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The Effect of Acupuncture on Pain in Inpatient Medicine

Abstract

Background: Pain management has become a controversial topic. Opioids, which once held the promise of improving quality of life for millions of Americans, have resulted in an epidemic of addiction. As a result, national organizations are investigating alternative methods to treat pain, including acupuncture. The purpose of this review is to investigate the effect of acupuncture on the general symptom of pain, within the context of the controlled environment of inpatient medicine.

Methods: An exhaustive search of MEDLINE-Ovid, CINAHL, and Web of Science was conducted using the search terms *acupuncture, inpatient*, and *pain*. Included studies measured pain scores before and after acupuncture treatments in U.S. inpatient medical settings. Additional inclusion criteria were study design (interventional studies, and cohort studies), English language, and publication type (peer-reviewed journals). Studies were excluded if they compared acupuncture treatment to sham, due to controversy surrounding sham. Studies were also excluded if they did not analyze effects of acupuncture separate from other alternative health modalities. Quality of publications were assessed using GRADE criteria.

Results: Seven studies were included in this systematic review, meeting the inclusion and exclusion criteria: two pre-post studies, four cohort studies, and one randomized control trial (RCT). All included studies showed acupuncture significantly reduced immediate pain in an inpatient setting, regardless of the underlying cause of pain. However, overall quality of evidence was low as a result of lack of control groups, lack of blinding, loss to follow up, reporting bias, and small sample size.

Conclusion: Every study that met criteria for this review showed data promising for acupuncture's capacity to decrease pain in an inpatient setting. However, study design flaws limited confidence in the data. Ultimately, further research is needed.

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The Effect of Acupuncture on Pain in Inpatient Medicine

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A Clinical Graduate Project Submitted to the Faculty of the

School of Physician Assistant Studies

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Clinical Graduate Project Coordinator: Annjanette Sommers, PA-C, MS

|| Biography ||

Jessica Kolahi was raised in Connecticut, and received her Bachelor of Science from Portland State University in Biology. She trained as an acupuncturist at the American College of Traditional Chinese Medicine, in San Francisco, and established Vitalize Acupuncture in Portland in 2011, where she practiced Chinese Medicine for four years. Jessica volunteered as a clinical research assistant for two years before starting PA school, and hopes to pursue a career in women's health, integrative medicine, and health policy.

|| Abstract ||

Background: Pain management has become a controversial topic. Opioids, which once held the promise of reducing pain and therefore improving quality of life for millions of Americans, have resulted in an epidemic of addiction. As a result, national organizations are investigating alternative methods to treat pain, including acupuncture. The purpose of this review is to investigate the effect of acupuncture on the general symptom of pain, within the context of the controlled environment of inpatient medicine.

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List of Abbreviations

CI	Confidence Interval
ESAS	Edmonton Symptom Assessment Scale
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HHS	US Department of Health and Human Services
NIH	National Institutes of Health
PCA	Percutaneous analgesia
RCT	Randomized controlled trials
SCD	Sickle Cell Disease
SD	Standard deviation
SE	Standard error
тсм	Traditional Chinese Medicine
VOC	Vaso-occlusive Crisis

The Effect of Acupuncture on Pain in Inpatient Medicine

BACKGROUND

According to the US Department of Health and Human Services (HHS), our country is experiencing a "public health emergency" as a result of opioid prescribing trends. The HHS reported that in 2016, 11.5 million people misused prescription opioids, and more than 42 thousand people died from overdosing on opioids, costing the US a total of 504 billion dollars in economic loss.¹ In 2017, the HHS, the US Department of Defense, and the US Department of Veteran affairs partnered to fund an 81 million dollar research project into non-pharmacologic approaches for the treatment of pain, investigating methodologies such as acupuncture and integrative medicine.²

Acupuncture is the practice of inserting needles to stimulate specific points on the body.³ It has been practiced for thousands of years, and is one of several modalities used in Traditional Chinese Medicine (TCM).⁴ Evidence maps for the efficacy of acupuncture show that high quality research has sufficiently proven acupuncture has a positive effect in the treatment of chronic pain, headache, and migraines. There is also high, medium, and low quality evidence of a potential positive effect of acupuncture for a number of other distinct pain conditions.⁵ Widespread use of acupuncture for pain is limited, however, by the fact that most research and reviews have focused on the effect of acupuncture on specific types of pain, making it difficult for providers to understand the generalizability of acupuncture for the treatment of pain.

