, and “pain reduction”. All articles were published in peer-reviewed journals and in the English language. The author researched the articles through PubMed and Medline and selected them based on POEMs. English speaking participants over the age of 17 years diagnosed with gynecologic or breast cancer was included. Women with end-stage cancer, who received Reiki therapy in the past and all other cancers not associated with breast or gynecological were excluded. The statistics used in the studies to evaluate the patient outcomes included: p-value, X difference, t-test.

Table 1: Demographics & characteristics of studies

Study	Type	# Pt	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Catlin ⁴ (2011)	Double blind RCT	189	> 18	- >18 yo -diagnosed with cancer -English speaking	N/A	0	20 minutes of Reiki therapy
Cook ⁵ (2004)	2-arm Single blind RCT	78	>17	-Newly diagnosed with gynecological or breast cancer - >17 yo -Women have completed no more than one third of their radiation	-Women with end-stage cancer whose condition had a reasonable likelihood of rapid deterioration.	16	6 sessions of Reiki therapy

				therapy.	-Women who received Healing therapy (HT) in the past		
Post-White ⁶ (2003)	Randomized, prospective, 2-period, cross over intervention study.	230	27-83	-Adult patients from 2 outpatient Midwestern chemotherapy clinics who had a histological documented cancer diagnosis. -Were receiving chemotherapy with an identical repeating cycle for 2 or more remaining cycles. -Presents with pain, nausea, or fatigue rated 3 or more on a scale of 0 to 10 (where 10 is worst imaginable) -Were able to read and write English & give informed consent.	N/A	66	4 weeks of either Massage therapy (MT), Reiki therapy (HT), or caring presence (P) with sessions lasting 45 minutes. Followed by 4 weeks of standard care.

OUTCOMES MEASURED

The outcomes measured were based on the HTCQ linear scale, Well-being analog scale, BPI (brief pain inventory linear analog scale), SF-36 questionnaire, and daily log of medication use. Caitlin et al evaluated pain reduction by having the subjects complete a pre-test, then blindly administering 20 minutes of intervention whether it was Reiki, sham Reiki, or standard care. Neither the nurses nor patients knew which therapy was administered that day. After the session was over, patients filled out a short demographic form as well as the HTCQ and Well-

being Analog Scale.⁶ The HTCQ linear scale measures 35 items describing comfort states. 14 questions were selected and created by expert practitioners in the field and items from the healing touch literature that could be easily scored by patients during their chemotherapy treatment.⁶ The scale ranges from 1 (strongly disagree) to 6 (strongly agree). This scale is used to study the relationship of comfort and alternative medicine in patients with breast cancer receiving radiation therapy.⁶ The Well-being Analog scale was developed to assess the well-being of patients with cancer in relation to therapeutic touch treatments. The patient places a mark between 0 and 10, which correlates with how much pain is felt to the level of general well being, 0 being no pain and 10 being the worst.⁶

Cook et al evaluated pain by using the SF-36 questionnaire which measures the HRQoL at baseline and after the final treatment. The patients were randomly assigned to the Healing touch (HT) treatment group or Mock therapy (MT) group. The study coordinator was also blinded to which group of treatment providers administered HT or MT. After six sessions of either HT or MT, the patients were asked to fill out an SF-36 questionnaire. The 36 items measured are related to 9 health-related domains: physical functioning, physical role functioning, pain, general health, vitality, social functioning, emotional role functioning, mental health, health transition.⁸

Post-White et al used Brief Pain Index (BPI), Brief Nausea Index (BNI), fatigue, anxiety, and mood disturbance by Profile of Mood States (POMS).⁸ All patients received 4 weekly 45-minute sessions of either Healing therapy (HT), Massage Therapy (MT), or caring presence (P). After 4 weeks, the patients crossed over, receiving the alternate therapy for 4 weeks, totaling an 8 week study. Before and after each session, patients filled out an assessment of their vital signs, report of their current pain and nausea status.⁸ The BPI has been used in pain research and found

reliable to assess levels of pain and pain relief from various interventions.⁸ Pain was rated on a linear analog scale ranging from 0 (no pain) to 10 (worst possible pain). Analgesics and antiemetic use was recorded daily and calculated as total weekly dose. Data included medication name, dose, route, frequency of use, and total amounts used of each analgesic. NSAIDs, Acetaminophen and Opioids, which were converted into morphine equivalents were used and recorded.⁸

RESULTS

In all three studies, patients either received Reiki therapy, sham placebo or alternative treatment (massage therapy) to assess whether or not Reiki therapy has a true therapeutic effect in reducing pain. The practice is safe and there were no reported incidences of it harming the patients during the studies. Data was analyzed using mean change from baseline, p-value and t-test.

