

The paradox of acupuncture efficacy for chronic knee pain

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Comment

Abstract: In a recent clinical trial, Hinman and colleagues concluded that “neither laser nor needle acupuncture conferred benefit over sham for pain or function in patients older than 50 years with moderate or severe chronic knee pain”, which contradicts with NIH’s recognition and the positive clinical experience of most acupuncturists. This review article highlights - major shortfalls from Hinman et al’s clinical trial as follows. Laser acupuncture, defined as “low intensity laser therapy to acupuncture points”, should not be labeled as acupuncture. A sham acupuncture control was not -set by the trial design. As for the trial design, there was a greater degree of randomness in selecting acupoints and inconsistencies of needling parameters among multiple subjects, acupuncture providers and facilities. Furthermore, the acupuncture needles used in this study were also too short to achieve any targeted efficacy, and the total number of treatments was insufficient, which is less than that commonly applied by most acupuncturists. In addition, the trial lacked observations or comparisons of short-term acupuncture efficacy. By revealing these shortfalls of Hinman et al’s clinical trial, one may understand more about the paradox of acupuncture efficacy for chronic knee pain.

Key words: Paradox; acupuncture efficacy; chronic knee pain; laser acupuncture; needle acupuncture; sham laser therapy; sham acupuncture; placebo.

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Over the past few decades, numerous studies have been conducted to assess the efficacy of acupuncture for pain conditions (1-2), such as neck pain (3-5), knee pain (6-8), back pain (9), and headaches (10). Most studies found acupuncture had positive efficacy for treating those conditions. For example, the study of Berman and colleagues (6) drew the conclusion that acupuncture seemed to provide improvement in function and pain relief as an adjunct therapy for osteoarthritis of the knee when compared with credible sham acupuncture and education control groups (11). This conclusion is consistent with NIH’s recognition (12) as well as common experience of the acupuncturist in the clinic where patients often report pain relief after treatment.

On the other hand, the recent clinical trial by Hinman and colleagues (6) reached a negative conclusion in which neither laser nor needle acupuncture conferred benefit over sham for pain or function in patients older than 50 years with moderate or severe chronic knee pain. However, the trial has several major shortfalls and many of them have been pointed out by previous comments (13-21).

In order to fully understand the paradox of acupuncture efficacy for chronic knee pain, the clinical trial (hereafter often referred as “the trial”) by Hinman and colleagues (hereafter often referred as “the researchers”) has been carefully examined, with its protocol design extensively reviewed. Although the trial -involved a large pool of subjects along with some convincing evidence regarding laser acupuncture, it contains the following major shortfalls.

First of all, the trial improperly lumped both “laser acupuncture” and “needle acupuncture” into “acupuncture” as part of the trial title. This is misleading because laser acupuncture as described by the researchers is “low intensity laser therapy to acupuncture points”, without -

acupuncture needles. It is common knowledge that «acupuncture» refers only to needling or penetrating the skin with acupuncture needles. On the other hand, electro-acupuncture (EA) can also be called “acupuncture” as electrical stimulation is connected to the acupuncture needle directly, while laser acupuncture does not involve any needles.

No matter the dispute on the correct terminology for “laser acupuncture”, it is clear that laser therapy on acupuncture points (acupoints) and needle acupuncture are fundamentally different, either from their mechanisms of action or types of energy delivery during stimulation. From the perspective of delivered energy, laser is optical energy, while needling is mechanical energy. Needle acupuncture has a completely different mechanism of action from laser, as the needles can input therapeutic information by activating various mechanical receptors at the body surface.

In a broader sense, if laser therapy on acupoints would be categorized as a form of laser acupuncture, there should be a prerequisite of efficacy from laser equivalent to needling. However, laser’s efficacy does not equate to that of needling, as shown in a recent meta-data study that showed the efficacy of laser on acupoints was far less than that of needle acupuncture (22). Actually, because laser therapy on acupoints does not involve any needles, no matter how effective it is, it has nothing to do with acupuncture. Therefore, it is misleading that the researchers improperly tagged the word “acupuncture” to summarize their results by both laser and needle acupuncture.

