Original Article

Symptom Management with Massage and Acupuncture in Postoperative Cancer Patients: A Randomized Controlled Trial

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Abstract
The level of evidence for the use of acupuncture and massage for the management of perioperative symptoms in cancer patients is encouraging but inconclusive. We conducted a randomized, controlled trial assessing the effect of massage and acupuncture added to usual care vs. usual care alone in postoperative cancer patients. Cancer patients undergoing surgery were randomly assigned to receive either massage and acupuncture on postoperative Days 1 and 2 in addition to usual care, or usual care alone, and were followed over three days. Patients' pain, nausea, vomiting, and mood were assessed at four time points. Data on health care utilization were collected. Analyses were done by mixed-effects regression analyses for repeated measures. One hundred fifty of 180 consecutively approached cancer patients were eligible and consented before surgery. Twelve patients rescheduled or declined after surgery, and 138 patients were randomly assigned in a 2:1 scheme to receive massage and acupuncture ($n = 93$*) or to receive usual care only (*$n = 45$*). Participants in the intervention group experienced a decrease of 1.4 points on a 0–10 pain scale, compared to 0.6 in the control group (*$P = 0.038$*), and a decrease in depressive mood of 0.4 (on a scale of 1–5) compared to* ± 0 *in the control group (*$P = 0.003$*). Providing massage and acupuncture in addition to usual care resulted in decreased pain and depressive mood among postoperative cancer patients when compared with usual care alone. These findings merit independent confirmation using larger sample sizes and attention control.* J Pain Symptom Manage 2007;33:258–266. *© 2007 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.*

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Key Words
Cancer, surgery, symptom management, cancer pain, acupuncture, massage

Introduction

More than 40% of people with cancer report using complementary and alternative medicine (CAM) therapies.[1] Leading cancer centers in the United States offer massage and acupuncture to inpatients and outpatients. A recent review concluded that the judicious integration of these therapies into cancer patient care is warranted, although strong evidence of measurable benefits is often missing.[2] A National Institutes of Health consensus panel and numerous clinical trials support the efficacy and safety of acupuncture for postoperative pain, postoperative nausea and vomiting, and perioperative anxiety,[3] and the National Comprehensive Cancer Network guidelines[4] recommend consideration of massage and acupuncture for symptom management.

A systematic review on the effects of massage in cancer patients concluded that massage confers short-term benefit on psychological well-being, including anxiety, and that it may confer benefits on physical symptoms; more trials are needed.[5] We found only one small study published on the effect of massage in the postoperative setting that suggested it might reduce postoperative pain.[6]

Reviews of acupuncture for perioperative or chemotherapy-induced nausea and vomiting have concluded that acupuncture is efficacious.[7–10] Acupuncture reduced cancer pain in three uncontrolled single-arm studies[11–13] and in one randomized placebo-controlled trial.[14] Systematic reviews of acupuncture for various noncancer pain conditions[15] and three clinical trials of acupuncture for noncancer perioperative pain[16–18] reported improvement. Although these data on acupuncture and perioperative pain are promising, limitations include variance in the timing of the intervention and noncancer-related diagnoses.

In summary, the literature suggests that the level of evidence for the use of acupuncture and massage in the management of perioperative symptoms in cancer patients is relatively strong for the use of massage for anxiety and acupuncture for nausea, and is encouraging but nonconclusive for the use of acupuncture or massage for pain. The combination of massage and acupuncture for symptom management in perioperative cancer patients has never been studied. Massage and acupuncture are components of traditional Chinese medicine (TCM) and, as such, often are used in combination. Although mechanisms of action are still unclear for both modalities, they are viewed as complementary and additive within the frame of TCM. Recently, the Institute of Medicine report on "Complementary and Alternative Medicine in the United States" strongly recommended innovative study designs, including studies of combinations of therapies.[19]

We conducted a randomized, controlled clinical trial exploring the effect of a combination of massage and acupuncture added to usual care vs. usual care alone on postoperative symptoms (pain, nausea, and mood) and costs for symptom-related medications in hospitalized cancer patients in the first three days after cancer-related surgery.

