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Evidence-Based Integrative Medicine

Effectiveness of Acupuncture on Pain, Physical Function and Health-Related Quality of Life in Patients with Rheumatoid Arthritis: A Systematic Review of Quantitative Evidence

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ABSTRACT **Objective:** To identify and synthesize the most recent available evidence of effectiveness of acupuncture on pain, physical function and health-related quality of life (HRQoL) in patients with rheumatoid arthritis (RA). **Methods:** A comprehensive search of 12 Western and Chinese databases was undertaken from their inception up to end of 2016. Randomized controlled trials (RCTs), concerning patients with RA treated with needle acupuncture, written in English, Portuguese, German or Chinese were included. Primary outcomes included pain, physical function and HRQoL. Secondary outcomes included morning stiffness, functional impairment, number of tender and swollen joints and serum concentrations of inflamatory markers. Methodological quality was assessed by three independent reviewers using the standardized critical appraisal instrument from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument. **Results:** Twenty-two studies met the inclusion criteria. Of those, 9 studies were excluded after assessment of their methodological quality. The remaining 13 original RCTs included 974 patients. Ten of these studies published in China, showed favorable statistical significant effects of acupuncture in relieving symptoms of RA compared with controls. **Conclusions:** Evidence suggests that acupuncture interventions may have a positive effect in pain relief, physical function and HRQoL in RA patients. However, due to the heterogeneity and methodologic limitations of the studies included in this systematic review, evidence is not strong enough to produce a best practice guideline.

KEYWORDS acupuncture, rheumatoid arthritis, quality of life, pain, physical function, randomized clinical trial

Rheumatoid arthritis (RA) is a chronic inflammatory, multisystemic and autoimmune disease manifested by acute and chronic rheumatic pain, symmetrical persistent inflammatory synovitis, involving destructive polyarthritis of the synovium.[1] Untreated RA leads to joint destruction, physical function (PF) limitation and severe disability. The worldwide prevalence is estimated at 1%.[2] Reduced health-related quality of life (HRQoL) in RA patients,[3] particularly increased levels of depression, lack of vitality, social functioning and global health, is associated with high social-economic impact and increased the use of healthcare resources.[4-6] The conventional treatment of RA is dominated by the use of non-steroidal anti-Inflammatory drugs (NSAIDs), glucocorticoids, disease modifying anti-rheumatic drugs, analgesics and biological agents.[3] These treatments are associated with higher costs, unwanted side effects, toxicity and limited efficacy.[7,8] These and other limitations led almost 60%–90% of unsatisfied arthritis patients to use complementary and alternative medicine, including acupuncture.[7,9,10]

Pain and inflammation relief can be achieved by acupuncture through adjusting the impedances of the meridian system,[11-13] connected internally with viscera and externally with limbs and sensory

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organs.[14-16] Acupuncture is often advocated for the treatment of RA.[17-19] Relatively few rigorous clinical trials have been published, the recent scientific evidence is scarce and the most recent systematic review for this topic is over 5 years old.[7-9] These systematic reviews showed methodologic concerns and questionable conclusions regarding the effects of acupuncture in the treatment of RA.[7,9] Our objective is to analyze the most recent state of scientific evidence-based of worldwide published studies and possibly find scientific proof which enable us to conclude if acupuncture is effective in pain relief, PF and HRQoL improvement in patients with RA.

METHODS

Inclusion Criteria

We considered randomized clinical trials (RCTs), regarding patients suffering from RA classified according to the American College of Rheumatology (ACR),[20] that were treated with acupuncture performed with metallic needle in specific acupoints or by laser stream instead of the classical needle insertion and combined with moxibustion or electrical stimulation.[9,10,21]

Exclusion Criteria

We excluded animal studies, acupuncture trials that exclude patients being submitted to Western therapy, studies that used phytotherapy or Chinese herbs, bee venom acupuncture, transcutaneous electrical nerve stimulator, Tuina (Chinese massage therapy) and mesotherapy.

Outcomes

Primary Outcomes

The primary outcomes included the followings: (1) pain [measurement tools: Visual Analogue Scale (VAS), Numeric scale, Faces Scale, Qualitative Scale)]; (2) physical function (measurements tools:[17] item response theory, VAS and computerized adaptive testing, Disease-specific Health Assessment Questionnaire, Groningen Activity Restriction Scale, McMaster Health Index Questionnaire); (3) HRQoL [measurement tools:[5,20] 36-item Short-Form Health Survey (SF-36), Arthritis Impact Measurement Scales, Health Assessment Questionnaire Disability Index, Health Assessment Questionnaire (HAQ), Rheumatoid Arthritis Quality of Life Instrument].

