

Assessing the Impact of Acupuncture on Pain, Nausea, Anxiety, and Coping in Women Undergoing a Mastectomy

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This research was funded by the Abbott Northwestern Hospital Foundation. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the *Oncology Nursing Forum* or the Oncology Nursing Society.

Quinlan-Woodward, Gode, Dusek, Reinstein, and Sendelbach contributed to the conceptualization and design. Quinlan-Woodward and Reinstein completed the data collection. Quinlan-Woodward, Dusek, Johnson, and Sendelbach provided statistical support. Quinlan-Woodward, Gode, Dusek, Johnson, and Sendelbach contributed to the analysis. All authors contributed to the manuscript preparation.

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Submitted December 2015. Accepted for publication February 16, 2016.

Key words: anxiety; pain; nausea/vomiting; breast cancer; acupuncture

ONF, 43(6), 725–732.

doi: 10.1188/16.ONF.725-732

Purpose/Objectives: To compare the effect of acupuncture to a standard-of-care (control) group on pain, nausea, anxiety, and ability to cope.

Design: Pilot randomized, controlled trial.

Setting: Abbott Northwestern Hospital, a large, urban, tertiary care hospital in Minneapolis, Minnesota.

Sample: 30 adult women undergoing surgery for breast cancer.

Methods: Women were randomly assigned to two hospital-based acupuncture treatments versus usual care after breast cancer surgery. Pain, nausea, anxiety, and the patient's ability to cope pre- and post-treatment were compared within and between groups at two different time points postoperatively.

Main Research Variables: Mean change in pain, nausea, anxiety, and ability to cope by treatment group.

Findings: Compared to women assigned to the control group, women who received acupuncture reported a statistically significant greater reduction in pain, nausea, anxiety, and increase in ability to cope on the first postoperative day and in pain on the second postoperative day following mastectomy surgery.

Conclusions: Acupuncture delivered postoperatively in the hospital after mastectomy can reduce the severity of symptoms experienced, as well as increase the patient's ability to cope with her symptoms. However, before implementation as a standard of care, further research needs to be conducted.

Implications for Nursing: Acupuncture adds a nonpharmacologic intervention for symptom management in women undergoing mastectomies for breast cancer.

Breast cancer will develop in about one in eight U.S. women during their lifetimes, and surgical intervention is an important component of care for patients with breast cancer (American Cancer Society, 2016; National Comprehensive Cancer Network, 2015). Patients undergoing breast cancer surgery may experience complications and distressing symptoms, including pain, nausea, and vomiting, that affect quality of life. Pain can lead to increased length of stay, increased readmissions, and decreased quality of life (Hutchison, 2007; Potter, Thomson, Greenwood, Hopwood, & Winters, 2009; Ware, Bruckenthal, Davis, & O'Conner-Von, 2011). Challenges still exist in relieving pain in the postoperative period (Hutchison, 2007; Ware et al., 2011). In a study by Fecho et al. (2009), 58% of women undergoing mastectomies experienced severe postoperative pain immediately after surgery, and 22% of those same patients experienced severe pain at one month. Postoperative nausea and vomiting (PONV) occurs in about 75 million patients annually (Collins, 2011).

In a survey to identify research priorities, Oncology Nursing Society members were asked to report the top three symptoms that were most distressing

to patients with cancer and the top three that were most difficult to manage in general (LoBiondo-Wood et al., 2014). The top five symptoms were fatigue, pain, nausea, psychological distress, and neuropathy. In identifying what symptoms were most difficult to manage and most distressing to patients, psychological distress, anxiety, and pain were in the top 10. The survey also assessed where research was needed in oncology via open-ended question, and the most frequent response was in symptom management.

