

Factors Influencing Acupuncture Research



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Abstract Acupuncture research has been conducted in western countries for more than 50 years, with both positive and negative results being published. Therefore, some researchers question whether acupuncture is just a placebo effect. We believe that acupuncture signal production, process and outcomes are complex and need careful investigation. Many factors may contribute to the failure of a study and result in a wrong conclusion. In this chapter, we aim to analyze the factors that might influence acupuncture research and outcomes. There are mistakes and errors in current acupuncture research in several aspects, including acupuncture methodology, personal ability of acupuncture, study design, data analysis, and selection of participants. We hope that future acupuncture researchers will pay attention to these factors and avoid mistakes and misunderstandings of acupuncture effects.

Keywords Acupuncture · Placebo effect · Influencing factors · Research design

1 Introduction

Acupuncture has been studied for more than 50 years in western countries with both positive and negative results being published, especially in clinical studies. Most published studies support that acupuncture has a unique healing effect, but there are also a lot of data that do not support this view because the acupuncture healing effect in an acupuncture group is not significantly different from that in a sham acupuncture group. It seems that both sides of the argument insisted their own opinions but are hardly able to point out possible mistakes or errors of the opposite side. Indeed,

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contradicting data are still published up to now (2016) (Fleckenstein et al. 2016; Schiller et al. 2016; Feng et al. 2016).

Acupuncture research is not simple, as some researchers believed. For example, in western medicine, the quality of a new drug in a clinical study is standardized for its purity or concentration. Whether the drug is used in New York or in Vancouver, it is regarded the same in quality. However, clinical acupuncture is a very person-skill dependent therapy. The success of the acupuncture treatment largely depends on the person that performs the acupuncture treatment. It is not as simple as inserting a needle into skin and leaving it for 20 min to expect a healing effect.

Furthermore, in a new drug study in western medicine, the sham tablets or sham pills are relatively easy to prepare. It is difficult for study participants to tell the difference between a true tablet and sham tablet. In acupuncture, it is still questionable what the best and most reliable sham acupuncture group to use is. Sham acupuncture should exert only a placebo effect and no healing effect, but none of the sham acupuncture groups used have ever met this characteristic. Therefore, much more attention is needed in regards to acupuncture research in clinical settings.

We feel that it is necessary to analyze the methodology of the current acupuncture research and indicate potential factor(s) that may contribute to the failure of an acupuncture study that have not been well recognized yet. This chapter will summarize these potential factors that influence the outcomes of acupuncture research. We hope that our summary would be helpful to reduce the errors and mistakes in the acupuncture research and move the acupuncture study forward.

2 Method of Acupuncture

2.1 What Is Acupuncture?

From the research articles published from western countries, it was found that acupuncture researchers had confused electrical acupuncture, finger-press, acupuncture point massage, point injection, ear point press, and etc. all as just “acupuncture”.

All of these therapies belong to traditional Chinese medicine (TCM) and are broadly used in acupuncture clinics. However, each therapy has its own favorite spectrum to fit the scope of the treatment. Mixing all these therapies with acupuncture therapy and attributing their therapeutic outcomes, either success or failure, are not appropriate in terms of the evaluation of acupuncture healing effects. Acupuncture has its own and unique way in clinical practice.

In many past review articles on acupuncture, these various therapies were considered as acupuncture for the review and analysis. For example, they were classed as acupuncture in the review by Colquhoun (2015), Colquhoun and Novella (2013), Furlan et al. (2010) and by Linde et al. (2009a, b).

In the acupuncture review by Liu et al. (2015) the author collected randomly designed articles from 2011 from Science Citation Index Expanded (SCIE), but

excluded those articles published in Chinese journals, or those in which the first author was from China. Using this method, they collected 33 articles from totally 867 articles. Among these, 17 articles are negative and 23 articles are positive regarding the acupuncture efficiency. We found that in these 33 articles, some of the studies used electrical acupuncture, auricular press, auricular acupuncture, or finger press, acupuncture injection or cupping, and acupuncture was actually not the main therapy in these studies. Furthermore, most of these studies only paid attention to the treatment costs, residence days or long-term healing effect. In addition, some authors might make a wrong conclusion for their study results (e.g., an apparently negative result was interpreted and concluded as a positive one (Smith et al. 2011)). After exclusion of these articles, we can actually only be able to get 21 “valid” articles in which 7 articles showed negative results and 14 showed positive results.

Azad and John (2013) listed 25 negative articles about acupuncture. Among them, there are 8 articles that used intradermal needling, acupuncture point press, auricular press, or magnetic therapy.

Matthews (2015) collected 55 articles about acupuncture treatment of nausea/vomiting in early stages of pregnancy. From these articles, the author had chosen 27 articles for review. Among which only 2 articles can be regarded as true studies on typical acupuncture and all other studies included in the review were Fresh-ginger press (10 articles), finger-press (5 articles), TENS (1 article), auricular press (1 article), moxibustion (1 article), Vitamin B6 (2 articles) and antiemetic (6 articles).

One current question in acupuncture research is if acupuncture is a placebo effect. It is therefore better to test the effect of acupuncture therapy alone, rather than the cupping, moxibustion, acupressure, point injection, auricular acupuncture, or the combination of them with acupuncture. In this article, we try to separate the healing effect of acupuncture from that by other therapies. This is possibly a better way to test if acupuncture is a placebo effect, or if it has its own specific healing effect.

2.2 *Different Acupuncture Systems*

There are various forms, styles, and systems of acupuncture. The traditional style of acupuncture chooses acupuncture points according to the theory of Chinese medicine or that of meridians, while some other styles do in different ways.

Furthermore, based on the acupuncture points chosen from the whole body or from just a local part of the body, acupuncture can be separated into two major categories:

Whole body acupuncture that includes those introduced in classical acupuncture textbook, and other personalized acupuncture styles such as Pan’s Classical Chinese Acupuncture system (<https://doi.org/10.1002/14651858.cd007575.pub4>), the Dong Shi Qi Xue style (Dr. Dong’s out-meridian acupuncture system Huang 2010; 2002), Ping Heng Zhen Fa (Balancing acupuncture system, Wang 2014a, b; Ding and Ding 2005) Fu Zhen (Fu’s transcutaneous acupuncture system), Fu et al. (2006) as well as Japanese acupuncture style.

Local acupuncture that includes scalp acupuncture, ear acupuncture (also known as auricular acupuncture), facial acupuncture, nose acupuncture, tongue acupuncture, wrist/ankle acupuncture, palm acupuncture, abdomen acupuncture, and etc.

We will mostly discuss possible factors that may affect the whole body acupuncture treatment and study, though each of these styles of acupuncture has its own advantage and disadvantage.

2.3 Selection of Acupuncture Points

One of the principles in the selection of acupuncture points is the combination of basic and complementary points.

Basic acupuncture points can be on meridians, such as the ST36 point for disorders in the abdominal area, PC6 point for disorders of heart beat and nausea, or Hegu (L14) point for disorders in the face and head. In the treatment of disorders in the leg, the basic points are ST36, Snayinjiao (SP6) and Taichong (LIV3) in the Jin-San-Zhen acupuncture system. In the treatment of pain in the knee, the basic point is the Jianzhong point in the Ping-Hen-Zhen-Fa system. Evidently, the basic point can be one or more points. The number of complementary acupuncture points can also be small or large, depending on the disease treated.

There are two ways to choose complementary points: the diagnosis according to TCM basic theory or that according to meridian theory. In acupuncture treatment, the meridian diagnosis is relatively more important.

Generally speaking, acute diseases need lower numbers of basic or complementary acupuncture points, but chronic disease needs higher numbers. For example, in the treatment of menopause, the basic points are Guanyuan (REN4), Qihai (REN6), Zhongyuan (REN12), Shenshu (UB23), L14, ST36, Yingtang (EX2). The diagnosed points (based on TCM diagnosis) would be Taixi (KID3), Ganshu (UB18), Baihui (DU20) for Liver-kidney Yin deficiency, Xinshu (UB15), Tongli (HT5), Zhishi (UB52) for Heart-kidney un-connection syndrome, or Pishu(UB20), Yinlingquan (SP9), Sanyinjiao (SP6) in Spleen-kidney Yang deficiency.

In the treatment of migraine, the meridian diagnosis is mostly used. Some basic points and chosen complementary points together are necessary for better healing results. For example, if the migraine pain is mostly located on the side of the head, acupuncture points on the Shaoyang meridian should be chosen. If the pain expands down to the arm, acupoints on the hand Shaoyang meridian should be used for the treatment. Otherwise, if such pain expands down to the shoulders or also has muscle spasm on calf, acupuncture points on the foot Shaoyang meridian should be chosen.

Most acupuncture studies in western countries have basic acupuncture points but not complementary points, or they use the same basic point and the complementary points for all patients. There should be some healing effects with this method, but they are not as strong those with the selection of acupuncture points that match the need of each individual.

For example, in the treatment of menopause, we must use complementary acupuncture points according to TCM diagnosis. This is a tough task for a doctor with a western medicine background or for someone who is not used to evaluating patients from TCM point of view. For proper treatment of infectious diseases in western medicine, it is important to make a precise diagnosis to identify the infectious source, i.e., bacteria, virus, fungus, or something else. Even in the category of bacterial infection, it is still necessary to determine if it is due to gram-positive or to gram-negative bacteria. The same is true in TCM. An effective treatment needs a precise TCM diagnosis for each clinic condition, by which suitable acupoint and acupuncture manipulation can be properly selected. Failure to do so may lead to an unsuccessful attempt to true results of the acupuncture research.

For the treatment of hot flashes and night sweats, using only a basic acupuncture point is not enough if symptoms are due to chemotherapy or radiation therapy, the use of estrogen, hysterectomy, or ovariectomy. On the other hand, one PC6 point (or with an ST36 point) might be able to solve the problem in the treatment of a nausea/vomiting, if it is caused by acute gastritis, motion sickness, or anesthesia. However, if nausea/vomiting is due to chemotherapy/radiation therapy, one PC6 point acupuncture usually is not enough to solve the problem. It would be necessary to use a combination of the PC6 with more complementary acupuncture points, or use a different acupuncture point combination.

2.4 Specificity and Universality of Acupuncture Point

The effects of acupuncture points have specificity and universality. The healing effects of an acupuncture point are usually shared more or less by neighbor points as well (Lu 1994). These neighbor points can belong to the same meridian, or to different meridians. For example, the ST36 and Yanglingquan (GB34) points in the Foot Yangming meridian are under and outside of the knee and can be used to treat pain and bloating in the abdomen. The SP9 and Diji (SP8) points in the Foot Spleen meridian are located under and inside the knee and can also be used to treat the stomach pain and bloating.

Acupuncture points also have specificity in healing functions. It is reported that acupuncture on the Shuigou (GV26) point of the rabbit can increase the blood pressure of the rabbit with hemorrhagic shock, whereas acupuncture on the ST36 point cannot (Zhu 2003). Acupuncture on the Suliao (GV25) point can treat severe cranio-cerebral injury coma (Xu et al. 2014). The wake-up effect of this acupuncture point is stronger than Renzhong (DU26) point. Although these two points are very close to each other and both of them belong to the same meridian (the Du meridian), their healing effects are different in terms of efficacy.

2.5 *Acupuncture Sensation*

To obtain a reasonable level of healing effects, patients need to feel special sensations on the acupuncture spots. The typical acupuncture sensation is described as a tingling, numb, bloating, pressure, or tired feeling on and around the acupuncture spot. This is the Deqi sensation. It is not the Deqi sensation if the patient feels sharp pain (suggesting that the needle touches blood vessels or bone membrane); or pain as an electric shock (suggesting that the needle touches nerve). So, if the sensation is mostly a painful one, the spot of needling might not be correct.

However, it should be noted that the most important mark for the Deqi is the feeling of the acupuncturist. The acupuncturist should feel a descending, tight, or unsmooth feeling under the needle. If there is a hollow, loose, or slippery feeling under the needle, the Deqi sensation has not been reached yet.