The purpose of this review is to investigate the efficacy of acupuncture on a population with diverse pain conditions, to determine its applicability to the general

complaint of pain, regardless of underlying pathophysiology. Inpatient medicine may be the key to better understanding the effect of acupuncture on broad pain symptomology, since it is a controlled setting that allows for systematic treatment delivery, and methodical measurement of effect.

Methods

An exhaustive search of MEDLINE-Ovid, CINAHL, and Web of Science was conducted using the search terms *acupuncture*, *inpatient*, and *pain*. Included studies measured pain scores before and after acupuncture treatments in U.S. inpatient medical settings. Additional inclusion criteria were study design (interventional studies, and cohort studies), English language, and publication type (peer-reviewed journals). Studies were excluded if they compared acupuncture treatment to sham, due to controversy surrounding sham. Studies were also excluded if they did not analyze effects of acupuncture separate from other alternative health modalities. Quality of publications were assessed using GRADE criteria.⁶

Results

An initial search of MEDLINE-Ovid, CINAHL, and Web of Science revealed 134 studies. Forty-three duplicates were removed. Abstracts for the remaining 91 articles were screened, and 82 were removed for not meeting eligibility criteria. Nine full-text articles were reviewed, of which, 7 met full criteria (Figure 1), including 2 pre-post trials, ^{7,8} 4 cohort studies, ^{9,10,11,12} and 1 RCT.¹³ All 7 studies showed significant improvement of pain immediately following treatment with acupuncture (see Table 1). However, the

majority of publications were cohort studies and quasi interventions, which are intrinsically low quality evidence (See Table 2).

Garcia et al (2018)

This pre-post study was performed at The University of Texas M.D. Anderson Cancer Center Integrative Medicine Center between December 2014 and December 2015. Depending on presenting symptomology, an advanced practice provider offered oncology patients acupuncture or other integrative medicine modalities. Before and immediately following each acupuncture treatment, patients completed a modified Edmonton Symptom Assessment Scale (ESAS), which measured pain, as well as other patient markers (including nausea, fatigue, sleep disturbance, shortness of breath, appetite, drowsiness, depression, anxiety, and wellbeing) on a scale of 0-10 (0 referring to no symptoms, and 10 referring to the "worst possible" symptoms). Patients were only included in the analysis if they had a symptom score \geq 1 at the original ESAS.⁷

One hundred seventy-two oncology patients received at least one acupuncture treatment during the study period. Participants ranged in age from 17 to 90 years old, and were diagnosed with a variety of cancer types at various stages of presentation. Sixty-nine patients completed post-ERAS assessments and were analyzed for effects of the first treatment. Twenty additional patients received a second, follow-up acupuncture treatment, and results from this treatment were analyzed as well.⁷

The mean pain score prior to the first treatment was 4.9 (standard deviation, SD = 3.0). Pain scores for the analyzed patients decreased by an average of 1.8 points (SD = 2.2) after the initial treatment (p-value <0.0001). Of all analyzed patients from the first

treatment, 74% experienced a clinically significant improvement in pain, determined as a decrease in pain by \geq 1 point. After the second treatment, pain decreased by an average of 2.3 points (SD = 2.7) (p-value <0.001).⁷

Feeney et al (2017)

This pre-post study took place at Highland Hospital in Oakland, California, in collaboration with University of California, Berkeley. Eligible patients from the medical, trauma, and neurosurgery ICU at Highland Hospital, between November 3rd 2014 and April 2nd 2015, were offered acupuncture for the treatment of pain and nausea. ⁸

Prior to acupuncture treatment, patients completed a pretreatment survey, collecting data on the location, type, characteristic, and severity of pain on a scale of 0 to 10. Data was also collected on severity of nausea and vomiting, and morphine equivalent dosing of patient analgesia. After treatment, a nurse entered the room and administered the post-treatment survey. Acupuncture was offered for 3 consecutive days to patients who remained eligible. Secondary outcomes, including vital signs before and after treatment, as well as medication use and length of stay were also recorded.