Secondary Outcomes

The secondary outcomes included the followings: (1) symptoms (morning stiffness and functional impairment) following the ACR criteria;[20] (2) the number of tender and swollen joints [assessed by a disease activity score 28 (DAS28) and tender joint count; (3) serum concentrations of inflammatory markers [erythrocyte sedimentation rate (ESR), C-reactive protein level, cortisol, interleukins, anti-citrullinated protein antibodies and rheumatoid factor (RF)].

Search Strategy

Studies published in English, Portuguese, German and Chinese were considered, from their inception up to the end of 2016. The search was done between January and May to 2017 (Appendix 1). The searched databases (DB) included were: MEDLINE; Cochrane Central Register of Controlled Trials (CENTRAL); AMED; CINAHL; China Academic Journal, Century Journal Project. The search for unpublished studies were: China Doctor/Master Dissertation Full Text DB, China Proceedings Conference Full Text DB, Proquest, RCAAP and Open Grey. Initial keywords to be used were: acupuncture, rheumatoid arthritis, quality of life, pain, functional impairment, physical function, randomized controlled clinical trial.

Method of Review

Duplicates were removed manually. All identified studies were assessed for relevance based on title and abstract. Whenever the title and abstract lacked data to make a decision, the inclusion criteria described above were verified in full-text papers.

Assessment of Methodological Quality

The papers selected for retrieval were methodological assessed by two independent reviewers (SS and DM). BN and SS reviewed the Chinese papers with the help of JG. BN and JG have high-level proficiency of Chinese language. Any disagreements between the reviewers were resolved through discussion, or with a third reviewer (DC). To exclude studies with high risk of bias, the reviewers established that a study required "yes" answers to at least 5 questions in the standardized critical appraisal instrument from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI).[23]

RESULTS

Methodological Quality of Included Studies

After methodological quality assessment, we to included 13 RCTs: 5 written in English and 8 in Chinese; 9 adopted a two-armed parallel-group design,[19,24-31] 3 adopted three-armed parallel group design[33,35] and 1 was a cross-over trial (Figure 1).[34]

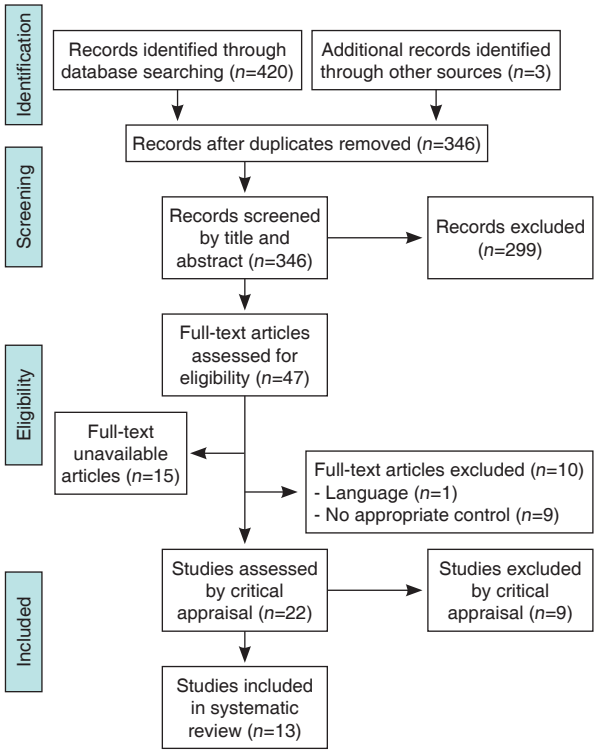

Figure 1. Flowchart for Search and Study Selection Process of Acupuncture Studies for RA Treatment

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 2009;(6)7: e1000097

The studies were published between 1999 and 2015, included 974 patients, aged between 25 and 77 years. Sample sizes ranged from 36[32] to 150[30] participants and disease duration between 3 months and 35 years. All studies showed similarity at baseline between the groups. The methodological quality of the included studies was low to moderate (Appendix 2). Details related to participants, interventions and possible limitations reported by the authors are presented in Table 1 (Appendix 3). Three placebo-controlled trials employed sham acupuncture,[19,32,34] but, did not give promising results for acupuncture treatments and reported conflicting evidence. Ten[24-31,33,35] of the 13 included RCTs showed favorable and statistically significant results of acupuncture treatments in relieving RA clinical symptoms and health status.

Primary Outcomes

Effectiveness of Acupuncture on Pain in Patients with RA

Regarding pain relief assessed with the VAS, evaluation between patients treated with auricular EA and autogenic training (AT), significant differences between groups in favor of EA group were found after the 4th treatment week.[24] Wang, et al[35] concluded that the total effective rate of acupuncture treatments with moxibustion were significantly higher than acupuncture or moxibustion used alone. Wan, et al[26] found that acupuncture improved symptoms of finger joint pain better than Western medicine alone (P<0.05). Zhou, et al[29] showed that the number of painful joints decreased after treatment with acupuncture (P<0.05).

