

How Can the Efficacy of Acupuncture be Assessed in Improving Chronic Pain?

Dr Niestrata-Ortiz M

July 2014

Volume 6

Issue 1

Doctors Academy Publications

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ISSN 2052-1715



WJMER

World Journal of Medical Education and Research

An Official Publication of the Education and Research Division of Doctors Academy



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The World Journal of Medical Education and Research (WJMERE) (ISSN 2052-1715) is an online publication of the Doctors Academy Group of Educational Establishments. Published on a quarterly basis, the aim of the journal is to promote academia and research amongst members of the multi-disciplinary healthcare team including doctors, dentists, scientists, and students of these specialties from around the world. The principal objective of this journal is to encourage the aforementioned, from developing countries in particular, to publish their work. The journal intends to promote the healthy transfer of knowledge, opinions and expertise between those who have the benefit of cutting edge technology and those who need to innovate within their resource constraints. It is our hope that this will help to develop medical knowledge and to provide optimal clinical care in different settings. We envisage an incessant stream of information flowing along the channels that WJMERE will create and that a surfeit of ideas will be gleaned from this process. We look forward to sharing these experiences with our readers in our editions. We are honoured to welcome you to WJMERE.

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Volume 6, Issue 1, 2014, World Journal of Medical Education and Research (WJMERE). An Official Publication of the Education and Research Division of Doctors Academy Group of Educational Establishments.

Electronic version

Doctors Academy, PO Box 4283,

published at

: Cardiff, CF14 8GN, United Kingdom

Print version printed

: Abbey Bookbinding and Print Co.,

and published at

: Unit 3, Gabalfa Workshops, Clos

Menter, Cardiff CF14 3AY

ISBN

: 978-93-80573-35-9

Designing and Setting

: Doctors Academy, DA House, Judges Paradise, Kaimanam,

Trivandrum, 695018, Kerala, India

Cover page design and graphics

: Sreekanth S.S

Type Setting

: Lakshmi Sreekanth

Contact

: wjmer@doctorsacademy.org.uk

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How Can the Efficacy of Acupuncture be Assessed in Improving Chronic Pain?

Dr Magdalena Nistrata-Ortiz BSc (Honours), MBChB (Honours)

Foundation Year 1 Doctor

Chelsea and Westminster Hospital

Address for correspondence:

Dr Magdalena Nistrata-Ortiz: maqdalena.nistrata@doctors.org.uk

Keywords:

Acupuncture efficacy, Acupuncture effectiveness, Chronic pain

Abstract

Acupuncture is a complex multi-methodological treatment approach, used for alleviation of a variety of complaints, including chronic pain. Due to the subjective nature of pain as well as the unique features of acupuncture, the double-blind placebo-controlled trials are impractical and often fail to reliably measure the range of responses to acupuncture in clinical practice. In order to evaluate the acupuncture treatment effects more accurately, it is important to assess the level of perceived dysfunction or pain, taking into account the individual variation as well as the systemic effects. Therefore, preferably, the assessment methods employed in acupuncture research should have proven utility in controlled trials and the statistical analysis tools ought to consider non-metric properties of the variable and the contribution of the individual's variation in the results. Furthermore, trial designs need to account for acupuncture's specifics and, hence, the pragmatic trials, enriched enrolment with randomised withdrawal, naturalistic protocols and/or observational studies including quality of life adjusted years analysis are more suited for the evaluation of acupuncture's effect than standard randomised controlled trials.

Introduction

Acupuncture means treatment with needles. It is a branch of medicine in which fine needles are inserted through the skin to a depth of a few millimeters or more, left in place, sometimes manipulated, and then withdrawn. It is used to treat a variety of conditions including pain. This treatment modality originated in

China more than 2000 years ago, where it has been an integral part of medicine ever since. It may have developed independently in other parts of the world.

The modern history of Western acupuncture started in the 19th century. This approach, also called 'medical acupuncture' differs from the traditional Chinese philosophy in that it relies on scientific explanations of its mechanisms of action. The British Medical Acupuncture Society encourages the attempt to reinterpret acupuncture according to the conventional Western understanding of the anatomy and physiology. Therefore, in recent years there has been extensive research into acupuncture, which has confirmed its physiological effect revealing some of the mechanisms of action of needle stimulation. This has led to the development of various applications of acupuncture, such as myofascial trigger point stimulation for chronic pain.