A total of 114 treatments were administered. Forty-five of forty-six patients who received acupuncture on day 1 completed a post-treatment survey and were analyzed. Thirty-eight of thirty-eight were analyzed after treatment day 2, and thirty of thirty were analyzed after treatment day 3. Self-reported pain, measured before and immediately after treatment, decreased by an average of 2.56 points after the first treatment, 2.36 points after the second treatment, and 1.98 points after the third treatment, (p-value < 0.05). After the first treatment, 65% of patients reported a decrease in pain greater than

1.5 points. Mean morphine dosages, calculated in oral morphine equivalents, also dropped after treatment. Prior to the any acupuncture, and then 4 hours after the initial treatment, mean doses were calculated as: 21.44 mg and 19.96 mg.

Schlegel et al (2016)

This retrospective cohort study analyzed the effects of integrative medicine modalities on high risk pregnant inpatients in the antepartum unit at Mercy Hospital in St. Louis, MO, over an 18-month period between 2013 and 2014. Patients were referred to integrative therapies by either a nurse or physician for the treatment of pain or anxiety. Integrative therapy options included acupuncture, healing touch, massage, guided imagery, or reflexology. Patients completed pre and post treatment assessments on pain and anxiety using a 0-10 Auditory Analog Scale administered by the integrative medicine provider. ⁹

A total of 83 patients received acupuncture, 80 of which successfully completed pre and post treatment assessments. Prior to acupuncture, average pain was recorded as 2.95, and after treatment, average pain was reported as 0.62. Overall, there was a mean decrease in pain of 78.9% (p value <0.0001).

Johnson et al (2014)

This retrospective cohort study analyzed data collected from inpatients with ICD9 codes reflecting cardiovascular diagnoses at the Penny George Institute for Health and Healing, within Abbot Northwestern Hospital, in Minneapolis, MN. Between July 2009 and December 2012, included patients were offered integrative medicine treatments, and 0-10 pain and anxiety scores were collected before and after each

treatment. Offered modalities included bodywork, mind-body and energy therapies, TCM, and combination therapies. In this study, TCM included acupuncture, acupressure, and Korean hand therapy. Responses to treatment were further clarified based on 6 subsets of cardiovascular diagnoses, including: *arteries arterioles and capillaries*, *cerebrovascular, hypertension, ischemic heart disease, pulmonary circulation,* and *other*. Patients were excluded from the analysis if demographics information was missing, or if pre and post pain and anxiety scores were not recorded, or scores were not greater than 0 prior to treatment. Logistic regression was also used to determine the likelihood of receiving integrative therapies based on patient demographics.¹⁰

Within the study period, a total 1248 patients with cardiovascular diagnoses were treated for pain with TCM, and experienced a 48.4% average decrease in pain immediately following the treatment (standard error, SE = 1.3). In the subset analysis, patients with *arteries, arterioles and capillary* diagnoses experienced 46.3% decrease in pain, *cerebrovascular* patients received 53.0% decrease, *hypertension* patients received 47.1% decrease, *ischemic heart* disease patients received 44.6% decrease, and *pulmonary* circulation patients received 59.7% decrease in pain.

Johnson et al (2014)

This retrospective cohort study analyzed data collected at the Penny George Institute for Health and Healing, for inpatients with ICD9 codes for primary malignant neoplasms. Between July 2009 and December 2012, pre and post pain scores on a scale of 0-10 were collected for patients who received bodywork, mind-body and energy therapies, TCM, and combination therapies. A subset analysis was performed based on

the site of original neoplasm. Patients were included in the analysis if all pertinent demographic information was available, if they reported greater than a 0 for pain and anxiety, and if pre and post pain and anxiety scores were recorded. This study also performed a logistic regression to determine the probability of receiving an integrative therapy during admission based on patient demographic information. ¹¹

One hundred fifteen patients received TCM for the treatment of pain and anxiety. These patients received an average of 45.7% reduction in pain (Confidence interval (CI) = 35.6-55.8, p value <0.001). In the subset analysis, patients with original neoplasm location at the *breast* received a 56.2% reduction in pain, *colorectal* neoplasm patients received a 54.1% reduction in pain, *lymph* and hematopoietic neoplasm patients received a 52.0% reduction in pain, *prostate* neoplasm patients received a 31.2% reduction in pain, and patients with all *other* original neoplasm sites received a 40.4% reduction in pain.

