Auricular acupuncture for chronic back pain in adults: a systematic review and metanalysis

Acupuntura auricular para dor crônica nas costas em adultos: revisão sistemática e metanálise

Acupuntura auricular para dolor crónico en la espalda: revisión sistemática y metaanálisis

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ABSTRACT

Objective: To investigate randomized clinical trials on the action of auricular acupuncture for chronic back pain in adults, and to identify the most commonly used outcomes for assessing this condition, the protocol used for applying the intervention, and the efficacy of the therapy on pain intensity. **Method:** A systematic review and a metanalysis were carried out between June 2017 and May 2018, based on the PubMed, CINAHL, PEDro, Embase, Scopus, and the Virtual Health Library databases. Reference lists of systematic reviews were also explored. **Results:** 427 studies were located, 15 included in the qualitative analysis, and seven in the quantitative analysis. Auricular acupuncture led to positive results in 80% of the studies. The most commonly used outcomes were pain intensity and quality, medication consumption, physical disability, and quality of life. There is a lack of protocol standardization for auricular acupuncture for chronic back pain. The metanalysis results showed that auricular acupuncture was effective in reducing pain intensity scores (p=0.038). **Conclusion:** Auricular acupuncture is a promising practice for the treatment of chronic back pain in adults.

DESCRIPTORS

Chronic Pain; Back Pain; Acupuncture, Ear; Complementary Therapies; Review.

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INTRODUCTION

Chronic back pain, which may affect cervical, thoracic, and/or lumbar regions, presents a considerable individual and social impact on public health[1]. Between the 1990s and 2013, lower back pain ranked first and cervical fourth among the 25 overall causes of years living with a disability, according to the Global Burden of Disease Study[2].

In the last 10 years, lower back pain increased 18%, being considered one of the most common musculoskeletal disorders in current society[3]. Regarding cervical pain, yearly prevalence is higher than 30%[4]. As for the thoracic region, however, epidemiological characteristics have not been well-documented; yet, this prevalence varies from 4.8% to 7%, approximately[5].

The most current international guidelines recommend drug management for relieving back pain. However, most drugs produce limited relief and several serious side-effects. In this regard, a movement towards non-pharmacological approaches becomes necessary, including multidisciplinary rehabilitation based on physical therapy, massage therapy, cognitive behavior therapy, acupuncture, among others[3].

Auricular acupuncture (AA) is an adjuvant therapy to the regular acupuncture treatment. It has been used as a therapeutic approach in China since the Han dynasty, and a modern version of the technique was developed at the end of the 1950s[6], which consists of a method for diagnosis and treatment of physical and psychosomatic disorders by stimulating specific areas of the ear[7]. The effects of the intervention have been explained by neurophysiology and reflexology[7]. The technique has already been tested for the control of chronic pain[6], however, due to heterogeneity and methodological failures in randomized clinical trials (RCT), the evidence on AA for its management is incipient[6]. In addition, despite having a synthesis of the evidence in the literature on the effects of acupuncture in specific segments of the spine, mainly in the lumbar region[8-9], up to the present moment, systematic analyses designed specifically for investigating AA effects for chronic pain in all segments of the spine (cervical, thoracic, and/or lumbar) have not been identified.

Therefore, the objective of this study was to investigate and analyze RCT found in the literature on the action of AA for chronic back pain in adults, and to identify the most commonly used outcomes for assessing this condition, the protocol used for applying the intervention, and the effect of the therapy on pain intensity in these studies.

METHOD

A systematic literature review and a metanalysis were developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement) criteria.[10]

The PICO (P – population; I – intervention; C – comparison; O – outcomes)[11] strategy was used to formulate the guiding question: "What are the effects of auricular acupuncture for chronic pain in adults?"

The search for articles, conducted by two independent reviewers with the help of a librarian in the field of health sciences, was carried out using the following databases: Medline via PUBMED, Web of Science, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Physiotherapy Evidence Database (PEDro), Embase, Scopus, and databases indexed in the Virtual Health Library (VHL), such as the Latin American and Caribbean Center on Health Sciences Information (LILACS), the Brazilian Nursing Database (BDENF), and the National Center of Information of Medical Sciences of Cuba (CUMED). Reference lists of systematic reviews were also used for searching relevant studies related to the guiding question. All searches in the electronic databases were carried out in May 2018.

Controlled descriptors, extracted from the Health Sciences Descriptors (DeCS) and from the Medical Subject Headings (MeSH), and uncontrolled descriptors were combined using Boolean operators OR and AND as follows: ("Back Pain" OR "Low Back Pain" OR Sciatica OR "Chronic Pain" OR "Musculoskeletal Pain" OR "Myalgia" OR "Neck Pain" OR Lumbago OR "lumbar pain" OR "Low Back Pains" OR "Musculoskeletal Pains" OR "Muscle Pain" OR "Neck Pains" OR "Cervical Pain" OR "Cervical Pains") AND ("Auricular Acupuncture" OR "Ear Acupuncture" OR "Auricular Acupunctures" OR auriculopressure). The search strategy was adapted for each electronic database, and the terminologies were searched in all fields (title/abstract/descriptors/text).

The eligibility criteria for selection of articles, based on the PICO strategy, were: RCT with adults (18 years or over) (*population*); use of auricular acupuncture (puncture, pressure, electrical stimulation, magnetic stimulation, among others) (*intervention*); comparison with one or more of the following groups: sham, waiting list, standard medical treatment/active treatment or no treatment (*comparison*); and chronic pain (3 months or more)[12] in at least one of the spine segments (cervical, thoracic, and/or lumbar) (*outcomes*). The studies excluded were those that did not provide the full abstract online, those that were not located by any means, and studies with pregnant women. It should be noted that there were no restrictions on the year of publication and the language of the analyzed studies.

The data of the studies included in the review were extracted by two independent researchers, using a standardized data collection form,[13] and adapted by the study researchers. The following data were extracted: article identification (title, author(s)/area of study, journal, year of publication, country/study language); objectives; methodological characteristics (design, sample size, loss to follow-up; inclusion and exclusion criteria); clinical data (number of patients by gender, age, diagnosis, duration of symptoms); description of interventions in the follow-up groups (treatment line, number of sessions, treatment duration, application device, time the device was kept on, application points, unilateral or bilateral application, location of the points, type of protocol, professional who performed the intervention, years of experience in the field; outcomes and assessment methods (number of evaluations, intervals among them, measuring tools); data analysis; main results; and conclusions. A third researcher cross-checked the information collected to reach a final consensus on the extracted data.