The goal of current research is to provide scientific evidence for the effectiveness of acupuncture so that it can be formally integrated into the policy of any National Health Service provider. It is especially valuable due to acupuncture's potential to improve chronic pain, for the management of which other currently available therapies are often insufficient. However, due to the nature of acupuncture, the measurement of its efficacy by the conventional scientific method of double-blinded randomized control trials has proven limited. The aim of the present study is to determine the means by which acupuncture's effectiveness in improving chronic pain can be assessed.

Myofascial trigger point stimulation for improving chronic pain

Myofascial trigger point stimulation is a system for the diagnosis and treatment of myofascial pain syndromes, which adapted the needle technique from Chinese acupuncture, updating and enhancing it with anatomy and neurophysiology. Myofascial pain syndromes are chronic pain conditions occurring in the musculoskeletal system without any obvious injury or inflammation. They include, among others, headaches, low back pain, tennis elbow and trigeminal neuralgia. All these conditions are thought to be caused by distorted function and hypersensitivity in the peripheral nervous system – ‘neuropathic pain’. Since the neuropathies almost invariably occur at the nerve root, they are often referred to as radiculopathies. They are characterized by the presence of tender points in affected myotomes, which lead to muscle shortening¹. Stimulation of trigger points aims at decreasing the oversensitivity of the nerves involved, hence, releasing muscle shortening and reducing the pain.

The challenges of clinical research into the effectiveness of acupuncture in improving chronic pain

According to the current General Medical Council guidelines, all the medical practice in the United Kingdom has to be evidence based. Aiming for objectiveness, the efficacy of most treatment modalities is evaluated by means of double-blind randomized controlled trials, where a treatment in question is assessed against a placebo. One of the biggest problems in acupuncture research is lack of an ideal placebo for acupuncture needles. This is due to the fact that any potential placebo (called sham acupuncture), e.g. pressure with blunt needles, will be a form of physical stimulation, which will cause some degree of physiological response. Hence, no reliable comparison can be made between the effect of sham and real acupuncture. There is also considerable inter-practitioner variability in terms of techniques, accuracy of needling the acupuncture points, choice of points and depth of needling, which poses another difficulty while assessing acupuncture’s effectiveness.

Furthermore, due to the nature of acupuncture, it is difficult to ensure double blinding. Although patient blinding is possible during the treatment, the subsequent verification of its success has its limitations. This is because the best way to test blinding is to ask patients whether they think they had real or sham acupuncture, which may interfere with the effectiveness of the treatment being tested by causing the patient to doubt the therapy. In addition, it is hard to ensure practitioner blinding in an acupuncture trial. As a result, a ‘placebo-controlled’, double-blinded trial of acupuncture is technically impossible.

Another factor limiting clinical research in acupuncture in Britain is the lack of research resources. Unlike in pharmacological research, in acupuncture trials, no preliminary studies are undertaken to compare different types of acupuncture and find the most adequate type for any given patient. This can lead to provision of suboptimal acupuncture treatment, compromising clinical trials.

Finally, the principal challenge with regard to measuring the effectiveness of acupuncture in improving pain is its subjectivity. Pain is an individual multifactorial experience with a sensory as well as an affective component. Therefore, it cannot be assessed in isolation from the patient by means of any objective scientific tools¹.

Discussion

Accurate outcome measures are essential in order to provide the most suitable treatment for each patient. Therefore, they must be valid, reliable, specific and sensitive for the particular condition. Outcome measures are the crux for validation of any research and, hence, for a justifiable inclusion of a given therapy in the National Health Service policy. Recommendations for treatment are commonly based on results evaluating variation in systematic effects (group response) from randomized controlled trials without accounting for the individual patient’s variation. In the evaluation of acupuncture-related treatment effects for conditions such as pain, the trial design and statistical analysis used are a challenge since the assessed variables commonly have subjective properties and are based on the person’s self-report. Therefore, the preferable assessment methods used should have proven useful in controlled trials and the statistical analysis tools ought to consider non-metric properties of the variables such as pain as well as the contribution of the individual’s variation in the result².

Due to the recognition of difficulties finding valid outcome measures for acupuncture and the need for determination of its evidence-based role in the treatment of certain illnesses, the German Federal Committee of Physicians and Health Insurers commenced special Model Projects on Acupuncture (*‘Modellvorhaben Akupunktur’*) in 2000 evaluating acupuncture’s effectiveness. The project includes the largest clinical studies on acupuncture ever performed and has proven to be a tremendous achievement, laying the basis for reliable clinical research methods into acupuncture.

One of the most frequent complaints of patients referred for acupuncture is chronic pain. In order to successfully determine the effectiveness of acupuncture for its

improvement, it is vital to have reliable tools for the measurement of pain. It is now recognized that pain cannot be measured directly^{2,3}. As a subjective, multidimensional experience, it needs to be judged from the patient's response. Its measurement ought to include pain intensity, frequency, relief-seeking behaviour and changes in function³.

