

Acupuncture Does Work and is Not Just Based on a Mere Placebo Effect!

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Acupuncture (a treatment method through stimulation with needles of specific treatment points aimed at energy pathways, the meridians, to bring the body back into balance) has been part of traditional Chinese medicine (TCM) for over 2000 years now. Modern medical acupuncturists trained in the West understand and use acupuncture in addition to or even as an alternative to modern therapeutic concepts. In addition to the mother country of China, acupuncture is used by millions of patients in the US and Germany, and for certain indications simply reimbursed by health insurers. So far, no real physiological mechanism explains its action, although an analgesic effect has been proven. In the current age of evidence-based medicine, this leads to controversial discussions that are usually very emotional and where physician-acupuncturists are often portrayed as quacks. Most studies on acupuncture come from China and are mostly published in Chinese and all too often of poor quality. However, there are also good randomized controlled trials (RCTs) on acupuncture that show significant effects at least in pain and postoperative nausea and vomiting (PONV).

In California, USA, the provision of acupuncture for the treatment of pain and nausea has now been enacted by the federal Patient Protection and Affordable Care Act (PPACA) [1], also known as "Obamacare".

The largest German acupuncture study is from 2006 (GERAC) [2]. Patients with head, shoulder, knee, and low back pain were examined. For the headache, a clear reduction was seen in patients with headaches of a few days, and no difference was found between acupuncture and drug migraine

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prophylaxis. There was no significant difference between verum (true acupuncture according to TCM) and sham acupuncture (imitation treatment, in which the patient actually believes to have been treated according to TCM, but this has not taken place). There is, however, a significant difference between the subgroups.

The same was found for gonarthrosis and low back pain [3,4]. Again, a significant difference between acupuncture and standard therapy, but again no significant difference between verum and sham acupuncture.

After extensive discussion and analysis of the GERAC Study by the German government in the form of the G-BA, the German CVZ, it was decided in 2006 to have acupuncture reimbursed by the health insurers for certain indications (headache, gonarthrosis, low back pain).

Drawing conclusions from meta-analyses only works if sham acupuncture is the same in all studies, which is often not the case. Due to the non-standardized sham design in the various acupuncture effect studies, the difference between sham and actual acupuncture cannot be compared. Individual patient data meta-analysis is much better than the summary data meta-analysis, because it improves data quality, allows different forms of outcome to be combined, and allows to use of more accurate statistical calculation methods. In a recently in Archives of Internal Medicine published individual patient data meta-analysis by Vickers AJ, et al. [5], all 82 existing RCTs related to acupuncture treatment of 1 of the 4 following indications were reviewed-non-specific back

or neck pain, shoulder pain, chronic headache or osteoarthritis-where the complaints had to exist for at least 4 weeks. Of these, 31 RCTs were selected according to the Vickers protocol Vickers AJ, et al. [6] in which the 'adequacy of blinding' was such that the probability of bias was minimal. The blinding was checked by a questionnaire (where no differences were found between the groups) or by using the Streitberger sham device [7], where the blinding was validated.

Vickers shows that acupuncture is superior to the sham and non-acupuncture control group for all 4 conditions ($P < 0.001$)-non-specific back or neck pain, shoulder pain, chronic headache, and osteoarthritis.

The authors conclude that by using individual patient data meta-analysis (in 29 of the 31 selected RCTs, nearly 18,000 patients were analyzed) their analysis clearly shows that acupuncture is a serious therapeutic option in the treatment of chronic pain. In addition, this meta-analysis has become a fine refinement of the publication of the World Health Organization (WHO) in 1999 [8], based on which a guideline was published in 2004 regarding the indication for acupuncture treatment for certain types of pain (Appendix).

In times of budget cuts in care and the current discussion about VAT and reimbursement of acupuncture, a study [9] from Great Britain is certainly interesting which concludes that the improvement of pain, function, and stiffness in patients with gonarthrosis by acupuncture leads to a savings of approximately € 100,000 per year in the studied group.

However, chronic pain is not the only indication for acupuncture. There is also an indication for acupuncture in PONV, and dozens of studies have also been conducted there which show a significant effect.

A 2009 metanalysis, it is concluded that stimulation of P6 (a known point on the forearm side) induces PONV prophylaxis [10]. A significant difference was seen between verum and sham or placebo acupuncture.

