

Academic Debate

Is sham acupuncture a real placebo: Skeptical for sham acupuncture

假针是否真正的安慰剂——假针质疑

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ABSTRACT

Since acupuncture came to western countries, research has been done to try and prove whether or not it is effective. Current Acupuncture research is most often based on the sham needle which was first designed by K Streitberger and J Kleinhenz in 1998. The sham acupuncture needles are developed for the control group and do not penetrate the skin. Sham acupuncture has been used in randomized controlled trial (RCT) for diseases which normally benefit from acupuncture treatment. The sham needle is not the best placebo needle though. Because of the use of sham acupuncture, the result of those research shows acupuncture having no effect or it shows there is no significant difference between real acupuncture (verum) and sham acupuncture (placebo). However, a detailed introduction of the Nine Classical Needles (ancient) and the Nine Modern Needles (SHI's nine needles) shows that the use of sham acupuncture in RCT research is flawed by design. This then casts doubt on the findings and conclusions reached by using sham acupuncture in RCT acupuncture research.

KEY WORDS: nine classical needles; sham needle; Blunt (Di) needle

Many acupuncture RCTs have concluded that acupuncture has no effective benefit. These conclusion come from acupuncture RCTs which use a real acupuncture group (traditional needle placement and manipulation) versus a sham acupuncture group (which is one of the placebo devices used for acupuncture research). In those study, there is no significant difference in treatment results between the real acupuncture group and the sham needle group.

Why are these RCTs showing results that are contradictory to actual clinical experience? Is this sham acupuncture needle properly designed? Does the sham needle group truly act as a placebo group in the RCT of acupuncture research?

Acupuncture was first introduced to the American public by *New York Times* journalist James

Reston. Acupuncture was pushed to the forefront after President Nixon visited China^[1]. Since then acupuncture has been a popular topic of discussion that is mentioned almost on a daily basis by American media. In traditional Chinese medicine, the special channels or meridians which carry vital energy (*qi*) and blood, balance *yin* and *yang*, connect organ systems, which are the foundation of the whole body are called meridians^[2]. Meridians would make a decision of life or death, cope with disease, regulate excess or deficiency. So the meridians have to be open without blockage^[3]. Acupuncture stimulates acupoints related to meridians and reopens them so they can treat diseases of the body. Since acupuncture is an ancient healing technique, many seem to be concerned with, or have doubts about acupuncture and are asking: does acupuncture really work? RCT studies of acupuncture, to prove whether acupuncture works

or not, are done by collecting and analyzing data sets, a real acupuncture group and a sham acupuncture group (placebo effect group). “Real acupuncture” uses a thin and fine needle inserted into the patient’s skin at certain acupoints that improve the flow of *qi* to aid healing. On the other hand, “sham acupuncture” uses a dull-ended needle which does not break patient’s skin but provides the patient with the same feeling. During the experiment, the term “single blind” will often be mentioned, which means the test subjects (in this case, the patients) are “blinded”, and do not know whether the acupuncturist is administering the real needle or the sham needle on them. Without further explanations, everyone would be thinking that “sham acupuncture” as a placebo effect group would serve its role perfectly. However, if you know the types of acupuncture needles very well, you will realize that the RCT methodology used to study the effectiveness of acupuncture is flawed by design. This explains why some of the acupuncture research shows that real acupuncture has no significant improvement when compared to sham needling.

THE CLASSICAL NEEDLES (ANCIENT)

Acupuncture is an old healing technique from China that has been used to treat multiple diseases and is used most commonly today for treating pain. Acupuncture is the use of needles inserted into the skin at predetermined, specific points on the body to free up energy blockage. Most people even in China, think that there is only one type of thin and sharp tipped needle used in acupuncture and acupuncturists use only that one needle to handle every patient for a variety of situations. However, this is not true. Acupuncture is a very complicated subject which utilizes not only different types of acupuncture points, but also has a variety of needles in different shapes, sizes, and temperatures which are inserted in different locations, strengths, and depths.

