Acupuncture for Treating Anxiety and Depression in Women: A Clinical Systematic Review

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ABSTRACT

Background: Anxiety and depression are high in prevalence, especially in the female population, whose incidence is approximately double that of the male population. In addition, these conditions are difficult to treat and have high relapse rates and medication side-effects. There is evidence to suggest that acupuncture may be an effective treatment modality.

Objective: The aim of this review is to summarize the existing evidence on acupuncture as a therapy for anxiety and depression in women and to present a novel method for assessing acupuncture trial quality.

Methods: Published randomized controlled trials were included, whereby acupuncture was compared with any control procedure in subjects with anxiety and/or depression. Two authors extracted data independently. A novel acupuncture trial quality-assessment tool was developed to analyze the literature quality.

Results: Six articles used the desired inclusion and exclusion criteria. The quality of research varied heavily. Five studies were properly randomized. Three were double-blinded. Three used individualized acupuncture. Four studies were of at least reasonable quality. One was of marginal quality, and one was of poor quality. There was a significant difference between acupuncture and at least one control in all six trials.

Conclusions: With respect to six reviewed studies, there is high-level evidence to support the use of acupuncture for treating major depressive disorder in pregnancy.

Key Words: Anxiety, Depression, Depressive Disorders, Acupuncture, Women, Female, Pregnancy, Integrative Medicine, Complementary and Alternative Medicine, Systematic

INTRODUCTION

PSYCHIATRIC DISORDERS are some of the most common and difficult illnesses to treat in medicine. They have a lifetime prevalence of nearly 50% and account for approximately 15% of disability.[1,2] Anxiety and depression are two of the most common psychiatric disorders, both of which are much more prevalent in women.[3] Anxiety often includes feelings of fear, apprehension, and excessive anxiety energy. Depression, as a primary disturbance or secondary effect of anxiety disorder, manifests in feelings of emptiness, deep sadness or misery, loss of hope, and even thoughts of suicide.[4]

Anxiety disorders are the most prevalent of psychiatric disorders and afflict 15.7 million people in the United States each year, and 30 million people in the United States at some point in their lives.[5] Anxiety tends to be chronic, and the individual and social burden is high. Furthermore, patients who have anxiety place a strain on the health care system, because they tend to present to general practitioners more frequently than to psychiatric professionals. Additional economic costs to the health care system include reduced productivity, absenteeism from work, suicide, hospitalization, prescription drugs, and emergency care.[5]

Depression affects ∼121 million people worldwide,[6] and it has been predicted to be the second leading cause of

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global disease burden by 2020.[2] According to the World Health Organization, as of the year 2000, depression was the leading cause of disability as measured by Years Lived with Disability (YLD) and was the fourth leading contributor to the global burden of disease in 2000.[6] The lifetime incidence of unipolar or major depressive (MDD) disorder is roughly 18%, and is approximately twice as common in women as in men.[7] In addition, it is one of the most frequently encountered women's mental-health problem.[3,7,8] The lifetime prevalence of anxiety disorders is ∼30%, with a 12-month prevalence of 18%.[9,10] Like MDD, generalized anxiety disorder (GAD) affects women twice as often as men.[11]

Both depression and anxiety are difficult to treat. Despite the evidence-based effectiveness of antidepressants, anxiolytics, and psychotherapy, relapse rates for both anxiety and depression both approach 50%.[12,13] Noncompliance secondary to intolerable side-effects of treatments (medications) or costs (psychotherapy) play a large role in the high rates of relapse, and both drug and psychotherapy have similar rates of withdrawal from treatment.[14] Ultimately, many patients turn to complementary and alternative medicines (CAMs), such as acupuncture.[15] Acupuncture is gaining in popularity in the United States,[16,17] and the number of patients, particularly women, seeking acupuncture treatment for affective disorders is increasing.[18–20]

According to Chinese Medicine, anxiety and depression in women is the result of ''complex interactions between diverse factors, many of which are not yet fully understood.''[21] According to Schnyer, the Chinese Medicine explanation for why depression is twice as common in women can be explained, in part, by the relationship between Liver depression and the menstrual cycle.[21] Qi Deficiency (Lung and/or Kidney), Blood Deficiency (usually Liver and Spleen), Blood Stagnation (Liver), Cold Invasion causing Qi and Blood Stagnation, as well as *Jing* and *Yuan* Qi Deficiency are all part of the constellation of findings associated with depression, and all affect the *Shen* or Mind. As such, in practice, Chinese Medicine treatment of depression relies upon the diagnosis of each individual patient and on formulating use of a distinct group of acupoints unique to each individual, along with a strategy that may also include other recommendations, including, but not limited to, exercise, herbal therapy and lifestyle modifications. These varied diagnoses and ever-changing constellations of acupoints make research more challenging and make the need for individualized acupuncture treatment plans vital.