A small body of literature suggests that the use of integrative therapies, including acupuncture, may be helpful in managing symptoms in patients with cancer generally and postoperatively (Cho et al., 2015; Greenlee et al., 2014; Kreindler et al., 2014; Lee & Fan, 2009). Acupuncture, a key component in traditional Chinese medicine, is a nonpharmacologic intervention used by patients with cancer for symptom management (Greenlee et al., 2014; Mao, Palmer, Healy, Desai, & Amsterdam, 2011). According to the 2012 National Health Interview Survey, about 3.5 million U.S. adults had received acupuncture in the past year (National Center for Complementary and Integrative Health, 2015).

Lee and Fan (2009), in a Cochrane Review, concluded that the stimulation of the wrist acupuncture point P6 was effective in preventing postoperative nausea and vomiting in patients undergoing general surgery. Mehling et al. (2007) studied 138 patients with cancer undergoing surgery who were randomized either to usual care or acupuncture and massage. Patients who received acupuncture and massage had decreased pain and depressive mood compared to usual care. Similarly, Mallory et al. (2015) examined 20 adult patients with breast cancer undergoing a mastectomy and/or breast reconstruction who received acupuncture starting postoperative day one until discharge. In this descriptive study, anxiety, pain, relaxation, and muscular tension were measured before and after the acupuncture treatment, with significant reductions in all symptoms except relaxation.

Observational studies in hospitalized patients with cancer (Johnson, Crespin, Griffin, Finch, & Dusek, 2014) or cardiac disease (Johnson, Crespin, Griffin, Finch, Rivard, et al., 2014) and patients undergoing joint replacement surgery (Crespin et al., 2015) have demonstrated the effectiveness of integrative therapies for pain management. Although little is known about how acupuncture works, a body of knowledge exists that has examined possible mechanisms of action (Stone & Johnstone, 2010). In a critical review of the research on pain and acupuncture, Wang, Kain, and White (2008) suggested that acupuncture triggered a sequence of events that included the release of neurotransmitters and endogenous opioid-like substances (e.g., enkephalin, β -endorphin, endomor-

phin) that modulated pain signals processed along the pathway. Part of their conclusion was based on imaging studies that demonstrated areas of the brain affected by acupuncture stimulation.

Although some researchers examining acupuncture-induced gastric relaxation in rat models concluded that relaxation is mediated via the somatosympathetic reflex (Tada et al., 2003), other researchers have not been able to suggest the mechanisms for action.

Rat models were also used to examine the effect of acupuncture on anxiety. Chae et al. (2008) and Park et al. (2005) demonstrated that anxiety-like behavior was reduced in adult rats who were given acupuncture following maternal separation and suggested that it was because of the modulating effect of acupuncture on the neuropeptide Y, which is involved in the expression of anxiety.

No randomized, controlled trials could be found that examined the effects of acupuncture as an integrative therapy in an inpatient setting on pain, nausea, anxiety, and ability to cope in women undergoing surgery for breast cancer. In addition, challenges exist in the ability to deliver acupuncture in patients with a short length of stay. Therefore, the primary aim of this study was to determine if a difference existed on the level of postoperative pain, nausea, anxiety, and ability to cope for women receiving acupuncture compared to usual care. A secondary aim was to examine the feasibility of delivering acupuncture to women undergoing unilateral or bilateral mastectomy. The study was approved by the Schulman Institutional Review Board.

Methods

Sample and Setting

The sample included women who were admitted to Abbott Northwestern Hospital, scheduled to undergo a mastectomy (i.e., unilateral simple mastectomy, bilateral simple mastectomy, unilateral extended simple mastectomy, or bilateral extended simple mastectomy), aged 18 years or older, and were willing to forego other integrative therapies through the Penny GeorgeTM Institute for Health and Healing (PGIHH) services. To ensure that patients were able to be seen within the confines of the study, only those scheduled for surgery from 7 am–1 pm, Monday–Thursday were eligible. Women who were non-English speaking, pregnant, or also undergoing an oophorectomy, transverse rectus abdominis, or latissimus dorsi flap surgery were excluded. For women of childbearing age, a pregnancy test was completed by Abbott Northwestern Hospital staff as a part of routine care.

