Title

Efficacy of Acupuncture on Rheumatoid Arthritis of the Hand - results of the first prospective double-blind randomized clinical trial -

Susana Seca[1], Miguel Patrício[2], Sebastian Kirch[3], Giovanna Franconi[4], António S. Cabrita[5], Henry J. Greten[6]

1. Heidelberg School of Chinese Medicine, Germany¸ Faculty of Medicine, University of Coimbra; Institute of Science Biomedicine Abel Salazar, University of Porto. susana.seca@hotmail.com

2. Faculty of Medicine, University of Coimbra, 3045-137 Coimbra, Portugal; Institute of Biomedical Sciences Abel Salazar, University of Porto, 4050-313 Porto, Portugal. miguelpatricio@gmail.com

3. Heidelberg School of Chinese Medicine, Germany; Institute of Science Biomedicine Abel Salazar, University of Porto. seb.kirch@web.de

4. Dept. of Systems Medicine, University of Rome Tor Vergata, 00133 Rome, Italy. franconi.giovanna@gmail.com

5. Faculty of Medicine, University of Coimbra. amscabrita@gmail.com

6. Institute of Science Biomedicine Abel Salazar, University of Porto; Heidelberg School of Chinese Medicine, Germany. heidelbergschool@aol.com

Corresponding author: Susana Seca. Heidelberg School of Chinese Medicine, Karlsruhe Strasse 12. 69126 Heidelberg. Germany. susana.seca@hotmail.com. +351 914265319

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ABSTRACT

Importance: Rheumatoid Arthritis (RA) is characterized by pain, functional disability, poor quality of life (QoL), high socio-economic impact and annual costs of over $56 billion in the United States. Acupuncture (AC) is widely in use, however, studies show contradictory results and severe methodological shortcomings.

Objective: To assess AC-effects on RA, based on clear allocation criteria of acupoints, objective assessment of effects and valid, double-blind controls.

Methods: 105 RA patients with the functional diagnosis of a "pivotal syndrome" were randomly assigned to (1) verum-AC, (2) control-AC or (3) waiting list (each group n=35) applying the exact same number, depth and stimulation of needles in a double-blind assay described previously.

Outcomes: self-reported pain (Visual Analogue Scale), pressure algometry, arm and hand grip strength (Jamar® **Hydraulic Hand Dynamometer**), health status (Health Assessment Questionnaire), QoL (Short Form-36 health survey), number of tender and swollen joints, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP).

Results: (1) verum-AC significantly improved self-reported pain ($Z=-5.099$, $p<0.001$) and pressure algometry ($Z=-5.086$, $p<0.001$); hand grip strength ($Z=-5.086$, $p<0.001$), and arm strength ($Z=-5.086$, $p<0.001$); heath status improved significantly ($p=0.000$, $Z=-4.895$; QoL improved significantly in 7/8 survey domains; number of swollen joints ($Z=-2.862$, $p=0.004$) and tender joints ($Z=-3.986$, $p=0.000$) significantly decreased. ESR and CRP rate did not change. **(2) control-AC** showed no significant changes, **(3) waiting list group** showed an overall worsening, though ESR and CRP rate remained unchanged.

Conclusions and Relevance: This rigorous, first double-blind controlled study on AC in RA objectively assesses positive effects supporting its integration in rheumatology.

Key Words: Rheumatoid Arthritis, Acupuncture, Hand pain, Heidelberg model, Double-blind, Quality of Life

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