Another major shortfall of the trial is that a new control group called sham needle acupuncture should be added to the trial design to properly show any needle acupuncture efficacy for chronic knee pain. The original aim of the

trial was to evaluate the efficacy of laser acupuncture for chronic knee pain. With randomization of groupings, three control groups were sham laser acupuncture, needle acupuncture, and no treatment at all, but no sham acupuncture group was ever set up as a control in the trial (6). The trial also found no significant difference of effectiveness among laser, needle and sham laser acupuncture, but when compared with the no treatment at all group, needle and laser acupuncture groups resulted in moderate improvement of pain at 12 weeks. This indicated sham laser therapy did have placebo effects of analgesia (23). However, as there was no prior research to compare sham acupuncture with sham laser therapy, sham acupuncture cannot simply be replaced by sham laser acupuncture. Thus, it is improper for the researchers to quickly reach a negative conclusion about acupuncture's benefits without adding sham acupuncture as a control group.

Moreover, the needle acupuncture protocol in the trial design lacks considerations regarding a great degree of randomness when selecting acupoints and implementing stimulation parameters (needling depth, angle, stimulation intensity and frequency, needle-retention duration, treatment intervals, etc). It is well known that needle acupuncture has a great degree of randomness of stimulation parameters than laser or sham laser therapy. Also, this is true even for the same acupuncturist to deal with the same subject, one-on-one, resulting in varying degree of efficacy across different sessions. For this trial that was conducted across multiple facilities where multiple family doctors performed laser or needle acupuncture, there would inevitably be a large degree of randomness of stimulation parameters. Although these family doctors are considered experienced clinicians, and received some acupuncture training, they opted not to follow the CONSORT statement of acupuncture trials (that requires details of needling, such as needle manipulation, depth of needle insertion, and points selected unilateral, bilateral or both) (24). Thus, it is difficult to evaluate whether an effective acupuncture regimen was compared against the sham in the trial.

In the trial, the family doctors were required to select a standardized combination of acupoints composed of both local knee points and other distal points. Other acupoints were selected based on clinical examination. The initial treatment allowed selecting no more than six acupoints (four in the affected limb, the other two depending on the individual). Other subsequent treatments allowed modification or adding acupoints on an as needed basis.

As shown from the trial, a total of 27 acupoints were available for selection. Out of these acupoints, 12 were local acupoints at the knee region, five were distal acupoints, five were segmental acupoints and the other five were non-segmental acupoints. Just looking at the initial treatment, that allowed selecting no more than six acupoints from a total of 12 local points, there were still 924 kinds of possible mathematical combinations (if stimulation order was not important). In addition, as the trial did not indicate specific needling parameters for each acupoint, the inconsistencies in the implementation of acupuncture were abundant throughout the trial.

The dosage of acupuncture implemented in the trial was inadequate due to extreme superficial needling depth, not requiring "deqi" (a renowned acupuncture sensation)

(25), insufficient acupuncture sessions, and longer intervals between consecutive sessions (8). In the trial, subjects receiving acupuncture had an average weight of 86.3 kg and an average height of 1.71 meters. Yet, the needles used on the subjects were only 40mm long, which brings the question of potentially insufficient needling depth. Also, the trial protocol did not require deqi, which is profoundly regarded as the predictor and a prerequisite of a desired acupuncture efficacy. Every experienced acupuncturist knows the importance of proper needling depth when stimulating acupoints around the knee, especially on Dubi (ST37) or Xiyian (EX17). The key is that acupuncture needles should be able to enter the articular cavity and activate corresponding receptors. If the acupuncture needles applied were only 40mm long, it is considerably more difficult to achieve sufficient needling sensation in the articular cavity of the knee. In other words, shorter acupuncture needles usually cannot guarantee an adequate amount of stimulation to activate corresponding receptors - inside the knee joint. Therefore, one of the major shortcomings of the trial was the lack of using longer acupuncture needles. Also, needle acupuncture without deqi requirement can only be considered as a weak or insufficient stimulus, and presumably unable to reach an optimal outcome.