Clinicians rely on current published reviews and clinical practice guidelines (CPGs) to make decisions based on the best available scientific evidence. Unfortunately, many of the CAM (i.e., acupuncture) studies and review articles do not appear in conventional medical journals, where most medical providers obtain information about developments in medicine. In addition, there is a limited library of quality acupuncture-related scientific evidence on the topic of anxiety and depression in women, which makes it even more difficult to make informed decisions about using acupuncture to treat women with these conditions.[22]

Published randomized controlled trials (RCTs) were reviewed with respect to the efficacy of acupuncture for treating anxiety and depression in women. While there are many established methods of assessing the quality of RCTs (i.e., Jadad scale, GRADE assessment, SIGN 50 guideline, etc.), acupuncture trials have unique aspects that affect study quality that are not identified by these general RCT assessments. Therefore, the authors found it important to create a new tool to assess the quality of the studies that accounts for study design characteristics specific to acupuncture (i.e., acupuncture method and treatment course length) but still measures characteristics generalizable to all RCTs (i.e., randomization, blinding). This is called the Quality Score for Acupuncture Trials (QSAT). Ultimately, the QSAT will help categorize acupuncture literature quality to assist in drawing relevant clinical conclusions; not only in this article, but in future acupuncture reviews.

METHODS

Choosing Studies for Review

Studies included in the review were published, randomized, and quasirandomized controlled trials that addressed the efficacy of acupuncture for treating depression, anxiety, or both. All accepted subjects were female and had to have a clinical diagnosis of depression or anxiety, or have a medical condition with an evidence-based positive correlation with depression or anxiety. The active intervention had to include manual acupuncture; electroacupuncture (EA), laser acupuncture, and acupressure were excluded. The control intervention could include sham acupuncture, other manual therapy, pharmacologic treatment, psychotherapy, no treatment (wait-list), or any other reasonable control. Studies that assessed acupuncture as a monotherapy or an adjunctive therapy were included. All studies had to use an established and tested rating scale to measure symptoms of anxiety or depression. These included the Hamilton Rating Scale (HRS) for anxiety (HAS) or depression (HDS); the Beck Inventory (BI) for anxiety (BAI) or depression (BDI); the Inventory of Depressive Symptomology (IDS); the Structured Clinical Interview for *DSM** (SCID); or another rating scale based on *DSM-IV* criteria.

Studies were found using three comprehensive electronic databases of clinical trials: the Cochrane Central Register of Controlled Trials; MEDLINE®; and Ovid. Search criteria included English publications with the search key words: acupuncture, anxiety, depression, mood disorder, depressive disorder, women, and female. Although only clinical trials

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*DSM, the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*.

were included in this review, other articles (reviews, meta-analyses, retrospective studies) found through the same search criteria were used to identify other relevant studies via their references.

All studies were independently searched for and reviewed by 2 researchers. Each publication was assessed for quality through ten separate study design characteristics (quality measures). These characteristics were then quantified and assigned a numeric value (0, 1, or 2) based on the quality of each individual characteristic. Each received 2 points if ideal, 1 point if inferior, and 0 points if unsatisfactory. The points in the ten design characteristics were then added to create a QSAT out of a total possible score of 20. Unlike other quality-assessment tools, the overall QSAT combines quality measures that are specific to acupuncture trials with measures that are generalizable to all RCTs. It can be used to assess any RCT that assesses acupuncture as a treatment modality.