Abbott Northwestern Hospital is a Magnet[®]-designated tertiary hospital, staffed for 650 beds.

Virginia Piper Cancer Institute® (VPCI) at Abbott Northwestern Hospital is the oncology clinical service line of Allina Health®. The VPCI provides comprehensive care through all aspects of cancer prevention, early detection, treatment, and survivorship to help individuals maintain quality of life and find ways to live with and beyond cancer. In 2014, the Piper Breast Center® at VPCI treated about 712 patients with breast cancer. Hospitalized patients at Abbott Northwestern Hospital are eligible to receive PGIHH integrative services for pain relief, anxiety reduction, and healing. In 2014, about 16% of inpatients with breast cancer were seen by a PGIHH practitioner for an integrative medicine service. These services were provided by integrative healthcare professionals for patients during their hospital stay and were offered at no charge.

Procedures

All potential participants were identified and approached by cancer care coordinators (CCCs) during their preoperative visits to the Piper Breast Center or the surgeon's office. CCCs met with women after the surgeon's visit to help guide them with their treatment decisions. As part of this visit or during the follow-up contact, the CCC introduced the study to the patient. If the patient expressed interest in the study, the staff provided the patient with additional information. The CCC obtained consent for the research staff to contact the patient or asked the patient to contact the study staff if interested in the study. This was followed up by a screening phone call where the research coordinator reviewed the informed consent and answered any questions the patient had. A partial waiver of authorization for recruitment was obtained to collect screening data. If the patient agreed to be a part of the study, the consent form, with Health Insurance Portability and Accountability Act (HIPAA) authorization, was given to the patient along with a demographic survey. The patients either mailed the research materials back or provided it to the research coordinator at the hospital.

Participants had the option of completing parts of the study online through Assessment CenterSM. Assessment Center is an online data collection tool that enables researchers to create study-specific websites for capturing participant data securely. If the participant chose to complete the consent form online, it was electronically signed and dated. A waiver of documentation of the informed consent was used for participants completing the form online. Participants discussed the consent form with the research coordinator during the screening phone call. In addition, a study contact number was given to the participant to answer additional questions.

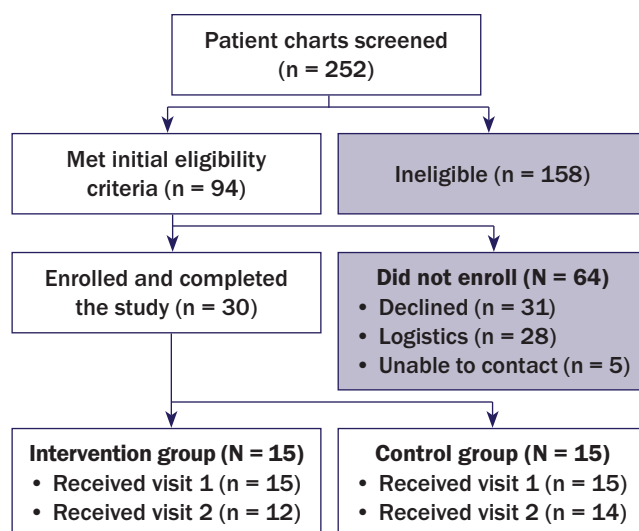


FIGURE 1. Consolidated Statements of Reporting Trials (CONSORT) Diagram

After informed consent and HIPAA authorization were obtained, patients were randomly assigned to the intervention (acupuncture) group or control group. Participants were randomized with a two- or four-block design per a computerized program.

A baseline demographic survey (i.e., age, race/ethnicity, highest level of education, current marital status, employment status, and household income) was completed by the participant prior to undergoing surgery in both groups. For women assigned to the intervention group, acupuncture was delivered as many as two times during postsurgery hospitalization at least 12 hours apart. Women assigned to the usual care group were seen two times postoperatively and at least 12 hours apart to collect the same variables.