The methodological quality of the eligible studies was assessed using the Jadad scale[14], which focuses on internal

validity. The questions have yes or no answer options, with a total score of five points: three questions are given one point each for affirmative answers, and two additional points are given to appropriate methods of randomization and allocation confidentiality[10]. Two independent reviewers carried out the evaluation, and a third researcher was consulted to solve possible differences.

Data analyses were carried out using the Stata SE/12.0 statistical software. The absolute difference among the means, with a 95% confidence interval, was selected to describe the mean differences among the treated groups and the assessment control carried out at the end of the treatment. A p<005 value was considered statistically significant. The potential heterogeneity among the studies was checked using the Cochran's Q[15] and the I[2(16)] statistical tests. Because the heterogeneity results in the test were statistically significant (p<0.05) and the calculated value of I^2 suggested high heterogeneity (86.8%)[16], the model of random effects was adopted for the analysis.

RESULTS

A total of 427 studies were found in the electronic and manual searches. Because they were duplicated, 161 studies were removed from the list. After reviewing their titles and abstracts, 225 articles were excluded, whereas 41 remained for full text analysis. Out of these, the texts of four studies were not located (online, through bibliographic commutation, or direct contact with the authors), and 22 articles were excluded. Thus, 15 articles were included in the synthesis of the qualitative analysis, and seven in the quantitative analysis (Figure 1).
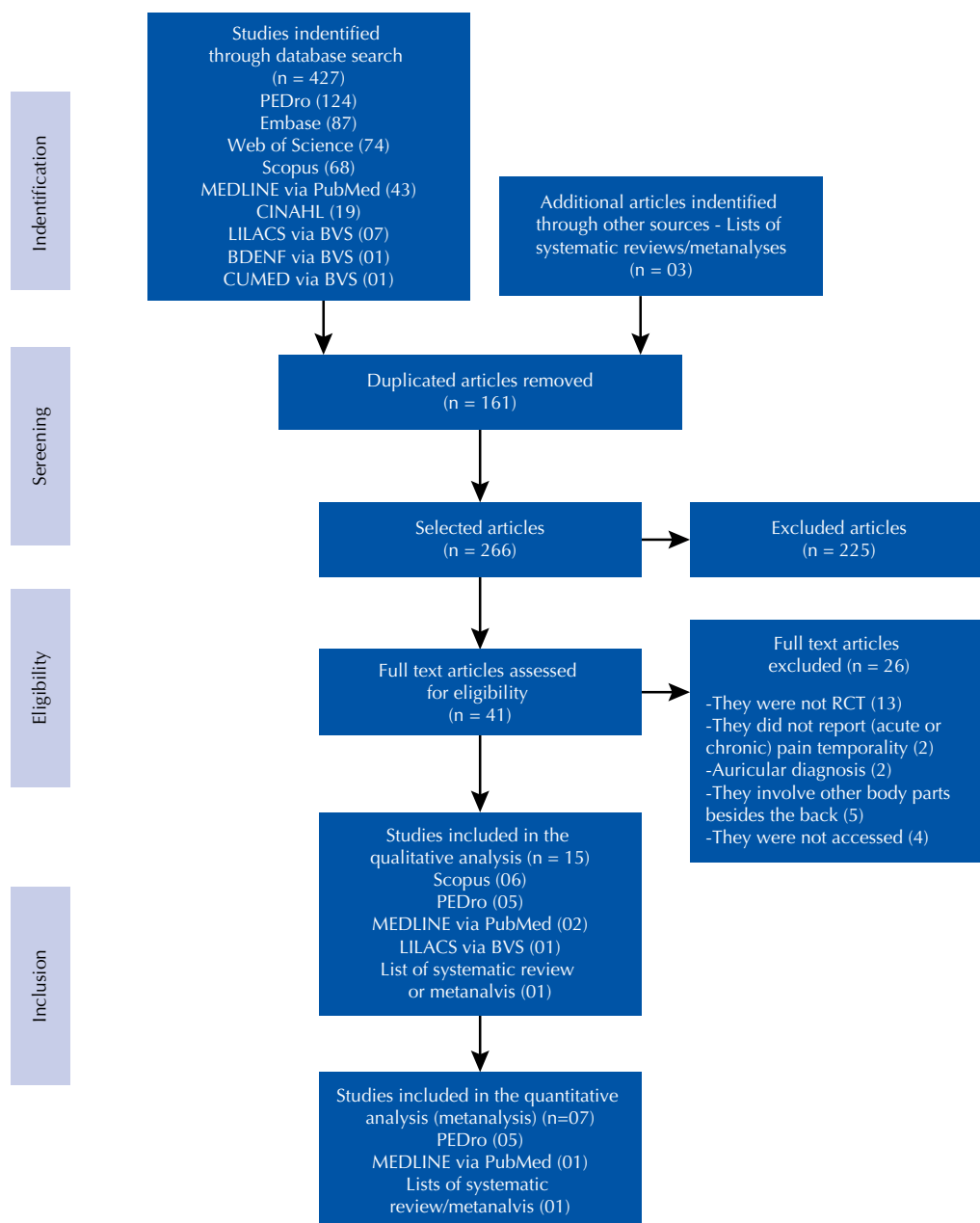

Figure 1 – Flowchart of article selection for the systematic review – Belo Horizonte, MG, Brasil, 2018.

A total of 930 individuals participated in the selected studies, with age varying from 18 to 90 years of age, whereas 462 were in the groups that received auricular acupuncture, and 468 were in the control groups. All participants presented chronic pain conditions[8], whereas the lumbar spine was the most affected region (n=10),[17-26] followed by the cervical region (n=3)[27-29], and the dorsal region as a whole (n=2)[30-31].

Chart 1 shows the characterization of the studies regarding the interventions applied in the experimental and control groups and their main findings.