QSAT Measures and Point System

The ten QSAT quality measures are: (1) inclusion and exclusion criteria; (2) study design; (3) control treatment; (4) sample size; (5) randomization; (6) blinding; (7) acupuncture method; (8) acupuncture treatment course; (9) outcome measure; and (10) patients lost at follow-up. For the inclusion and exclusion criteria, 1 point is awarded for adequate inclusion criteria and 1 point for adequate exclusion criteria. For study design, 2 points are awarded for a parallel design, 1 point for a cluster design or a crossover design with an adequately described washout period, and 0 points for a crossover design without a properly described washout period. For control treatment, 2 points are awarded for acupuncture (sham, nonspecific, or other valid acupuncture control) or other standards of care. One point is given for another placebo treatment, and 0 points are given for no treatment (wait-list). If there are multiple arms, the arm that would generate the greater amount of points is used, and only the results against that control arm are used in the analysis. For sample size, 2 points are awarded for an adequate description of the how the proper sample size was determined (i.e., power statistic, sample-size calculation, etc.) and if the study met the sample-size requirement determined by the analysis. One point is given if the sample size did not meet the requirement set out by the sample-size determination and 0 points are awarded if the description in inadequate or not present. For randomization, 2 points are awarded for complete randomization with a proven method (i.e., computerized block randomization), 1 point for any description of the trial being randomized, and 0 points if the trial is not randomized. For blinding, 2 points are awarded if the trial is double-blinded, 1 point if it is single-blinded, and 0 points if it is not blinded at all. For acupuncture method, 2 points are awarded for individualized acupuncture, 1 point is given for standard acupuncture, and 0 points are given if the acupuncture method is inappropriate for the specific

condition being treated. For acupuncture treatment course, 2 points are awarded if at least eight acupuncture treatments are given over at least 8 weeks, 1 point is awarded if one of the previous two conditions are met (i.e., 8 acupuncture treatments over 2 weeks or 4 acupuncture treatments over 8 weeks); 0 points are given if neither condition is met. For outcome measure, 2 points are awarded if the measurement tool has been proven via prior studies to have adequate interrater and intrarater reliability and accuracy. One point is given for an unproven, yet reasonably adequate measurement tool, and 0 points are given for an inadequate measurement tool. Finally, for patients lost at follow-up, 2 points are awarded if subjects who are initially randomized are included in the statistical analysis and a number needed to treat (NTT) statistic is computed, while 1 point is given if lost subjects are included, but no NNT is calculated, and 0 points are given if any randomized patients are not included in the statistical analysis. Overall, for any of these measures, full credit for points is only awarded if the characteristic in question is properly described and properly implemented. For example, if a study describes itself as completely randomized, but the method of randomization is not properly explained or not properly conducted, only 1 point is awarded.

The complete QSAT score ranges from 0 points to 20 points. A QSAT score of 18–20 indicates an acupuncture trial of the highest quality, a score range of 15–17 indicates reasonable quality, a score range of 11–14 indicates marginal quality, while a score 10 or less indicates poor quality. The QSAT scores for each trial were correlated with its corresponding Jadad score through the calculation of a correlation coefficient (r). This is an attempt to find evidence supporting that the QSAT assesses study quality appropriately.

Study results are presented by subject population and disorder tested. In addition results are categorized further according to overall quality of trials available for each population/disorder category. Safety and adverse events are also reported.

RESULTS

General Characteristics

Overall, six trials met the inclusion and exclusion criteria (see Table 1). Four assessed depression,[23–26] one assessed anxiety,[27] and one assessed both.[28] Of the four that assessed depression, three focused solely on MDD.[23,25,26] Sample sizes ranged from 33[23] to 246,[28] with a total of 605 subjects among the six studies, 347 of whom were in the treatment arms. Participant ages ranged from 18 to 71, with four of the six studies using only patients younger than 45.[23,25–27] Three studies were conducted in the United States,[23,25,26] and three were conducted outside the United States, with

TABLE 1. STUDY CHARACTERISTICS AND QUALITY SCORE FOR ACUPUNCTURE TRIALS (QSAT)