Methods

Participants

Patients who were at least 18 years of age and scheduled to undergo cancer-related surgery requiring hospitalization for at least 48 hours were eligible to participate in the study. Patients were recruited during their preoperative anesthesia screening clinic visit. Cancer surgery was defined as any surgery related to a diagnosis of malignancy but including one of the following five groups: breast cancer surgery: mastectomy or reconstructive surgery; abdominal surgery for intestinal or hepatic malignancies; pelvic surgery for ovarian, uterine, or cervical malignancies; urological surgery for testicular, prostate, bladder, or renal malignancies; and head and neck cancer surgery.

Patients were excluded if they were not fluent in English, were diagnosed with deep vein thrombosis, or were receiving blood-thinning medication.

Recruitment

The study was approved by both the Committee of Human Research at the University of California, San Francisco (UCSF) and the Protocol Review Committee of the UCSF Cancer Center. Participants were recruited during their preoperative clinic visit scheduled for the medical and anesthesia clearance for the surgery planned for the following days. As part of the standard preoperative information package, all patients received a flyer describing the study. After reviewing data obtained from the clinic schedule, the research assistant approached consecutive patients potentially eligible for the study and, when they were eligible and interested, obtained informed consent.

Randomization

Following the baseline symptom assessment on postoperative Day 1 (POD1), the research assistant opened, at the bedside, a consecutively numbered, opaque envelope containing the random assignment to the intervention or control group. Using a computerized random number generator, these envelopes were prepared by the study statistician, who had no contact with the participants. To make participation as attractive as possible, we chose a 2:1 randomization scheme favoring the intervention.

Interventions

Massage and acupuncture were each provided on POD1 and POD2 at the bedside by one of two certified massage therapists and by one of two licensed acupuncturists. Practitioners had over 10 years of clinical experience treating cancer patients and had been credentialed and privileged by UCSF. The timing and sequence of massage and acupuncture was variable due to the providers' schedules and the patients' postoperative procedures scheduled for the same days.

Massage comprised standard ("Swedish") massage (applying kneading and strokes to soft tissue and muscles), and acupressure-type foot massage. Duration varied from 10 to 30 minutes depending on the participant's clinical needs and condition; the intended duration of 30 minutes could not always be achieved due to nursing care requirements (mean duration 20 minutes, SD ±3).

Acupuncture treatment was based on symptom report and physical exam and was semi-standardized according to leading symptom (e.g., pain or nausea): a standardized core set of acupuncture points according to TCM was used for each presenting symptom and additional points were added (and documented) depending on history and examination at the discretion of the practitioner. We used 34-gauge needles (manufacturer: Seirin, Japan) at the following standardized points: for *pain*, large intestine-4, spleen-6, and auricular points corresponding to the area of pain; for *nausea*, pericardium-6 and stomach-36; for *anxiety*, liver-3, large intestine-4, and Yin Tang. An average of 10 acupuncture needles (range 4–14) were placed bilaterally in symmetrical points and unilaterally for auricular points to a depth of 1 fen to 3 tsun until de qi was obtained and were retained for 20 minutes.

Patients in the control group received usual care and were offered a 30-minute massage after completion of the questionnaire on POD3.

Measurements

Baseline demographic and medical history data were collected by questionnaire during the preoperative anesthesia clinic visit. Baseline clinical data were collected at the bedside before randomization on POD1. We collected further clinical data at three time points: on POD1 and POD2 within 3 hours after interventions (or equivalent time points) and on POD3 (no intervention). When the patient was discharged from the hospital prior to the final POD3 assessment, we contacted the patient over the phone. Data on costs of pain-, nausea-, and anxiety-related medications, on procedures, anesthesia, pathology, and length of hospital stay were obtained after the patient's discharge from the hospital from chart review and electronic databases. Costs were assessed for the entire postoperative hospital stay for all variables except medications, which were compared for the first three postoperative days only.