Chart 1 – Characterization of the studies regarding the applied intervention – Belo Horizonte, MG, Brazil, 2018.

Authors/Year	Country	Intervention in the experimental group	Intervention in the control group	Main findings
Ushinohama et al., 2016[17]	Brazil	Auricular acupuncture (n=40)	Ultrasound turned off (n=40)	Auricular acupuncture was effective in reducing temporarily the intensity of the pain, but not sufficiently to improve body balance.
Yeh et al., 2015[18]	United States	Auricular acupressure (AAP) (n=30)	Auricular acupressure on points not related to the focus of the treatment (n=31)	Among the participants in the intervention group (real AAP), a 30% reduction in the worst pain was showed after the first day of treatment, and the steady reduction of the pain (44%) was reported after concluding four weeks. The use of painkillers by the intervention group participants was also reduced compared to the sham group.
Eberhardt et al., 2015[30]	Brazil	Auricular acupuncture (n=18)	*Zen Shiatsu* (n=17)	Auricular acupuncture and Zen Shiatsu are effective in reducing the levels of chronic lower back pain in nursing professionals. This effect lasted for 7 days. One treatment is not better than the other.
Silva et al., 2015[27]	Brazil	Auricular acupuncture (n=12)	Auricular acupuncture in points not related to the focus of the treatment (n=12)	The intervention effect on pain symptoms in patients with non-specific cervical pain was inconclusive, since the observed reductions through protocols of simulated and real auricular acupuncture treatment were practically the same.
Yeh et al., 2014[19]	United States	Auricular acupressure (n=19)	Auricular acupressure in points not related to the focus of the treatment (n=18)	The reduction of the worst pain from the baseline up to the end of the intervention was 41% for the intervention group (real AAP) and 5% for the sham group. The disability scores in the Roland-Morris Disability Questionnaire showed a reduction of 29% in the real group and remained unchanged in the simulated group.
Vas et al., 2014[31]	Spain	Auricular acupressure (n=130)	Patches with an inactive black plastic disc (n=135)	Auriculopressure reduced the pain in the short- and medium-term and improved quality of life of the patients with unspecific chronic rachialgia.
Marignan, 2014[20]	France	Auricular acupuncture with electric stimulus (n=6)	Auricular acupuncture with electric stimulus on points that do not correspond to the affected areas (n=6)	The effects on the pain and on lumbar flexibility were significant, especially for the group that received real treatment.
Yeh et al., 2013[21]	United States	Auricular acupressure (n=11)	Auricular acupressure on points not related to the focus of the treatment (n=10)	The participants of the real group showed a 70% reduction in the worst pain intensity, a 75% reduction in the overall pain intensity, and a 42% improvement in disability due to back pain. These findings were statistically higher than those found in the simulated group.
Hunter et al., 2012[22]	Northern Ireland	Auricular acupuncture associated to an exercise program (n=24)	Exercise program (n=28)	There is an increase in clinical outcome benefits when auricular acupuncture is associated with an exercise program.
Zhangxiu et al., 2011[23]	China	Auricular acupressure with medicated patch associated with the application of medicated patch on the affected area (n=30)	Medicated patch application on the affected area (n=30)	The combination of auricular points and the external application of medicated patch led to a better result. After a 3-day treatment, the combined therapy showed a statistically significant difference compared to the group treated with a single therapy, proving that the auricular points may strengthen the effect of the medicated patch in the short-term.

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Authors/Year	Country	Intervention in the experimental group	Intervention in the control group	Main findings
Suen, Wong, 2008[24]	Hong Kong	Auriculotherapy with magnetic pellets (n=40)	Auriculotherapy with Vaccariae seeds (n=39)	The participants in the experimental group showed a significant reduction in the level of the lumbar pain, evidenced by a decrease in pain intensity, mobility improvement, and functional status, compared to the participants in the control group.
Suen et al., 2007[25]	Hong Kong	Auriculotherapy with magnetic pellets (n=30)	Auriculotherapy with Vaccariae seeds (n=30)	The participants in the experimental group showed a significant reduction in the level of the lumbar pain, evidenced by a decrease in pain intensity, when compared to the participants in the control group.
Ceccherelli et al., 2006[28]	Italy	Auricular acupuncture associated with somatic acupuncture (n=31)	Systemic acupuncture (n=31)	Regarding cervical myofascial pain control, systemic acupuncture associated with auriculotherapy did not show a statistically significant difference compared to the group treated only with systemic acupuncture.
Sator-Katzenschlager et al., 2004[26]	Austria	Auricular acupuncture with electric stimulus (n=31)	Auricular acupuncture without electric stimulus (n=30)	The treatment of chronic lumbar pain is significantly optimized with the use of electric stimulation on auricular acupuncture points with the P-Stim™ device.
Sator-Katzenschlager et al., 2003[29]	Austria	Auricular acupuncture with electric stimulus (n=10)	Auricular acupuncture without electric stimulus (n=11)	The reduction in pain scores was significantly higher in the electric acupuncture group compared to the conventional group with manual acupuncture. The psychological well-being, activity, and sleep improved significantly in patients that received electric stimulation. Drug consumption was significantly higher in the control group compared to the electric acupuncture group.

Note: (n=15)

Regarding the RCT methodological quality, all studies reported using the random sequence generation method, and in just three this process was not appropriate[23-25]. In two RCT[13-30] there was no description of masking, and in other two[24-25] this masking was considered inadequate. There was no description of loss to follow-up in three RCT[20,23,27]. Therefore, 90% (n=9) of the studies[17-19,21-22,26,28-29,31] obtained score five in the Jadad score; 13.3% (n=2)[20,27] obtained score four; 6.7% (n=1)[30] obtained score three; and 20% (n=3)[21-25] obtained score one.

Study outcomes and the way of measuring them, the number of evaluations, and the interval between them are described in Chart 2.

Chart 2 – Evaluated outcomes, measuring tools, number of evaluations, and interval between them. Belo Horizonte, MG, Brazil, 2018.