	General characteristics						Quality measures							Quality scores	
Study & ref.	Disorder	Patient population	Inc/exc criteria	Study type	Control treatment		Sample size calculation/ goal met	Randomization	Blinding	Acup method	Acup treatment course	Outcome measure	Included lost subjects w/ NNT	QSAT (20)	Jadad (5)
Courbasson et al. 2007[28]	Anxiety Dep.	Women enrolled in a substance-abuse program	Yes/Yes*	Parallel RCT*	Counseling, psychotherapy†/#		No††	None††	None††	Standardized†	9 over 3 weeks†	BI*	No††	9	2
Allen et al. 1998[23]	MDD	Women 18–45 yo w/ MDD	Yes/Yes*	Crossover RCT††,#	Nonspecific acup and none*		Yes/No†	Block*	Double-blinded*	Individualized*	12 over 8 weeks*	BI, HRS, IDS, SCID*	No††	15	4
Manber et al. 2004[25]	MDD	Pregnant women >18yo w/ MDD	Yes/Yes*	Parallel RCT*	Nonspecific acup and massage*		No††	Block*	Double-blinded*	Individualized*	12 over 8 weeks*	BI, SCID, HRS*	Yes, NNT 2.7*	18	5
Manber et al. 2010[26]	MDD	Pregnant women >18yo w/ MDD	Yes/Yes*	Parallel RCT*	Nonspecific acup and massage*		Yes/Yes*	Block*	Double-blinded¶	Individualized*	12 over 8 weeks*	HRS, DSM IV*	Yes, NNT 5.3*	19	4
Dormaenen et al. 2011[24]	Dep.	Women in menopause w/ hot flashes	Yes/Yes*	Parallel RCT*	Patient education††		No††	Block*	None††	Individualized*	10 over 12 weeks*	BI*	No††	12	3
Isoyama et al. 2012[27]	Anxiety	Women < 45 undergoing IVF	Yes/Yes*	Parallel RCT*	Sham acup*		Yes/Yes*	Block*	Single-blinded†	Standardized†	4–6 over 4 weeks††	HRS*	Yes, none†	15	3

Legend: *, ideal (2 points); †inferior (1 point); ††, unsatisfactory (0 points); #, lack of adequate description, ¶lack of adequate implementation.
Outcome measures: BI, Beck Inventory; HRS, Hamilton Rating Scale; IDS, Inventory of Depressive Symptomology; SCID, Structured Clinical Interview for *DSM*; *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th ed. rev.*, Arlington, VA: American Psychiatric Association, 2000.
Inc, inclusion; exc, exclusion; Acup, acupuncture; w/, with; NNT, number needed to treat ; Dep., depression; MDD, major depressive disorder; yo, years old; IVF, *in vitro* fertilization; RCT, randomized controlled trial.

one each in Brazil,[27] Canada,[28] and Norway.[24] Two studies only included pregnant women,[25,26] one study only had women with vasomotor menopausal symptoms,[24] one study only had women who were undergoing in vitro fertilization (IVF),[27] and one study only had patients enrolled in a sub-stance-abuse recovery program.[28] Five of the six studies used acupuncture as the sole treatment in the study arm, while one study used acupuncture as an adjunct with counseling and psychotherapy.[28] Three of the studies assessed the outcome measure from 1 to 6 months after cessation of treatment in an attempt to determine the rate of remission of symptoms.[23,25,28] Three of the studies used only corporal acupuncture,[23,24,27] while one used only auricular acupuncture,[28] and two used both forms of acupuncture.[25,26]

Quality Measures

Five studies used a parallel-group design (ideal [2 points]).[24–28] One used the crossover method but did not report a washout period (unsatisfactory [0 points]).[23] All studies had described inclusion and exclusion criteria adequately (ideal). The exclusion criteria varied slightly among the studies, but all studies excluded patients with psychotic or suicidal symptoms. Other common exclusion criteria were other Axis I diagnoses, other medical conditions that can cause anxiety and/or depression, and concurrent treatment with psychopharmaceuticals or psychotherapy. Two studies had proper sample- size calculations and met the calculated goal (ideal),[26,27] one study had a proper calculation, but did not meet the sample size goal (inferior [1 point]),[23] and three did not report sample size calculation.[24,25,28] Five studies were completely randomized, and had adequately performed and described randomization methods (ideal),[23–27] while one study was quasirandomized (inferior).[28] Three studies were double-blinded (ideal) [23,25,26]; however, in one, the method for blinding of acupuncturists may have been ineffective, so its score was lowered to inferior.[26] One study was blinded only to subjects (inferior),[27] and two studies lacked any blinding (unsatisfactory).[24,28]

Four studies individualized acupuncture treatments to each individual using pulse and tongue (ideal) methods of diagnosis,[23–26] whereas two studies used standardized acupuncture points for every patient (inferior).[27,28] Four studies had at least eight acupuncture treatments over a treatment course of at least 8 weeks (ideal).[23–26] One study had nine acupuncture sessions, but they were over a treatment course of 3 weeks (inferior),[28] and one trial had tested only 4–6 treatments over 4 weeks (unsatisfactory).[27]