Prior to the patient receiving an acupuncture treatment, a discussion about the risks and benefits of acupuncture was had. Once patients signed the consent form, they were instructed to enter their scores for their current level of pain, anxiety, nausea, and ability to cope into the tablet computer. Next, the patients' conditions and symptoms were used by the acupuncturist to formulate specific treatments. Although no predetermined acupuncture point treatment plan was used, many patients received similar acupuncture treatments based on their presenting symptoms.

Postoperatively, on the day of the surgery or the day after, women assigned to the intervention group entered pain, nausea, anxiety, and ability to cope levels (all on a 0–10 scale, with higher scores indicating more pain, nausea, and anxiety, as well as an increased ability to cope) into a tablet computer immediately before and immediately after receiving acupuncture, with an average needle time of 36 minutes.

TABLE 1. Sample Characteristics by Treatment Group

Characteristic	Intervention (N = 15)		Control (N = 15)		p
	\bar{X}	SD	\bar{X}	SD	
Age (years)	53.7	9.4	62.5	11.5	0.031
Characteristic	n		n		p
Race					-
Caucasian	15		15		
Ethnicity					-
Not Hispanic or Latino	15		15		
Education					0.599
Some high school	-		1		
High school graduate	4		3		
Some college or associate degree	5		7		
Bachelor's degree or higher	6		4		
Employment status					0.343
Full-time	8		4		
Part-time	3		3		
Homemaker	2		2		
Retired	2		6		
Family income (\$)					0.216
Less than 24,999	-		2		
25,000–39,999	1		-		
40,000–54,999	4		1		
55,000–74,999	2		3		
75,000 or more	8		7		
Unknown	-		2		
Marital status					0.059
Married	12		12		
Divorced or separated	2		3		
Widowed	1		-		

Note. P value is from t test or chi-square test comparing intervention and control groups.

The acupuncture treatments were delivered using Japanese-manufactured Seirin J-Type, plastic-handled, stainless steel single-use needles, which were 30 mm in length and either 0.16 mm, 0.18 mm, or 0.2 mm in diameter. All acupuncture treatments were delivered by a single licensed acupuncturist with more than six years of experience.

In the usual care group, the research coordinator instructed the participant to enter pain, nausea, anxiety, and ability to cope scores into the tablet. The research coordinator then left the patient's room and returned an average of 32 minutes later to collect the second set of scores. The number and times of visits were determined by the patient's availability, the research staff's availability, and the time of hospital discharge.

Both groups entered scores into a tablet computer. All scores were not visible once entered into the tablet, so the acupuncturist and research coordinator

were blinded to the data. The scores were captured in Assessment Center and exported to a password-protected database by the research coordinator.

Instruments

Numeric rating scales, with a 0–10 scale, were used to measure pain, nausea, and anxiety levels, with 0 indicating absence of the variable and 10 as the most severe. A numeric rating scale was also used to measure the patient's ability to cope, where 0 signified "no ability to cope" and 10 was "completely able to cope."

Studies have demonstrated support for these numeric rating scales for pain, nausea, and anxiety. A systematic review by Hjermstad et al. (2011) concluded that these scales were applicable for unidimensional assessment of pain intensity and were considered superior in 11 of 54 articles examined. Dibble et al. (2007) demonstrated a 0.922 correlation between a numeric rating scale and the Rhodes Index of Nausea when examining nausea in patients receiving acupuncture after chemotherapy. A combination of a visual analog scale and a numeric rating scale (i.e., the Numeric Visual Analog Anxiety Scale [NVAAS]) was compared to the State-Trait Anxiety Inventory (STAI) in patients undergoing colorectal surgery where a significant correlation (0.64, $p < 0.0001$) was found between STAI and NVAAS scores (Elkins, Staniunas, Rajab, Marcus, & Snyder, 2004). Finally, the use of the 0–10 numeric scale for the ability to cope measure was pilot tested for use within the current study.