There are three types of acupuncture sensations. The first one is the Deqi sensation. Clinically, inducing such sensation is not difficult in most patients, except for those who are in poor health conditions.

The second kind of acupuncture sensation is along-meridian sensation, where the Deqi feeling passes up or down the meridian to some distance. Whenever there is such along-meridian sensation, the healing effect is usually good (Xie et al. 2014; Along-meridian sensation and clinic efficacy of acupuncture treatment 2011). It is the aim of an acupuncture expert to induce this along-meridian sensation, since it is the key to having marvelous healing effects in acupuncture treatment.

For example, in the treatment of peri-arthritis of the shoulder, Dazhui (DU14) points are stimulated. After manipulating the needle to induce the Deqi sensation, the needle tip is turned towards the affected shoulder and continues to be manipulated to let the patient feel the Deqi sensation passing towards the affected shoulder. Clinical experience showed that healing effects are better with farther passes of the along-meridian sensation. The ability of an acupuncture expert is reflected, at least, in his or her ability to induce this along-meridian sensation. Due to the higher healing effects with the along-meridian sensation, acupuncture experts do not need to use lots of needles or acupuncture points for the treatment, nor do they need to repeat the treatment many times.

The third kind of acupuncture sensation is far-away acupuncture sensation. This is when upon acupuncture on a point, the patient feels a strange feeling far away in some other part of the body. The feeling can be typical Deqi feeling, or something else. Such far-away acupuncture sensation does not need to manipulate the needle for a long time to happen. People feel these far-away sensations fairly easily. They may belong to a special group of people, whom we call as “meridian-sensitive people”. If such far-away acupuncture sensations happen, the healing effect is usually very good, no matter the experience of the acupuncturist.

We noticed that in a majority of the acupuncture studies, there are indications that the researchers have paid attention to induce such Deqi sensations for the patients. However, it is difficult to tell if these acupuncturists have stimulated out the Deqi sensation every acupuncture point, or only some points. Our doubt comes from the

blinded study design (single or double blind); if we do not know whether the patients receive a real acupuncture treatment, how do we know if the patients feel the Deqi sensation or not? Moreover, we do not know if the Deqi feeling is from the patient's description, or from the feeling of the acupuncturist's feeling (under the needle). Again, we did not find any articles describing attempts to induce the along-meridian sensation during treatment.

Though we believe that the acupuncture sensation is very important for a better healing effect, it is difficult to study since it is hard to standardize the intensity of the feeling (Zhou and Benharash 2014).

There are more data telling that the manipulation of the acupuncture needle is important to get higher healing effects (Hu and Shi 1982; Yuan et al. 2004; Ding et al. 2004; Shen et al. 2005a, b; Wang and Di 2006; Xiong et al. 2006; Zeng et al. 2006; Zhang 2006; Liu et al. 2007; Luo and Wang 2008; Deng 2007; Liu and Zhu 2008; Guo and Shi 2013; Meng et al. 2006; Ni et al. 2011; Shi 2005; Zhao 2003; Wang 2015; Wang and Wu 2006; Zhu 2013; Liu 2013; Zhu and Shi 2008).

2.6 *Along-Meridian Acupuncture Sensation*

As stated previously, the first kind of acupuncture sensation, Deqi, is not difficult to induce, while the second acupuncture sensation, along-meridian needling sensation, is. The second sensation requires the acupuncturist to focus on the needle handling with various manual skills, such as to insert and to pull the needle with different frequency and speed, and so on. The proficiency of an acupuncturist is defined by the acupuncturist's ability to induce this along-meridian sensation, and if the sensation can pass on to the diseased spot of the body. It is commonly accepted clinically that if such a sensation can reach the diseased spot, the disorder on that spot will be improved much faster (He 2004; Liu et al. 2005; Cheng 1997; Sun 2006; Li et al. 2001).

To induce the along-meridian sensation, an acupuncture master must use different acupuncture manual techniques on different acupuncture points. For example, the needle may be manipulated for different insertion directions or depths. The needle can twist, pull, and push up and down, with various frequencies. These manipulations may last one minute or longer. A variety of special manipulating technique may also be used, such as Slow-inserting technique (Cheng et al. 2004; Huang et al. 2005), Fei-Jing-Zou-Qi technique (Cao et al. 2014), Short-Distance-Following technique (Liu and Jiang 1981; He et al. 1991), Jie-Qi-Tong-Jing technique, (Cheng and Zheng 2001) Needle-Detaining technique (Cheng et al. 2015), Yi-Teng-Zhu-Tong technique (Zhang et al. 2014), the Both-Hand-Manipulation technique (Lou 1998), and many more.

When considering acupuncture anesthesia, most clinic observations showed that if the along-meridian sensation reaches the area of the surgical operation, the effect of the acupuncture anesthesia is better (Lin et al. 1999). However, this effect is not related to the types of the surgical operations.

The patch of the along-meridian sensation mostly follows that of a meridian, though there could be differences among persons, and meridians, but not follows the long axis of muscle, blood vessels, or nerves (Xie et al. 2014). Patients may feel bloating or numbness. Some may feel water flowing, ant crumbing, or cold or warm sensations. This sensation passes slower than that of a nerve signal. The width of the patch is variable among people. Most of the path is as broad as a band, not a line, which can be narrow or broad. The depth of the along-meridian sensation varies from person to person. The direction of the sensation is mostly the same as that of a meridian. Depending on the acupoint stimulated, the direction of the feeling goes either single direction or also to opposite directions. The sensation can be stopped by external interference, such as pressing the skin with a finger between the needle and the sensation spot. The along-meridian sensation can also induce internal organ reactions, such as changes in heart beat and intestine movement. The presence of the along-meridian sensation supports the meridian theory, but its nature still needs in-depth investigations.

A study on 97 students with Myopia (Yang et al. 2003) showed that the intensity of the along-meridian sensation tends to increase with the increase in stimulation. The younger students have stronger sensations than older students. A pure numbness feeling from the along-meridian sensation is better than a mixed feeling of numbness, tingling, bloating, or sore. With another needle on a far end of the same meridian, this sensation is easier to induce than with only the needle on the tested acupoint.

The along-meridian acupuncture sensation is correlated with patient body constitution and nationality. It was found that a patient in a diseased condition is less prone to feel the along-meridian sensation, than someone in a healthy condition with the similar physical attributes (You and You 2002). However, the reverse is true when the patient is stimulated with Hot-moxibustion-sensitive stimulation (Xie and Cheng 2015).

The incidence of the along-meridian sensation in Chinese is reported as 12–24% (Cooperation study groups on along-meridian phenomenon 1979), 4% in Japanese (Wang and Wang 1984), 81.8% in Mozambique (Li 1982), and 30% in Guinea (Zhang 1984).

In clinical observation, we found that the healing effect of acupuncture was usually good when the skin around the inserted needle showed pink color. This observation suggests that the healing effect may be partially related to the body constitution of the patients. We also noticed that for patients using steroid medications in Chinese herbal therapy, including steroid injection into an acupuncture point or a trigger point, the healing reaction to the herbal therapy is relatively poor.

In practice, acupuncturists try to use multiple acupuncture needles to enhance the chance for such sensation and therefore increase the healing effect. Some acupuncturists may use different methods to induce such acupuncture sensation and maintain a high healing effect. For example, they may use “Reverse-horse needle technique”, “Paralleling-needle technique”, and “Needling-in-circle technique.”

We may also use electrical acupuncture or warm-needle acupuncture (to warm up the needle by a burning moxi cone) (He et al. 2014), electrical-warm needle, or hot needle (burn or heat the needle on fire, then inserted into the acupuncture point

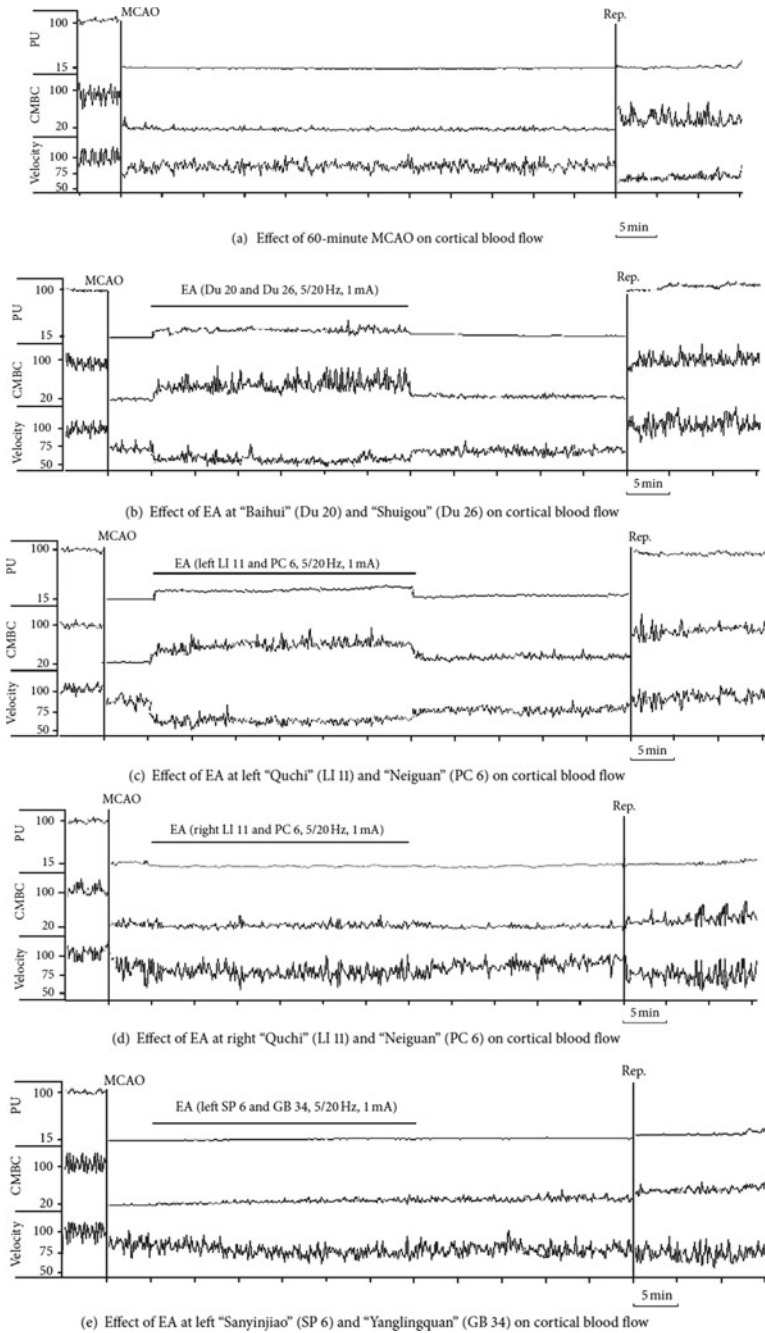
very quickly and pulling out very quickly too). Someone may use Needle-detaining technique (Cheng et al. 2015), or Yang-Ci technique, or insert several needles around a painful spot or a diseased spot of the body. If the healing effect is still not so satisfied, we may increase the acupuncture frequency and times, by doing acupuncture every day, or even twice a day.

Since the sensitivity to along-meridian acupuncture sensation is different among study participants, this could be one of the factors affecting the healing effect of acupuncture among studies.

2.7 Proper Selection of Acupuncture Points

Proper selection of acupoints is extremely important for acupuncture efficacy. Here we mean two issues: proper acupoints for different diseases or clinical conditions and accurate insertion of needles to the acupoint(s).