Lu et al (2014)

This retrospective cohort study analyzed the effect of acupuncture on acute pain in sickle cell patients. Between January 2005 and September 2011, 47 sickle cell disease (SCD) patients were referred by the National Institutes of Health (NIH) to both inpatient and outpatient acupuncture for pain. Twenty-four total patients received acupuncture, 9 of which received inpatient only-treatment for management of symptoms related to acute vaso-occlusive crisis (VOC). At the time of treatment, all patients were receiving optimal opioid therapy.¹²

Acupuncturists collected pre and post pain scores (on a scale of 0-10) for all inpatients receiving treatment. Each individual received an average of 3 sessions, for a total of 48 treatment effects measured. Mean pain scores decreased by 2.1 points (p value <0.0001), and 100% of patients reported a decrease in pain after every treatment.

Quinlan-Woodward et al (2016)

This RCT measured the effect of acupuncture on inpatients with breast cancer undergoing a mastectomy at Abbott Northwestern Hospital in Minneapolis, MN. Eligible patients were referred to the study by cancer care coordinators during preoperative visits. Patients were randomly assigned to intervention group (acupuncture) or control group (standard of care). Women in the intervention group received up to 2 postsurgical treatments. Immediately before and after acupuncture, patients entered scores on a 0-10 scale for pain, nausea, anxiety, and ability to cope on a tablet computer. Acupuncturists and research coordinators were blinded to scores entered into the tablet.¹³

A total of 30 patients were randomized for the trial, 15 of which received acupuncture at least once. 12 women randomized to the intervention group also received second acupuncture treatment, although 2 participants could not be analyzed due to a technical error during that visit. Mean change in pain after the first acupuncture treatment was -1.47 points (SD = 1.06). Mean change in control group pain at the first visit was -0.07 points (SD = 1.67). Change in pain after the second treatment was -1.5 (SD = 0.97), compared to a -0.43 (SD = 1.02) change in the control group.

DISCUSSION

All studies that met criteria conclude that acupuncture has the potential to immediately reduce pain in inpatient medicine settings. Moreover, the diversity of disease processes represented in this review demonstrate that acupuncture may benefit the general complaint of pain, regardless of underlying cause. In the context of today's opioid crisis, these studies show that acupuncture is a reasonable adjunct therapy for pain management in inpatient care. However, in spite of all studies showing universal benefit with acupuncture for pain reduction, the overall quality of evidence is low. Further, meticulously designed, research would be of benefit for validation that acupuncture effectively reduces pain, and also reduces opioid consumption in inpatient settings. In addition, research demonstrating cost-effectiveness of acupuncture for inpatient pain reduction would provide economic impetuous for healthcare institutions to create inpatient acupuncture programs.

Every study that met criteria showed benefit of acupuncture. The study hosted at University of Texas M.D. Anderson Cancer Center Integrative Medicine Center showed acupuncture reduced pain in oncology patients by an average of -1.8 points after one treatment and -2.3 points after a second.⁷ Pain in in medical, neurosurgical, and trauma ICU patients at Highland Hospital showed an average reduction in pain of 2.56 points after a first treatment, 2.36 points after a second treatment, and 1.98 points after a third.⁸ Researchers at Mercy Hospital in St. Louis, MO showed acupuncture in high-risk antepartum patients reduced pain by a calculated 2.33 points.⁹ Studies at Penny George Institute for Health and Healing showed a 48.4% average decrease in pain