In 2002, Yoo SS, et al. [11], after puncture of P (ericardium) 6, were able to detect the activity of several specific regions in the brain that could substantiate the effect of the antiemetic effect of this acupuncture point. As a control, sham acupuncture was also performed in the same patients, where this was not seen.

Still, opponents of acupuncture argue that acupuncture doesn't work, although none of them have an explanation as to how it does work. They are always of the opinion that acupuncture does nothing. On the other hand, there are dozens of functional magnetic resonance imaging (fMRI) studies that do show a demonstrable and reproducible effect when treated with acupuncture.

The 2009 randomized study by Chae Y, et al. [12], used verum acupuncture versus placebo acupuncture with non-penetrating placebo needles (sham) in healthy volunteers. Chae showed that needle stimulation by verum acupuncture produces a significant action in the motor function-related cerebral areas (caudate nucleus, basal ganglia, cerebellum, medial frontal gyrus, cingulate gyrus, and fusiform gyrus).

However, sham acupuncture also works and is sometimes better than placebo as a few studies show [13,14]. Like verum acupuncture, it stimulates areas in the brain, where the effects are different between sham and verum acupuncture. Verum acupuncture, unlike sham, also works in the long term and shows greater brain activity in the cognitive/evaluative (posterior dorsomedial prefrontal cortex) and the emotional/interoceptive (anterior dorsomedial prefrontal cortex) cortical areas. This makes acupuncture a significant component in the top-down modulation of the central pain sensation and a "somatosensory guided mind-body therapy".

Colleague Veelo mentions in the counter piece the review by Ernst E, et al. [15], which apparently would demonstrate how badly acupuncture works and that it is dangerous. However, the conclusion does not seem correct. After all, the article lists several reviews in a table in which studies are listed which are classified as good by the authors and where the authors' primary studies are good. These studies show that acupuncture does have a positive effect. Ernst himself published a review a few years ago [16] concluding that acupuncture for low back pain is better than some Western interventions. In fact, the authors themselves apparently disagree with their own conclusions. In the introduction they state that there is only a strong scientific basis for acupuncture treatment for neck pain, only to conclude later in the discussion that: "The majority of the (high-quality) reviews were positive for low back pain and osteoarthritis". Furthermore, the authors of this review

conclude that "there is no plausible reason why acupuncture should reduce pain in some conditions while failing to work in many others".

Authors endorse this last comment with the caveat that for many of our current Western treatment techniques, which are not discussed, exactly the same applies.

Over the years 95 serious complications are mentioned in the reviews, especially infections and pneumothorax. The infections are most common in countries in Asia, where hygiene measures are different than here in the West, where sterile, individually packaged, single-use needles are used. To put it into perspective, these 95 complications in recent years, of which only 5 were fatal, compared to approximately 103,000 hospitalizations and 16,500 deaths per year from NSAIDs in the US alone.

Opponents of acupuncture often argue that a large number of reviews show no effect and that therefore pain relievers should not use acupuncture. It is even argued by some that these MD-acupuncturists should be expelled from the Dutch Association of Anesthesiology. Anyone who enters the words "TENS" and "Review" at PubMed will have difficulty seeing 3 reviews (TENS is an abbreviation for the term Transcutaneous Electro Neuro Stimulation and means that an electrical current is passed through the skin (transcutaneously), which is assumed to affect nerves (neuro) (stimulation) to reduce pain). One author concludes that "The results of the meta-analysis present no evidence to support the use or nonuse of TENS alone in the treatment of chronic low back pain" [17].

Another author believes that TENS is "...shown to be effective in pain control over placebo..." but sees a heterogeneity in the studies and thus concludes that "More well-designed studies with a standardized protocol and an adequate number of participants are needed..." [18]. And finally, another review with the following conclusion: "The results of this review are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. Large multi-center randomized controlled trials of TENS in chronic pain are urgently needed" [19].

Surprisingly a widely known non-Western therapy such as acupuncture is still under criticism because its effect is not understood, but another therapy is totally accepted, although in the literature no better or even worse results can be found.

When drafting the book 'Practical guidelines for anesthesiological pain management' based on clinical diagnosis [22], it was also stated with an equivalent 'level of evidence' and 'recommendation grade' for the Western treatment method that further research had to be done, but with the conclusion that this was not an option for acupuncture.