Study identification	Outcomes	Measuring tools	Number of evaluations / Interval between evaluations
Ushinohama et al., 2016[17]	1-Pain intensity 2-Physical disability 3-Postural control	1-Numerical scale (0-10) 2-Roland-Morris Disability Questionnaire 3-Portable force platform	02 (Baseline and after intervention)
Yeh et al., 2015[18]	1-Pain intensity 2-Painkiller consumption	1-Brief Pain Inventory (0-10) 2-Medication Quantification Scale Version III (MQS III)	06 (Baseline, during consultations, immediately, and after 1 month)
Eberhardt et al., 2015[30]	1-Pain intensity	1-VAS (Visual Analogue Scale) (0-10)	03 (7 days prior, immediately, after treatment, and after 7 days)
Silva et al., 2015[27]	1-Pain intensity 2-Electromyographic muscular activity	1-Numeric Pain Rating Scale (0-10) 2-Electromyography	02 (Baseline, at the end of 30-minutes treatment)
Yeh et al., 2014[19]	1-Pain intensity 2-Physical disability 3-Quality of life 4-Quality of pain 5-Affective distress and life control 6-Emotional function (anxiety and depression) 7-Beliefs on how physical activity and work affect pain 8-Exaggerated and negative interpretations of pain 9-Inflammatory markers 10-Painkiller consumption	1-Brief Pain Inventory (0-10) 2-Roland-Morris Disability Questionnaire 3-WHOQOL-BREF 4-Short-Form McGill Pain Questionnaire (MPQ-SF) 5-Multidimensional Pain Inventory-Screening 6-Generalized Anxiety Disorder Scale 6-Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form 7-Fear Avoidance Beliefs Questionnaire (FABQ) 8-Pain and Catastrophizing Scale (PCS) 9-Blood sample 10-Journal	06 (Baseline, weekly for 4 weeks, and 1 month of follow-up)

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Study identification	Outcomes	Measuring tools	Number of evaluations / Interval between evaluations
Vas et al., 2014[31]	1-Pain intensity 2-Pain rate 3-Painkiller consumption 4-Level of activity and night rest 5-Quality of life 6-Quality of pain 7-Treatment expectations and credibility	1-VAS (0-100) 1/2/3/4-Lattinen index 5-12-item Short-Form Health Survey (SF-12) 6-McGill Pain Questionnaire 7-Original scale of Borkovec & Nau	03 (Baseline, at the end of treatment, and after 6 months)
Marignan, 2014[20]	1-Pain intensity 2-Lumbar spine flexibility	1-VAS (0-10) 2-Schober's test	02 (Immediately before and after intervention)
Yeh et al., 2013[21]	1-Pain intensity 2-Physical disability 3-Quality of life 4-Exaggerated and negative interpretations of pain 5-Treatment satisfaction 6- Painkiller consumption	1-Brief Pain Inventory (0-10) 2-Rolland-Morris Disability Questionnaire 2/3-Modified Oswestry Low Back Pain Disability Index The Pain (ODI) 3-WHOQOL-BREF 4-Pain and Catastrophizing Scale (PCS) 5-Treatment Satisfaction 6- Journal	06 (Baseline, weekly for 4 weeks, and 1 month of follow-up)
Hunter et al., 2012[22]	1-Pain intensity 2-Physical disability 3-Quality of life 4-Level of physical activity 5-Beliefs of fear/avoidance 6-Beliefs and thoughts related to lower back pain 7-Beliefs on complementary and alternative medicine 8-Self-efficacy 9- Painkiller consumption	1-VAS (0-10) 2-Oswestry Disability Questionnaire 3-EuroQol 5D 4-International Physical Activity Questionnaire 5-Fear Avoidance Beliefs Questionnaire (FABQ) 6-Back Belief Questionnaire 7-Holistic Complementary and Alternative Health Questionnaire 8-General Self-Efficacy Scale 9-Journal	04 (Baseline, 8th week, 13th week, and 6 months)
Zhangxiu et al., 2011[23]	1.1-Pain intensity 1.2-Quality of pain 1.3-Current pain intensity	1-Short-Form McGill Pain Questionnaire (SFMPQ) 1.1-VAS (0-10) 1.2-Pain Rating Index (PRI) 1.3-Present Pain Intensity (PPI)	03 (Baseline, after 3-day treatment, and after 2 weeks)
Suen, Wong, 2008[24]	1-Pain intensity and sensation 2-Physical disability 3-Functional disability	1/2/3-Modified Aberdeen Low Back Pain Disability Scale	05 (Baseline, in 1.5 and 3 weeks of treatment, and 2 and 3 weeks post-treatment)
Suen et al., 2007[25]	1-Pain intensity	1-Chinese Pain Intensity Verbal Rating Scale (0-10)	04 (Baseline, immediately, 2 and 4 weeks after treatment)
Ceccherelli et al., 2006[28]	1-Pain intensity 2-Quality of pain	1-VAS (0-100) 2-McGill Pain Questionnaire (MPQ)	04 (Baseline, after therapy, and after 1 and 3 months)
Sator-Katzenschlager et al., 2004[26]	1-Pain intensity 2-Quality of pain 3-Psychological well-being 4-Level of activity 5-Sleep quality 6-Painkiller consumption 7-Treatment satisfaction	1/2/3/4/5-VAS (0-10) 2- McGill Pain Questionnaire 6-Amount of consumed pills 7-Dichotomous variable categorized in yes or no	18 (three evaluations a day – morning, afternoon, and night – during 6 weeks)
Sator-Katzenschlager et al., 2003[29]	1-Pain intensity 2-Psychological well-being 3-Level of activity 4-Sleep quality 5- Painkiller consumption 6-Treatment satisfaction	1-VAS (0-10) 2/3/4- Rating scale from 0 (without involvement) to 10 (worst imaginable deterioration) 5-Amount of consumed pills 6-Dichotomous variable categorized in yes or no	08 (Baseline, weekly, and after 4 weeks)

Note: (n=15)

Pain intensity was addressed in all studies. The second most evaluated outcome was drug consumption, identified in 46.6% (n=7) of the studies[18-19,21-22,26,29,31], followed by physical disability (33.3%; n=5)[17,19,21-22,24], quality of pain (33.3%; n=5)[19,23,26,28,31], and quality of life (26.6%; n=4)[19,21-22,31] (Chart 2).