Patients from an outpatient chemotherapy clinic over the age of 18 diagnosed with cancer were candidates for the study conducted by Caitlin et al. All 189 patients remained throughout the intervention. The subjects were divided into three groups, Reiki, Sham Reiki placebo, and standard care. Each received 20 minutes of therapy and was asked to complete the pre- and post-test questionnaire assessing their physical comfort. Reiki therapy (p-value=0.0051) and sham Reiki placebo (p-value=0.005) both showed a statistically significant increase in physical comfort when compared to standard therapy.⁶ However, no differences were noted between actual Reiki therapy and sham Reiki placebo.⁶ The change in physical comfort between pre- and post-test scores showed no statistical significance.⁶ In addition, the change in mean from baseline for Reiki therapy was 2.75 suggesting there was not an increase of physical comfort in comparison to standard care.⁶

The study conducted by Cook et al was modified based on an intention to treat. 78 subjects were randomly split into two groups, 44 in Healing touch (HT) and 34 in Mock treatment (MT). The participants were patients at a large Midwestern university-affiliated hospital who had to be older than 17 years, newly diagnosed with breast or gynecological cancer who completed no more than one third of their radiation therapy. Women who were diagnosed with end-stage cancer with a likelihood of rapid deterioration and who already received HT in the past were excluded.⁷ Each subject received 6 weekly sessions of HT or MT immediately after their radiation treatment. Out of 78 subjects, 62 completed the study while 16 or 20.5% dropped out.⁷ Majority of the losses were due to becoming too sick, religious obligations, family problems, no time, and drug use.⁷ Decrease in pain among the HT group was statistically significant following radiation therapy than their counterparts who received MT.⁷ In specific, HT ratings on pain had a baseline score of 63.0 +/- 32.1 and an outcome score of 70.6 +/- 23.6 with a t-score of 1.61 (Table 2). In comparison, MT had a baseline score of 51.5 +/-28.9 and an outcome score of 54.5 +/- 29.0 with a t-score of 0.58 (Table 2). In addition, the overall outcome scores were HT (63.3, $t^2=8.13$) and MT (54.3, $t^2= 1.13$). This data suggest a statistically significant ($p<0.05$) mean change in pain in HT (70.6) and MT (54.5), respectively $t=2.40$, $P<0.02$).⁷

Table 2: Comparison of Within-Group Mean Changes in Baseline and Outcome SF-36 Scores by Group Assignment (n=62).^a

Subscale	HT Group (n=34)				MT Group (n=28)			
	Baseline	Outcome	t^2	P	Baseline	Outcome	t^2	P
Overall score	55.2 +/- 19.9	63.3 +/- 16.3	8.13	0.00	50.4 +/- 19.2	54.3 +/- 20.1	1.13	ns
Subscale Score: Pain	63 +/- 32.1	70.6 +/- 23.6	1.61	Ns	51.5 +/- 28.9	54.5 +/- 29.0	0.58	ns
^a Data from Cook CA, Guerrierio JF, Slater VE ⁷								