In a study on the effect of electroacupuncture (EA) on cerebral blood flow in the stroke model (MCAO), (Zhang et al. 2013) we found that EA-induced changes in cerebral blood flow varied with different acupoints (Fig. 1). Using a laser-doppler perfusion monitor, we monitored the real-time changes in cerebral blood flow in all experimental groups. Firstly, we tested if brief stimulation of these acupoints alters the blood flow in the ischemic rats ($n \geq 6$, repeated ≥ 6 times for each pair of acupoints). EA with 5/20 Hz sparse-dense current at 1.0 mA was delivered to the acupoints in a manner of 5 min stimulation/5 min cessation. When a nylon suture was successfully inserted into the appropriate place of right middle cerebral artery (MCAO), the blood perfusion (PU) of the monitored cortex decreased immediately from average 100 ± 20 PU to 15 ± 2 PU, that is, a $\sim 85\%$ drop in blood supply with a decrease in CMBC by $\sim 80\%$ and relatively slight deceleration of blood cell velocity by $\sim 25\%$ ($P < 0.05$) (Fig. 1). EA stimulation at Baihui (Du20) and Renzhong (Du26) immediately induced a significant increase in blood flow. This increase in blood perfusion was synchronous to EA. Among the changes in blood flow, EA induced a 2-fold increase in PU (from ~ 15 to $\sim 32\%$ of the base level before MCAO, $P < 0.01$) with a 3-fold increase in CMBC (from ~ 20 to $\sim 65\%$ of the base level, $P < 0.01$) and a slight decrease in the Velocity (from ~ 75 to $\sim 50\%$ of the base-value, $P < 0.05$). Similarly, EA at left Quchi (LI11) and Neiguan (PC6) also significantly increased the blood flow immediately after the onset of EA. During the EA stimulation, PU increased almost 2 folds (from ~ 15 to $\sim 29\%$ of the base-value, $P < 0.01$) with a significant 3-fold increase in CMBC (from ~ 20 to $\sim 60\%$ of the base level ($P < 0.01$), and a slight decrease in the Velocity (from ~ 75 to $\sim 50\%$ of the base level, $P < 0.05$). In sharp contrast, EA at right Quchi (LI11) and Neiguan (PC6) or left Sanyinjiao (SP6) and Yanglingquan (GB34) did not induce any significant changes in blood flow despite the use of same EA parameters. Our data strongly suggest the importance of proper selection of acupoints in the outcomes of acupuncture (Schiller et al. 2016).



◀**Fig. 1** Representative trace recordings of the blood flow. Blood perfusion (PU), concentration of moving blood cells (CMBC), and Velocity of blood cells (Velocity) were measured in the ischemic rats by a laser Doppler perfusion monitor system. **a** Effect of MCAO-60 min on CBF during ischemia and reperfusion in the Ischemia group. **b** Effect of EA at acupoints Baihui (DU20) and Renzhong (DU26) on CBF. **c** Effect of EA at left Quchi (LI11) and Neiguan (PC6) on CBF. **d** Effect of EA at acupoints right Quchi (LI11) and Neiguan (PC6) on CBF. **e** Effect of EA at acupoints left Sanyinjiao (SP6) and Yanglingquan (GB34) on CBF. Note that the PU and CMBC decreased immediately after the right middle cerebral artery was occluded by a nylon suture. The blood flow was kept at a low level with fluctuant waves during the entire MCAO duration. After onset of reperfusion, PU and CMBC increased while the velocity further decreased. EA at right Quchi (LI11) and Neiguan (PC6) acupoints induced no significant change in the CBF during or after MCAO. EA at left Sanyinjiao (SP6) and Yanglingquan (GB34) acupoints induced no significant change in the CBF during the early stages of MCAO, but slightly increased the CMBC after a 10–15 min period of EA. EA stimulation at acupoints Baihui (Du20) and Renzhong (Du26) or left Quchi (LI11) and Neiguan (PC6) induced an isochronous increase in PU and CMBC with a decrease in velocity. After reperfusion, PU, CMBC, and Velocity all increased rapidly and reached the baseline values Cited from Zhou et al. (2013)

On the other hand, the needle must be inserted into the correct spot of the acupuncture point for a high healing effect (Zhang et al. 2013; Cheng and Kang 2007; Wan et al. 2014). When the needle is in the right spot, it would be easier to induce the acupuncture sensation. The farther the distance from the acupuncture point, the less the intensity of the acupuncture sensation will be (Yang 2008).

In acupuncture studies that involve sham acupuncture group, the needles are usually inserted several millimeters away from true points (inserted sham group). Theoretically, the insertion of needles as such may have some level of healing effect. This is one of the reasons why some researchers give up the inserted sham group and turn to more “proper,” non-inserted sham techniques. However, we do not believe that simply inserting needles into sham spots induces any noticeable healing effect, especially if the insertions are shallow and not manipulated to induce acupuncture sensation. This is because there is no sufficient data suggesting that the inserted sham group may yield higher healing effect than non-inserted sham group (see below).

2.8 Size of Acupuncture Point

The effective surface area of an acupuncture point describes two things. First, it describes the size of the skin area, within which an inserted acupuncture needle could exercise a healing effect. Second, it describes the size under the skin area, within which an inserted acupuncture needle can also exercise a healing effect.

Generally, it is believed that the healing effect would be highest if the acupuncture needle is inserted into the acupuncture point. If it is inserted into the surrounding areas, the healing effect would not be as strong, and decreases with increasing distance from the acupuncture point. Most acupuncture points are zones or areas of significant size, though some acupuncture points may be small.

In the clinic, if the location of an acupuncture point is not correctly chosen, the overall healing effect of the acupuncture treatment could be compensated by choosing more acupuncture points, electrical acupuncture, or moxi acupuncture to increase the stimulation to the points. We may also insert the needle vertically into the skin first, and then insert the needle obliquely in different directions under the skin. This means that even if the point chosen to insert the needle is not the exact acupuncture point, moving the needle under the skin can still stimulate the effective area of the acupuncture point to induce a healing effect.

2.9 Nourishing or Depleting Technique of Acupuncture Manipulation

The way of manipulation of the acupuncture needle is important to induce a higher healing effect (Li 2014). The needle is handled by the acupuncturist to control the speed to insert the needle, the direction of the needle, the ways to pull or push the needle, and to bend or to scrape the needle. Different ways of needle manipulation have different impacts to the body function, yielding a so-called nourishing or a depleting effect to the body Qi (the Qi can be understood as body energy Zhang and Lin 2004; Cui et al. 2010).

Studies on human (Zheng 1995) and animal (Zheng et al. 1996) showed that different methods of the nourishing or depleting technique in acupuncture treatment can differentially influence body functions. It was further found that the overall effect of the nourishing or depleting technique depends on the body condition too. The body condition, i.e., healthy or sick, is also important for the final effect of the acupuncture technique (Ding et al. 2004; Gao 2002). If a patient is in a weak condition, both the nourishing technique and the depleting technique could produce a nourishing to the body, though the nourishing technique induces a higher nourishing effect than the depleting technique. If a patient is in an overwhelming condition (TCM concept), both the nourishing and the depleting technique could induce a depleting effect, but the depleting technique induces more depleting effect than the nourishing technique (Sun and Meng 1994; Sun and Yao 1995).

Paying more attention to the nourishing or depleting technique would yield higher healing effect than otherwise (Li 2014; Liu 2013; He et al. 2007), and yield even higher healing effects than those of electrical acupuncture (Xie and Wen 2013; Zhang 2010). If we insert the needle into the acupuncture point, pull or insert the needle to induce the Deqi sensation, and then stop the handling of the needle further, then there will be a healing effect. However, this method of acupuncture can only exercise a low level of healing effect.

2.10 Depth of Acupuncture Needle Under Skin

In acupuncture treatment, different acupuncture points require different depths of needle. In area with more muscle mass, the needle needs a deeper insertion; in areas with less muscle mass, the insertion needs to be shallow. This suggests that even shallow insertions of needles can also have healing effect.

Furthermore, even for a given acupuncture point, different depths of needle stimulation may induce different healing effects. For example, in Dr. Dong's out-meridian acupuncture system, stimulating the Ren Shi, Tian Shi and Di Shi points at 0.5 in. treats asthma; at 1 in., it treats heart failure. For Di Zong point, shallow stimulations at 1 in. treat mild diseases, while deeper stimulations at 2 in. treat severe diseases. When the Ren Zong, Tian Zong and Di Zong points are stimulated at 0.8 in., it treats the common cold; at 1 in., it treats upper arm pain; at 1.2 in., it treats diseases of the liver, spleen, and gallbladder.

Based on the literature, it is difficult to tell if the acupuncture needles were in proper depths, since the Deqi sensation was always reported to have occurred.

2.11 Length of Acupuncture Treatment for Each Session

The Chinese style of acupuncture requires the continuous manipulation of the needle after the Deqi sensation in order to get as much as possible of the along-meridian sensation. If such along-meridian sensation cannot be induced, we may need to leave the needle in longer, use electrical acupuncture, or use warm-needle acupuncture to increase the stimulating dose.

The time to manipulate the needle might be several seconds, one minute (Ding et al. 2004; Liu and Zhu 2008; Meng et al. 2006; Shen et al. 2005; Wang and Wu 2006; Li et al. 2015), two minutes (Cheng et al. 2015; Wang 1983), 1–3 min (Yang 2011), or 3–5 min (Sun 2006; Wang et al. 2003).

It was found (Lin et al. 2012) that in the treatment of post-stroke syndrome, after getting the Deqi sensation, continuous manipulation of the needles for 30 s induces a better efficacy than the immediate ending of manipulation after “Deqi”.

One unclear question about acupuncture in western countries is how long the acupuncturists manipulate the needles during the treatment. Do they stop the needle manipulation right after the patients feel the Deqi sensation, or do they continue the manipulation after the induction of the Deqi sensation?

In our previous studies, we found that appropriate length of continuous EA stimulation gained better outcomes in terms of brain protection against cerebral ischemia in the rat model of right middle cerebral artery occlusion (MCAO) (Guo et al. 2010). EA starting at 5 min after the onset of MCAO induced a marked protection against cerebral ischemia, leading to a significant reduction of infarct volume, neurological deficits, and death rate (Wang et al. 2009). Interestingly, increased periods of the stimulation from 5 to 30 min increased EA protection as shown in Fig. 2. In the group

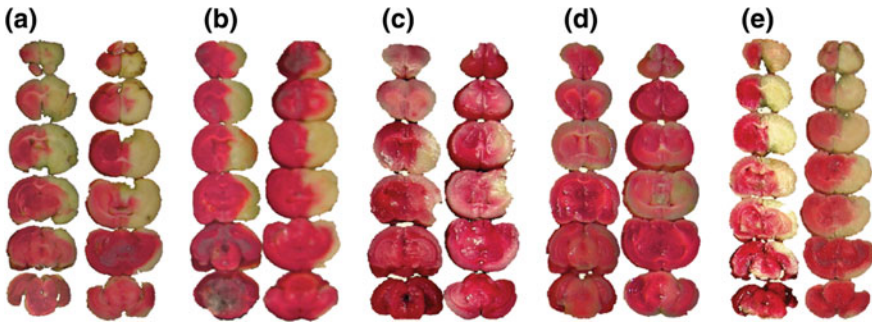


Fig. 2 EA-induced changes in cerebral infarct size in a time-dependent manner. The brain slices were subjected to TTC staining and the ischemic infarct volume was quantified by a computerized image system. The slices on the right of each column show the backside of the left slices. Note that the infarct region (pale-white portion) was mainly located in the striatum and the frontoparietal cortex in the right hemisphere. The MCAO-induced infarction **a** was significantly reduced by EA at Baihui (DU20) and Renzhong (DU26) acupoints for 5 min (**b**), 15 min (**c**), and 30 min (**d**). In contrast, EA for 45 min (**e**) enabled no protection against the cerebral infarction. Cited from Wang et al. (2009)

of MCAO plus EA for 5 min (EA-5 min, $n = 18$), except for 2 rats that died at 5 and 15 h after the onset of reperfusion (11%, 2/18, $P < 0.01$ versus Ischemia), the degree of average neurological deficits in the living ischemic rats was slightly improved ($n = 16$, $P < 0.05$ versus Ischemia). The infarct volume was slightly reduced ($25.6\% \pm 5.3\%$, $n = 12$, $P < 0.05$ versus Ischemia). In the group of MCAO plus EA for 15 min (EA-15 min, $n = 16$), only one rat died at ~ 3 h after the onset of reperfusion (6%, 1/16, $P < 0.01$ versus Ischemia), with a greater improvement in average neurological deficits ($n = 15$, $P < 0.01$ versus Ischemia) along with a significant reduction in infarct volume ($15.4\% \pm 4.2\%$, $n = 12$, $P < 0.01$ versus Ischemia). In the group of MCAO plus EA for 30 min (EA-30 min, $n = 30$), the neurological deficits were greatly attenuated ($n = 28$, $P < 0.01$ versus Ischemia) and a significant decrease in death rate (7%, 2/30, $P < 0.01$ versus Ischemia) was noted. The infarct volume was reduced by 85% ($4.9\% \pm 1.2\%$, $n = 12$, $P < 0.01$ versus Ischemia). In comparison to the groups of EA for 5 min and EA for 15 min, EA for 30 min induced more beneficial effects in all aspects including neurological deficits, ischemic infarct and death rate. These results suggest that the EA protection is dependent on an appropriate duration of EA duration (Wang et al. 2009).