The characteristics of the protocol for AA intervention are described in Chart 3, based on the recommendations provided by the Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)[32].

Chart 3 – Auricular acupuncture intervention protocol for treating chronic back pain – Belo Horizonte, MG, Brazil, 2018.

Study identification	Treatment line	Number of sessions	Treatment duration	Application device	Time the device was kept in place	Type of stimulus	Application points	Uni- / bilateral application	Location of the points
Ushinohama et al., 2016[17]	//	1	20 minutes	Systemic needles (0.15x30mm – Dong Bang)	20 minutes	//	*Shenmen* Pain relief Lumbar pain	//	//
Yeh et al., 2015[18]	Chinese	4	4 weeks	Vaccariae seeds	5 days	Manual (orientation: press the seeds 3x/day for 3 min each time, even without symptoms).	*Shenmen* Sympathetic Nerve Subcortex Points inside two regions for lumbar pain	Bilateral	According to the map of Chinese standard acupoints.
Eberhardt et al., 2015[30]	Brazilian (Marcelo Pereira de Souza)	1	7 days	Semi-permanent needles (1.5mm in length)	7 days	Without stimulus (orientation: do not stimulate the needles).	*Shenmen* Kidney Sympathetic Pain relief Muscle relaxation Thoracic vertebrae Lumbar vertebrae	//	According to Marcelo Pereira de Souza.
Silva et al., 2015[27]	French (Nogier's method)	1	30 minutes	Sterile acupuncture needles (0.25x3mm – Suzhou Huanqiu Acupuncture Medical Appliance Co, Ltd.)	30 minutes	//	Scapular waist Shoulder	//	According to Nogier's method.
Yeh et al., 2014[19]	Chinese	4	4 weeks	Non-specific seeds (2 mm diameter)	5 days	Manual (orientation: press the seeds 3x/day for 3 min each time. And for 3 min always when experiencing pain).	*Shenmen* Sympathetic Nerve Subcortex Active points corresponding to chronic lumbar pain	Bilateral	Electric detector of acupoints.
Vas et al., 2014[31]	Chinese	8	8 weeks	Vaccariae seeds	7 days	Manual (orientation: perform 10 pressures with the finger in each point 3x/day).	*Shenmen* Thalamus Points were added according to sensibility in auricular zones	Unilateral (Ear alternation, starting at the most sensitive ear)	According to Chinese mapping / Pressure detector of 250 g.
Marignan, 2014[20]	//	//	//	Electrical Stimulator	//	Electric (30 s in each point).	Spinal cord Cerebellar peduncles Cerebellar formation Vestibular nuclei	Uni- or bilateral (in case of pain in one or both ears)	Electric detector of acupoints.
Yeh et al., 2013[21]	Chinese	4	4 weeks	Vaccariae seeds	5 days	Manual (orientation: press the seeds 3x/day for 3 min each time. And for 3 min always when experiencing pain).	*Shenmen* Sympathetic Nerve Sub-cortex Acupuncture points corresponding to lower part of the back.	//	Electric detector of acupoints.
Hunter et al., 2012[22]	//	6	6 weeks	Conventional auricular needles (1.80x0.26 mm – Seirin Pyonex, Japan)	2 days	Manual (orientation: to record the rate of manual stimulation of needles during 48 hours treatment period in a weekly logbook during the intervention phase).	*Shenmen* Lumbar spine *Cushion*	//	//

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Study identification	Treatment line	Number of sessions	Treatment duration	Application device	Time the device was kept in place	Type of stimulus	Application points	Uni- / bilateral application	Location of the points
Zhangxiu et al., 2011[23]	Chinese	4	2 weeks	Patches of Vaccariae seeds	//	Manual (orientation: press the patches 3x/day, 3-5 minutes each time).	Shenmen Kidney *Ashi* Points Lumbosacral vertebrae Liver Sub-cortex	Unilateral (Ear alternation)	According to the MTC* holistic concept, and guided by the theories of Zang-Fu and the meridians.
Suen, Wong, 2008[24]	Chinese	7	3 weeks	Magnetic pellets and Vaccariae seeds (control)	3 days	Without stimulation (orientation: do not press the seed / magnet pellets).	*Shenmen* Kidney Bladder Lumbosacral vertebrae Buttocks Liver Spleen	Unilateral (Ear alternation)	Electric detector of acupoints.
Suen et al., 2007[25]	Chinese	4	3 weeks	Magnets (66 gauss, 0.13 cm diameter) and Vaccariae seeds (control)	3 days	Without stimulation (orientation: do not press the seed / magnet pellets).	*Shenmen* Kidney Urinary bladder Lumbosacral vertebrae Buttocks Liver Spleen	Unilateral (Ear alternation)	Electric detector of acupoints / According to the map of Chinese standard acupoints.
Ceccherelli et al., 2006[28]	//	8	8 weeks	Disposable Sedatelec® needles (300 μmx18 mm) (group 1) / Auricular needles (group 2)	//	Manual (rotational movement, for 20 s, at the time of insertion and for the appearance of sensation of –qi (except point SI) (Group 1) / Auricular needles: rotating movement for 20 s, only at the time of insertion (Group 2).	*Shenmen* Lung Cervical spine region Occipital	//	//
Sator-Katzenschlager et al., 2004[26]	French (Nogier's nomenclature)	6	6 weeks	Disposable titanium needles (27 gauge, 3 mm in length) linked to P-Stim ™ device (Biegler GmbH, Mauerbach, Austria)	2 days	Electric (electric stimulation with low continuous frequency using P-Stim ™ – constant current: 1 Hz 2-phase, 2 mA).	*Shenmen* Lumbar spine *Cushion*	Unilateral (Ear alternation, starting at the dominant side)	Electric detector of acupoints.
Sator-Katzenschlager et al., 2003[29]	French (Nogier's nomenclature)	6	6 weeks	Disposable titanium needles (27 gauss, 3 mm in length) linked to P-Stim ™ device (Biegler GmbH, Mauerbach, Austria)	2 days	Electric (needles were continuously stimulated with 2 mA of constant current with low frequency of 1 Hz during 48 h).	*Shenmen* Cervical spine *Cushion*	Unilateral (Ear alternation, starting at the dominant side)	Electric detector of acupoints.