Three studies used nonspecific acupuncture (real acupuncture points not used to treat psychiatric or related illness) as the control (ideal).[23,25,26] All three of these studies also had third arms, one of which used no treatment,[23] and two used therapeutic massage.[25,26] One study used only

sham acupuncture as the control (ideal),[27] and one study used no treatment as the sole control (unsatisfactory).[24]

All studies used at least one widely accepted and tested outcome measure for depression and/or anxiety (ideal), with three of the studies using multiple scales.[23,25,26] The Beck Inventory for Depression was the most commonly used outcome measure.

QSATs ranged from 1228 to 19.[25,26] Jadad scores ranged from 228 to 5.25. There was a statistically significant correlation between QSAT and Jadad scores ($r = 0.887$). Based on the QSAT, two studies were of the highest quality,[25,26] two studies were of reasonable quality,[23,27] one study was marginal in quality,[24] and one was of poor quality.[28]

Outcomes

Two studies assessed the effects of acupuncture on anxiety.[27,28] Both studies used special patient populations: women undergoing IVF[27] and women enrolled in a substance abuse program.[28] The study by Isoyama et al was classified as reasonable quality,[27] while Courbasson et al.'s study was classified as poor quality per QSAT.[28] Courbasson et al. found a significantly greater reduction in the BAI in patients who received acupuncture in addition to counseling and psychotherapy than patients who received counseling and psychotherapy alone ($P = 0.005$).[28] It should also be noted that Courbasson et al. also found similar results for depression in this population using the BDI ($P = 0.004$).[28] Isoyama et al. found a significant reduction in the HAS post acupuncture treatment versus what occurred in subjects who received sham acupuncture ($P = 0.0008$).[27]

Only one study evaluated the effects of acupuncture on women in the general population with a diagnosis of MDD.[23] The Allen et al. study was classified as reasonable quality by the QSAT, and that study found a significantly greater reduction in BDI and HDS in subjects who received treatment acupuncture versus nonspecific acupuncture ($P < 0.05$).[23]

Two studies evaluated MDD in pregnant patients.[25,26] Both of these studies were labeled as the highest of quality by the QSAT. In 2004, Manber et al. ($N = 62$) found a greater reduction in BDI and HDS in patients treated with depression-specific acupuncture versus depression nonspecific acupuncture; however, this was not significant.[25] In 2010, Manber et al. ($N = 150$) found a significantly greater response (>50% decrease in HDS) rate in pregnant patients with MDD receiving depression specific acupuncture verses nonspecific acupuncture ($P < 0.05$).[26]

One study looked at symptoms of depression in women in menopause suffering from vasomotor symptoms.[24] This study, by Dormaenan et al., was of marginal quality per the QSAT. The researchers found that patients who received acupuncture had a significantly greater decrease in BDI than those who did not receive acupuncture (wait-list; $P = 0.0005$).[24]

Three of the studies reassessed outcomes at a later follow-up time to determine remission rates.[23,25,28] Manber et al.

(in the 2004 study) found significantly greater rates of remission at 10 weeks in patients who received depression specific acupuncture versus nonspecific acupuncture.[25] Courbasson et al. found nonsignificant reductions in both the BAI and BDI at 1 and 3 months.[28] Gallagher et al. (data from Allen et al.[23]) found rates of remission in patients with MDD treated with acupuncture similar to other treatments (i.e., psychopharmaceuticals, psychotherapy); however that study did not report significantly greater rate of remission than placebo.[29]

Only two studies reported results on safety and/or adverse events.[25,26] Both looked at adverse events in pregnant women in those receiving acupuncture versus those receiving massage. In both studies, there was no significant difference in adverse events in either the mothers or infants. The most common acupuncture related side-effect was pain at the site of needle insertion, which was reported at some point in time by 21 of the 101 participants who received acupuncture.[26] One participant reported bleeding at the insertion site.[26]

DISCUSSION

Overall, the availability of quality scientific research on the effects of acupuncture on depression and anxiety in women is limited. Only six studies met the inclusion and exclusion criteria of this review.[23–28] Furthermore, only two studies used similar patient populations, and had the same chief researcher.[25,26] Ultimately, this makes it more difficult to formulate a strong conclusion from the body of available scientific evidence. Yet, some conclusions can be drawn using the classification of evidence table (see Table 2).