However, the EA protection was not further enhanced by a longer duration of EA stimulation. In contrast, an “over-length” stimulation of EA exacerbated ischemic injury. We assigned a few rats to a new group with MCAO plus EA for 45 min (EA-45 min, $n = 30$). To our surprise, EA for 45 min significantly increased the mortality in this group of ischemic rats. More than half of the animals in this group (60%, 18/30) died within 0.5–10 h after the onset of reperfusion. All of the dying rats manifested symptoms such as convulsions, tumbling, piloerection, and perspiration (wet feathers) and other abnormalities. When compared the Ischemia group, the

death rate increased by 3 folds (60%, 18 out of 30, $P < 0.01$ versus Ischemia) in this group. Although the remaining 12 living rats survived for 24 h after the reperfusion, they suffered from severe neurological deficits and were even worse than the group with only Ischemia. In terms of the infarct volume, EA for 45 min did not reduce the infarct volume at all ($34.3\% \pm 2.4\%$, $n = 12$, $P > 0.05$ versus Ischemia) (Fig. 2e). These results suggest that an increased duration, beyond “appropriate” period, for EA stimulation may exacerbate the ischemic insult, instead of conferring any protection. (Wang et al. 2009)

Interestingly, Wang et al. (2009) also observed a similar phenomenon in their studies on EA-induced hypoalgesia in healthy volunteers. The subjects were randomized to receive different durations (0, 20, 30, or 40 min) of asynchronous EA stimulations and then subjected to the test of hypoalgesia using a human experimental cold thermal pain threshold model. They found that 30 min of asynchronous EA stimulation resulted in the most significant hypoalgesic effect compared with 0, 20, or 40 min stimulations. Therefore, it seems that a 30 min period is the most optimal duration for EA-induced analgesia and brain protection against ischemic injury. In fact, most acupuncturists in China apply acupuncture or EA on patients for 20–30 min each time.

2.12 Retention Time

Retention time is one of the ways to enhance the stimulation of acupuncture treatment, by keeping the needle in place for the period after the Deqi sensation.

Liu et al. (1999) treated 30 cases of primary dysmenorrhea. The pain reduction started from 10 min after acupuncture. The painless period prolonged with the stay of the needle remained in the spot. The healing effect of acupuncture to stop the pain with 30 min retention time is better than that with 20 min retention.

He et al. (1999) treated post-stroke syndrome. He found that retention time of 60 min or 30 min is better than that of 20 min.

Acupuncturists in China have done a lot of studies on the relationship between retention time and the healing effect. The overall results showed that the proper length of retention time is related to the type of the disease treated.

- (1) Post-stroke syndrome: retention of 60 min is better than 40 and 20 min (He et al. 2005a).
- (2) Acute cerebral infarction: 12 h is better than 15 min (Fang and Yu 1996).
- (3) Cervical vertigo: 60 min is better than 45 min or 30 min (He and Ma 2013).
- (4) Trigeminal Neuralgia: 1.5–3 h is better than 30 min (Huang 1999).
- (5) Intractable facial pain: 60–90 min is better than 30 min (Cai 1996).
- (6) Primary dysmenorrhea: 30 min is better than 20 min (Liu et al. 2014).
- (7) Acute ankle sprain: 20–40 min is better than 5 min or 60 min (Xu and Cheng 2001).
- (8) Chronic ankle sprain: 60 min is better than 5–40 min (He and Ma 2013)

- (9) Prolapse of lumbar intervertebral disc: 45 min is better than 15–30 min (Hou et al. 2015).
- (10) Intractable hiccup: 60 min is better than 30 min (Bao et al. 2003).
- (11) Vertebral basilar artery insufficiency vertigo: 4 h is better than 30 min (Dong and Xing 2013).

For these diseases, it seems that longer times of retention yield a better effect than shorter times. Each disease has its own proper retention time for the highest healing effect. However, for some diseases, shorter retention times seem to work better than longer retention times.

- (1) Simple facial nerve palsy: 10 min is better than 40 min (Yu 2004); 20 min is better than 10 min or 40 min (Zhang et al. 1991).
- (2) Trigeminal Neuralgia (by electrical acupuncture): 20–30 min works better than 2–3 h (Lin 2002), 10 min is better than 30 min (Su and Cui 2011).
- (3) Acute fever diseases: Without retention, the reduction effect of fever has already reached 59.6% (Wei 1999).

It is difficult to measure a unique proper retention time for all types of diseases. For a given disease, once the method of the acupuncture treatment is changed, the proper retention time would also change. For example, in the treatment of trigeminal neuralgia, with ordinary manual acupuncture, a retention of 1.5–3 h is better than 30 min (He et al. 2005), but with electrical acupuncture, a retention of 10–30 min is more effective (Bao et al. 2003; Dong and Xing 2013). Therefore, for the acupuncture treatment of a given disorder, it is needed to check the literature for available data on the proper retention time to use.

In most articles published in China and other countries, the needles were left on the spot for 30 min. Some needles were left in for 20 min. In most of the articles reported from western countries, the needle was also left for 20–30 min. However, acupuncturists in the UK did not leave the needle for a retention time after manipulating the needle to reach a Deqi sensation (Ecevit et al. 2011; White et al. 2000). Generally speaking, if the needle does not remain in place for some time, the stimulation intensity must be made? stronger by other means (see below).

2.13 Intensity of Acupuncture Stimulation

Similar to most medical therapies, acupuncture treatment needs a proper dose of stimulation. For different kinds of diseases or clinical conditions, it is important to stimulate proper numbers of acupuncture points, induce the Deqi sensation, manipulate the needles for a proper length of time, leave the needle for a suitable time in the acupuncture points, and repeat the treatment for proper treatment frequencies.

Indeed, we have found that stimulation intensity at acupoints critically matters acupuncture outcomes (Qing et al. 2015). In our studies on cerebral blood flow in the stroke model (MCAO), we examined the effects of EA intensity on the blood

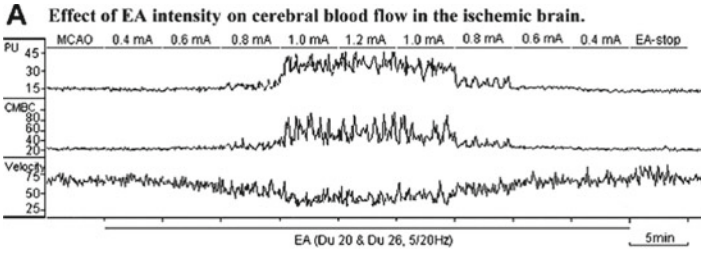
flow (Fig. 3) and found that an intensity of <0.6 mA with 5/20 Hz did not induce any significant change in the blood flow. When the intensity was enhanced from 0.6 to 0.8 mA, there was a significant increase in the blood flow with EA. The blood flow further increased when the intensity was enhanced to 1.0 mA. As shown in Fig. 3c, PU (perfusion units, an index of blood flow value) during EA were more than 100% higher than that during the non-EA period ($P < 0.05$). However, the intensity at 1.2 mA failed to boost a further increase in the blood flow (Fig. 3). The EA-induced increase in the blood flow was isochronous to the current impulse in response to EA stimulation and disappeared immediately after discontinuing EA (Qing et al. 2015). These data suggest that EA induces a temporal increase in the blood flow, with an intensity between 1.0 and 1.2 mA being the optimal range (Qing et al. 2015).

As stated above, however, stimulation intensity is differentially required for different disease/conditions. In certain conditions, mild intensity is optimal for acupuncture treatment. Sometime, only one or two acupoints are needed for the treatment, such as for acute pain, or nausea from motion sickness. In these cases, it is needed to pay more attention to a proper stimulation dose. The use of trigger point acupuncture, catgut embedding therapy, or acupuncture injection therapy are just some examples where stronger and long-lasting stimulations should be given due to small numbers of acupuncture points in the treatment. Since acupuncture treatment for nausea and vomit is a common practice in acupuncture clinics, we take it as a typical example to specially discuss this issue below.

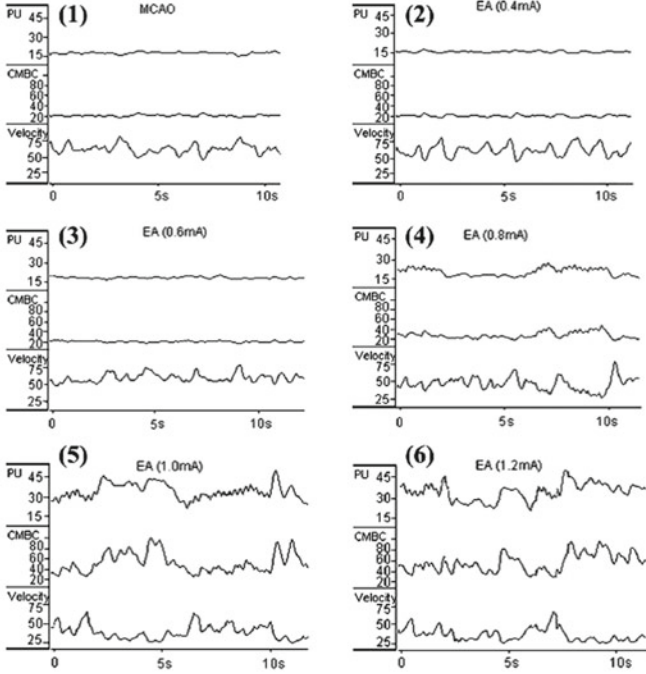
2.13.1 Nausea and Vomiting After Surgical Operation

To stop post-operative nausea and vomit, the acupuncturists in western countries commonly used a single acupuncture point named Neiguan (PC6). The way of stimulation of the point can be acupuncture needle (Streitberger et al. 2004; Gamermanna et al. 2015; Rusy et al. 2002; Al-Sadi et al. 1997; Kotani et al. 2001; Weightman et al. 1987; Liodden et al. 2015; Korinenko et al. 2009; Wani et al. 2015; Yentis and Vashisht 1998; Alizadeh et al. 2014; Sharma et al. 2007) point injection (Irnich et al. 2001), point massage, (Agarwal et al. 2000; Agarwal et al. 2002; Alkaissi et al. 1999; Alkaissi et al. 2002; Allen et al. 1994; Barsoum et al. 1990; Duggal et al. 1998; Ferrara-Love et al. 1996; Gieron et al. 1993; Harmon et al. 1999; Harmon et al. 2000; Ho et al. 1989; Klein et al. 2004; Lewis et al. 1991; Samad et al. 2003; Schultz et al. 2003; Turgut et al. 2007), acupuncture plus point pressure (Shenkman et al. 1999; Norheim et al. 2010), electrical stimulation, (El-Deeb and Ahmady 2011; Gan et al. 2004) Transcutaneous electrical nerve stimulation (TENS), (Frey et al. 2009; Habib 2006) laser (Schlager et al. 1998), or dermal needle (Weightman et al. 1987).