“Acupuncture needles have been believed to be in use about 4000 years. The earliest acupuncture instruments found in archaeological findings in China were made out of stone and were called *bian* (1700 B.C.)”.[4] It was discovered that ancient Chinese people were using sharp edged stones to cut the skin and allow pus and blood to drain out for healing and pain relief, which is the fundamental concept of the basic and traditional acupuncture points and needles[5]. As time passed, the primary stone needle developed into a set of systematic needles which was called “The Classical Nine Needles” (also known as Ancient Nine Needle). Around 2200 years ago (*Qin* dynasty, 221-

206 B.C.), “The Nine Classical Needles” were first documented in the famous ancient Chinese medical book, *Huángdì Nèijīng* (《黄帝内经》 *The Yellow Emperor’s Inner Classic*). This book introduced “The Nine Classical Needles” in detailed description including shape, length and function. Below is a detailed chart of the nine needles from the book that will give a better understanding. Specifically, pay close attention to Blunt needle (*Di zhen*)^[6].

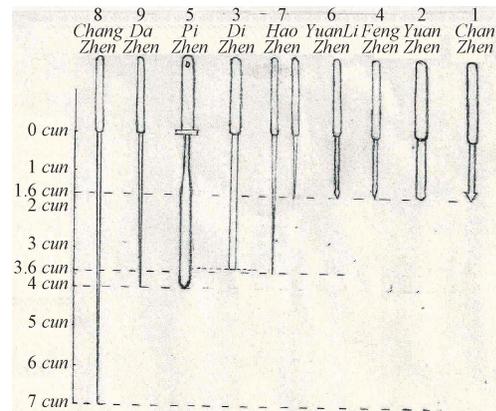


Figure 1 The Nine Classical Needles

THE MODERN NINE NEEDLES (SHI’S NINE NEEDLES)

“The Classical Needles” acupuncture system has been used to treat millions of Chinese people to help them recover from illnesses or injuries and even to extend their lifespan.

Over time, Acupuncturists have continued developing not only the acupuncture needles, but also the acupuncture system itself. In the late 20th century, acupuncture professor and head of Shanxi acupuncture graduate school, SHI Huai-tang, modified “The Nine Classical Needles”, and added two new types of needles “SHI’s *Huo Zhen* (Fire needle)” and “SHI’s *Meihua Zhen* (Plum-blossom needle)”. This new acupuncture system is called “The Modern Nine Needles”, or “SHI’s Nine Needles”. “The Modern Nine Needles” maintains the advantages of “The Nine Classical Needles” and combines traditional acupuncture with modern medical technology, therefore, the new system can treat illness even more efficiently. The needle most likely to be used by acupuncturists is filiform needle. The thin tip and sharp needle allows the acupuncturist to penetrate skin accurately and easily with minimal discomfort. Below is a detailed chart of “The Modern Nine Needles”, take special note of Blunt needle or SHI’s *Di zhen* (SHI’s blunt needle).

The Blunt needle in Table 1 and SHI’s *Di*

Table 1 The Classical Needles^[3]

Name	Shape	Size	Function
1. <i>Chan Zhen</i> (Shear needle)	It is in the shape of an arrow. The top of the shear needle is big, relatively to other nine needles, and the tip of the needle is sharp.	The tip of the needle is 5 <i>fen</i> long. The length of the needle is 1 <i>cun</i> 6 <i>fen</i> .	Treating unfixed redness skin problems.
2. <i>Yuan Zhen</i> (Round-pointed needle)	The body of the needle looks like a pipe, and the tip of the body is in oval shape.	The length of the needle is 1 <i>cun</i> 6 <i>fen</i> .	Treating problems that take place between superficial soft tissues like muscles and tendon etc.
3. <i>Di Zhen</i> (Blunt needle)	Has round shape tip. With a little bit of sharpness.	The length of the needle is 3 <i>cun</i> 5 <i>fen</i> .	Treating problems that take place in channel. Treating patients who have <i>qi</i> deficiency with tonifying method by pressing <i>jing</i> -well point and <i>xing</i> -spring point. (Do not insert the needle to the skin)
4. <i>Feng Zhen</i> (Lance needle)	The body of the needle looks like a pipe, and the tip of the needle has three sharp edges.	The length of the needle is 1 <i>cun</i> 6 <i>fen</i>	Treating problems that take place in meridians. Refractory <i>bi</i> syndromes. Also can treat carbuncle.
5. <i>Pi Zhen</i> (Stiletto needle)	The tip of the needle is as sharp as a sword.	The width of the needle is 2.5 <i>fen</i> , and the length is 4 <i>cun</i> .	Treating abscess and carbuncle on the body surface.
6. <i>Yuan Li Zhen</i> (Round-sharp needle)	The needle has a long tip and a short body which is used for deep insertion.	The length of the needle is 1 <i>cun</i> 6 <i>fen</i> .	Treating acute condition of <i>bi</i> syndromes.
7. <i>Hao Zhen</i> (Filiform needle)	The tip of the needle is as sharp as a mosquito's beak.	The length of the needle is 1 <i>cun</i> 6 <i>fen</i> or 3 <i>cun</i> 6 <i>fen</i> .	Treating chronic pain of <i>bi</i> syndromes.
8. <i>Chang Zhen</i> (Long needle)	The needle has a sharp tip and a thin body.	The length of the needle is 7 <i>cun</i> .	Treating internal, deep problems.
9. <i>Da Zhen</i> (Big needle)	The needle has a thick and large body and a bit round tip.	The length of the needle is 4 <i>cun</i> .	Treating edema and joint problems.