Conclusion

The authors are aware that a large number of studies on acupuncture are currently small-scale and not of good enough quality to be taken seriously. However, recent publications show that despite this large number of bad studies, there are also good quality studies

that provide scientifically demonstrable evidence that acupuncture does have a significant meaning for certain types of pain [5]. It is known from practice that acupuncture does not help everyone, but in certain indications, it does lead to a reduction in medication, pain sensation, and improvement of the quality of life of our patient population.

Liem KSAE, et al. [20,21], already showed in 2010 that in patients with chronic pain who had been treated according to the Western available treatment techniques, 60% still showed a pain reduction after treatment with acupuncture. In 37% of the cases, there was even a pain reduction of 50% or more. 79% of the treated patients were satisfied or very satisfied with the treatment. In times of placebo-controlled evidence-based medicine, this is not the highest scientific research achievable, but it is the reality.

Even now, pain physicians often use therapies for chronic pain relief, such as TENS, where really hard scientific evidence is lacking. TENS is prescribed to our patients because it helps some patients without causing major or serious complications. Also, with TENS, there is no clear scientifically demonstrable method, but it has been shown through fMRI that, just like with acupuncture, this affects certain parts of the brain.

Opponents of acupuncture always show reviews where it becomes clear that verum acupuncture is no better than sham acupuncture. However, it is always forgotten to mention that verum and sham acupuncture always works better than doing nothing or sometimes even work better than

the usual drug therapy. In this context, it is often concluded that the results of acupuncture could only be a placebo effect that is seen. Now, however, a large number of fMRIs and blood tests have been done that show that acupuncture leads to changes in certain brain regions and also increases concentrations of endogenous opioids. These facts reproducible with an acupuncture treatment cannot be explained by assuming that it is only a placebo effect. In addition, individual patient data meta-analysis clearly demonstrated that acupuncture is superior to the sham and non-acupuncture control group for non-specific back or neck pain, shoulder pain, chronic headache, and osteoarthritis [5].

Suppose, if ignored, nevertheless put all these scientifically reproducible significant facts aside and still assume that the effect of an acupuncture treatment is based solely on a placebo effect. Again, it is believed that such a beneficial effect should be used in treating chronic pain without a high risk of damage. However, it is not just a placebo effect, as tried to demonstrate here. The authors suggest the medical discussion about acupuncture as an alternative or complementary therapy be shifted from 'whether to use it, to 'when'. It is believed that patients should be allowed to choose for themselves whether they want this therapy or not and it is no longer up to the physician whether he should allow it. However, the primarily physicians who believe that more qualitative studies (RCTs) with placebo acupuncture needles [7] should take place in order to find more scientific evidence for (several) certain indications.

Acupuncture has been around for many years longer than Western civilization. It is a treatment that has endured this time for a reason. The evidence desired by some is now trickling in. It is believed that it is evidence of

short-sightedness if the effect of the acupuncture treatment is regarded purely as a placebo. It is believed that acupuncture is an addition to our Western pain relief treatment techniques.

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Appendix

List of treatments that are eligible for acupuncture according to WHO, where the well-known international evidence ratings have been compared.

Head and neck

Head

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of head conditions

- Tension Headache
- Migraine Headache
- Cluster Headache
- Sinus Headache
- Hypertensive Headache
- Cervicogenic Headache
- Head Trauma
- Temporomandibular Dysfunction
- Facial Pain

Quality of Evidence: Level I

Recommendation Grade: Grade A

Neck

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of neck conditions

- Injuries to the Cervical Spine
- Cervical Strain and Whiplash
- Cervical Radiculopathy
- Cervical Stenosis and Spondylosis

- Herniated Cervical Disc
- Torticollis
- Unspecified Neck Pain
- Cervical Arthritis
- Degenerative Disc Disease
- Muscle Spasm

Quality of Evidence: Level I

Recommendation Grade: Grade A

Upper extremity

Shoulder

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of shoulder conditions

- Injuries to the Shoulder– General
- Acromioclavicular Joint
- Separation/Compression
- Rotator Cuff Tear
- Biceps Tendon Injury
- Adhesive Capsulitis (Frozen Shoulder)
- Shoulder Tendinitis/Bursitis
- Thoracic Outlet Syndrome
- Muscle Spasm