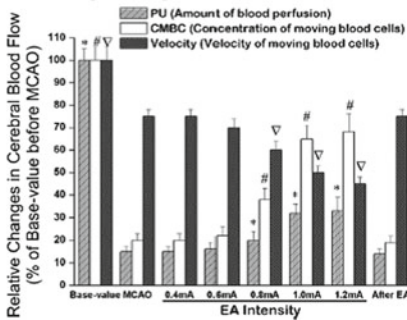
Some studies reported positive (Gamermanna et al. 2015; Kotani et al. 2001; Weightman et al. 1987; Liodden et al. 2015), whereas others reported negative results (Rusy et al. 2002; Al-Sadi et al. 1997) of the effect of acupuncture as compared with their sham groups. This controversy also existed when comparing the effect of acupuncture group with that of no-treatment groups. For example, acupuncture worked better for reducing the incidence of nausea/vomit in some studies, (Wani



B Differential responses of cerebral blood flow to EA at different intensities.



C Averaged changes in cerebral blood flow in response to EA at different intensities



◀**Fig. 3** The EA-induced changes in the blood flow varied with EA intensity. PU: perfusion units. CMBC: concentration of the moving blood cells. Velocity: velocity of blood cells. A: comparative view of changes in cerebral blood flow. B: changes in the blood flow in response to EA at different intensities. C: statistical summary of the changes in the blood flow in response to EA stimuli. *P < 0.01, MCAO versus MCAO plus EA (PU). #P < 0.01, MCAO versus MCAO plus EA (CMBC). ΔP < 0.01, MCAO versus MCAO plus EA (Velocity). The frequency of EA was 5/20 Hz. Note that EA at < 0.6 mA could induce an isochronous increase in PU and CMBC with a decrease in Velocity. Within the ranges of 0.6–1.0 mA, the EA-induced increase in the blood flow was proportional to the increase in the EA intensity. Cited from Zhou et al. (2011)

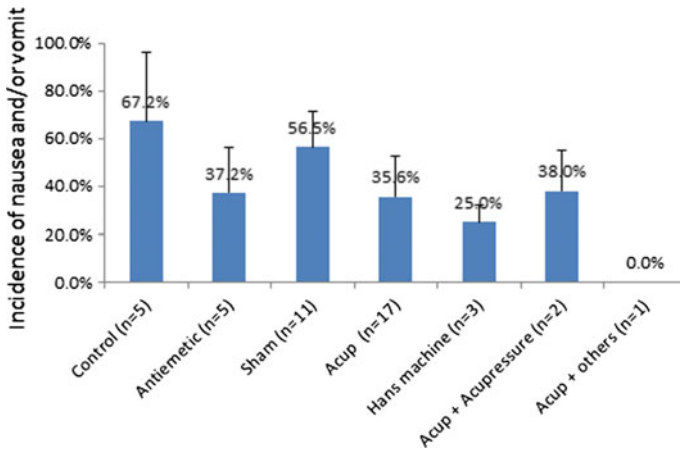


Fig. 4 Incidence of postoperative nausea after treatment with various remedies (data from western countries). n = experiment groups. Data not include articles that use grade scale for healing effects (Mean ± SD)

et al. 2015; Agarwal et al. 2000) but not so in other studies (Korinenko et al. 2009). However, the effect of electrical acupuncture seems always better than that of a sham group (Gan et al. 2004; Frey et al. 2009). More than one acupuncture point of acupuncture treatment seems better than a single point (Sharma and Goswami 2007).

After pooling all the data together, it can be seen that without treatment, the incidence of nausea/vomiting after operation is 67.2%. Sham acupuncture can only reduce it down to 56.5%, antiemetic drugs can reduce it to 37.2%, acupuncture can reduce it to 35.6%, and TENS can reduce it to 25% (Fig. 4).

To treat the post-operative nausea/vomiting, acupuncturists in China also choose the PC6 point (Fig. 5), but they mostly use point injection (Zhao et al. 2013; Liu et al. 2015; Zhu et al. 2010; Lu 2010; Chen et al. 2014; Wang and Kain 2002; Zhu et al. 2010) TENS (Yu et al. 2012; Zhou et al. 2014; Jin et al. 2013; Wang et al. 2010), or combine acupuncture with antiemetics (Li and Wu 2015; Cheng et al. 2015; Huang et al. 2013). It is not common to use ordinary acupuncture. (Lu et al. 2013; Lu 2011; Ouyang et al. 2009; Tang and Cheng 2015) Studies comparing acupuncture to sham acupuncture are rare.

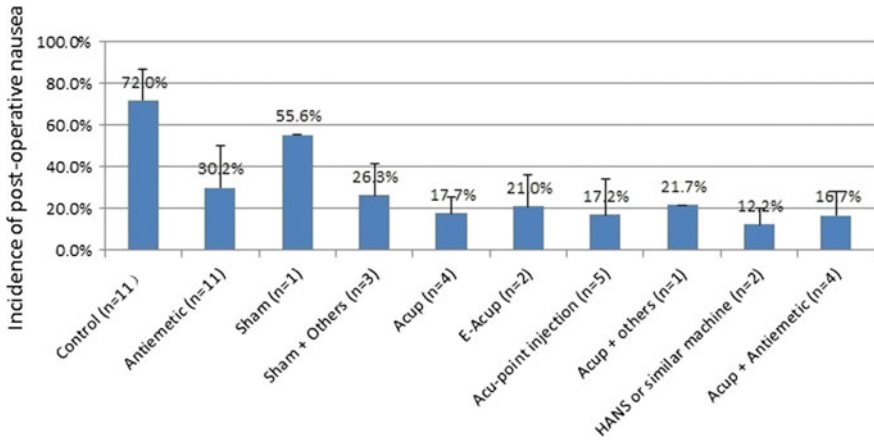


Fig. 5 Incidence of post-operative nausea after treated by various methods (data from China). n = experiment groups. Sham + others: Sham acupuncture plus Ondansetron, or vitamin B1 injection into either acupuncture points or into non-acupuncture points. Acupuncture + others: acupuncture plus acupressure (Mean \pm SD)

Figure 5 shows that without treatment, the incidence of nausea/vomiting after a surgery could be as much as 73%, similar to that summarized in the western group. Antiemetic medicine can reduce the incidence down to 30.2%, and acupuncture reduces it to 17.7%. Other forms of acupuncture (including electrical acupuncture, TENS, joint injection) had the same effect as ordinary acupuncture. The combination of acupuncture with antiemetics did not further reduce the incidence.

Comparing Figs. 4 and 5, it can be seen that the incidence of post-operative nausea/vomiting in Fig. 1 both western Chinese groups are similar in the non-treatment group and in the antiemetic group. Acupuncturists in China have successfully reduced the incidence of postoperative nausea/vomiting to less than 20%, while the acupuncturists in western countries can only reduce it to about 35.6%.

Data in Figs. 4 and 5 suggest that, for the treatment of post-operative nausea/vomiting, the ordinary acupuncture for only one session using a single point worked to reduce the incidence. This is consistent with the reviews by Lee and Fan (2009), Bao (2011), Stoicesa et al. (2015).

Even so, for the four acupuncture studies in China, one used acupuncture from the start to the end of anesthesia, while another used more than three rounds of acupuncture. This might explain the more reduction in the incidence of post-operative nausea in China compared to the western country group. It appears that even when using single point acupuncture, acupuncturists in China tend to have stronger stimulations of acupuncture points than those of acupuncturists in western countries.

Possibly because acupuncture works well to reduce the incidence of postoperative nausea/vomiting, acupuncturists in western countries have tried to simplify acupuncture into acupressure on the same points. However, acupressure is not the same as acupuncture. It is not as reliable as acupuncture by a professional acupuncturist,

especially if the acupressure is performed by patients themselves at home. So, it is no wonder that the healing effect of acupressure in the treatment of post-operative nausea/vomiting could be repeatedly reported as either positive or negative.

2.13.2 Nausea/Vomiting After Chemotherapy or Radiation Therapy

For the treatment of nausea/vomit after chemotherapy or radiation therapy, acupuncturists in the western countries also use point-pressure (Molassiotis et al. 2007; Dibble et al. 2000; Dundee and Yang 1990; Dibble et al. 2007; Gardani et al. 2007; Genç and Tan 2015), auricular needle (Yeh et al. 2012), electrical acupuncture (Choo et al. 2006; McKeon et al. 2015), TENS (Roscoe et al. 2002), acupuncture plus antiemetics (Aglietti et al. 1990; Gottschling et al. 2008; Streitberger et al. 2003), electrical acupuncture plus antiemetics (Shen et al. 2000), acupuncture alone (no sham group) (Tas et al. 2014; Nystrom et al. 2008; Kasymjanova et al. 2013; Reindl et al. 2006; Rithirangsiroj et al. 2015), acupuncture plus point-pressure (Melchart et al. 2006). Only the studies by Enblom et al. (2011, 2012) compared acupuncture to sham acupuncture. These two publications, however, seem to be the same article.

As for the acupuncture treatment of post-operative nausea/vomiting, the acupuncturists in western countries also used single PC6 point for treatment of nausea/vomiting due to the chemotherapy and radiation therapy. Indeed, most articles reported using this single acupuncture point for the treatment. The acupuncture was performed twice a week, (Roscoe et al. 2002; Shen et al. 2000; Rithirangsiroj et al. 2015) once to twice per week, (Reindl et al. 2006) or three times per week, (Kasymjanova et al. 2013; Enblom et al. 2012; Liu et al. 2011) Only one paper stated the use of acupuncture every day for five days (Tas et al. 2014). In the views of acupuncturists in China, the stimulation dose is not enough to induce a reasonable healing effect due to the low treatment frequency.

Acupuncturists in China tend to use multiple acupuncture points, such as the ST36 (ST36) or Yongquan (K11) points for treatment, and rarely use a single point. They also tend to use point injection, (Liu et al. 2011; Chen 2007; Tao et al. 2000; Tong 2007; Hu 2003; You et al. 2009) electrical acupuncture (Fu et al. 2006; Yang et al. 2009), TENS (Zhang et al. 2014), or acupuncture plus auricular pressing plus antiemetic (Sima and Wang 2009). No matter the type, all suggest that acupuncturists in China apply higher doses of stimulation to the acupuncture point for the treatment, compared to those in western countries.

Stimulation by point injection and electrical acupuncture are usually stronger stimulation therapies, but for the treatment of nausea/vomiting due to chemotherapy or radiation therapy, higher treatment frequencies and more treatment sessions are required.

2.13.3 Nausea/Vomiting During Early Stage of Pregnancy

Matthews (2015) reviewed 27 articles on the treatment of early stages of pregnancy. Among the 27 articles, 2 articles are acupuncture studies. The other studies are using Fresh-ginger press (10 articles), finger-press (5 articles), TENS (1 article), auricular press (1 article), moxibustion (1 article), Vitamin B6 (2 articles) and antiemetic (6 articles). The stimulations by the fresh-ginger press, finger-press, auricular press, moxibustion, are not stronger than the acupuncture stimulation.

Between the two articles on acupuncture, one is from Knight et al. (2001). The authors used multiple acupoints, twice a week for two weeks, then once a week for another two weeks. The authors reported no difference in reducing the nausea/vomiting rate between real acupuncture and sham acupuncture.

The second article is by Smith et al. (2002), which used acupuncture in the same frequencies as above. The author reported that the healing effect of using multiple acupoints worked better than a single point (PC6 point), and much better than the sham group and the no-treatment group.

These two studies used typical western style acupuncture: twice a week, for less than 10 sessions. These methods of acupuncture work for some, but not for others (see below).

Acupuncturists in China tend to use multiple acupoints. More importantly, they perform acupuncture every day (Jiang 2014; Song 2012; Mao 2012; Wang and Chui 2002; Xie 2013; Xie 2014; Yan et al. 2012; Cheng 2001) and reported much higher success rates. However, it is hard to tell if such higher healing effects are better than a sham acupuncture, since most clinical studies in China do not design a sham group for a control.