Effectiveness of Acupuncture on Physical Function in Patients with RA

Xie, et al[31] found that after acupuncture treatments the total effective rate, tender joint count, swollen joint count and DAS28 were better than those treated with Western medicine alone (P<0.05). Zanette, et al[19] also demonstrated a significant improvement in physician global assessment of the disease activity (P<0.012), physician (P<0.003) and patient (P<0.011) global assessment after the acupuncture treatment.

Effectiveness of Acupuncture on HRQoL in Patients with RA

Zhu[27] found that after the acupuncture treatments, symptoms affecting the HRQoL, DAS28 and HAQ scores improved significantly and the results were better than the patients treated only with Western medicine (P<0.05). Xie, et al[31] showed that after the treatment and 4-months of follow-up, HRQoL scores of the group treated with acupuncture were significantly higher than those of the control group (P<0.05). Ouyang, et al[28] compared the effects of acupuncture with or without electro-stimulation and the overall effect of EA was better than TA alone.[28] All HRQoL parameters were significantly improved (P<0.05) except emotional functions. Somatic function, physical functions, somatic pain and mental health were better in patients treated with EA than the control group (P<0.05).

Secondary Outcomes

Zanette, et al[19] showed that 40% (8/20) of the participants of the group treated with acupuncture reached ACR20 standard in comparison with only 10% (2/20) reached ACR-20 standard to the control group.[19] For Tam, et al[32] the ACR score to patients treated with EA showed significant reduction of the physician's global assessment (P=0.04) and number of tender joints (P=0.03), as also to the patients treated with TA (P=0.01). The group treated with sham acupuncture,

ACR score showed reduction of the physician's global assessment (P=0.03).[32] Comparison of auricular EA with TA showed that DAS28 score had a more marked decrease in the EA group, the clinical global impression was successful in both groups but after the 6th week of treatments, symptoms and clinical outcomes were better in the EA group than in the TA group.[24]

Selection of major acupuncture points for Bi syndrome showed that the morning stiffness duration, joint tender index, joint swelling index and ESR significantly improved after acupuncture treatment using major acupuncture points (P<0.01) and the total effective rate was 93.3%.[25] Patients treated with acupuncture in acupoints selected to the Bi-impediment syndrome due to wind showed the total effective rate was 76.6%.[25] The difference of the total effective rate between observation group and control group (P<0.01) indicated that the therapeutic effect of the group that used major points was higher than the control group.[25] Integration of different Chinese medicine (CM) treatment approaches as midnight-noon ebb-flow method had an positive therapeutic effect on RA clinical signs (P<0.01), which could improve the effect combining with syndrome differentiation therapy.[33]

RA symptoms, DAS28, HAQ scores and HRQoL improved significantly more in the acupuncture group than in the Western medicine group (P<0.05 or P<0.01).[26,27,31] Zhou, et al[29] showed an effective rate of 83.3% for the acupuncture group. The number of painful joints, number of swollen joints, duration time of morning stiffness and grip strength significantly improved (P<0.05). ESR, titer of RF, activity of superoxide dismutase (SOD) and level of serum lipid peroxide (LPO) decreased after treatment with acupuncture.[29] Ouyang, et al[28] showed that 22 cases (68.75%) in the EA group reached ACR-20 standard and 6 (18.75%) reached ACR-50 standard. Clinical symptoms, activity of pathological condition, DAS28 and health status tended to improve after the acupuncture treatments and the results were better than treated with Western medicine alone (P<0.05). Patients treated only with usual care showed that 13 cases (41.9%) reached ACR-20 standard and 4 (12.90%) reached ACR-50. ESR and C-reactive protein improved in both groups (P<0.01).[31]

DISCUSSION

RA has major diverse effects on patients's HRQoL, spanning both physical and mental domains.[36] Given the complexity of the therapeutic used in RA, acupuncture has been heavily advertised with broad, attractive claims. Ten of the 13 RCTs pointed out that acupuncture was effective in relieving pain, PF and HRQoL in patients with RA compared to controls.[24-31,33,35] A particularity of these 10 studies is that they were published in China and variation between East and Western cultures cannot be denied. Chinese clinical trials combined acupuncture with other CM interventions as moxibustion, acupoints were chosen according specific CM theories and patients were treated according to a litany of symptoms interpreted from a CM perspective and not just in a Western medicine point of view. Three placebo-controlled trials employed sham acupuncture[19,32,34] and reported no statistical significant results for treatments using real or verum acupuncture in terms of RA symptom. The lack of evidence reported is subject of few interpretations. It is doubtful whether the acupuncture treatment administered was ideal. The results could be related to the type of intervention, the number of treatment sessions could have been too small to generate a significant effect; possibly insufficient stimulation; unsuitability of the protocol for treating RA. Different levels of expertise in acupuncture interventions, and differences in methodologic considerations, such as lack of a real double-blind, higher doses (intensity and duration), the type of acupuncture (acupuncture combined with moxibustion or acupuncture versus EA), the site of intervention, the small sample size and the lack of a CM differential diagnosis might had influenced the lack of efficacy of acupuncture.