Notes: *fen* and *cun* are dimensional units in ancient China. 1 *cun*≈10 *fen*≈2.3 cm^[7].

Zhen (SHI's blunt needle) in Table 2, do not require penetrating the patient's skin, but give the patient the feeling of a needle breaking into their skin. Blunt needle does not have a fine and sharp tip, it has a round tip similar to a grain of rice. The round design minimizes friction to the patient's skin while remaining on the skin. When pressing the needle down on patient's skin, the pressure opens blocked channels and allows *qi* to flow.

THE SHAM ACUPUNCTURE NEEDLE

There are two categories of placebo groups. One uses a real acupuncture needle but shallowly inserted or it uses different acupoints which has too many variables for a proper study. The other uses non-penetrating needles, called a sham needle, which we will discuss in this paper^[9]. The sham needle, also known as the placebo effect needle, is commonly used in acupuncture RCT research. The idea of a sham needle was first introduced by K Streitberger and J Kleinhenz in their article *Introducing a placebo needle into acupuncture research*^[10]. When the sham needle is flipped on the skin, the patient receives a pricking sensation and believes the needle was inserted into the body when it was not^[10]. There are two types of sham needle commonly used in acupuncture RCT research. The one that K Stritberger and J Kleinhenz designed, and the other designed by Jongbae Parker and colleagues. However, sham needle follows a

basic principal, which is to not penetrate the skin and to give a pricking sensation. Sham needles are designed to mimic a real needle, so the patient cannot tell the difference by sight or feeling^[11], because experiments showed that the patient can't distinguish between real needles, sham needles. Based on this they concluded that the sham needle was credible for use in acupuncture research^[12]. Once the article was published, sham needles became well known and have since been used in RCT acupuncture research. Since both the real acupuncture needle and the sham needle would give patients the same feeling of the needle breaking into the skin, patients would not be able to tell the difference between real acupuncture treatment and sham acupuncture treatment without being told prior to treatment. In order to set up the control group, participants in the sham needle group and the real acupuncture group had needles placed in the same spot. So that the real acupuncture group and the sham needle group, which was set up as a controlled group, would be able to compare the treatment result.

DISCUSSION

From a scientific perspective, this is not the best way to set up acupuncture RCT research to prove whether acupuncture treatment works or not. Acupuncture started using non-insert skin needle (Blunt needle) more than a thousand years ago. Today different acupuncturists prefer different types of

Table 2 The Modern Nine Needles^[6]