Using a single point (e.g., PC6) may be effective enough for the treatment of post-operative nausea/vomiting, but not enough for that from early stages of pregnancy, or from chemotherapy or radiation therapy. The post-operative nausea/vomiting is due to side effects of anesthesia medications. After several hours, blood concentration of the medication reduces (usually within 24 h), and nausea/vomiting will therefore subside. So, one-time acupuncture with single acupoint might be good enough to stop the nausea/vomiting. However, nausea/vomiting during pregnancy is due to the disorder of hormones in the body that could last several weeks or months. The nausea/vomiting during chemotherapy and radiation therapy is due to the side effects of the highly toxic therapies. The chemotherapy must be used several days in a row, and repeated continuously. Radiation therapy is one occasion, but the toxic materials from damaged and dead cells need several days to excrete out of the body, and cause nausea/vomiting. Therefore a one-time acupuncture with single point stimulation for 20 to 30 min is not effective in treating nausea/vomiting in early stages of pregnancy and in chemotherapy and radiation therapy.

2.14 *Frequency of Acupuncture Treatment*

Acupuncture frequency and schedules are different in various clinics. For example, it may be performed 1–2 times per week for 2 weeks, and then once a week for the following weeks. It may also be performed as once a day for 5 days and after a 2-day break, it continues for five more sessions. In the former case, the first two weeks is regarded as the first treatment course, and in the later, the first 7 days is regarded as the first treatment course.

The healing effect of acupuncture is not only determined by the stimulation dose of each session, but also by the frequency of the acupuncture treatment and the total number of sessions.

2.14.1 **Acupuncture Stimulation Dose: Treatment Frequency in the First Session**

We have tried to compare the acupuncture treatment frequency and the total number of treatment sessions in western countries and in China (Wang 2016). The data of western countries come from the review of Colquhoun (2015), Colquhoun and Novella (2013), Wang and Kain (2013), Furlan et al. (2010) Linde et al. (2009a, b), Madsen (2009), Vickers (2012), Azad and John (2013), Moffet (2009). The Chinese data from the reviews of Furlan et al. (2010), the journal of Shang Hai Acupuncture and Moxibustion (January 2015–August 2015), and other sources (Cheng and Kang 2007; Yao 2015; Wan 2015; Song et al. 2012; Song and Chen 2013; Huang et al. 2010; Li 2010; Ai et al. 2011; Huang et al. 2010; Cheng et al. 2009; Yang 2013; Shi et al. 2012; Chang et al. 2011; Zhang and Dong 2013; He 2013; Liu 2013; Lin 2013; Wang 2014; Tian and Yin 2006; Fang 2014; Zou 2014; Guo et al. 2014; Han 2014; Huang and Zhou 2014; Lu and Yao 2014; Yu and Zhang 2016; Xu et al. 2014; Wang and Liu 2015; Xie 2001; Dou 2015; Wang et al. 2013; Wu 2013; Li 2013; Jia 2013; Yang 2015; Hou et al. 2014; Zhan 2014; Shen 2013; Zhao 2014; Liu 2011; Liu and Xu 2003; Wei 2013; Zu et al. 2013; Wu 2011; Cong et al. 2015; Shi and Li 2006; Sun et al. 2003; Sun and Tao 2015; Yang et al. 2014; Yu et al. 2015; Bao et al. 2015; Li and Yu 2002; Pan 2014; Wang 2014; Liu et al. 2004; Shen et al. 2003; Sun et al. 2010; Jin et al. 2008, 2007; He et al. 2005; Shi et al. 2011, 2015; Zhou et al. 2006; Jiao and Xiao 2015; Xia et al. 2008; Er et al. 2015; Li et al. 2009; Dong et al. 2010; Guo and Liu 2005; Ma et al. 2011; Song and Xiao 2013; Wang and Yin 2005; Tang 2004; Zhang 2012; Cai and Long 2004; Ding 2007; Bao and Cao 2008; Wang and Xie 2006; Liu 2005; Dong 2001; Gao 2014; Fu et al. 2007; Kang and Li 2006; Yang and Lan 2004; Lu 2013; Liu 2000; Zhang 2005; Fan and Yang 2006; Chen et al. 2003; Wei et al. 2012).

When comparing the schedules of acupuncture treatment in the first treatment course, it is found that about 77.4% of acupuncture treatments in the published papers in China are 5–6 sessions a week, while also about 90% of the acupuncture treatment reported in western journals are once or twice a week (Fig. 6). This means

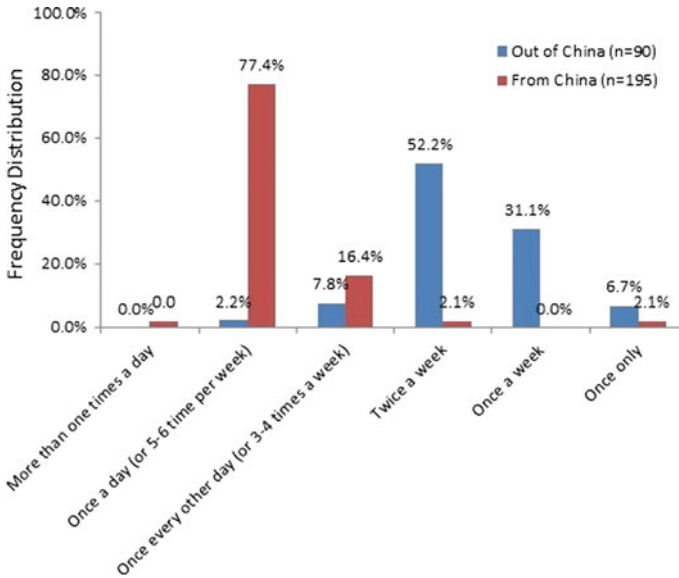
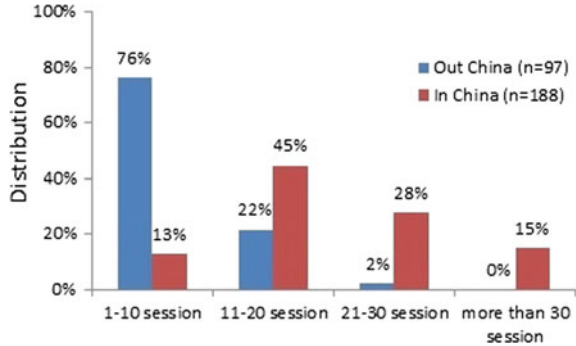


Fig. 6 Acupuncture frequency in the first week of treatment in or out of China. n = number of published articles. Note: Duplicated articles have been deleted. Articles indicating the acupuncture treatment such as “10 times over 3 months” is hard to interpret, so they are not included in the summary

Fig. 7 Total number of acupuncture treatment in or out of China. n = number of published articles



that in the first 7–10 days, Chinese acupuncturists performed acupuncture treatment nearly every day to their patients, while the western acupuncturists leave their patients at home to wait for next acupuncture treatment several days later.

Figure 7 shows that most (76%) of the acupuncture treatment in the western groups are within 10 sessions, while most treatments (88%) in China are between 11 and 20 or more sessions.

Chinese acupuncturists use such concentrated acupuncture schedules, not only in acupuncture research, but also in practical acupuncture clinical treatments. Only when the disease is not severe, or when the patient has difficulty financially, or when

the acupuncture is used together with other therapies, would the Chinese acupuncturists use a less concentrated schedule of acupuncture, such as once every 2 or 3 days.

2.14.2 Average Daily Dose and Total Course Dose

There is a simple way to calculate the acupuncture dose. If the acupuncture is performed twice a week for two weeks and then once a week for two weeks, the average daily dose of the stimulation in the first two weeks (the first treatment course) is $4/14 = 0.28$ and that in the second course is $2/14 = 0.14$. The course dose of the first course is $0.28 \times 4 = 1.12$, and that in the second course is $0.14 \times 2 = 0.28$. The total course dose from the first and the second courses will be therefore $1.12 + 0.28 = 1.40$.

Based on the published studies, it seems that acupuncturists in China performed acupuncture in different ways than those in western countries. The major difference is that the former used much higher average daily doses of acupuncture stimulation over the first course, as well as in total.

For further comparisons in the treatment schedules between western countries and China, we compared the average daily dose and total course dose. This is because the acupuncture treatment is usually performed through scheduled courses in China. Each course could be between 7 and 10 days or between 7 and 10 sessions. The next course will be started if there has not been progression from previous courses.

It was found that the average daily dose values for the three western groups are around 0.26 and for Chinese groups, 0.80 (Fig. 8). The total course doses for western groups are about 2.4, while it is about 18–20 for Chinese groups (Fig. 9). Evidently, the average daily stimulation dose and the total course dose are much higher in China than those in western countries.

2.14.3 Acupuncture Efficiency Comparison

We have also tried to compare the healing effects of acupuncture on non-specific lower back/neck pain and migraine/tension headache between the acupuncturists in China and those in western countries, by using the above data sources.

For non-specific lower back and neck pain, the healing effect of the acupuncture groups is higher in Chinese groups than in the western groups (50.8% vs. 37.2%) (Figs. 10 and 11).

For migraine and tension headache, the healing effect of acupuncture groups in China is also much better than in western groups (42.7% vs. 28.0%) (Fig. 12).

All the data above suggest that there might be some relationship between a higher average daily stimulation dose and the total course dose of acupuncture, and the higher healing effect of acupuncture treatment in China.

In the clinic, for the treatment of acute diseases or disorders, such as acute neck pain, acute low back pain, acute ankle sprain, and etc., it can be said that acupuncture

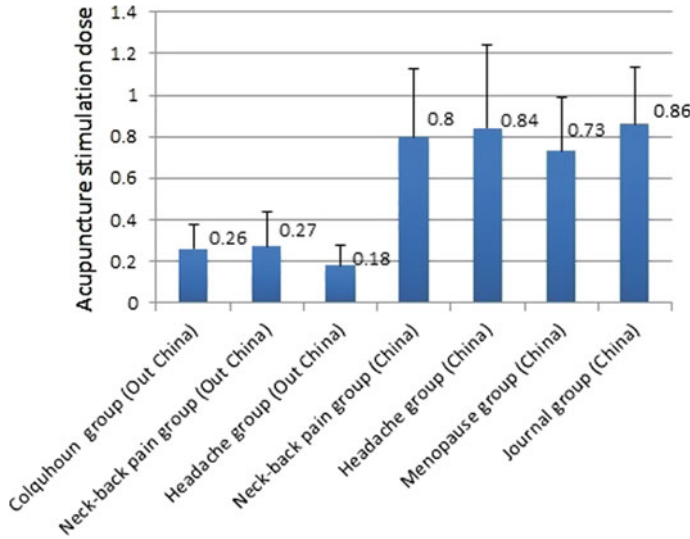


Fig. 8 Average daily stimulation dose of acupuncture in and out of China

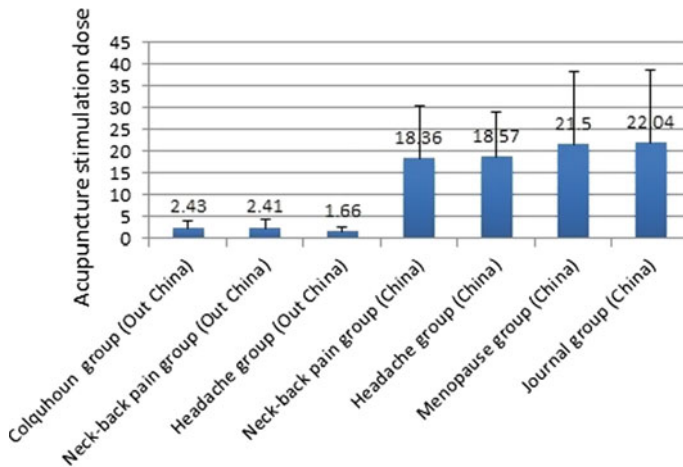


Fig. 9 Total stimulation dose of acupuncture in and out of China

one to two times can stop the pain dramatically, and even reduce the pain level down to zero.