The study by Post-White et al consisted of 230 subjects divided into three groups; healing therapy (HT), massage therapy (MT), and caring presence (P). Adults from two outpatient Midwestern chemotherapy clinics with a histological documented cancer diagnosis (52% breast cancer and 19% Gynecological cancer) who present with pain, nausea, or fatigue rated 3 or more were included in the study. By the end, 66 subjects or 29% of the population dropped out leaving 164 patients completing the study.⁸ The high dropout rate contributed to the subjects wanting to be in a different treatment group, treatment protocol or schedule changes, they no longer met the crossover criteria, or they died.⁸ Pain levels as a response to immediate interventions were lower in MT ($p < 0.001$) and HT ($p < 0.11$) compared to caring presence (P).⁸ Intervention effects over 4 weeks showed there were no statistically significant changes overtime in any of the intervention groups on pain index. In specific, interventions effect of pain in HT from session 1 to session 4 demonstrates a standard deviation (SD) of 1.8 to 1.7 with a p-value = 0.94 and z-score = -0.08.⁸ In other words, data representing HT effects on reducing pain is not statistically significant. In addition, there was not a significant decrease in analgesic use when HT was administered. Over the 4 week period, subjects in the HT group decreased NSAID use from 4,564mg to 4,116.2 mg with a SD = 5,586, z-score = -0.66, and P value = 0.51.⁸ This data suggests HT does not decrease pain levels enough to decrease use of NSAIDS.

DISCUSSION

This systematic review investigated the effectiveness of Reiki therapy reducing pain in breast and/or gynecological cancer patients undergoing chemotherapy and radiation. The studies by Caitlin et al and Post-White et al demonstrated pain reduction in all forms of healing touch whether it was Reiki, sham Reiki, or Massage therapy. Caitlin et al showed a statistical significant increase in physical comfort in Reiki and sham Reiki compared to standard care. On

the other hand, statistical significance was not reached in the study conducted by Post-White et al; however, subjective responses on the evaluation survey support HT and MT were more effective in reducing short term pain than standard care alone. Similarly, Cook et al discovered a statistically significant decrease in pain with Reiki therapy when comparing it to standard care (MT).

Pain is a debilitating side effect of many illnesses and treatments. Specifically, it is a common complication of chemotherapy and radiation. Reiki therapy has been used as an alternative approach to reduce pain and in turn increase a patient's quality of life. These articles mainly focus on pain reduction in breast and gynecological cancers, however, Reiki therapy is also used to decrease pain and improve functioning in patients with osteoarthritis, severe burns, post-op abdominal surgery, tension headaches and anxiety.^{7,8} Reiki therapy is not covered by insurance, thus it may be challenging for the patient to pay out of pocket for every session. The cost is individualized to each therapist and can range from \$60 to \$100 per hour. However, if the practitioner is trained in Reiki, whether it is a Doctor, Physician Assistant, or Nurse Practitioner, they are able to bill it as an office visit. There are no proven contraindications to Reiki therapy and no adverse effects were reported in the studies. It is a safe practice based on restoring energy balance in the body.

Each of the studies analyzed in this review faced various limitations. Caitlin et al conducted the study in one medical center with a homogeneous group of clients. Results may have differed if a heterogeneous group from additional sites were included. In addition, the study took longer than expected because the same group of patients came in week after week; therefore no new patients were left to recruit.⁶ The limited sample size in Cook et al prohibited the use of more sophisticated statistical tests with more control over confounding factors which

may have influenced outcomes. Long term effects of Reiki therapy beyond the last radiation treatment were not evaluated, limiting the effectiveness of the study. Furthermore, data on medical characteristics were not verified for their validity but were obtained by reviewing medical records only.⁷ Post-White et al proposed a potential bias of the 42% who consented versus the 58% who declined to participate.⁸ The outcomes are likely to be altered after 66 of the subjects dropped out leaving 164 who chose to complete the study. In addition, the lack of blinding and variability of the research assistant and practitioners as well as the variation in intervention technique alter the accuracy of the study.⁸ Despite the numerous limitations, this study reflects the largest database (164 subjects) for an outcome study of HT and MT.

CONCLUSION

Reiki therapy is a safe alternative to manage pain of a patient receiving chemotherapy and radiation. However, there is no convincing evidence that Reiki alone helps relieve pain. The studies discussed in this review demonstrated human touch with or without energy transfer decreased the patient's pain level. Those who received Reiki, sham Reiki, and Massage therapy all reported a reduction in their pain levels compared to the groups who received standard care. Therefore, alternative therapy is an option for patients who cannot or do not want to take medications for pain.

Future studies should focus on creating a greater variety of participants from multiple oncology centers. Increasing the variety and number of participants will generate stronger statistical evidence in proving the effectiveness of Reiki therapy. Another direction for future research is to conduct studies comparing the long term effects of Reiki versus Massage therapy.

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