*TCM: Traditional Chinese Medicine. Note: (n=16)

Only 6.7% (n=1) of the studies[31] carried out the intervention in an individualized format. In all the others (93.3%; n=14), the intervention took place with fixed treatment protocols.

In 26.6% (n=4) of the studies[18-19,21,31], the intervention was carried out by nurses, followed by physical therapists (20%; n=3)[17,22,27], physicians (13.3%; n=2)[28,31], and one therapist without specification of training in the field (n=1; 6.6%)[30]. In 26.6% of the studies (n=4)[20,23,26,29], no information was provided.

It is important to note that only 13.3% of the studies (n=2) presented the period of experience of the professional that carried out the intervention, which varied between 11[17] and 15 years[27]. Only one study indicated that the intervention was performed by specialized professionals, but did not provide the length of training[22].

Auricular acupuncture was able to reduce pain intensity in 80% of the studies(n=12).[17-26,29,31] In the remaining 20%

(n=3)[27,28,30], the effects of the interventions in the experimental and control groups were similar.

Seven RCT, which reported pain intensity scores at the end of the treatment period through the VAS[20,23,28], the Brief Pain Inventory[18-19,21], or the Pain Intensity Verbal Rating Scale[25], were added to the metanalysis. The remaining studies[17,20,22,24,26,29-30] did not provide sufficient data for this analysis.

The results showed that AA was more effective in reducing pain intensity scores (absolute difference between means: -0.56, [95% confidence interval: -1.09 to -0.03]; p = 0.038), with high heterogeneity $I^2 = 86.8\%$, p < 0.001) (Figure 2). Thus, pain intensity in patients submitted to AA is, on average, 0.560 lower in a scale from 0 to 10, than the pain intensity in the control group. Indeed, the metanalysis average effect, represented by the center of the diamond, is at the left of the vertical center line, indicating that the intervention reduces the probability of the outcome.
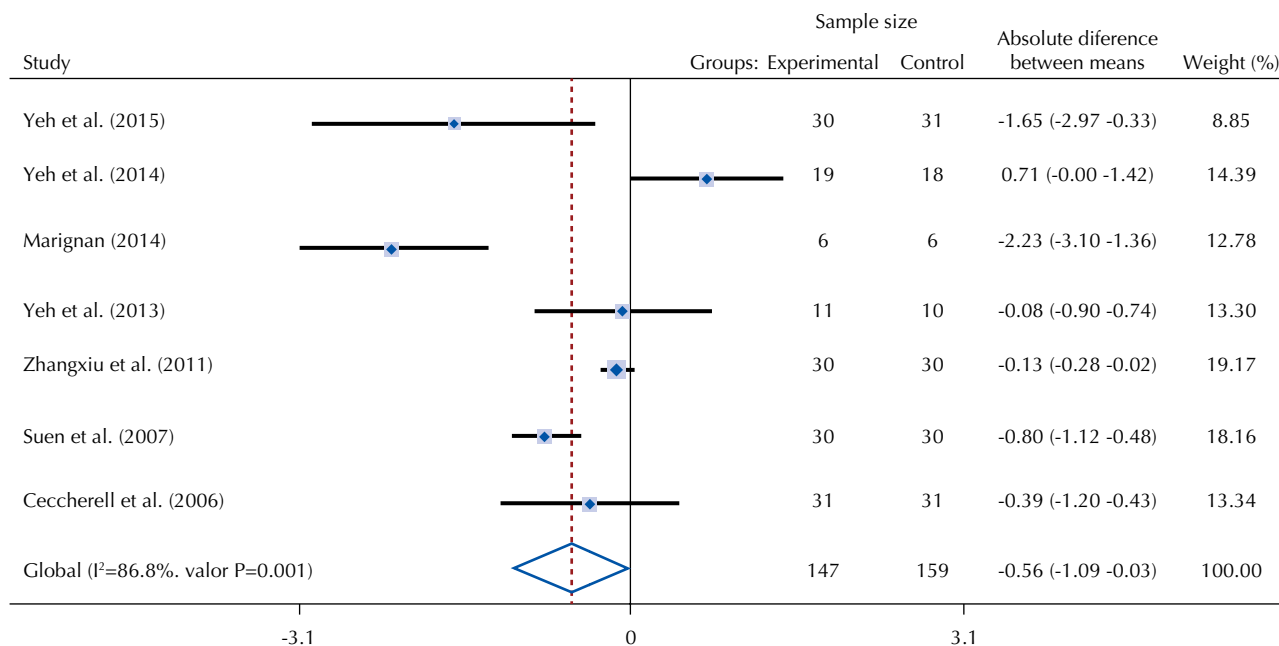

| Study | | Sample size | | Absolute diference | Weight (%) |
		Groups: Experimental	Control	between means	
Yeh et al. (2015)		30	31	-1.65 (-2.97 -0.33)	8.85
Yeh et al. (2014)		19	18	0.71 (-0.00 -1.42)	14.39
Marignan (2014)		6	6	-2.23 (-3.10 -1.36)	12.78
Yeh et al. (2013)		11	10	-0.08 (-0.90 -0.74)	13.30
Zhangxiu et al. (2011)		30	30	-0.13 (-0.28 -0.02)	19.17
Suen et al. (2007)		30	30	-0.80 (-1.12 -0.48)	18.16
Ceccherell et al. (2006)		31	31	-0.39 (-1.20 -0.43)	13.34
Global (I^2=86.8%. valor P=0.001)		147	159	-0.56 (-1.09 -0.03)	100.00

-3.1   0   3.1

Figure 2 – Forest plot of the pain intensity score – Belo Horizonte, MG, Brazil, 2018.

DISCUSSION

The current study proved the benefits of AA for chronic back pain in adults in several pain assessment parameters, whether subjective or physiological, in most of the evaluated RCT. Therefore, the synthesis of the best scientific evidence on the subject may contribute to the implementation of the intervention in clinical practice.