The primary outcome was the between-group difference in pain scores on an 11-point (0–10) pain numeric rating scale (NRS) for severity of current pain and for pain during the previous 24 hours.

Secondary outcome measures included the following: 1) nausea on an 11-point (0–10)

nausea NRS for current nausea intensity and nausea during the previous 24 hours, similar to a measure used previously;[20] 2) vomiting as the self-reported number of vomiting episodes during the previous 24 hours; 3) mood by tension (six items) and depressive mood (eight items) subscales of the Profile of Mood States Short Form (POMS-SF)[21] (reported as unweighted average score across all individual items, range 1–5); and 4) costs of health care, as assessed by type of care for the postoperative stay, except for medications, which were compared for the three-day study period only.

Statistical Analyses

Estimating that 150 patients would agree to participate in this study during a three-month recruitment period and a 20% drop-out rate, we expected to obtain complete data from 120 patients. With a 2:1-randomization scheme, this would suffice to show a change score difference of 1.1 points on the pain NRS between treatment and control groups (estimated SD of 2.0[20]), with alpha of 0.05 and beta of 0.2, using a two-sided *t*-test.

Repeated measures for pain, nausea, mood scales, and number of vomiting episodes were compared by mixed-effects regression analyses. We controlled for significant ($P < 0.1$) differences in baseline characteristics and for baseline values of the outcome variables. *t*-Tests were used to compare the same-day prepost intervention changes in symptom scores and health care costs. For analysis of medication cost data by categories, which included many zeros, we used a randomization test (SAS PROC MULTTEST)[22] with 100,000 resamples.

We conducted prespecified exploratory subgroup analyses for trends in the four different surgery groups to see if there were particular types of surgery in which the intervention appeared to be particularly useful or ineffective, without expecting to obtain statistical significant differences for between-group comparisons.

Intention-to-treat analyses included all patients as randomized irrespective of whether they actually received the intervention, no intervention, or only part of it. We used SAS and Stata software[22,23] to perform statistical analyses.

Results

From the preoperative clinic schedule, we identified 180 consecutive, potentially eligible cancer patients, of whom 150 were eligible and consented before surgery to enroll in the study. Of these 150 patients, 12 ultimately did not participate because the surgery was rescheduled or they declined participation after surgery. The remaining 138 patients were randomly assigned to the intervention (93) or control (45) groups (Fig. 1).

Patient characteristics at baseline are summarized in Table 1. They were similar in both groups with the exception that the intervention group was more educated and more depressed (45% of standard deviation).

The average baseline pain score (range 0–10; mean 3.4 ±2.3) improved by 1.1 in the intervention group compared with 0.1 in the control group after the first intervention on POD1 ($P = 0.01$). Thirty-four of 90 (38%) patients in the intervention group improved their pain score by at least two points, compared with eight of 44 (18%) in the control group ($P = 0.02$). The average time interval between the intervention and the following assessment was 3 hours (SD 4.2 hours; range 0.08–12.4). Average pain scores improved from POD1 baseline (prior to first treatment) to POD3 in the intervention group by 1.6 vs. 0.6 in the control group ($P = 0.04$; Table 2, top rows). Thirty-eight of 88 (43%) patients

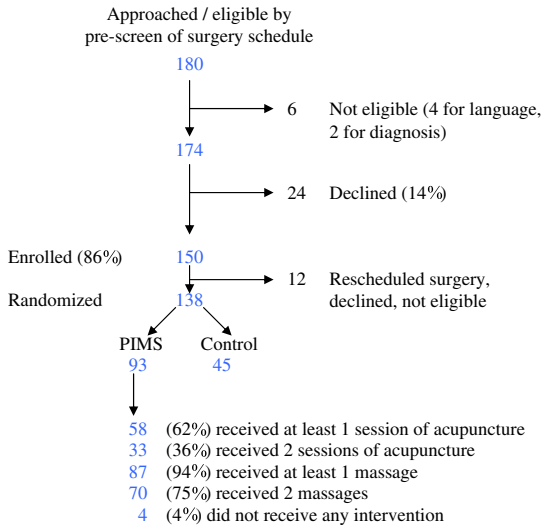

Fig. 1. Recruitment and randomization. (PIMS = Perioperative Integrative Medicine Service).

