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

We read with interest the pilot randomized, controlled trial by Quinlan-Woodward et al. (2016) published in *Oncology Nursing Forum* about the impact of acupuncture on pain, nausea, anxiety, and coping in women undergoing a mastectomy. We think that there are both theoretical and methodologic issues that do not allow the authors to conclude that their study demonstrated that acupuncture delivered postoperatively in the hospital after mastectomy can reduce the severity of symptoms experienced and increase the patient's ability to cope with her symptoms.

Briefly, from the theoretical point of view, there are issues with the study design: no sham acupuncture group, extremely small sample size, high attrition rate (33.33% in the acupuncture group versus 6.66% in the control group), and data analysis (use of parametric methods, such as student t test, without confirming the necessary assumptions) (Strasak, Zaman, Pfeiffer, Göbel, & Ulmer, 2007). We do not want to extend our dissertation in this point, but it is relevant regarding the authors' emphatic development of conclusions from this trial.

We want to discuss the analysis of the data presented by the authors in the manuscript. Although we do not share their election of statistical methods, we would accept them and would like to partially re-analyze some of the data presented with parametric methods just for pedagogic purposes. A complete re-analysis of the presented data with nonparametric methods would require access to the raw data, which was not provided, but some estimates could be done with the provided data.

First, although not affecting the overall information reported in Table 1 from the Quinlan-Woodward et al. (2016) article, the p value shown for marital status is inaccurate; recalculation shows a p value of 0.548 versus 0.059 reported by authors. However, the recalculation is still inaccurate because the use of chi-square test when the expected values are less than 5 has been widely questioned. If an expected value is less than 5 (Strasak et al., 2007), authors should use an alternative, such as an exact test.

Second, the authors' conclusions are substantiated in the comparisons of pre- and postinterventions in both groups. Basically, the majority of pre- and postintervention comparisons in the acupuncture group yielded significant changes, and pre- and postintervention comparisons in the control group were all nonsignificant ($p > 0.05$). This result extends to all the areas studied by the authors (pain, nausea, anxiety, and coping) and to the two visits. These results lead the authors to conclude that their pilot study supports reductions in pain, nausea, and anxiety, as well as an increase in ability to cope, and that they found that it is feasible to deliver acupuncture postoperatively to women undergoing surgery for breast cancer who have a short length of hospital stay. We think that authors have not correctly addressed the analysis of their data because of the following reasons:

- There are no differences in the baseline characteristics of the two groups (preintervention measurements) with the sole exception of coping and nausea at visit 1. For coping at visit 1, the value was significantly higher in the control group; for nausea, it was higher in the acupuncture group. It is difficult to interpret evolution of the numeric rating scale between groups when both groups start from different points and with such a small sample, but, for the rest of the studied areas and the whole visit 2, the baseline was the same. This point was not discussed by the authors.
- There are no statistically significant differences in the numeric rating scales during postintervention between the studied groups ($p > 0.05$ in all cases) (see Table 1) in visit 1 or 2. This extends to all the studied areas. Using the interpretation of the p value that the authors have applied to their own article, this indicates that patients with acupuncture treatment and patients without acupuncture treatment reached a similar point in the numeric rating scales across all the studied areas after the acupuncture intervention and in the control group. It indicates that, with or without acupuncture, the result was the same, which

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TABLE 1. Recalculation of P Values in the Quinlan-Woodward et al. (2016) Article

	Preintervention					Postintervention				
	Acupuncture		Control			Acupuncture		Control		
Symptom	$\bar{X}$	SD	$\bar{X}$	SD	p	$\bar{X}$	SD	$\bar{X}$	SD	p
Visit 1	(n = 15)		(n = 15)			(n = 15)		(n = 15)		
Anxiety	2.33	1.8	1.27	1.39	0.082	1	1.31	1.8	2.37	0.262
Coping	6.67	2.72	8.53	1.81	0.036	8.53	2.17	8.07	2.25	0.573
Nausea	2.6	3.31	0.27	0.46	0.012	1.07	2.12	1	1.69	0.921
Pain	4.2	1.01	3.67	2.13	0.391	2.73	1.39	3.6	1.99	0.176
Visit 2	(n = 10)		(n = 14)			(n = 10)		(n = 14)		
Anxiety	1.4	1.65	1.57	1.5	0.795	0.5	0.71	1.71	1.82	0.06
Coping	7.6	3.06	8.5	1.51	0.35	7.9	3.73	8.57	1.7	0.558
Nausea	1	1.7	0.79	1.97	0.788	0.5	0.97	0.5	1.16	1
Pain	3.1	1.52	3.07	2.13	0.97	1.6	1.35	2.64	2.31	0.217

is to say it had no effect. This analysis was not accomplished in the article or in the peer review process.

Therefore, we would like to express our concerns about the analysis performed by the authors. The trial does not add to the body of research supporting the feasibility and effectiveness of acupuncture as a nonpharmacologic option for treatment of symptoms after mastectomy. The presented data indicate that, without acupuncture, the results are exactly the same as with acupuncture. We feel that the article does not support the adoption of acupuncture as an option to manage symptoms and that it leads to an increase in quality of life for patients having breast cancer surgery.

