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Feasibility of a Brief Yoga Intervention for Improving Acute Pain and Distress Post Gynecologic Surgery

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Abstract

Background—Women undergoing surgical procedures for suspected gynecologic malignancies frequently experience pain and psychological distress related to surgery. Yoga may reduce these negative surgical outcomes. The primary objective of this pilot study was to assess the feasibility of evaluating a perioperative brief Yoga Skills Training (YST) in this population. Secondary objectives were to (1) assess the immediate effects of the YST on pain and psychological distress; and (2) provide preliminary data for future studies.

Method—Adult women scheduled to undergo an exploratory laparotomy for a suspected gynecologic malignancy were recruited to this one-arm feasibility study. Each woman received the YST, which consisted of three 15-minute sessions, one before and two after surgery. The following constructs were assessed: feasibility (rates of accrual, intervention adherence, measure completion, retention, and level of satisfaction), immediate effects of the YST (visual analogue scale ratings of pain and distress immediately before and after each session), and descriptive statistics for measures to be used in future studies.

Results—Of the 33 eligible women, 18 were approached and 10 agreed to participate (mean age = 54.7 years; 90% White). Two women discontinued the study prior to starting the YST sessions. Of the eight participants who received the YST, five completed the pre-surgery session (63%) and seven completed (88%) both post-surgical sessions; one woman withdrew after one YST session. Participants reported high satisfaction with the YST. Acute pain and distress decreased from before to immediately after the YST session with moderate to large effects: pain, $d's = -0.67$ to -0.95 ; distress, $d's = -0.66$ to -1.08 .

Conclusions—This study demonstrated reasonable indicators of feasibility. In addition, patients showed short-term reductions in pain and distress. Next steps include attention to improving staff availability and intervention implementation in order to feasibly evaluate the perioperative YST, which shows promise for reducing post-operative pain and distress.

Keywords

yoga; mind-body therapies; complementary therapies; gynecologic cancer; gynecologic surgery; pain management; psychological distress

Introduction

Women diagnosed with gynecologic cancers often face major abdominal surgery accompanied by pain (64%) and psychological distress (20%) (Liu, Ercolano, Siefert, & McCorkle, 2010). Yet the management of postoperative pain in this population is still inadequate (Good et al., 2000). In addition, psychological distress often accompanies and sometimes adds to the experience of pain (Liu et al., 2010).

Interventions to reduce pain are likely most effective if they target both sensory and affective aspects of pain (Lumley et al., 2011). Yoga is a promising intervention to simultaneously improve these aspects of pain and other negative surgical outcomes such as distress. Key elements of yoga are movements, breathing practices, and meditation. Research supports the efficacy of yoga for reducing pain (Posadzki, Ernst, Terry, & Lee, 2011) and psychological distress (Uebelacker et al., 2010) in a variety of populations. There is also some preliminary evidence for yoga in a surgical context. Yoga taught to women undergoing surgery for suspected breast cancer reduced length of hospital stay and improved wound healing (Rao et al., 2008). However, this prior study of perioperative yoga did not assess the effect of yoga on pain or distress. Yoga may have an advantage over other perioperative interventions because its synergistic components may benefit multiple outcomes.

The primary objective of this study was to assess the feasibility (i.e., accrual, intervention adherence, measure completion, retention, satisfaction) of implementing and evaluating a brief yoga skills training (YST) in women scheduled for surgery for a suspected gynecologic malignancy. The protocol stated *a priori* that a recruitment rate >50% and a drop-out rate <30% would indicate feasibility for a larger study. Secondary objectives were to investigate immediate effects of the YST for reducing pain and distress and to collect data to describe the proposed primary (i.e., pain) and secondary (i.e., distress) outcomes.

Method

Participants

Women were eligible for the study if they were (1) 18 years or older; and (2) scheduled for an abdominal gynecological surgery to remove a mass that was suspected to be malignant by laparotomy. Women were excluded who (1) did not read or understand English; and (2) were cognitively impaired and not able to complete interviews as judged by the referring physician.

Procedures

Ethical approval was obtained from an institutional board prior to implementing study procedures. Patients were recruited from the local cancer center between May 2012 and March 2013. Immediate effects of the YST were assessed before and after each YST session for pain and distress levels. Questionnaire data for the proposed primary and secondary outcomes were collected at baseline before surgery and at follow-up (two days after surgery). Medical chart reviews were conducted immediately after hospitalization.