Table 1
Patient Characteristics ($n = 138$)

	PIMS	Control
Demographics		
Sex (female)	48 (52%)	20 (44%)
Age	55.9 (±1.9)	59.2 (±1.7)
Ethnicity (white)	63 (69%)	35 (78%)
Education (college +)	61%	53%
Medical history		
Type of cancer		
Abdominal/pelvic (GI, gyn)	23 (25%)	7 (16%)
Prostate/testicular	16 (18%)	14 (31%)
Bladder/kidney	19 (21%)	11 (24%)
Breast	18 (20%)	7 (16%)
Presurgery narcotic use[a]	15%	14%
Characteristics of surgery		
General anesthesia only	64%	68%
Epidural	31%	25%
Hours of anesthesia	5.4 (±1.7)	4.5 (±2.2)
Hours of procedure	3.8 (±1.8)	4.1 (±2.4)
Symptoms postoperative Day 1 (baseline)		
Depressive mood[b]	1.7 (±0.8)	1.4 (±0.4)
Tension/anxiety[b]	2.1 (±0.9)	1.8 (±0.9)
Pain[c]	3.5 (±2.2)	3.1 (±2.4)
Nausea[c]	0.7 (±2.0)	0.6 (±1.7)
Episodes of vomiting[d]	0.6 (±2.0)	0.3 (±1.6)

Data presented as n (%), mean (±SD), or %.
PIMS = Perioperative Integrative Medicine Service; GI = gastrointestinal; gyn = gynecologic.
[a]Current use of narcotic medication in preoperative week.
[b]POMS Likert scale 1–5.
[c]NRS, 0–10.
[d]Number of episodes of vomiting per last 24 hours.

in the intervention group improved their pain score by at least two points, compared with 11 of 43 (26%) in the control group ($P = 0.05$). Since 31% of participants reported mild (less than 3/10) or no pain at baseline, we performed a post hoc subgroup analysis to mitigate floor effects. Among patients reporting moderate-to-severe (at least 3/10) pain at baseline on POD1, average pain scores improved during the study period by 1.8 points in the intervention group ($P < 0.0001$) and by 0.3 points in the control group ($P = 0.34$; Table 2, bottom rows; Fig. 2). Repeated measures analyses in all 138 patients for all time points from POD1 to POD3 showed a statistically significant improvement in pain for the intervention group, whereas the control group remained essentially unchanged. Mixed-effects regression analyses over all four time points showed a significant (unadjusted: $P = 0.036$) between-group difference for the average pain curves, which was not altered by controlling for level of education, baseline depression, and baseline pain (adjusted: $P = 0.038$).

When compared to the control group and using all enrolled patients irrespective of the presence of the respective symptom, we found a standardized effect size (ES) for the change in pain from before to after the first intervention on POD1 of 0.68, and from baseline to POD3 of 0.36. In the symptomatic patients with pain of at least 3/10, ES was 0.65 with a mean reduction in pain by 25.5%.

Prespecified subgroup analysis by type of cancer showed significant improvement for pain among patients undergoing prostate and testicular surgery ($n = 30$, $P = 0.04$). Exploratory analysis among those reporting pain demonstrated the greatest ES for patients undergoing abdominal (gastrointestinal and gynecologic) surgery and prostate/testicular surgery (ES 0.98 and 0.97, $n = 21$ and $n = 14$, respectively; Table 3).

In an exploratory analysis of actual treatment received, we found patients receiving massage only ($n = 33$) reported greater improvement in pain after their first massage on POD1 than patients in usual care ($P = 0.03$).