Regarding the methodological quality of the studies, only three[21-25] did not achieve a satisfactory score (higher than three) in the Jadad scale[14], due to lack of information for the measurement[23] or mismatches in the randomization and masking processes[24-25]. These are key prerequisites for the good quality of the RCT, since they are universally considered gold standard accepted for evidence-based practice and,

if properly conducted, its use is recommended for clinical and policy decision-making on health priorities[33].

In acupuncture clinical trials, the ideal control group has not yet been determined[34]; however, the comparison with this group, whether with gold standard therapy or no procedure at all, is the best way to verify the real effects of the intervention. In fact, some studies have applied[22-26,28-30] active treatment in the control group, which is justifiable when the best treatment for the clinical condition has already been determined. Other studies[18-21,27] applied auricular acupuncture in points that were not related to the phenomenon being studied, an acupuncture technique called sham (placebo, fake, or simulated). This technique violates traditional acupuncture theories on location or indications

of the acupoints and, therefore, it is unable to achieve the results intended by real acupuncture[34]. Finally, two other studies[17,31] applied inactive treatments in the control group with the intention of checking whether the expectations of the patient related to the therapy could have an impact on the treatment[35].

Regarding the evaluated outcomes, it is important to investigate, besides pain intensity, other intervention actions on the chronic algic process, as it was carried out in all included RCT. A comprehensive pain assessment is essential to identify, besides the intensity, social, biological, cultural, and psychological factors that have an impact on it, as well as the negative impact that this experience can cause in the lives of those who were affected[36]. In fact, auricular acupuncture may alter other phenomena related to chronic pain, such as the psychological well-being, level of activity, quality of sleep, amount of consumed medication, and even facilitate the return to work activities[26], thus highlighting the importance of investigating such outcomes. In addition, physiological parameters are important indicators capable to provide a broad assessment of the health status of individuals who suffer from pain and the changes that take place over time[37], thus allowing the analysis of the response to treatment[38].

Through the systematic analysis of the included RCT, it was possible to confirm that there was no standardization in the AA protocol for chronic back pain, in relation to the number of sessions, treatment time, application device, time the device was kept on, type of stimulation, and points of application.

Nonetheless, it was noted that most of the studies[18-19,21,23-25,31] opted for the Chinese treatment approach. The treatment principles in Traditional Chinese Medicine (TCM) are based on the belief that the ear is related to all body parts and internal organs, and as the auricular acupoints are stimulated, the meridians may be activated[24], which are passages for the flow of "qi" and "blood". These two body fluids are relevant in the TCM, and spread to the entire body surface, connecting the inter to the outer body[39].

The number of AA sessions for chronic back pain is approximately five (variation from one to eight – average of 4.57 sessions), and the treatment time is from 20 minutes to 8 weeks (average of 3.93 weeks) with a weekly application of seeds or auricular needles, and the mean time the devices are kept on the ear is 4 days with a maximum period of 7 days.

Regarding the application devices, a study with the objective of analyzing the efficacy of auriculotherapy with needles and seeds in stressed professionals identified better results with the application of needles[40]. However, the use of this device can be uncomfortable during application and permanence, thus evidencing the disadvantage of needles in relation to seeds[40]. In the case of using seeds, patient participation is necessary, that is, the effect caused by the application of seeds is proportional to the manual stimulation exerted upon it; therefore, if the patient forgets to press it, it will not have any effect, which could be considered a limiting factor, besides representing a source of bias to the research[13].

In relation to the stimulation exerted on the device, manual stimulation is indispensable for the cases using seeds[13], and for the cases in which auricular needles were adopted, whether manual or electric[20,40]. In addition, auricular acupuncture performed with electric stimulation may lead to faster pain relief after some minutes of stimulation[20], which demonstrate that the association of this intervention with electric current ensures even more positive results reducing pain intensity, especially in the cases of severe pain. However, it is worth noting the need for further research.

Regarding the applied auricular acupoints, the most common were *Shenmen* (central nervous system), kidney, sympathetic (sympathetic nervous system or neurovegetative system), subcortex, liver, bladder, points at the pain site (cervical, thoracic, and/or lumbar), on a unilateral basis. The painkiller or pain relief point, which is also indicated for this clinical condition, was used in only two studies[13,26]. However, this point does not appear in the World Federation of Acupuncture-Moxibustion Societies[41] map with this nomenclature; therefore, a validation process is recommended for the location of this point before safely using it.

The use of an electric detector of acupoints for tracking the auricular points is recommended. The trackers detect the electric resistance of the points that[25], under pathological conditions, are lower than the normal conditions. It is also important to point out that to obtain better precision locating the auricular points, they should be related to patient complains. In addition, the likely point location must be guided by an auricular map, since the distribution of the points follows the configuration of an upside-down fetus in these maps[7], as some studies have shown[18,25,30-31].

Only one study[31] carried out the intervention in an individualized format. Such an approach is positive, since it takes into consideration the reestablishment of the energy balance of the body as a whole, promoting a faster recovery of the health status. When auricular acupuncture is strictly based on the TCM principles, variations in the auricular points, number of sessions and application devices may be justified. According to such principles, treatment customization is important, since each individual is unique, and the imbalance patterns may affect each person differently[40].

In fact, researchers[42] have pointed out that, to assess the efficacy of the intervention applied with a protocol of points, as required by scientific research, and without a protocol, as guided by the TCM, the best results are obtained in the group without a protocol, demonstrating that auriculotherapy carried out individually, with an aim at the energy balance of the individual, is capable of improving the range of the therapy.

However, the establishment of fixed protocols favors its replicability and further implementation in clinical practice. It is important to point out that, to determine the best forms for treating patients, it is first necessary to demonstrate scientifically the efficacy of the intervention, and then to apply this evidence into practice. This takes place through replicability of the studies and, for such scope, it becomes crucial to establish consistent methodological protocols, as recommended by STRICTA[32].

Acupuncture RCT intervention reports recommend the description of the participating acupuncturists, with qualifications or professional affiliation, years of expertise, among other information[32]. Most of the included RCT[17,18-19,21-22,27-28,31] mentioned the training area of these professionals; however, only two[17,27] provided the length of experience in the area. In fact, professional knowledge, experience related to the application of the technique, and clinical practice are indispensable factors for reaching positive results[43].