Intervention

The YST intervention had been developed for a prior study (Sohl, Danhauer, Schnur, Daly, Suslov, & Montgomery, 2012) and adapted to be taught in bed. The YST is designed to be brief (three 15-minute sessions) and implemented in hospital to optimize adherence, target the critical perioperative timeframe, and reduce barriers to implementing yoga. The YST consisted of three sessions taught by a registered yoga instructor with cancer-specific yoga training (Integral Yoga Academy's Yoga Therapy in Cancer and Chronic Illness Teacher Training, www.yogaforpeoplewithcancer.com) prior to surgery (Session 1), one day (Session 2), and two days after surgery (Session 3). This intervention was presented to patients as "Mindful Movement and Breathing" to be descriptive of what actually would be experienced during the study because the level of intensity of physical activity incorporated in our intervention (i.e., gentle movements that could be done in a bed) was minimal as compared to other types of yoga. Thus, we hoped to prevent unnecessarily raising any concerns about discomfort that is sometimes associated with yoga (Sohl, Schnur, Daly, Suslov, & Montgomery, 2011).

The content of the YST was informed by the same cancer-specific yoga training and the Urban Zen Integrative Therapy Program (www.urbanzen.org/uzit). Sessions were designed to teach (a) **Meditation** – five minutes of awareness meditation that involved simply noticing the current state of the body, emotions, thoughts, energy, and breath; (b) **Movement** – five minutes of gentle movements coordinated with the breath (e.g., bending and straightening the legs) that aimed to keep the mind focused on the present moment and to facilitate bowel movements and blood flow; and (c) **Breathing and Relaxation** – five minutes of placing the hands above the navel (rather than on the belly to avoid discomfort) with a focus on exhaling completely. This breathing practice aimed to improve lung capacity and reduce pain and distress through inducing relaxation. Each session contained the same content but movements were individualized based on ability. Self-compassion (i.e., gentleness and self-care) was highlighted throughout each session.

Measures

Immediate effects—Visual analog scales (VAS) were used to assess pain and distress ranging from 0 (*none at all*) to 10 (*as much as there could be*) before and after each session. This measure is sensitive to perioperative symptom change in oncology patients (Montgomery et al., 2007).

Pain was measured at baseline and follow-up with the Brief Pain Inventory (Cleeland, 1991) that assesses severity (four items; $\alpha = 0.81\text{--}0.89$) and interference (seven of the initial eight items, minus the work item; $\alpha = 0.97$) of pain in the last 24 hours (range: 0–10). Higher scores indicate greater pain severity and interference.

Distress was assessed at baseline and follow-up with the Profile of Mood States–Short Version (37 items; DiLorenzo, Bovbjerg, Montgomery, Jacobsen, & Valdimarsdottir, 1999) total mood disturbance score, which is determined from how participants report feeling in the past week of measurement using a scale from 0 (*not at all*) to 4 (*extremely*) regarding six

factors (tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment).

Satisfaction with the YST—Three items asked participants to rate the extent to which they liked the YST, found it helpful, and planned to use what they learned on a scale from 1 (*not at all*) to 5 (*very much*) at the follow-up visit.

Demographic and clinical characteristics—Some demographic and clinical characteristics (i.e., age, ethnicity, cancer site, length of stay) were abstracted from medical charts, whereas other information (i.e., level of education, income, experience with yoga) was self-reported at baseline.

Statistical Analysis

The target sample size for the study ($n = 10$) was based on the goals of estimating feasibility and providing preliminary data to inform a larger trial. Descriptive analyses were conducted to characterize feasibility, participant characteristics, and estimated effect sizes of the immediate effects of the YST on pain and distress. Estimated effect sizes were calculated by subtracting pre-session values from post-session values and dividing by the standard deviation of the difference to account for within-person correlation stratified by session. Differences in the immediate effects of the YST on pain and distress were assessed using Wilcoxon paired signed rank tests. A Mann-Whitney U test (age) and Fisher's Exact Test (race) analysis were performed to compare those who consented to those who did not. All analyses were conducted using IBM SPSS Statistics Version 22 (Armonk, New York).

Results

A total of 33 women were eligible, 18 of whom were approached about the study (Figure 1). Of those approached, 10 agreed to participate (54.7 ± 8.7 years; 90% White [$n = 9$]; 10% African American [$n = 1$]). The most common reason for declining was lack of interest ($n = 7$). There were no significant differences in age (Mann-Whitney $U = 40.0$, $p = 0.72$) or race ($p = 0.58$) among those who consented compared to those who did not. Five participants (71%) had a high school education or greater, including one participant who reported graduating college (14%), and three participants (43%) had a household income of greater than \$60,000 (from the $n = 7$ who responded to these questions). Sixty percent of women enrolled had ovarian cancer, 20% cervical cancer, and 20% uterine cancer. At baseline, one participant reported trying yoga less than 10 times and no participants reported practicing yoga in the past two weeks. Two women discontinued the study after enrollment and prior to starting the YST sessions. One discontinued because she did not have surgery and the other because of scheduling. Of the eight participants who received the YST, five completed the pre-surgical session (63%) and seven completed (88%) both post-surgical sessions; one woman withdrew after one YST session. Baseline and follow-up questionnaires were completed by seven participants; baseline was not completed by the woman who withdrew (two enrolled were not given questionnaires). Length of hospital stay ($n = 8$) ranged from 2–5 days (3.4 ± 0.9 days). Six of seven participants (86%) indicated that they practiced the YST during hospitalization (e.g., “Just before bed to relax,” “just before getting out of bed to