Secondary outcomes, such as nausea, vomiting, and mood, were different between groups only for depression ($P = 0.003$), after adjustment for baseline differences (Table 4). In patients with at least mild depression at baseline ($n = 56$), ES was 0.67 favoring the intervention. After controlling for education and depression, as well as for baseline nausea or anxiety, both nausea and tension/anxiety

Table 2
Mean Pain Scores (±SD) in All 138 Patients and in 90 Patients with at Least 3/10 Pain After Surgery

	n	POD1 Pre	POD1 Post	POD2 Post	POD3	Change POD1–3	P[a]
All 138 patients	PIMS (93)	3.5 (±2.2)	2.5 (±2.1)	2.2 (±1.9)	2.1 (±1.8)	−1.4 (±2.2)	0.038
	Control (45)	3.1 (±2.4)	3.1 (±2.3)	2.9 (±2.4)	2.7 (±2.0)	−0.6 (±2.3)	
Symptomatic patients ($n = 90$)	PIMS (62)	4.3 (±2.0)	3.0 (±2.2)	2.2 (±1.8)	2.5 (±1.9)	−1.8 (±2.3)	0.001
	Control (28)	3.6 (±2.1)	3.6 (±2.3)	3.8 (±2.2)	3.3 (±1.9)	−0.3 (±2.3)	

PIMS = Perioperative Integrative Medicine Service.
[a]Mixed-effects regression analyses for repeated measures from baseline POD1 to POD3 controlled for education, baseline pain, and depression.

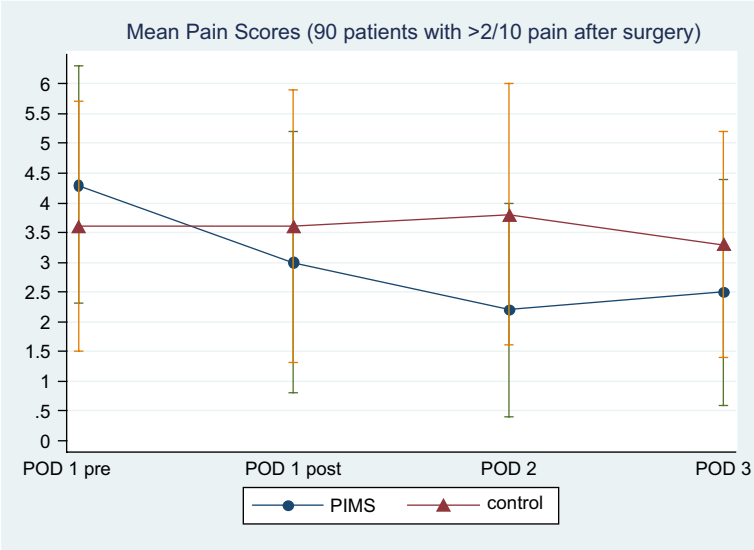

Fig. 2. Pain scores at all time points in patients with pain of at least 3/10 at baseline (90 patients, 62 PIMS, 28 control). (POD = postoperative day; PIMS = Perioperative Integrative Medicine Service).

improved in the intervention group on POD1 more than in the control group ($P = 0.043$ and 0.048, respectively), but these improvements were not maintained on POD2 and POD3. Although the ESs for the treatment of vomiting were relatively high (ES 0.36), the small sample size with this symptom ($n = 30$) limited the ability to find a statistically significant difference between groups ($P = 0.20$; Table 4). Only 25 (18% of all) patients (18 intervention, 7 control) reported any degree of nausea, of whom 12 received both acupuncture and massage on POD1. Pre-postintervention (same day), the patients reporting nausea improved by 4.5 (SD ±3.1) on an 11-point scale with the intervention and by 2.1 points (SD ±3.1) without (between-group difference $P = 0.13$).