for cardiovascular diagnosis, and a 45.7% decrease in patients with primary malignant neoplasms.¹⁰⁻¹¹ The NIH showed a mean pain reduction of 2.1 points in patients experiencing a sickle cell VOC.¹² Researchers at Abbott Northwestern Hospital showed a mean decrease in post-operative mastectomy pain of-1.47 points compared to a control group reduction of -0.07 points after initial treatment, and a mean reduction of -1.5 points after a second treatment compared to -0.43 for the control.¹³ It is interesting to observe that patients report an immediate decrease in pain of what appears to be about 2 points regardless of type of pain treated. This potentially speaks to a common mechanism of action. It may also indicate a baseline expectation for treatment effect regardless of the underlying cause of pain.

Regarding validity of evidence, study design and lack of blinding were the most consistent limitations to the quality of evidence for this review. Six of the seven included studies lacked control groups.⁷⁻¹² Absence of control groups results in an uncertainty about the magnitude of treatment effect. Additionally, none of the included articles were double blinded, resulting in potential for bias.⁷⁻¹³ Since lack of control and blinding were the most common limitations, it could be postulated that they are the greatest challenges to acupuncture research. It should be noted that double blinded RCTs, the pinnacle of high quality evidence, are virtually impossible to perform in regards to acupuncture.¹⁴ This is due to the challenge of blinding the provider and patient to insertion of needles, resulting in difficulty creating true control groups. Sham acupuncture was developed to overcome the obstacle of inadequate blinding, but articles including sham were excluded for the purpose of this review since their

methodologies have a controversial impact on results.[‡] The challenge at hand is that acupuncture studies that compare treatment versus sham show decreased benefit of acupuncture when compared to studies that analyze acupuncture versus no treatment, and experts argue that this is due to intrinsic flaws in sham methodologies. The potential consequence of excluding sham studies from this review is that the effects may show an inflated benefit to acupuncture as a result of placebo effect.

Additional limitations to study design included loss to follow up, sample size, and reporting bias. In Garcia's study, a significant number of patients were lost to follow up. Only 42% (n=69) completed the post assessment after the initial treatment and were included in the treatment analysis, seriously limiting quality. Small sample size, as seen in studies by Lu and Quinlan-Woodward resulted in data of unknown applicability to a larger population.^{12,13} Lu analyzed 24 patients, while Quinlan-Woodward analyzed 30. Potential for reporting bias was seen in all studies where integrative medicine providers, themselves, administered the pre and post pain assessments.⁷⁻¹² It was postulated that by having the acupuncturist collect these assessments, patients might alter their true pain scores. One theory is that they might increase the benefit to please the acupuncturist, while another concern is that they may report a lesser benefit to maintain access to narcotics.

On the other side of the spectrum, while limitations to study design cause critical readers to question if acupuncture actually has any benefit, practitioners of acupuncture argue that results published actually show *reduced* efficacy as a result of study design. Feeney mentioned this concern in their discussion section, "Classically, acupuncturists

individualize therapy to address the pattern of pathologies observed from the complete Chinese medicine diagnosis. For the sake of standardization, we limited the number of points to eight, and we did not individualize further. From a TCM point of view, this could potentially reduce the effectiveness of treatment."⁸ For reproducibility, most acupuncture studies require providers to use a protocolled acupuncture treatment plan. The challenge is that acupuncture is practiced with more fluidity in a clinical setting, where patients receive acupuncture points based on their individualized Chinese medicine pattern. Acupuncturists criticize studies that use acupuncture protocols rather than individualized treatments tailored to each patient, because they theorize that this is an artificial practice that reduces measurable benefit. In essence, standardized acupuncture treatment protocols provide researchers with reproducible study designs, thereby increasing confidence in results, but at the possible cost of decreased magnitude of effect.