get ready to get up”). Participants ($n = 7$) reported that they liked the YST (4.3 ± 0.8), found it helpful (3.7 ± 1.0), and planned to continue to use what they had learned (3.7 ± 1.1).

Acute pain and distress decreased from before to immediately after the YST session with moderate to large effects: pain, $d's = -0.67$ to -0.95 (Figure 2a); distress, $d's = -0.66$ to -1.08 (Figure 2b). Changes in these immediate effects were significant for pain at both post-surgical sessions and distress at two time points (see Figures 2a and 2b). Descriptive statistics of the outcome measures were as follows: Brief Pain Inventory at baseline (Pain Severity: 2.7 ± 1.8 ; Pain Interference: 2.3 ± 2.8) and follow-up (Pain Severity: 3.9 ± 1.5 ; change from baseline 1.2 ± 1.7 ; Pain Interference: 5.9 ± 2.3 ; change from baseline 3.6 ± 3.2) and Profile of Mood States – Short Version Total Mood Disturbance at baseline (56.0 ± 27.7) and follow-up (56.2 ± 22.8 ; change from baseline 0.20 ± 14.6).

Discussion

This study demonstrated reasonable rates of accrual, measure completion, retention, and adherence to YST sessions following surgery. Although the recruitment rate of eligible women (30%) was lower than initially considered feasible, the recruitment rate of women approached was adequate (53%). Participants also expressed satisfaction with the YST and were able to experience short-term reductions in pain and distress in the inpatient setting. Thus, results support the feasibility of investigating the YST in this population and show promise for reducing pain and distress.

Limitations of this study included the small number of participants and single-arm design. These results are preliminary and are intended to inform the development of a future study examining the efficacy of the YST for reducing pain, psychological distress, and additional variables such as length of stay that are important from both a clinical and cost perspective. Future studies need to address challenges regarding recruitment due to limited funding for personnel time in this pilot study (e.g., by increasing study staff availability) and the YST sessions missed prior to surgery, which was primarily due to scheduling issues. In addition to increasing the effort of study personnel, other methodical changes such as focusing on the postoperative timeframe or implementing yoga via video conferencing could be considered to increase feasibility.

Despite its limitations, this study was the first to investigate a brief yoga intervention targeted to an inpatient sample that was designed to optimize benefits of yoga while minimizing patient burden. Implementing the YST individually in the hospital challenges the paradigm of yoga, which is typically taught to a group outside of the clinical setting. Teaching yoga in the clinical setting may reach patients who are unlikely to attend group classes and proactively reduce acute symptoms that may become chronic. In addition, the YST is promising because it has the potential to impact both psychological and physical surgical outcomes. Establishing a feasible study design for assessing efficacy of the YST in a future trial has important implications for improving surgical outcomes in this undertreated patient population and may generalize to other patients undergoing surgery.

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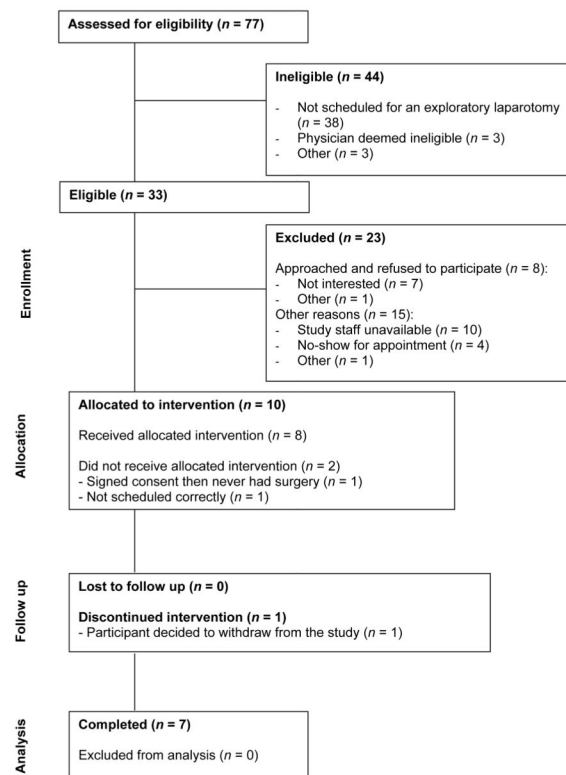


Figure 1.
Study flow diagram.