The strongest evidence lies within the population of pregnant women. One highest quality study, with a relatively large sample size ($N = 150$), provided evidence to support acupuncture as a monotherapy for pregnant women with MDD.[26] Therefore, the use of acupuncture is considered likely to be effective in this patient population. Given this evidence, and the fact that there are known adverse events associated with pharmacologic therapy for MDD for maturing fetuses, it would not be unreasonable to use acupuncture as a monotherapy for treating women who have MMD during pregnancy. In addition, there was not a

significant increase in morbidity or mortality in either the mothers or infants in participants who underwent acupuncture treatment versus massage.[26] However, there still needs to be head-to-head trials between acupuncture and selective serotonin reuptake inhbitors (SSRIs) and/or psychotherapy to determine if acupuncture can be considered a first-line treatment in this patient population. In any event, the evidence suggests that acupuncture is a reasonable alternative to SSRIs or psychotherapy for treating MDD during pregnancy.

For treating of MDD in the general female population, there is one study of reasonable quality that provides evidence to support acupuncture as a monotherapy for treating MDD.[23] However, the sample size was relatively small ($N = 33$). In addition, the same investigator conducted a larger, mirrored study with 150 subjects.[30] However, this was a mixed-gender study, so it was excluded from this review. This larger study found a decrease in BDI scores with specific acupuncture treatment, but the decrease was not significantly greater than that in the nonspecific acupuncture group. Furthermore, the same result was found when the statistical analysis was limited to the female subjects, who were 18–45 years old, of the study.[30] Ultimately, there is conflicting evidence for acupuncture as a monotherapy for treating MDD in the general female population, and thus, the information on effectiveness is inconclusive, and more research is necessary.

One study of marginal quality found significantly reduced symptoms of depression in menopausal women who had both depression and vasomotor symptoms.[24] It is important to note that, in this study, there was no correlation between reduction in depression and vasomotor symptoms. Thus, the reduction of depression was most likely from its direct treatment with acupuncture. There are no negative studies on this specific topic, therefore the effectiveness for acupuncture for this patient population appears to be promising. At this time, it is reasonable to use acupuncture as an adjunctive therapy for treating depression in postmenopausal women who have vasomotor symptoms; however, more quality studies are needed in this area.

There were only two studies that addressed anxiety and both had special patient populations.[27,28] One was of reasonable quality[27] and the other was of poor quality.[28] Courbasson et al. looked at both anxiety and depression

TABLE 2. CLASSIFICATION OF ACUPUNCTURE TREATMENT EFFECTIVENESS BASED ON AVAILABLE SCIENTIFIC EVIDENCE[36]

Category	Criteria used
Likely to be effective	At least one high-quality positive randomized trial or meta-analysis and no negative randomized trial data
Appears promising	Promising outcome data from multiple weaker randomized controlled trials
Evidence inconclusive	Conflicting data from clinical trials or no studies found
Likely to be ineffective	High-quality negative randomized controlled trials or meta-analyses or negative data from multiple weaker trials

Adapted from: Abrams D, Weil A. *Integrative Oncology*. New York: Oxford University Press;2009:471.[36]

symptoms in women recovering from substance abuse. The researchers found significant reductions in both depression and anxiety in this patient population when the subjects were treated with acupuncture plus counseling and psychotherapy, compared to subjects who received counseling and psychotherapy alone.[28] For both anxiety and depression in this population, the effectiveness of acupuncture as an adjunctive treatment appears to be promising, but there is still a need for higher-quality studies in this area.

Isoyama et al. found significantly decreased anxiety symptoms in women undergoing IVF treated with acupuncture verses sham acupuncture.[27] Although there is no negative evidence in this population, given the weaker quality of the study, the effectiveness for acupuncture in this population appears to promising. Thus, it would be reasonable to use acupuncture as an adjunctive treatment in this patient population at this time.

There were no studies that assessed the effectiveness of acupuncture for the treatment of anxiety disorders in the general female population. However, given that there are two studies, that found significant positive results in special female populations, and no negative studies, it is reasonable to state that the effectiveness of acupuncture for treating anxiety disorders in women appears to be promising. However, the scientific evidence is remarkably scarce, and much more quality research needs to be conducted in this area.