One of the well-recognized tools for assessing pain severity is McGill Pain Questionnaire which combines a patient's description of the pain with the perceived severity. Rating scales are a vastly used alternative to questionnaires. They include verbal, numerical and visual analogue scales. The response to treatment can also be measured by means of *Global assessment*, whereby the patient is asked to choose the most accurate description of the effect of treatment from the pre-prepared options. All the above methods, the questionnaires, rating scales and global assessment, can be potentially used before and after the treatment to assess its effect. They can also be applied at different time intervals to evaluate the long-term effects of acupuncture in chronic pain. Verbal scales may be less reliable due to possible variation in the interpretation of the adjectives used by individual patients. The numerical and visual analogue scales are both vastly used in clinical settings. However, the visual analogue scale (VAS) is a proper ratio scale which allows sensitive t-test and ANOVA methods to be used in the statistical data analysis³.

This enables the identification of significant differences with relatively small sample sizes or small differences between groups, which is vital for measuring the effect of acupuncture treatment and, therefore, makes the visual analogue scale superior for this purpose.

The visual analogue scale, together with pain severity and frequency were used as primary outcome measures in the Acupuncture Randomised Trials conducted as part of the German special Model Projects on Acupuncture (*'Modellvorhaben Akupunktur'*)⁴. The primary outcome measure for migraine and tension-headache was the difference in number of days with headache of moderate to severe intensity between 4 weeks before randomization (baseline phase) and weeks 9-12 after randomization. Responders were defined as those with a minimum of 50% reduction in frequency of moderate to severe headaches. The primary outcome for low back pain was the change of intensity by at least 50% from the baseline to the end of week 8 after randomization, as measured by the visual analogue scale. The trials confirmed effectiveness of acupuncture for migraines, tension-type headaches and low back pain⁵.

Another component of pain assessment is recording

relief-seeking behaviours. Measurable pain behaviours include e.g. use of analgesics and hot-water bottles and the amount of time spent resting during the day. They can be evaluated on the basis of patient records or clinician's observation. However, these methods are often not entirely reliable due to the variation in the severity of pain throughout the day, poor patient recollection, as well as the subjective and multifactorial nature of pain behaviours.

The final crucial aspect of pain assessment and, hence, treatment effect is functional change. It can be evaluated by examination or by patient questionnaires. Examination can assess the effect of acute acupuncture interventions, such as needling trigger points. However, for outcome measures in chronic pain, questionnaires are more valuable. They are designed to evaluate patients daily functioning before and after treatment. This includes the range of movements, ability to carry out daily activities, mood and sleep. In order to increase the sensitivity of these measurements, disease-specific functional questionnaires have been developed for different conditions that may be treated by acupuncture, e.g. neck pain, back pain, headache³. The disease specific questionnaires were employed in a number of Acupuncture Randomised Trials conducted as part of the *'Modellvorhaben Akupunktur'* project. The improvement from baseline in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used as the primary outcome measure of the efficacy of acupuncture in improving knee osteoarthritis pain. The responders were defined by a decrease of at least 50% in their WOMAC score and the trial proved acupuncture effective for improving chronic knee osteoarthritis pain⁵. The German Acupuncture Trials also used the back-specific Hanover Functional Ability Questionnaire (HFAQ) as well as the Neck Pain and Disability Scale (NPAD) as primary outcome measures for acupuncture's effect on chronic back and neck pain, respectively. It concluded that acupuncture was effective in improving both conditions⁵.

Chronic pain is often accompanied by depression and other psychological factors which strongly influence the experience and consequences of pain. Patient beliefs and attitudes towards pain can substantially affect the way they perceive it. Those beliefs can be investigated by the Illness Perception Questionnaire. Nevertheless, as pain and its emotional components are strongly interlinked, it is difficult to assess whether acupuncture has any beneficial psychological effect in addition to pain relief and whether these effects are specific to acupuncture or are the consequence of the hope associated with treatment. Evaluating these aspects may be a challenging, yet, valuable direction for future study. What can be measured, however, is patients' overall quality of

life. Two examples of quality of life questionnaires that have been validated are Short-Form-36 (SF-36) and Nottingham Health Profile³. QoL was assessed with the SF-36 questionnaire, using the subscales and the component scales, in the Acupuncture in Routine Care programme, as part of the 'Modellvorhaben Akupunktur' project.