Feasibility was assessed by the number of patients scheduled for surgery, the number of patients approached, the number of patients who consented, the number of patients who refused and why, and the number of patients who completed participation.

Statistical Analysis

The primary interest for the current analysis was to compare mean change in pain, nausea, anxiety, and coping scores by treatment group (i.e., acupuncture versus control) and to assess changes at two different time points. All analyses were performed using SAS®, version 9.3. Visit 1 and visit 2 measures were calculated as mean plus and minus standard deviations at pre- and post-treatment times. Means of pre- and post-treatment measurements were compared using paired, two-sided Student's t tests. P values were calculated comparing acupuncture and control mean change scores using unpaired two-sided Student's t tests. Tests of equal variances were performed, and p values for statistical differences between the groups were adjusted by pooled or Satterthwaite methods for equal or unequal variances, respectively. All tests of significance were two-sided, and a p value was considered statistically significant if it was less than 0.05.

A secondary outcome was to examine the feasibility of delivering acupuncture to women undergoing mastectomies postoperatively but before hospital discharge. The number of patients enrolled to receive acupuncture and the number (percentage) of acupuncture treatments completed was used to determine the feasibility of the intervention.

Results

A total of 252 patients were scheduled to receive a unilateral or bilateral mastectomy during the study period and were identified by a CCC during preoperative clinic visits. Of these patients, 94 met initial eligibility criteria via a medical chart review and received a telephone screening visit by a research assistant; 28 were ineligible because of logistics (i.e., surgery time and/or staffing), and 31 declined (see Figure 1). A total of 30 women provided informed consent and were randomized to the study protocol; 15 women were assigned to the acupuncture group, and 15 women were assigned to the control group. All 15 participants in each group received a first visit; 12 participants in the acupuncture group and 14 participants in the control group received a second visit. Because of a technical error in visit 2 data collection, two acupuncture participants could not be analyzed at that time point and were removed from that analysis.

Descriptive Statistics

All participants in this study were female, Caucasian, and not Hispanic or Latino (see Table 1). The mean age of patients in the acupuncture group was 53.7 years, which was about nine years younger than patients randomized to the control group (62.5 years) ($p = 0.031$). No statistically significant differences by group were found with respect to education, employment status, family income, or marital status.

Outcomes

Patients who were randomized to the acupuncture group showed statistically significant improvements in pain, nausea, anxiety, and ability to cope from pre- to postintervention at visit 1 (see Table 2). Conversely, patients who were randomized to the control group showed no statistically significant differences between pre- and post-standard care measurements in pain, nausea, anxiety, or ability to cope at visit 1. Mean change scores between the acupuncture and control groups were statistically significantly different for all outcome measures (pain, $p = 0.011$; nausea, $p = 0.011$; anxiety, $p = 0.039$; coping, $p = 0.012$).

At visit 2, patients who were randomized to the acupuncture group continued to show statistically significant improvements in pain and anxiety from pre- to postintervention (see Table 3). Similar to visit 1, patients who were randomized to the control group showed no statistically significant differences between pre- and post-standard care measurements in any of the four outcome measures. Mean change scores between the acupuncture and control groups were statistically significantly different for pain ($p = 0.017$) and anxiety ($p = 0.051$) at visit 2.

Discussion

Providing acupuncture postoperatively, in addition to usual care, resulted in decreased pain, nausea, and anxiety, as well as an increased ability to cope. Delivering acupuncture postoperatively in adult women undergoing a mastectomy for breast cancer is feasible. These results suggest that acupuncture could help with symptom management and provide support for a larger study. Symptom management is of primary concern to clinicians providing care to patients with cancer, as was identified in an Oncology Nursing Society survey identifying research priorities (LoBiondo-Wood et al., 2014).