Besides, subjects receiving needle acupuncture in the trial had a mean age of 64.3 years. Generally speaking, the acupuncture sensitivity for the elderly is significantly lower than young people. The trial protocol not only implemented shorter and thinner filiform needles (0.25x 40mm), but also specified that the acupuncture intervention as a 20-minute treatment once or twice weekly for 12 weeks, with eight to 12 sessions in total. This design seems to lack the necessary stimulation time and frequency to achieve an optimal outcome. Modern studies have shown that the analgesic effect of acupuncture gradually reaches the climax only after about a 30-minute of needle retention period (26-27). For patients with lower sensitivity, a stronger stimulus (such as adding EA), a longer needle-retention period (at least 30 minutes), or taking more frequent treatments (e.g. have acupuncture at least two times per week) is required (26-27). In the trial design, it is apparent that these basic measures were not adopted.

In the trial, the researchers overlooked the fact that scar tissues caused by previous surgical procedures or operations are critical factors influencing the efficacy of acupuncture. As shown from the trial, 37% of subjects who received needle acupuncture had surgical history, though there were no mentions of what specific types of surgery (arthroscopic or others). It is known that many patients are prone to develop scar tissues after surgeries or have certain post-surgical disturbance of normal tissue structures, which may lead to a reduction of needling sensation at the surgical region, and result in a reduced acupuncture efficacy. Indeed, no matter where the articular pain is, most acupuncture practitioners have experienced that patients without a surgery history of the joints generally have a better outcome than those with a surgical history of the joints.

Another major shortfall of the trial is that 40% of subjects who received needle acupuncture were also taking painkillers at the same time. This may be one of the main reasons behind a lack of significant difference of the efficacy between the needle acupuncture group and sham la-

ser group. Because the therapeutic information inputted to the body in the trial protocol (including selections of acupoints, needling depth, time and frequency) were mostly mild in nature, the triggered responses of the body were also slower and weaker than painkillers. In other words, if presuming the researchers had instructed subjects not to take painkillers during needle acupuncture, then potential therapeutic results from needle acupuncture might be observed. As for those taking painkillers at the same time while receiving needle acupuncture, the efficacy of acupuncture may have been overshadowed by painkillers.

According to our experience (26-27), in order to achieve a better outcome of acupuncture than painkillers, especially for the elderly patients with chronic moderate to severe knee pain, it is better to select regional reflex points (acupoints) with tenderness, or to apply more intensive needling methods, such as manipulations of deqi, multiple needles at a single point (28), or implementing EA, etc. Yet, all these important measures were not adopted in the trial protocol, inevitably resulting in the negative conclusion about acupuncture efficacy.

Also, the trial had a lack of observation or comparison about any possible short-term or instant analgesic effects from acupuncture. The researchers measured the outcome via self-questionnaires at the beginning, at 12 weeks and at 1 year later of the trial, which assessed the extent of knee pain intensity and functional activity from the previous week. However, the researchers did not record and compare any short-term changes of outcome immediately or a few days after the treatment, thus any potential short-term acupuncture efficacy for chronic knee pain were omitted from the trial. It is well known that even anti-inflammatory medications can only generate short-term analgesic effects. If there is proof that acupuncture has short-term or instant analgesic effects along with little to no side effects, acupuncture should be recommended for patients of knee pain over the age of 50. In the clinic, it is common for the acupuncturist to observe instant acute or chronic pain relief by acupuncture. Therefore, it is ludicrous to see that the trial used a long-term outcome (a full year) yet showed no significant difference of efficacy between needle acupuncture and sham laser therapy to discount the overall benefits of acupuncture. Furthermore, there were only a total of 8 to 12 sessions of acupuncture conducted at weekly intervals, which cannot ensure any long-term stable pain relief.

In summary, the above shortfalls of the trial along with the misleading concept of lumping laser therapy on acupoints (laser acupuncture) with acupuncture (needle acupuncture) has led to a negative conclusion of acupuncture. If this conclusion was believed, those with chronic knee pain over 50 years of age with moderate or severe chronic knee pain would miss a golden opportunity in choosing acupuncture, one of the more effective natural therapies available. By revealing these shortfalls of the trial, one may understand more about the paradox of acupuncture efficacy for chronic knee pain.

By analyzing the above trial as a case study, it is critical to recognize that a full understanding of factors influencing acupuncture efficacy is needed when designing future trials of acupuncture. Having only the standardization of statistical analysis and implementation of grouping randomization is not enough. Otherwise, similar erroneous

conclusions about acupuncture efficacy like the above trial might be reached again in the future.

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