Health care utilization and costs were not different between intervention and control groups with regard to the average length of the hospital stay (5.2 vs. 5.0 days; $P = 0.66$), total hospital costs ($14,556 vs. $14,819; $P = 0.87$), total direct hospital costs (defined as excluding overhead costs: $8,378 vs. $8,559; $P = 0.84$), or medication costs (during POD1–3: $184 vs. $169; $P = 0.71$). Subgroup analyses by therapeutic categories of medication demonstrated differences in the costs for average sleep and antianxiety medications ($5 vs. $16 in 22 intervention vs. 6 control patients, who used these medications; $P = 0.02$), amounting to an average of $1 vs. $2 over all 136 patients ($P = 0.42$). No differences were identified for pain, antiemetics, or laxative drug classes.

Discussion

We found that a bedside service of massage and acupuncture in addition to usual care resulted in decreased pain and depressive

Table 3
Mean Change (±SD) Scores for Pain from Baseline to Postoperative Day 3 by Diagnostic Subgroups for Patients with at Least 3/10 Pain at Baseline ($n = 86$)

Subgroup of Cancer (n)	PIMS (n)	Control (n)	P^a	ES
Prostate/testes (14)	−1.9 (±1.5) (9)	−0.2 (±2.2) (5)	0.03	0.97
Abdominal (GI, gyn) (21)	−2.3 (±2.2) (16)	+0.2 (±3.6) (5)	0.13	0.98
Breast (17)	−1.9 (±2.6) (14)	−0.3 (±0.6) (3)	0.14	0.66
Kidney/bladder (19)	−2.1 (±1.8) (11)	−2.3 (±2.0) (8)	0.86	−0.10
Others (15)	−2.6 (±1.8) (10)	−2.4 (±3.0) (5)	0.30	0.09

PIMS = Perioperative Integrative Medicine Service; GI = gastrointestinal; gyn = gynecologic.
[a]Mixed-effects regression analyses for repeated measures from baseline POD1 to POD3 controlled for education, baseline pain, and depression for complete subgroups irrespective of baseline symptom scores.

Table 4
Secondary Outcomes: Mean Change (±SD) Scores for Nausea, Vomiting, Anxiety/Tension, and Depression from Baseline to Postoperative Day 3

	PIMS	Control	P^a	n
Nausea[b]	−0.3 (±2.3)	−0.1 (±2.1)	0.26	88 + 43 = 131
Vomiting[c]	−0.6 (±2.0)	−0.1 (±1.9)	0.20	88 + 43 = 131
Anxiety/tension[d]	−0.3 (±0.9)	−0.02 (±1.0)	0.15	88 + 43 = 131
Depression[d]	−0.4 (±0.7)	+0.01 (±0.5)	0.003	88 + 43 = 131

PIMS = Perioperative Integrative Medicine Service.
[a]Mixed-effects regression analyses controlled for education, depression, and outcome at baseline.
[b]NRS, 0–10.
[c]Number of episodes of vomiting per last 24 hours.
[d]Likert scale 1–5; unweighted average score across all individual items.

mood among postoperative cancer patients when compared with usual care alone. Massage and acupuncture could add to symptom management in cancer care if confirmed by a larger clinical trial.

These results confirm in part findings from the largest, although uncontrolled, published study to date of massage among over 1200 cancer patients[20] unrelated to any surgery. In that study, for symptom measures obtained at baseline and within 3 hours after massage, the investigators reported an ES of 0.85 for pain and of 1.12 for anxiety. Mean improvements (SD) for pain and anxiety were 40.2% (±40.9) and 52.2% (±39.5), respectively. Tension/anxiety, rather than depression, was the predominant mood symptom and was the overall symptom with the largest treatment ES. However, ESs in uncontrolled studies are not compared to the effects of usual care or natural course of symptoms. Using identical assessment instruments, the findings in our controlled study in a postoperative setting were more modest: When compared to the control group and using all enrolled patients irrespective of the presence of the respective symptom, we found a smaller ES pre-postintervention (same day) of 0.68. When taking the improvement with usual care in the control group into account, the mean pain reduction from baseline in symptomatic patients was 25.5%.