Three of the studies reassessed outcomes at a later follow-up time to determine remission rates.[23,25,28] Only Manber et al. (in 2004) found significantly lower rates of relapse in patients treated with acupuncture verses placebo.[25] However, the researchers in all three studies claimed that the rates of remission were similar to those of antidepressants and psychotherapy.[23,25,28] Further research is needed to investigate relapse rates with acupuncture treatment, but, at this time, given that these two studies were without significant results, the effectiveness of maintaining remission with acupuncture remains inconclusive.

CONCLUSIONS

Overall, there is a lack of high-quality research on the effectiveness of acupuncture for treating anxiety and depression in women. This is an issue that is intrinsic throughout much of the scientific evidence for many conditions that acupuncture may be used to treat.[31] Many acupuncture studies lack important quality measures, such as true randomization, parallel study designs, and inclusion of lost subjects in statistical analyses. Lack of double-blinding has historically been one of the most common design flaws in acupuncture trials, but Manber et al. and Allen et al. have provided a reproducible method for double-blinding that all future acupuncture trials should emulate.[23,25,26,30] In addition, many studies use standardized

acupuncture points, which mitigate the utility of patient-specific treatments, and therefore, do not translate to clinical practice.

Upon recognizing these obstacles, newer applications of methods of design and analysis (including observational cohort analyses of databases using propensity scores and instrumental variables) are appealing and useful. In addition, methodological details, fundamental features of patients, interventions, and outcomes are important in interpreting evidence quality.

As a result of these challenges, comparative effectiveness research (CER) has become more popular within the entire health care industry, especially policy makers, funding agencies, and health care insurers. Much of the interest in CER is based on whether this methodology will help to improve evidence-based decisions by clinicians by incorporating patient preferences and patient-centered perspectives with the overall goal of improving quality of care and helping control health care costs. This is exemplified by the fact that the American Recovery and Reinvestment Act of 2009 allocated $1.1 billion to CER; $300 million in CER funding for the Agency for Healthcare Research and Quality; $400 million for the National Institutes of Health; and $400 million for the Office of the Secretary of Health and Human Services,[32] as well as the creation of the Patient-Centered Outcomes Research Institute (PCORI) as part of the Patient Protection and Affordable Care Act of 2010.[33]

Given the new landscape of the health care system, where every dollar is maximized and every treatment modality scrutinized, high quality CER is of even greater importance than ever before. Acupuncture has shown promise for treating a variety of conditions, but high-quality trials are still at a premium. To continue to establish itself an effective and economic treatment method, the standard of acupuncture trial quality must be raised. Therefore, to quantify and standardize acupuncture trial quality, the current authors constructed the QSAT.

In this study, the QSAT was used to evaluate the quality of the six acupuncture trials included in this review. The QSATs for these trials have a high correlation with their respective Jadad scores; however, the QSAT is unique in that provides more information that is relevant and specific to acupuncture trials. The QSAT, however, as a novel RCT quality score, is not without its limitations. While the QSAT provides more detail than a Jadad score, it is not as detailed as other quality-measurement tools such as the GRADE or SIGN 50.[34,35] This results from an attempt to make the QSAT a quantifiable scale that can be used easily by reviewers to classify and compare RCT quality. In addition, there are aspects of the QSAT that are likely to need revision in the future, as more evidence on acupuncture treatment becomes available. For example, in the current format, for acupuncture treatment length, a treatment length of 8 sessions over 8 weeks is considered ''ideal'' based only on anecdotal evidence and clinical experience. In the future,

there is likely to be evidence-based recommendations on minimum acupuncture treatment length to ensure response and, at that time, the QSAT will need adjusting. Furthermore, in its current state, the QSAT's qualitative correlations based on final numerical score were created subjectively. The quantitative-to-qualitative correlations have not been analyzed enough through other quality-assessment tools to determine if they correspond properly (i.e., a QSAT score of 15–17 equals reasonable quality, etc.) and are valid. However, it is important to note that the QSAT is the first quality-assessment tool that is specific to acupuncture trials, therefore, it differs from general RCT quality-assessment tools to a degree. While the QSAT is a novel assessment tool that requires further validation, it is a promising instrument to help evaluate the standards of future acupuncture trials.

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DISCLOSURE STATEMENT

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