However, for a better therapeutic effect of chronic diseases, such as chronic shoulder pain, chronic low back pain, chronic sciatic pain, chronic migraine, chronic knee pain, and etc., a concentrated treatment schedule, in addition to repeated treatment, is needed, e.g., acupuncture for once a day for many sessions. Generally, when repeating the treatment as such for about 3–5 times, the pain level can be reduced to 20–30%

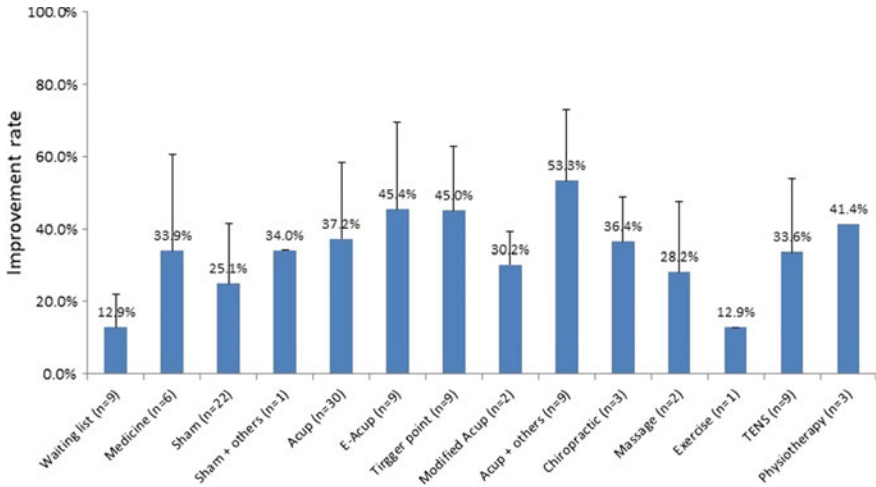


Fig. 10 Improvement rate of neck and low back pain by various modalities (Data from Furlan D review, western group)

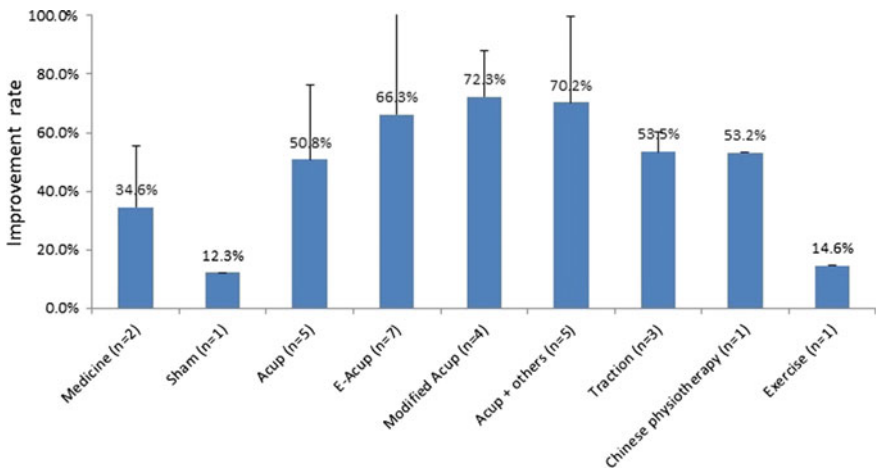


Fig. 11 Improvement rate of neck and low back pain by various modalities (Data from China)

of the initial pain level. After that, the treatment can be shifted to once every two to three days, until the pain subsides completely. After that, a maintenance course (acupuncture once per week for 3–4 weeks) is still necessary. An improvement of a chronic disease is not impossible through acupuncture using this treatment schedule. In the treatment of musculoskeletal pain, for example, the patients can gain a satisfactory efficacy so that they no longer need physical exercise or ice patch use on the painful spot at all. Since the pain can be reduced within 7–10 days, the patients

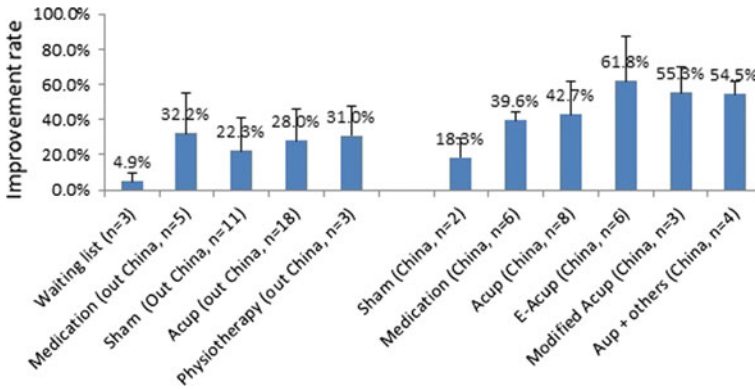


Fig. 12 Migraine and tension headache pain reduction in and out of China. n = number of published articles

usually stop the use of painkiller and have no need to visit their family doctors for the same problem.

Streitberger et al. (2003) treated nausea after chemotherapy on breast cancer patients. They performed acupuncture once a day for two days. The nausea rate in the acupuncture group and the sham group is 61% and 64%, respectively, with no significant differences. Shen (2000) also performed acupuncture on breast cancer patients after chemotherapy. The acupuncture, together with electrical stimulation, was performed on the patients once a day for 5 days. The number of the days with nausea was only 5 days in the acupuncture group, comparing to 10 days in the sham group and 15 days in the no-treatment group.

Meng et al. (2012) reported that when treating cancer patients with acupuncture three times a week for 6 weeks, the incidence of dry mouth in acupuncture group a month after stopping treatment is 25%, while that in the sham group is 90%, suggesting that high treatment frequency can yield dramatically prevent effects of dry mouth in cancer patient after chemotherapy.

In the treatment of hot flashes, Vincent (2007) used acupuncture once every two weeks for 5 weeks. The incidence of hot flash in the acupuncture group and the sham group has no significant difference. However, Huang (2006) also treated hot flash with acupuncture, but twice a week for two weeks, then once a week for the following 5 weeks. After 7 weeks of such treatment, hot flashes were reduced significantly in the acupuncture group compared to the sham group.

In the treatment of chronic low back pain, Ceccherelli et al. (2003) used acupuncture, five sessions per week for a pain reduction rate of 68.7%. When the acupuncture was performed 10 times a week, the pain reduction rate was 86.7%.

Acupuncturists in China have conducted more studies on the influence of treatment frequency on the healing effect of acupuncture treatment.

Qi et al. (2004) suspected the possible relationship between the low treatment frequency and the low healing effect of acupuncture treatment in western countries.

They treated 33 cases of stroke patients with acupuncture five times a week (first treatment group), 32 cases twice a week (second treatment group), and another 30 cases with conventional western medicine (medicine group), all for three weeks. After three months, they found that the Barthel scale reduced by 70.5% in the first treatment group, 31.5% in the second treatment group, and only 26.1% in the medicine group.

Li et al. (2015) treated 30 cases of slight cognitive disorder with acupuncture. They found that acupuncture once a day, 5 days a week for 3 weeks, yielded better results than that of 3 times a week for 5 weeks.

Xu et al. (2006) tested how acupuncture treatment once a day (treatment group A, 32 cases) or twice a day (treatment group B, 35 cases) would influence the healing effect of acupuncture treatment on functional recovery (using fugl-Meyer scale and ADL scale) of the arms or legs of post-stroke patients. They found that after two courses, treatment group B showed more improved functional recovery than treatment group A. They summarized that twice a day of acupuncture works better than once a day of acupuncture in these patients.

When using acupuncture for quitting smoking, acupuncture should be every day for 7–10 days. This method can reduce cigarette smoking from more than 20 cigarettes per day down to 0–1 per day. Acupuncture once a week for 7–10 weeks has no effect on the amount of daily cigarette smoking. Therefore when checking published studies on quitting smoking through acupuncture, the poor result may be due to a low treatment frequency.

There are data (Bian and Zhang 2003) showing that the half-life period of acupuncture treatment is 3–6 h. So, to increase the stimulating dose of acupuncture, one must increase the acupuncture session frequency. This opinion is supported by Xing et al. (1993) The author found that to treat post-stroke syndrome, acupuncture three times per day works better than once a day. For the same type of disease, Jiao (2008) reported that acupuncture twice a day with a retention time of 30 min works better than that of once a day with a retention time of 6 h. This suggests that frequency of acupuncture treatment is more important than the length of retention time.

Zhang (2014) believed that acupuncture treatment needs an interval between each session. For some acute diseases, such as acute laryngopharyngitis, acute conjunctivitis, or acute appendicitis, acupuncture can be performed twice to three times per day. For chronic diseases, it can be performed once a day, with 7-days as a healing course and a 2–3 day break between each course. The author noticed that in the treatment of some chronic diseases, such as post-stroke hemiplegia and facial paralysis, the healing effect usually is not apparent during the treatment, but it is if there is an interval between the healing courses.

Yuan et al. (2009) compared the healing effect of acupuncture twice a week for five weeks to that of five times a week for two weeks. There was no difference found between the 2-session group and the 5-session group. However, they used moxibustion and cupping together with the acupuncture. It was a comprehensive treatment, not acupuncture alone. This suggests that with the combination of other therapies, similar to a real clinic situation, the acupuncture treatment can be performed twice a week. However, the healing effect in the 5-session group is better than the 2-session group in the treatment of severe cases. Moreover, the healing effect in the 2-session

group has no improvement in the following weeks, but the treatment in the 5-session group may have further improvement if treatment was continued. This possible means that after five weeks, the healing effect in the 5-session group might be better than that of the 2-session group.

Current data show that different diseases need different treatment frequencies. Even for a given disease, the interval of acupuncture sessions might also be different between the acute and chronic phases of the diseases (Xu et al. 2006; Bian and Zhang 2003; Xing et al. 1993; Lin et al. 2013; Yu and Sheng 2015; Hu et al. 1995; Cai 2003). It has been reported that for the treatment of chronic fatigue after stroke (Lin et al. 2013), cervical spondylopathy (Wu et al. 2010), peripheral facial paralysis (Yang 2013), Bell's palsy (Cheng et al. 2009), three times a week of acupuncture (or once every other day) achieves the highest healing effect. Increasing the treatment frequency to once a day does not further increase the healing effect. However, these data still recommend three times of acupuncture sessions per week for the treatment. It is very rare for Chinese acupuncturists to perform acupuncture only once a week.

2.14.4 Healing Effect in High Frequency Treatment

Now a new question arises whether a placebo effect in a sham acupuncture group might be also higher with a higher treatment frequency of acupuncture.

It is not easy to answer this question with current data. Currently, it is hard to find an acupuncture study in western groups that perform acupuncture as 5–6 times per week for 10–20 sessions. On the other hand, acupuncture studies in China normally do not involve a sham group.

There are 27 articles on this topic (Cheng and Kang 2007; Dibble et al. 2000; Li and Yu 2002; Xu and Zhang 2015; Alfredo et al. 2012; Fukuda et al. 2015; Cheing et al. 2002; Hagstroem et al. 2009; Lazovic et al. 2014; Mollasadeghi et al. 2013; Warke et al. 2006; Li et al. 2012; Foroughipour et al. 2014; Zizic et al. 1995; Yeung et al. 2011; Zhan et al. 2015; Yu et al. 2001; Fan et al. 2005; Hollisaz 2006; Yeung et al. 2009; Zhang et al. 2013; Yao et al. 2012; Wang et al. 2015; Guo 2014). Among these articles, 15 were from western countries, and 12 from China. For a better analysis and reliable conclusion, we excluded the following studies: the studies is a thesis work of Ph.d. or master students; studies on animal or on healthy person; studies used grade parameters as a mark for healing effect; studies used continuous parameter as mark but the parameter is increased at the end of the study, and the studies that used acupuncture and other therapies at the same time (Liu 2013; Lu et al. 2009; Liao et al. 2015).