We agree with Quinlan-Woodward et al. (2016) that nurses must be knowledgeable of the potential benefits that the available therapies provide for the best evidence-based care for patients with breast cancer; for this reason, nurses should know that the reported potential benefits of acupuncture in this trial are nonexistent.

References

Quinlan-Woodward, J., Gode, A., Dusek, J.A., Reinstein, A.S., Johnson, J.R., & Sendelbach, S. (2016). Assessing the impact of acupuncture on pain, nausea, anxiety, and coping in women undergoing a mastectomy. *Oncology Nursing Forum, 43,* 725–732. doi:10.1188/16.ONF.725-732

Strasak, A.M., Zaman, Q., Pfeiffer, K.P., Göbel, G., & Ulmer, H. (2007). Statistical errors in medical research—A review of common pitfalls. *Swiss Medical Weekly, 137*(3-4), 44–49. doi:2007/03/smw-11587

Jose M. Moran, PhD
Professor
Faculty of Nursing and Occupational Therapy
University of Extremadura
Cáceres, Spain

Antonio Sánchez Fernández, MD
Extremadura Health Service
Optional Area Specialist
Hospital San Pedro de Alcántara
Cáceres, Spain

Juan D. Pedrera-Zamorano, MD, PhD
Professor
Faculty of Nursing and Occupational Therapy
University of Extremadura
Cáceres, Spain

The Author Responds

First, Moran et al. raised a question related to study design. This was a pilot study; by definition, sample sizes were admittedly small, and, as expected, population dynamics like attrition were uncontrolled. Part of the study logic was to explore the impact of these factors on the feasibility of measuring intervention effects at all.

Second, Moran et al. questioned the use of parametric statistics for project data analysis. Although this view on this issue is shared by some researchers, it is by no means universal. Review of the literature related to the application of parametric statistical analysis to numeric rating scales indicated a relatively even split of opinion regarding their validity (Dexter & Chestnut, 1995; Farrar, Polomano, Berlin, & Strom, 2010; Price, Staud, & Robinson, 2012).

Third, Moran et al. identified the typographic error related to the marital status p value in Table 1. We would like to thank the reviewer for bringing this error to the attention of the editor and authors. Such errors are regrettable but do sometimes occur despite the best intentions of the authors and reviewers.

Moran et al.'s last question relates to their repackaging of the statistical analysis and conclusions drawn related to observed group (intervention and control) differences. We believe they may be misinterpreting the central study objective and the logic model for applying the analytic methods that were used. The central differences of interest

were the matched pair pre- and postintervention measurements for the acupuncture intervention group. Other reported differences were provided as context.

In a small pilot study like this, the logical premise for using a matched pair analysis pre- and postintervention treatment was important to preserve. This approach compensates for possible effects of unmeasured confounding factors affecting outcomes at an individual level. For that reason, we would assert that the approach used to generate Tables 2 and 3 in the article was the most appropriate one possible.

Definitive quantification of intervention effects based on group comparisons (intervention versus control) were far beyond the objectives of this limited study. That approach would be more suited to formal hypothesis testing and exact quantification of measured outcome differences. Such an approach would have required much larger sample sizes and complex matching of any group attributes that could possibly be related to measured outcomes. Accordingly, if the analysis were to be conducted on the basis advocated by Moran et al., the control group would have required some procedure like propensity score matching to ensure unbiased group compositions as a precursor to meaningful analysis.

We concur with Moran et al. that measuring such group differences with the limited sample size available for this study often failed to demonstrate significant intervention differences, but we would also point out that this was not the goal of the study logic model. The within-subject pre- and postintervention differences shown in Tables 2 and 3 establish the intervention effect sufficiently for a pilot study.

References

Dexter, F., & Chestnut, D.H. (1995). Analysis of statistical tests to compare visual analog scale measurements among groups. *Anesthesiology, 82,* 896–902.

Farrar, J.T., Polomano, R.C., Berlin, J.A., & Strom, B.L. (2010). A comparison of change in the 0–10 numeric rating scale to a pain relief scale and global medication performance scale in a short-term clinical trial of breakthrough pain intensity. *Anesthesiology, 112,* 2464–1472. doi:10.1097/ALN.0b013e3181de0e6d

Price, D.D., Staud, R., & Robinson, M.E. (2012). How should we use the visual analogue scale (VAS) in rehabilitation outcomes? II: Visual analogue scales as ratio scales: An alternative to the view of Kersten et al. *Journal of Rehabilitation Medicine, 44,* 800–804. doi:10.2340/16501977-1031

Jessica Quinlan-Woodward, RN, BSN
Manager of Oncology
Care Coordination
Allina Health
Minneapolis, MN

Autumn Gode, APRN, CNS
Clinical Nurse Specialist
Allina Health
Minneapolis, MN

Jeffery A. Dusek, PhD
Director of Research
Allina Health
Minneapolis, MN

Adam S. Reinstein, Lac, MAOM
Acupuncturist
Allina Health
Minneapolis, MN

Jill R. Johnson, PhD, MPH
Faculty Member, MPH Program
University of Pennsylvania
Philadelphia, PA

Sue Sendelbach, PhD, APRN, CNS, FAHA, FAAN
Director of Nursing Research, retired
Abbott Northwestern Hospital
Minneapolis, MN