Nine Classical needles	Modern Nine needles	Using	Treatment
<i>Chan Zhen</i> (Shear needle)	SHI's <i>Chan Zhen</i>	Use Shear needle on specific selected areas by making tiny cuts.	Treating cold and drain pus.
<i>Yuan Zhen</i> (Round-pointed needle)	SHI's <i>Ci Yuan Zhen</i>	Tapping along the meridians.	Promote blood circulation to dispel blood stagnation. (ex. soft issue injury)
<i>Di Zhen</i> (Blunt needle)	SHI's <i>Di Zhen</i>	First, Put the needle at acupuncture points or trigger points. Second, hold the needle at that point and give it a little bit of pressure to form a depression (or just letting the patient feels the needle), but make sure the needle does not break through the skin.	Acupressure (points massage)
<i>Feng Zhen</i> (Lance needle)	SHI's <i>Feng Gou Zhen</i> (Three-edged needle)	First, insert the needle perpendicular to patient's skin. Second, continuously repeating the first step three to five times in order to cut up muscle fibers or to make it bleed.	Treating partial functional disorder or refractory pain caused by chronic disease. (ex. frozen shoulder)
<i>Pi Zhen</i> (Stiletto needle)	SHI's <i>Pi Zhen</i>	First, set <i>Pi Zhen</i> (Stiletto needle) on top of the alcohol lamp until the needle is scorched. Second, use the scorch needle to remove the root of small, soft skin growths, etc. You need to be quick when removing the root, so that the patient won't bleed as much.	Treating small, soft skin growths, etc.
<i>Yuan Li Zhen</i> (Round sharp needle)	SHI's <i>Yuan Li Zhen</i>	SHI's <i>Yuan Li Zhen</i> is a thicker version of filiform needle, and it is one of the most often used needles in clinics.	Treating pain syndromes.
<i>Hao Zhen</i> (Filiform needle) <i>Chang Zhen</i> (Long needle)	SHI's <i>Hao Zhen</i>	Filiform needle is also one of the most common used needles in clinics.	Treating internal disease.
<i>Da Zhen</i> (Big needle)	SHI's <i>Huo Zhen</i> (Fire needling)	SHI's <i>Huo Zhen</i> (Fire needling) does not have a specific needle, and it only represents a specific way of needling. Heating up any kinds of needles that you desire until searing and then apply.	Treating all kinds of disease.
	SHI's <i>Meihua Zhen</i> (Plum-blossom needle)	SHI's <i>Meihua Zhen</i> (Plum-blossom needle) has bundles of short needles on its tips. Holding <i>Meihua Zhen</i> arm that types along the meridians. Depending on different situations, there are three different strengths to apply to the needles: gentle, mild, strong.	Treating all kinds of disease.

acupuncture needles (modern nine needles) in clinical practice. Comparing Blunt needle with the designed sham needle, both Blunt needle and the sham needle are not made to pierce the patient's skin. However, they are made for different reasons. The tip of the sham needle does not penetrate skin because it needs to be different from the real acupuncture needle in order to make the comparison. The tip of SHI's Blunt needle is round because we need a special needle in the acupuncture field that does not break the skin but makes *qi* flow. Even though SHI's Blunt needle and the sham needle are made for different reasons, they have very similar designs. In fact, they are so similar in design, it is reasonable to assume they would have close to the same effect on patients and give very similar test results in treatment.

To be a proper placebo device they need not only to be indistinguishable by look and feel but also have no function. However, the sham needle has a treatment function. Looking at RCTs of acupuncture

research, many of these studies are done by comparing real acupuncture with sham acupuncture. Because of the similar design of the sham needle and Blunt needle, these studies are comparing real acupuncture that is modern filiform needle with the sham needle modern Blunt needle. These two acupuncture groups are actually comparing two types of acupuncture techniques. Because of flawed research design, the sham and the real acupuncture show no significant difference in treatment. This explains why some of the acupuncture RCT studies reached the conclusion that the real acupuncture has no significant difference from the sham acupuncture and both treatments are better than no treatment at all^[13].

Random control trial is a scientific method that if not appropriately designed and conducted can lead to inaccurate results^[14]. Acupuncture RCT studies which claim that acupuncture has no beneficial effect based on sham acupuncture as the placebo-control group are therefore questionable.

CONCLUSION

The sham acupuncture needle is not the perfect placebo. It is a real acupuncture needle based on Blunt needle's design. For sham acupuncture needles to be a proper placebo it needs to be indistinguishable and physiologically inserted but also have no treatment function. Furthermore, acupuncture is a complicated therapeutic technique. There are variety factors involved during the treatment procedure: the tool (needle), psychology (both patient and provider), technique and education level (provider). Finding an appropriate placebo needle is the challenge that RCT acupuncture researchers face in order to do a proper double blind study of acupuncture.

COMPETING INTEREST

None.

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ABSTRACT IN CHINESE

[摘要] 自针灸传到西方国家以来,证明针灸是否有效的研究从未中断。目前关于针灸有效与否的研究多基于假针,即由K Streitberger和J Kleinhenz于1998年最先设计并使用的。由他们所设计的假针是不穿透皮肤的针。现在假针已经广泛用于针灸治疗有效的常见病的RCT研究。但用假针作为安慰组的设计需要进一步完善,因为其研究结果表明针灸没有效果,或者说传统针灸(真)和假针灸(安慰剂)之间治疗结果没有显著差异。本文详细介绍了古代九针和现代九针(师氏)的内容,指出在针灸RCT研究中的应用的假针存在设计缺陷,因此,使用上述假针作为安慰剂所得出的研究结论值得商榷。

[关键词] 九针 假针 鍉针