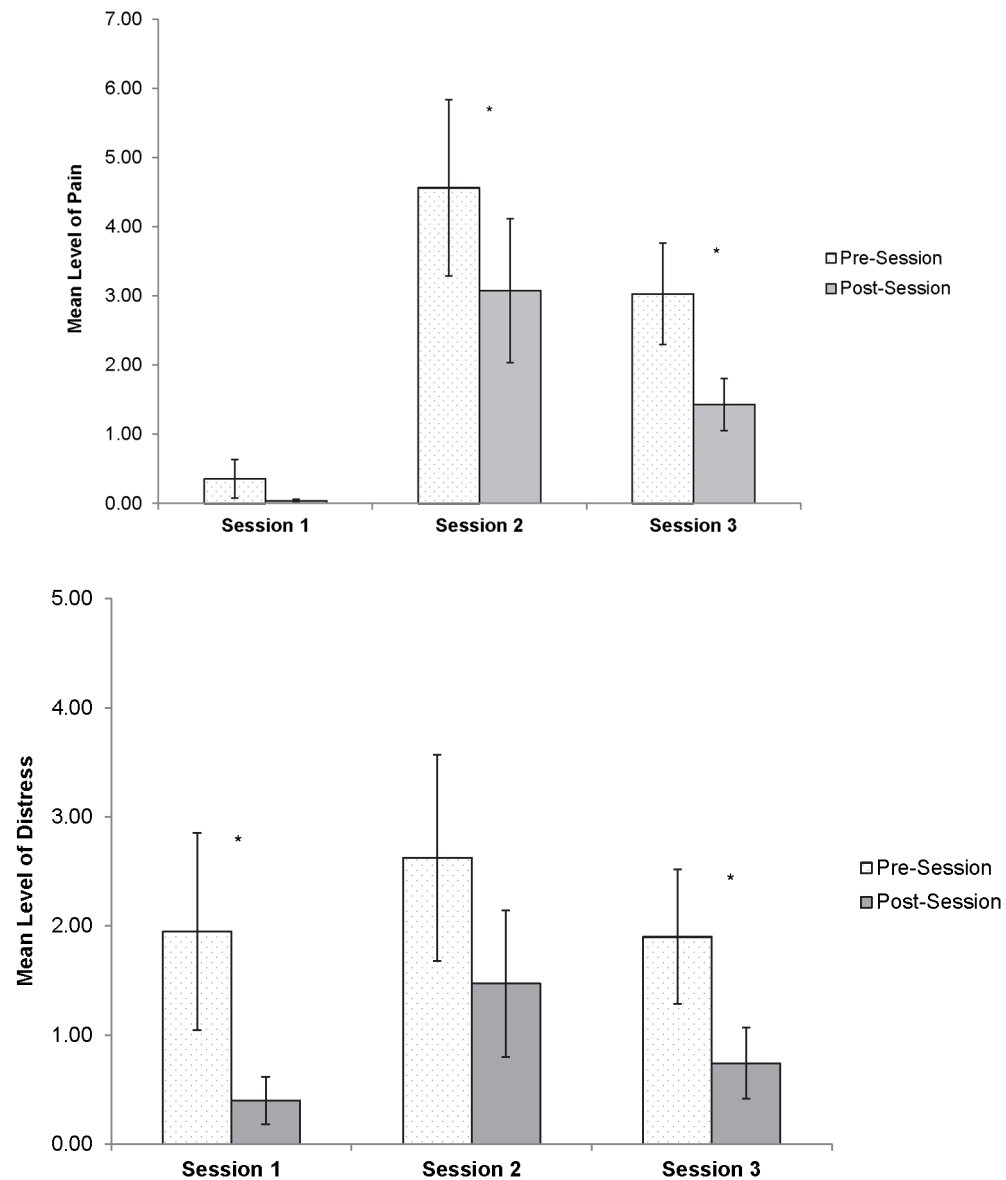


Figure 2.

Figure 2a. Immediate experience of pain before and after a Yoga Skills Training session.

Values are means (SE).

* Statistically significant Wilcoxon paired signed rank tests results (Session 1, $z = -1.342$, $p = 0.180$; Session 2, $z = -2.201$, $p = 0.028$; Session 3, $z = -1.997$, $p = .046$).

Figure 2b. Immediate experience of distress before and after a Yoga Skills Training session.

Values are means (SE).

* Statistically significant Wilcoxon paired signed rank tests results (Session 1, $z = -2.023$, $p = 0.043$; Session 2, $z = -1.483$, $p = 0.138$; Session 3, $z = -2.201$, $p = .028$).