TABLE 2. Visit 1 Mean Change in Outcome Measures by Treatment Group

Measure	Intervention (N = 15)							Control (N = 15)						
	Pre		Post		Change		p	Pre		Post		Change		p
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD		\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	
Anxiety	2.33	1.8	1	1.31	-1.33	1.59	0.006	1.27	1.39	1.8	2.37	0.53	2.88	0.484
Coping	6.67	2.72	8.53	2.17	1.87	2.97	0.029	8.53	1.81	8.07	2.25	-0.47	1.36	0.204
Nausea	2.6	3.31	1.07	2.12	-1.53	2.7	0.045	0.27	0.46	1	1.69	0.73	1.75	0.127
Pain	4.2	1.01	2.73	1.39	-1.47	1.06	< 0.001	3.67	2.13	3.60	1.99	-0.07	1.67	0.879

Note. All p values were calculated from paired t tests comparing pre- and postintervention and pre- and post-standard care outcome scores. P values less than 0.05 were considered significant.

Note. Numeric rating scales from 0–10 were used for anxiety, nausea, pain, and ability to cope, with higher scores indicating more anxiety, nausea, or pain, as well as increased ability to cope.

TABLE 3. Visit 2 Mean Change in Outcome Measures by Treatment Group

Measure	Intervention (N = 10)							Control (N = 14)						
	Pre		Post		Change		p	Pre		Post		Change		p
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD		\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	
Anxiety	1.4	1.65	0.5	0.71	-0.9	1.45	0.081	1.57	1.5	1.71	1.82	0.14	1.03	0.612
Coping	7.6	3.06	7.9	3.73	0.3	3.06	0.763	8.5	1.51	8.57	1.7	0.07	0.47	0.583
Nausea	1	1.7	0.5	0.97	-0.5	1.27	0.244	0.79	1.97	0.5	1.16	-0.29	1.38	0.453
Pain	3.1	1.52	1.6	1.35	-1.5	0.97	< 0.001	3.07	2.13	2.64	2.31	-0.43	1.02	0.139

Note. All p values were calculated from paired t tests comparing pre- and postintervention and pre- and post-standard care outcome scores. P values less than 0.05 were considered significant.

Note. Numeric rating scales from 0–10 were used for anxiety, nausea, pain, and ability to cope, with higher scores indicating more anxiety, nausea, or pain, as well as increased ability to cope.

Note. In the intervention group, three participants did not receive a second visit, and two participants were deleted from the analysis because of a technological error. In the control group, one participant did not receive a second visit.

Results are particularly promising considering that the usual length of hospital stay for women undergoing mastectomies is 1.9 days. Mehling et al. (2007) did a study with delivery of acupuncture to patients with cancer on postoperative days one and two that assessed the effects of acupuncture and massage. Although Mallory et al. (2015) also examined women postoperatively, the researchers did not identify the number of days the patients were in the hospital or how many days the patient received acupuncture. The outcomes from the current study support that acupuncture can be delivered in patients with a shortened length of hospital stay.

Other researchers also demonstrated reductions in pain for patients following surgery for cancer, including abdominal, pelvic, prostate, testicular, bladder, kidney, breast cancer, or head and neck cancer (Mallory et al., 2015; Mehling et al., 2007; Pfister et al., 2010). Pain management for postoperative pain with medication is not without risks from possible side effects. Therefore, in addition to patients dealing with symptom management of cancer or from surgery, they may also need to manage symptoms from medications given for pain relief. Providing acupuncture as an adjunctive therapy to medication intervention may decrease side effects by having patients require less pain medication.