Quality of Evidence: Level II

Recommendation Grade: Grade A

Elbow

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of elbow conditions

- Lateral Epicondylitis
- Medial Epicondylitis
- Olecranon Bursitis
- Ulnar Neuritis

In general, the application of acupuncture is recommended in the first 4 weeks of treatment

as a part of an overall, initial, conservative, treatment plan. Specifically, 3 to 6 acupuncture treatments over 7 to 21 days are listed as one Official Disability Guideline "Return-To-Work Pathway" for lateral epicondylitis (Work Loss Data Institute, 2003).

Quality of Evidence: Level I

Recommendation Grade: Grade A

Forearm, hand, wrist

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of forearm, hand, and wrist conditions

- Forearm Sprain/Strain
- Carpal Tunnel Syndrome
- DeQuervains Syndrome
- Trigger Finger
- Wrist/Finger Sprain/Strain
- Tendinitis of Forearm/Wrist
- Arthritis

Quality of Evidence: Level II

Recommendation Grade: Grade B

Torso and low back

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of thorax and low back conditions

- Thoracolumbar Area
- Injuries to the Costals
- Low Back Sprain/Strain
- Lumbar Facet Syndrome
- Lumbar Disc Herniation
- Sciatic Neuralgia
- Sacroiliac Sprain/Strain
- Spondylolisthesis
- Spondylosis
- Muscle Spasms
- Lumbar Radiculopathy
- Degenerative Disc Disease

Quality of Evidence: Level I

Recommendation Grade: Grade A

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Lower extremity

Hip and thigh

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of hip and thigh conditions

- Osteoarthritis
- Muscle Spasm
- Tendinitis/Bursitis
- Piriformis Syndrome
- Capsulitis
- Avascular Necrosis
- Post-Operative Fractures & Hip Replacements

Quality of Evidence: Level II

Recommendation Grade: Grade A

Knee

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of knee conditions

- Osteoarthritis
- Tendinitis
- Ligament Injuries
- Meniscus Injuries
- Patellofemoral Pain
- Post-Operative Pain
- Bakers Cyst

Quality of Evidence: Level I

Recommendation Grade: Grade A

Ankle and foot

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of ankle and foot conditions

- Ankle Sprain
- Achilles Tendinitis
- Plantar Fascitis
- Tarsal Tunnel Syndrome

- Diabetic Neuropathy
- Reflex Sympathetic Dystrophy
- Osteoarthritis
- Post-Operative Pain

Quality of Evidence: Level IV

Recommendation Grade: Grade B

Chronic and postoperative pain

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of chronic and postoperative pain conditions.

- Acupuncture, in combination with pharmacological interventions, may lower the need for medication and reduce the risk for side effects from these drugs (NIH, 2001) Acupuncture may reduce nausea and vomiting if used in early postoperative period ("Acupuncture"1997).

Quality of Evidence: Level II

Recommendation Grade: Grade A

Systemic and non-regional conditions

Fibromyalgia

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of systemic and non-regional conditions

- Fibromyalgia

Quality of Evidence: Level II

Recommendation Grade: Grade A

Definitions

Quality of evidence

- **Level 1:** Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
- **Level 2:** Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).
- **Level 3:** Evidence was obtained from well designed controlled trials without randomization.
- **Level 4:** Evidence consisted of the opinions of respected authorities, based on clinical experience, descriptive studies in case reports, or reports of expert committees.

Recommendation grades

- **Grade A:** A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.
- **Grade B:** A recommendation that was based on an evaluation of the available evidence and general consensus of the expert panel that acupuncture and electroacupuncture treatment should be considered acceptable, effective, and indicated.
- **Grade C:** A recommendation that is not well established by evidence, or for which there is conflicting evidence regarding usefulness or efficacy, but which the expert panel has determined that acupuncture and electroacupuncture treatment may be acceptable, effective, and indicated.
- **Grade D:** A recommendation, based on evidence or general agreement, that acupuncture and electroacupuncture treatment may be considered not useful or effective.
- **Grade E:** A strong recommendation, based on evidence or general agreement, that a given procedure or treatment is not useful or effective, or in some cases may be harmful, and should be excluded from consideration.