Finally, it was possible to identify a significant reduction in the pain intensity scores of adults with chronic back pain submitted to AA treatment (p=0.038 value). Therefore, it can be said that, when compared to a control group, this modality presents advantages in relieving pain.

The reduction of pain by AA is explained by some assumptions of pain relief by acupuncture, which include the "gate control theory of pain"[44]; descending inhibitory control; and patient expectations towards pain relief (pain relief placebo)[45-47]. In addition, the sensory-discriminative and affective-social aspects of the touch play an important role in the therapeutic effect of acupuncture, since there is an involvement of type Aβ myelinated nociceptive fibers providing spatial discriminative information to quickly identify where the stimulus is located in the body, besides the type C unmyelinated tactile fibers, with slow conduction velocities, which are involved in affective-emotional functions[45].

On the other hand, four studies[19,21,23,28] demonstrated a lack of effect, that is, these investigations did not show statistically significant differences between the groups regarding the benefit or harm caused by the intervention. In fact, two studies[19,21] worked with a very small sample: the first[19] refers to a pilot study, whereas in the second, a sample calculation to estimate the minimum necessary sample size was not carried out[21]. The third study[23] applied an active treatment in both groups (medicated patch), which may have led to considerable progress to the control group in relation to the VAS after 2-week treatment (p<0.01). This fact is believed to be associated with the lack of effect observed during the performance of the metanalysis. Finally, the last investigation[28] did not find effect superiority of the systemic acupuncture associated with auriculotherapy in relation to the isolated systemic acupuncture, which corresponds to the metanalysis result.

Overall, a substantial variation in auricular acupuncture was observed. These variations, especially in relation to the application device, including differences in the control group, made inviable the development of the subgroup analysis or meta-regression, respectively, due to the small number of studies in each of these specifications. In addition, differences related to the number of sessions, treatment time, time the device was kept on, type of stimulation, application points, location of the points, and experience of the professional who carried out the intervention may have an impact on the clinical effects, which reinforce the need for therapy standardization for this condition.

Another limitation of the current study is that the Chinese database was not consulted, and the articles in Mandarin found in the accessed electronic database were not included in the sample of the current review, since they were not located through bibliographic commutation or through contact with the authors. Further studies must take these databases into consideration, taking into account that China is the cradle of TCM and acupuncture.

CONCLUSION

Auricular acupuncture is an integrative, complementary, and promising health practice for the treatment of back pain, since it considerably reduced pain intensity scores in relation to a control group. However, the high heterogeneity present in the RCT limited the findings.

Nonetheless, a possible protocol may be established for this clinical condition: the application of the technique in 5 weekly sessions, with seeds or semi-permanent needles in the *Shenmen* points (central nervous system), kidney, sympathetic (sympathetic nervous system or neurovegetative), subcortex, liver, bladder, and points in the pain site (cervical, thoracic, and/or lumbar), unilaterally, changing the ear at each session, and mean time of 4 days with the devices kept on, with a maximum of 7 days. In addition, the use of an electric detector of acupoints is recommended to guide directions to the site, based on patient complains, and use of an auricular map. The most common outcomes to assess this clinical condition were pain intensity, medication consumption, physical disability, quality of pain, and quality of life.

This protocol needs validation by further studies, including the exact site of the point called pain relief, in order to verify whether it matches the subcortex points.

RESUMO

Objetivo: Investigar os ensaios clínicos randomizados sobre a ação da acupuntura auricular para a dor crônica nas costas em adultos, identificar os desfechos mais utilizados para avaliar essa condição, o protocolo utilizado para aplicar a intervenção e identificar nos estudos qual o efeito da terapia sobre a intensidade da dor. **Método:** Revisão sistemática e metanálise, conduzidas entre junho de 2017 e maio de 2018, nas bases de dados PubMed, CINAHL, PEDro, Embase, Scopus e na Biblioteca Virtual em Saúde. Listas de referências de revisões sistemáticas também foram exploradas. **Resultados:** Foram localizados 427 estudos, 15 incluídos na análise qualitativa, e sete na análise quantitativa. A acupuntura auricular obteve resultados positivos em 80% dos estudos. Os desfechos mais utilizados foram a intensidade e a qualidade da dor, consumo de medicação, incapacidade física e qualidade de vida. Não há padronização no protocolo de acupuntura auricular para dor crônica nas costas. Os resultados da metanálise apontaram que a acupuntura auricular foi eficaz em reduzir os escores de intensidade da dor (p=0,038). **Conclusão:** A acupuntura auricular é uma prática promissora para o tratamento da dor crônica nas costas em adultos.

DESCRITORES

Dor Crônica; Dor nas Costas; Acupuntura Auricular; Terapias Complementares; Revisão.

RESUMEN

Objetivo: Investigar los ensayos clínicos randomizados sobre la acción de la acupuntura auricular para dolor crónico en la espalda en adultos, identificar los resultados más utilizados para evaluar dicha condición, el protocolo utilizado para aplicar la intervención e identificar en los estudios cuál es el efecto de la terapia sobre la intensidad del dolor. **Método:** Revisión sistemática y metaanálisis, conducidas entre junio de 2017 y mayo de 2018, en las bases de datos PubMed, CINAHL, PEDro, Embase, Scopus y en la Biblioteca Virtual en Salud. Listas de referencias de revisiones sistemáticas también fueron exploradas. **Resultados:** Se localizaron 427 estudios, 15 incluidos en el análisis cualitativo, y siete en el análisis cuantitativo. La acupuntura auricular obtuvo resultados positivos en el 80% de los estudios. Los resultados más utilizados fueron la intensidad y la calidad del dolor, consumo de fármacos, incapacidad física y calidad de vida. No existe estandarización en el protocolo de acupuntura auricular para dolor crónico en la espalda. Los resultados del metaanálisis señalaron que la acupuntura auricular fue eficaz en reducir los scores de intensidad de dolor (p=0,038). **Conclusión**: La acupuntura auricular es una práctica prometedora para el tratamiento del dolor crónico en la espalda en adultos.

DESCRIPTORES

Dolor Crónico; Dolor de Espalda; Acupuntura Auricular; Terapias Complementarias; Revisión.

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