Acupuncture was demonstrated to decrease nausea in the current study, which is consistent with results from a Cochrane Review (Lee & Fan, 2009), as well as a systematic review and meta-analysis (Cheong, Zhang, Huang, & Zhang, 2013). Lee and Fan (2009) and Cheong et al. (2013) concluded that acupuncture prevented postoperative nausea and vomiting. However, those researchers examined studies that use acupressure in addition to acupuncture by delivery of an acupuncturist. Further studies should explore

self-administered acupressure to support patients being able to receive treatment at times other than when in the hospital. In addition, as identified previously, acupuncture could provide a nonpharmacologic intervention as adjunctive to or as an alternative for pharmacologic intervention without the side effects of medications.

Although Mehling et al.'s (2007) study was not able to demonstrate a reduction in anxiety in postoperative patients with cancer with the use of acupuncture, the current authors' results show a reduction in anxiety at visits 1 and 2. Data on patient perception of anxiety was collected immediately after the acupuncture treatment in the current study, and Mehling et al. (2007) allowed for a three-hour window that could suggest the effect of the acupuncture decreases over time. Mehling et al. (2007) also measured anxiety with "tension" from the short form of the Profile of Mood States. Conceptually, anxiety and tension differ, and patients were measuring tension as opposed to anxiety in that study.

Limitations

A limitation of the study is that the acupuncture treatment was not blinded. However, this is challenging. Two types of sham acupuncture exist: penetrative or non-penetrative. A study by Vase et al. (2015) examined whether acupuncture could be double-blinded in a randomized, controlled trial with a non-penetrating needle and was not successful.

Other limitations of the study are its small sample size and lack of diversity. The results of this study, along with the results of the Mallory et al. (2015) and Mehling et al. (2007) studies, provide support for additional studies with a larger sample sizes to evaluate acupuncture for symptoms following surgery for

patients with cancer. Prior to standardizing the use of acupuncture as a treatment modality for postsurgical breast cancer care, future studies should evaluate patients' acceptability of using needles. A difference in age was found between the two groups of women in the current study, and no known published data exist on differences in age with acceptance of acupuncture or its efficacy.

Implications for Nursing

Nurses, who were members of the Oncology Nursing Society, identified fatigue, pain, nausea, psychological distress and neuropathy as the top five symptoms most distressing to patients with cancer (LoBiondo-Wood et al., 2014). This pilot study examined the experience of women with breast cancer undergoing mastectomy surgery and addressed three of the top seven symptoms (i.e., pain, nausea, and anxiety). The results of this study add to the growing body of research supporting the feasibility and effectiveness of acupuncture as a nonpharmacologic option for treatment of symptoms after mastectomy. The current authors feel that the involvement of clinicians closest to the patients is valuable in identifying possible interventions to optimize patient care. The nurse's role is to assess and control postoperative symptoms. In addition, nurses educate patients on all effective treatment options for these symptoms. To provide the best evidence-based care for patients with breast cancer, nurses must be knowledgeable of the potential benefits of acupuncture. Healthcare providers' knowledge and adoption of acupuncture as an option to manage symptoms could lead to an increase in quality of life for patients having breast cancer surgery.

Additional randomized, controlled trials are needed to demonstrate the advantages of acupuncture for patients with breast cancer undergoing mastectomy surgery. In addition, these additional studies should include a larger, more diverse sample size. Nurses can be involved in future research as principal investigators (as in this study) or as gatherers of qualitative evidence to add to the body of research.

Conclusion

The results of this pilot study support reductions in pain, nausea, and anxiety, as well as an increase in ability to cope. In addition, the study found that it is feasible to deliver acupuncture postoperatively to women undergoing surgery for breast cancer who have a short length of hospital stay. However, before implementation as a standard of care, further research needs to be conducted.

Knowledge Translation

- Acupuncture may provide a nonpharmacologic adjunctive therapy for symptom management in women undergoing surgery for breast cancer.
- Delivering acupuncture in the postoperative period but before hospital discharge is feasible.
- This study provides support for further research of the use of acupuncture in women undergoing mastectomies.

The authors gratefully acknowledge Alison Kolste, BS, for her invaluable work as the research coordinator for this study.

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