We could not replicate the benefits for anxiety, however. Several factors might explain the discrepancy. First, our control group used more sleep/antianxiety medications than the experimental group, perhaps masking any difference in the anxiety/tension score. Also, the time interval between the intervention and the following assessment averaged 3 hours, with a range up to 12 hours. In exploratory analyses for POD1, we found no correlations between 1) length of time interval from massage to assessment, and 2) change in pain scores, but a strong correlation for the interval following acupuncture.

The "natural" course of acute symptoms in the hospital care setting immediately after surgery is quite different from the setting of chronic disease management. In the surgery setting, the interval between the study intervention and the following assessment is subject to wide fluctuations in pain and anxiety, depending on variables such as getting out of bed, having an epidural catheter removed, or receiving intravenous or epidural medications. Consequently, there is greater variability in reporting symptoms among postoperative patients than other settings. Median time of day for the assessment of outcome measures was around 2 PM and similar in both groups on all days.

Overall, we were unable to demonstrate any differences in health care costs over the entire hospital stay or for the three-day postoperative study period, except for a reduction in antianxiety/sleep medication costs. The small difference we saw for antianxiety/sleep medications might be an effect of the intervention, as it has been previously found that massage decreases anxiety.[5] Unfortunately, there were too few subjects and infrequent reporting of symptoms to more clearly determine whether these medications were masking a treatment effect. Both the short postoperative time period for following these costs and our lack of data on the exact analgesic amounts used with as needed orders were limitations in our ability to detect differences in cost that might exist between groups. We are not surprised by the lack of a difference in length of stay

(LOS). When LOS is short, it is a relatively insensitive measure of change for many treatments, especially when patients are discharged to intermediate care centers and home care. Further study should conduct a cost-benefit analysis taking into account both the economic costs and the noneconomic costs and benefits in a more complete economic model of the value of a new intervention. Until such analyses are available, hospital administrators will have to decide whether the added value from patient satisfaction and reduced pain warrants adoption.

Our resources were limited and did not permit the inclusion of an attention control group to isolate nonspecific treatment effects. Thus, it is possible that expectation or attention may have contributed to observed effects. However, the inclusion of a control group in this study, even without attention control, is an advance over similar prior uncontrolled studies.

Our analyses were potentially limited by a floor effect caused by numerous patients with no or minimal postoperative symptoms due to excellent postoperative pain management by usual care. Patients were enrolled into the study before surgery, which made it impossible to predict which patients would report significant symptoms after the surgery. Effects were stronger in subgroup analyses of those patients with significant symptoms at baseline, although particular care must be exercised in the interpretation of post hoc subgroup findings. However, results remained robust for improvement in pain when we included the entire study sample.

The patients in our sample were predominantly Caucasian-American and relatively well educated. Education has shown to be a factor in patients' expectations toward CAM. We cannot rule out that patients' expectations are a mediator for the observed effects, and our results might not be generalizable to a different population. Nonetheless, controlling for level of education did not change the results of our analyses.

Our results need confirmation by a larger trial that includes an attention control. A high acceptance rate, short recruitment time, minimal patient burden, and high patient satisfaction (data published elsewhere[24]) support the feasibility of such a trial. Several lessons for future efficacy studies can be learned from our study, which could be seen as a pilot study in regard to its limited scope. Postsurgery symptoms could guide stratified randomization, and subgroup analyses defined by baseline symptoms can be planned before recruitment. Due to our study design and our budget limitations, we were not able to separate the contributions of massage or acupuncture alone from the effects of the combination of these treatments; future multiarm studies would benefit from comparing these combined treatments to individual modalities. Effort should be made in standardizing the time interval between intervention and follow-up assessment. Patients from more diverse populations may allow more generalizable results. Measurement of patient expectations would permit assessment of the influence of expectation on treatment outcomes. Inclusion of more patients with anxiety and more frequent data collection on this symptom would allow a more refined assessment of relationships between drug use and anxiety scores. Despite these limitations, our results indicate that massage and acupuncture are likely to be a valuable addition to postoperative symptom management in cancer patients.

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