The questionnaire also served as the basic benefit estimator of the cost-effectiveness analyses. The QoL measures obtained were then converted to quality adjusted life years, QALYs. The study showed acupuncture's effectiveness in increasing patients' quality of life, as well as proved the treatment to be cost-effective⁶.

Finally, when measuring the outcome of any intervention for pain, one needs to be aware of the 'hello-goodbye' phenomenon, which describes patients' tendency to exaggerate symptoms when requesting help and to minimize them afterwards to please the therapist. While it is difficult to avoid this behaviour in clinical practice, it can be minimized in research. It is done by ensuring the patients that they will receive the treatment regardless of the severity of pain experienced and that the evaluation form for the treatment outcome will not be shown to the therapist.

Apart from the subjective nature of the conditions acupuncture is used for, the research into its effectiveness faces other challenges too. Due to acupuncture's nature, the double-blinded placebo-controlled randomised trials are impractical and often fail to reliably assess the effect of therapy. Acupuncture includes a number of different modes of stimulation producing varied results that have to be considered in decision-making about the use of acupuncture⁷.

In response to different modes of acupuncture stimulation, different endogenous pain inhibitory pathways are activated. This explains why different modes of acupuncture may cause distinct effects. As a result, sham acupuncture, a form of physical stimulation which has been proposed as a 'placebo' for acupuncture trials, will still produce a degree of physiological response. Therefore, a 'placebo' control, which, by definition, needs to be inert, is not achievable in the case of acupuncture. This has been confirmed by the Acupuncture Randomised Trials carried out as part of the Model Projects on Acupuncture in Germany. It was shown that sham acupuncture, in the form of minimal off-point needling in a therapeutic context, was still effective, being no different to prophylactic medication for migraine and superior to guideline-based standard care in chronic low back pain⁵.

Due to the limitations of randomized controlled trials in acupuncture research, alternative study designs have been proposed. In a comparative trial, the control group receives the best of a standard treatment, while the acupuncture group is given acupuncture. Hence, instead of equalising the 'placebo' effect between the two groups, this trial is designed to optimise the treatment effects in both arms of the trial, thereby enabling a reliable comparison between the two entities. A comparative trial of acupuncture and metoprolol (100-200 mg) was conducted as part of the German 'Modellvorhaben Akupunktur' project, which concluded superiority of acupuncture over metoprolol in the reduction of frequency of migraines⁸. McQuay and coauthors⁹ suggested another alternative trial design to capture the reality of the range of responses to acupuncture in clinical practice - the enriched enrolment with randomized withdrawal (EERW). The information gathered in the pre-randomisation phase, including the proportions of responders and non-responders, the optimal dose, and the number of withdrawals due to adverse effects or lack of efficacy, brings additional data for defining new treatment protocols. Allowing for a naturalistic approach whereby the patient undergoes trial treatments before selecting the modality preferred, this design optimizes the treatment effect. It has been proposed that the EERW trials may be used to avoid a false conclusion of lack of efficacy of acupuncture, especially in chronic pain conditions where treatments neither cure nor fundamentally alter the status of the underlying disease².

The search for valid outcome measures of acupuncture has led to the formulation of Standards for Reporting Interventions in Clinical Trials for Acupuncture (STRICTA). These guidelines were designed to facilitate transparency in published reports, enabling a better understanding and interpretation of results, aiding their critical appraisal and providing the detail necessary for replication, all of which are essential for validation of research. The guidelines were originally published in 2001 and have been recently revisited. To enhance awareness, endorsement and adherence, the revised STRICTA statement has been developed as an extension to the Consolidated Standards of Reporting Trials (CONSORT)¹⁰. The STRICTA guidelines were adhered to in the German Model Projects on Acupuncture, 'Modellvorhaben Akupunktur', which have gained vast recognition and now constitute the role models of research into acupuncture's effectiveness.

Conclusion

Acupuncture is a complex, multi-methodological treatment approach, with documented effectiveness in alleviation of subjective complaints, such as pain. As in any form of therapy, evidence-based medicine is

essential in acupuncture and, therefore, valid outcome measures are the crux for research validation. However, the 'evidence' should include patient's perspective, taking into account individual variation and measures such as health-related quality of life as well as systematic effects (group effects).

Furthermore, the practice of acupuncture has many unique features and research needs to be deferent of

this. Therefore, instead of the randomised controlled trials, which are impractical in the context of acupuncture, researchers ought to use alternative study designs such as, e.g. pragmatic trials, enriched enrolment with randomized withdrawal, naturalistic protocols and/or observational studies. Finally, it is essential for the studies to be correctly reported with the detail necessary for critical appraisal and replicability.

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