Regarding the challenges inherent to producing RCTs and other high quality acupuncture research, future researchers might consider strategies that enhance the quality of evidence for other types of study designs. Pre-post trial interventions and cohort studies, for example, have the capacity to produce high quality evidence if they are meticulously designed. Two-arm pre-post trials and cohort studies that compare acupuncture to standard of care, could produce high quality evidence if follow up is sufficient to measure dose-dependent gradients, especially related to secondary outcomes such as percutaneous analgesia (PCA) trends.⁶ Furthermore, including data from control groups receiving standard of care allows researchers to analyze the

magnitude of effect, creating additional opportunities to demonstrate benefit. Finally, implementing computerized, unidentifiable data collection methods is recommended for future studies in order to eliminate reporting bias.

In order to have a greater impact on applicability of acupuncture studies, future researchers may also consider collecting data on the associated costs of acupuncture in inpatient settings. One economic analysis performed at Children's Hospital Los Angeles investigated total costs of care one year prior, through one year following, treatment of chronic pain in an integrative pain clinic. One hundred ninety-one MediCal patients received individualized treatment plans including medication management, psychotherapy, biofeedback, acupuncture, and massage. Retrospective data included total costs per patient related to emergency room visits, hospital stays, and services rendered at outpatient visits. Mean total billable cost per patient one year prior to the integrative pain clinic were calculated at \$114,505 per patient (of which MediCal paid \$26,938). Mean billable cost after integrative therapies, for the duration of one year, was \$78,277 per patient (of which \$15,456 was paid by MediCal). In the context of medical costs on a population scale, a mean savings of \$11,482 per patient is substantial, favoring integrative medicine for the treatment of pain from a cost-savings perspective. If acupuncture is to be considered a sustainable adjunct for inpatient pain, similar cost analyses regarding the economic impact of acupuncture in a hospital setting would be of benefit.¹⁶

CONCLUSIONS

As the United States continues to struggle with opioid addiction, research that conclusively determines the efficacy and applicability of acupuncture becomes critical. While every study that met criteria for this review showed data promising for acupuncture's capacity to decrease pain in an inpatient setting, regardless of the underlying cause of pain, study design flaws limit confidence in the data. Lack of control groups, lack of blinding, loss to follow up, reporting bias, and small sample size reduced the overall quality of evidence. Ultimately, acupuncture shows promise as a methodology for inpatient pain management, although more research is needed. Future studies that include comparison of acupuncture to standard of care, as well as studies that investigate the economic impact of acupuncture would provide valuable information regarding acupuncture's role in management of inpatient pain.

[‡] The two most common types of sham acupuncture controls used are insertion and noninsertion sham.¹⁷ Insertion sham is the insertion of acupuncture needles into nonspecific areas on the body as a control. While insertion acupuncture provides blinding to the patient, experts argue that acupuncture points are "regions" rather than specific locations, and therefore insertion of a needle anywhere in the area may have a therapeutic effect.¹⁸ Non-insertion sham utilizes devices attached to the skin that blocks penetration of a needle, and newer devices can somewhat blind both the patient and provider.¹⁹ TCM authorities that criticize non-insertion sham claim that the pressure experienced by patients at the device stimulates the acupuncture points to the same effect as acupressure, another known practice methodology with measurable effects.

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TABLE 1: Summary of Findings

			Results			
Study	Clinical Setting	Outcomes Measured	% of Patients # of Patients		Measured Change in	
			Receiving Benefit	Analyzed	Pain Score	
Garcia et al	Inpatient Oncology	0-10 scores before and after	74%, determined	69 after 1 st	-1.8 points	
		acupuncture for pain, nausea,	as a decrease in	treatment		
		fatigue, sleep disturbance,	pain by \geq 1 point	20 after 2 nd	-2.3 points	
		shortness of breath, appetite,		treatment		
		drowsiness, depression, anxiety,				
		and wellbeing				
Feeney et	Medical, trauma,	0-10 Scores before and after	65%, determined	45 after 1 st	-2.56 points	
al	and neurosurgery	acupuncture for pain, nausea, and	as a decrease in	treatment		
	ICU	vomiting	pain ≥ 1.5 points	38 after 2 nd	-2.36 points	
				treatment		
				30 after 3 rd	-1.98 points	
				treatment		
Schlegel et	High risk pregnant	0-10 Pain and anxiety scores		80	-2.33 points, 78.9%	
al	inpatients	before and after acupuncture,			average decrease	
		healing touch, massage, guided			after acupuncture	
		imagery, and reflexology			treatment	
Johnson et	All inpatients with	0-10 Pain and anxiety scores		1248	48.6% average	
al	Cardiovascular	before and after TCM, bodywork,			decrease after TCM	
	ICD9 codes	or mind-body and energy			treatment	
		therapies				
Johnson et	All inpatients with	0-10 Pain and anxiety scores		115	45.7% average	
al	ICD9 codes for	before and after TCM, bodywork,			decrease after TCM	
	primary malignant	or mind-body and energy			treatment	
	neoplasms	therapies				
Lu et al	SCD inpatients	0-10 Pain scores before and after	100% of patients	9	-2.1 points	
	with VOC	acupuncture	experienced			
			decrease in pain			
			after treatment			
Quinlan-	Inpatients	0-10 Score before and after		15 after 1 st	-1.47 points	
Woodward	undergoing	acupuncture for pain, nausea,		treatment		
et al	mastectomy for	anxiety, and ability to cope		10 after 2 nd	-1.5 points	
	breast cancer			treatment		