We consider to exist consequences for the control intervention to be chosen.[19,32,34] Trials using streitberger placebos, shallow 2 mm needlings or pyonex controls,[32,36] the dosage of penetration is zero or low. The use of different numbers of needles in verum and control intervention, lead the searchers to compare high dosage of needling in the verum versus low dosage of penetration in controls. Specific effects of acupoints can only be shown if the method and time of puncture, number of needles and depth of insertion is the same on all groups, but selection of sham points is based on using areas that are external to the meridian channel to avoid the puncture in acupoints.[36]

Acupuncture seems to be promising when compared with conventional current RA-medication. The groups treated with acupuncture showed better results to pain relief, DAS28, HAQ scores and HRQoL than in the groups treated only with Western medicine.[26,27,31] Only

one study showed significant results between acupuncture and Western medicine alone, but acupuncture had effects on early RA with lower side effects and the mechanism of anti-inflammation and analgesia of acupuncture may be related to SOD and LPO.[29]

The studies from Asian countries tend to have positive results. However, the long-term benefits remain unknown and the results must be carefully interpreted because of the risk of methodological limitations, as well as unclear information about the methods of random assignment, inappropriate control interventions (non-comparable), no double-blind interventions and no real placebo. Acupuncture combined with moxibustion to treat RA had significant immunomodulatory effects and can improve the physiological function of the damaged joints as the morning stiffness duration, joint tender index and joint swelling index indicating that the therapeutic effect of the groups treated with acupuncture combined with moxibustion is higher than the control groups.[25,30,31,35] Acupuncture combined with the synergetic effects of heat from moxibustion might induce a comparison of the acupuncture effects to the analgesics, which claim to reduce pain through a stimulation of the serotonergic, noradrenergic and opioid system.[7]

Association of different strategies seems to be promissory as shown by Lin.[25] The systemic affects believed to be caused by the choice of points based on the syndrome differentiation and local ashi points. The integration of midnight-noon ebb-flow acupoint selection and acupuncture by differentiation of symptoms and signs group, combining points with systemic and local actions, showed better results (a total effective rate of 95% and $P<0.01$) than the application of each strategy alone.[33] Despite the promising results of 10 of the 13 studies included,[24-31,33,35] evidence displayed on these is limited due to methodological considerations. Lack of data on power analysis and effect sizes providing information about the impact of the acupuncture intervention is a limitation to most studies. This information could explain how much difference the intervention had made and to assist clinicians and policy makers in making informed decisions about the appropriate acupuncture use.

The ability to access articles on Chinese databases might have yielded further information pertaining to our topic. We included Chinese databases, as acupuncture is originated in China and there are many studies published in Chinese. However, we recognize that to search English words in Chinese database may inevitably lead to omissions. China Academic Journal and Century Journal Project are part of China National Knowledge Infrastructure and no inclusion of other Chinese biomedical literature database may lead to no identification of potential papers. Besides that, we were limited by the unavailability to access the full-text of 15 studies. The difficulty to access the Chinese literature was related to the fact that articles might not be indexed to conventional databases and also that access to local journals might be restricted. These facts might have resulted in an overestimation or underestimation of the effect of acupuncture interventions.

No meta-analysis could be performed due to clinical heterogeneity (acupuncture interventions, instruments, the dose/intensity of the treatments, the number of sessions and the fluctuations time elapsed between sessions) and methodological heterogeneity (designs) whereby, evidence is not strong enough to produce a better practice guideline. Future RCTs with more prevailing high quality designs, larger-scale samples, validated longer-term outcome measures for RA, appropriate control groups, appropriate sham methods, real double-blind and applying the CONSORT guidelines are required to strengthen the current evidence base on acupuncture treatments and to further understand its long-term effects in RA.

Conflict of Interest

The authors have no conflict of interest to declare.

Authors Contribution

SS and DM contributed equally to this review. SS, DM and DC contributed with the search strategy, selection of the papers for methodological validity, assessment and review of all the papers, analyses of the results and discussion. BN reviewed the Chinese papers with the help of SS. BN have high-level proficiency of Chinese language. ASC, HJG and MR contributed to the analysis of the results and discussion.

Electronic Supplementary Material: Supplementary materials (Appendix 1-3) are available in the online version of this article at http://dx. doi.org/10.1007/s11655-018-2914-x

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