TABLE 2: GRADE profile for Reviewed Studies

Design	Limitations	Indirectness	Inconsistency	Imprecision	Publication bias	Quality
Pre-Post	Very Serious ^{ab}	Not Serious	Not serious	Not Serious	Unlikely	Very Low
Pre-Post	Very Serious ^{ab}	Not Serious	Not Serious	Not Serious	Unlikely	Very Low
Cohort	Not Serious	Not Serious	Not Serious	Not Serious	Unlikely	Low
RCT	Serious ^a	Not Serious	Not Serious	Not Serious	Unlikely	Moderate
Cohort	Not Serious	Not serious	Not serious	Not serious	Unlikely	Low
Cohort	Not Serious	Not serious	Not serious	Not serious	Unlikely	Low
Cohort	Not Serious	Not serious	Not Serious	Not serious	Unlikely	Low
	Pre-Post Pre-Post Cohort RCT Cohort Cohort	Pre-PostVery Serious ^{ab} Pre-PostVery Serious ^{ab} CohortNot SeriousRCTSerious ^a CohortNot SeriousCohortNot Serious	Pre-PostVery Serious ^{ab} Not SeriousPre-PostVery Serious ^{ab} Not SeriousCohortNot SeriousNot SeriousRCTSerious ^a Not SeriousCohortNot SeriousNot seriousCohortNot SeriousNot seriousCohortNot SeriousNot serious	Pre-PostVery SeriousabNot SeriousNot seriousPre-PostVery SeriousabNot SeriousNot SeriousCohortNot SeriousNot SeriousNot SeriousRCTSeriousabNot SeriousNot SeriousCohortNot SeriousNot seriousNot seriousCohortNot SeriousNot seriousNot seriousCohortNot SeriousNot seriousNot seriousCohortNot SeriousNot seriousNot serious	Pre-PostVery Serious ^{ab} Not SeriousNot seriousNot SeriousPre-PostVery Serious ^{ab} Not SeriousNot SeriousNot SeriousCohortNot SeriousNot SeriousNot SeriousNot SeriousRCTSerious ^a Not SeriousNot SeriousNot SeriousCohortNot SeriousNot seriousNot seriousNot seriousCohortNot SeriousNot seriousNot seriousNot seriousCohortNot SeriousNot seriousNot seriousNot serious	Pre-PostVery Serious ^{ab} Not SeriousNot seriousNot SeriousUnlikelyPre-PostVery Serious ^{ab} Not SeriousNot SeriousNot SeriousUnlikelyCohortNot SeriousNot SeriousNot SeriousNot SeriousUnlikelyRCTSerious ^a Not SeriousNot SeriousNot SeriousUnlikelyCohortNot SeriousNot seriousNot SeriousUnlikelyCohortNot SeriousNot seriousNot seriousUnlikelyCohortNot SeriousNot seriousNot seriousUnlikely

Downgrade Criteria

^{*a} Lack of blinding and allocation concealment*</sup>

^b No control group