Figure 13 showed that with acupuncture or electroacupuncture for three sessions per week (middle frequency schedule) or five or six sessions per week (high frequency schedule), the healing effect of the sham group is only 17–20%. The healing effect of the inserted and the non-inserted sham groups (see below) were the same. For the inserted sham group, one article was from a western country, one from Taiwan, one from Hong Kong, and 6 from mainland China. For the non-inserted sham group, two articles were from western countries, three from Hong Kong, and three from mainland

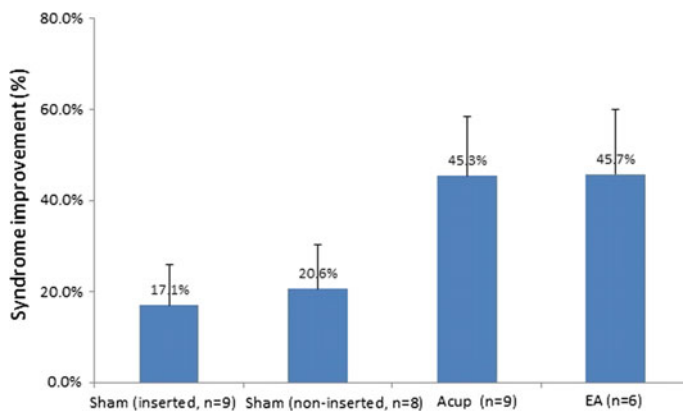


Fig. 13 Healing effect in Acupuncture and Electrical acupuncture, sham acupuncture groups with middle and high treatment frequency. n = number of published articles. EA: electroacupuncture

China. With the same treatment schedules, the healing effect of both the acupuncture group and the electrical acupuncture group reached 45%, which is much higher than both the sham groups. Clearly, with higher treatment frequency, the healing effect of the acupuncture groups was significantly higher than that of the sham groups.

It was also found that for the healing effect of TENS or laser at the middle or high treatment frequencies (Fig. 14), the healing effect of either the TENS or laser treatment seems less than that with higher treatment frequencies (5–6 sessions per week). (44.1% vs. 56.3%). Again, the healing effect of the sham TENS or the sham laser groups remained at low levels, i.e., 13–18%. There are major differences between the TENS or laser group, and sham groups. In these studies, all of the sham groups were non-inserted sham groups and the needles were not connected with either electric or laser energy. Among these studies 7 articles were from western countries, 2 from Hong Kong, and another 2 from the Mainland of China.

These data strongly suggest that the healing effect of acupuncture, electrical acupuncture, TENS or laser treatment is higher with higher treatment frequencies, while that of sham groups (inserted or not inserted sham group) remained low. This also suggests that the higher frequency of treatment schedules may not have enhanced the placebo effect in sham groups.

2.15 Proper Time to Start Acupuncture Treatment

When to start acupuncture treatment is a practical question. Generally speaking, for the treatment of chronic diseases, acupuncture can be started anytime. However, for paroxysmal diseases, such as paroxysmal hemicrania, or for periodic diseases, such as lower abdominal pain before menstruation, the time to start acupuncture is a

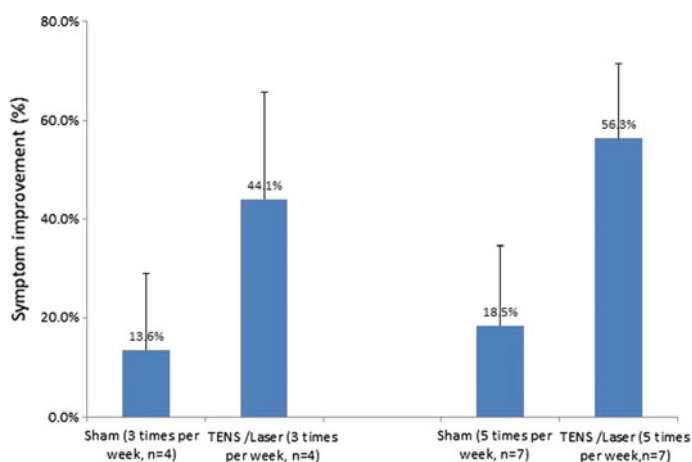


Fig. 14 Treatment by TENS or laser at three sessions per week or five sessions per week. n = number of published articles

question that needs to be discussed. For the treatment of these diseases, we normally start the acupuncture 2–3 days before the onset of diseases (once a day), rather than start the acupuncture after the onset.

For example, in the treatment of dysmenorrhea, acupuncture can be applied for 3 days before the menstruation, once a day for three to four days, or until the pain completely disappears. Usually it needs only 1–2 days or 4 days in a rare case before the pain subside. After that, acupuncture can be performed once or twice a week until the next period. This is one treatment course. This treatment plan can be repeated for 2–3 months. The level of the pain can be dramatically reduced or even disappear completely. The studies by Ma et al. (2013), Du et al. (2012), Cai (2012) support this schedule. This treatment plan is also suitable for the treatment of infertility, where the acupuncture should be started 3 days before ovulation day.

Zhang and Song (1994) reported their methods of treating acute stages of cerebral infarction plus cognitive dysfunction. They found that acupuncture started within 7 days of the infarction (20 cases) works better than acupuncture started after 7–30 days of the infarction (20 cases).

Acupuncturists in China have had many studies on the treatment of cerebral infarction (Zhang et al. 2013; Wang et al. 2009; Qing et al. 2015; Fan et al. 2005; Li and Huang 2001; Liu et al. 2010; Wang and Cai 2015; Liu et al. 2015; Zhang et al. 1998; Xu 2015; Qian et al. 2015; Hu et al. 2013). Indeed, acupuncture works in both acute and chronic phases of stroke. For the treatment of acute cerebral infarction or cerebral hemorrhage, the healing effect is the highest if acupuncture started within 72 h of onset (Du et al. 2012). In our laboratory studies with experimental stroke models, we also found that electroacupuncture is effective to induce neuroprotection against ischemic brain infarction (Fig. 15) and reduce neural defects and the EA-induced neuroprotection is better when applying before and immediately after the onset of

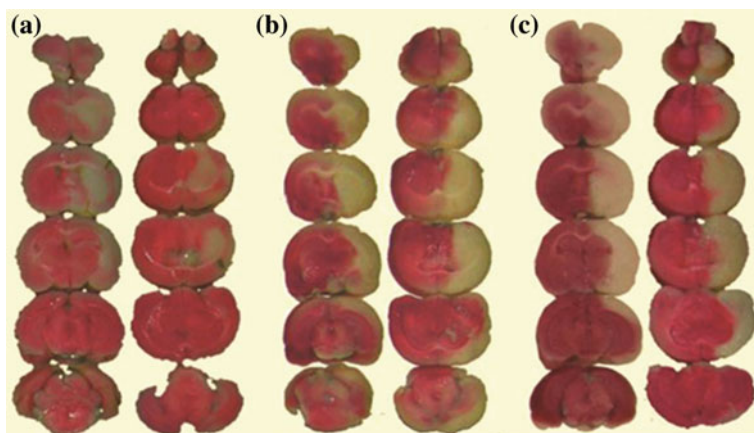


Fig. 15 Effect of electroacupuncture on ischemic infarction. Electroacupuncture was applied at different acupoints starting at 5 min after the onset of cerebral ischemia (MCAO). **a** Stimulation at contralateral QuChi (LI11) and NeiGuan (PC6). **b** Stimulation at ipsilateral QuChi (LI11) and NeiGuan (PC6). **c** Stimulation at contralateral SanYinJiao (SP6) and YangLingQuan (GB34). Note that the stimulation of suitable acupoints (contralateral QuChi and NeiGuan) greatly reduced ischemic brain infarction. Cited from Zhou et al. (2013)

ischemic stress (Zhang et al. 2013; Wang et al. 2009; Zhou et al. 2011; Zhou 2013; Xia 2015). Clearly, timing/applying windows is a determining factor for the healing effect of acupuncture.

2.16 Evaluation of Long Term Healing Effect

How long the healing effect of acupuncture treatment can last is one of the topics in many acupuncture studies in western countries. However, there is little reliable information in the literature to demonstrate the long term healing effect, i.e., from the beginning to the end (symptom relief and/or disappearance).

Most researchers counted the change of the post-treatment healing effect after several sessions of acupuncture treatment. For example, patients were given acupuncture treatment for 2, 3 or 6 months. The treatment stops and then observe the healing effect is observed for one year (Zhang 2014; Avis et al. 2016; Hervik and Mjåland 2009). The researchers measured the healing effect for all the patients as a group. It can be expected that in the group, the symptoms of some patients were possibly much improved, but the symptoms for other patients were not much improved yet. Some researchers even tested the cure rate of open wounds after only one time of acupuncture treatment (Saarto et al. 2010). It is too optimistic for acupuncture to have only a one-time treatment.

Bokmand and Flyger (2013) treated dysmenorrhea with acupuncture for 3 months. The time period of pain period was reduced from 53.8 to 31.5 h. In this particular study, although the pain level is still severe, the authors ended the acupuncture treatment to observe the long term healing effects after acupuncture treatment. The acupuncturists in China usually pursue no or minimal pain as their therapeutic goal.

Sánchez-Araujo and Puchi (2011) tested if acupuncture prevents relapses of recurrent otitis in dogs. The dogs were given acupuncture treatments once every three days, for a total 4 times (without manipulation of needles). They observed the recurrent rate from this treatment schedule. The success rate would be low if the otitis was not improved dramatically after the end of the acupuncture treatment.

Acupuncture is not a miracle cure. If the symptom has not been reduced to zero or to a very mild level, the chance for the relapse is very high, especially if the factors that caused the symptom were not removed or eliminated completely. For example, for knee pain due to prolonged bending of the knee from an occupation (such as in professions that repair floors), the long term healing effect is poor, even if acupuncture reduced the knee pain to zero. This is because patient continues the daily stress on the knees after acupuncture treatment.

Acupuncturists should also ask clients to change their life style or work style that cause these diseases to eliminate the factors that cause them. This is how the disease can be really “cured”. Otherwise, there is no other cure for knee pain for these patients. Therefore, it is meaningless to evaluate long term healing effects of acupuncture when the symptom has not been reduced to very low level and the patients are unable to eliminate factors that cause the symptoms.

2.17 Complementary Treatment

When treating many kinds of diseases, patients are asked to take a break from heavy labor or stressful work. Especially for the treatment of painful diseases, patients need to reduce or stop physical exercise, and not use ice on painful locations. This is to reduce the chance of causing more damage to the tissue. Pain is a signal of the body that something needs to be changed, rather than continued. However, in many articles, it is not mentioned whether the researchers asked patients to stop physical activity and the use of ice, which are both very common in physical therapy and in chiropractic treatments.

It is very common for clients to continue exercise and the use of ice on painful spots if we do not emphasize not to. Long term or frequent use of ice can reduce blood circulation on the affected area and cause accumulation of metabolic waste material in the tissue, and slow down the repair of the painful spot. Therefore, Chinese medicine mostly recommends the use of a hot/warm patch. The only condition in which an ice patch is used is for sprains (on knees or ankles, for instance). In this case, the ice patch would only be applied once, for no more than 20 min.

2.18 Suitable and Non-suitable Diseases for Acupuncture Treatment

Acupuncture may work for some diseases, but not for all diseases. For example, acupuncture may not work well for fibromyalgia. A survey (Du et al. 2007) showed that among total 3576 studies on the disease of muscle-bone and connective tissue, there were only 13 studies related to the treatment of fibromyalgia, which is only 0.4% of all of the 3576 publications. The low numbers of the literatures in some way also reflects the poor healing efficacy of the acupuncture on the treatment of fibromyalgia. This is true that in China, a negative study cannot be easily published. Acupuncturists in China are seeking for more effective ways of acupuncture treatment.

To meet the needs of acupuncture clinics and research, WHO held a meeting in Milan in 1996, where 64 kinds of diseases/disorders were proposed as the suitable categories for acupuncture treatment (<http://www.wfas.org.cn/who/files/2008>). The meeting stated:

(1) Diseases that are claimed as suitable to acupuncture treatment, supported by randomization studies:

Alcoholism, allergic nasitis, competitive syndrome, facial paralysis, cholecystalgia, asthma, heart neurosis, cervical spondylosis, chronic pain in motor system, depression, quit drugs, dysmenorrhea, headache, hemiplegic paralysis or other post-stroke syndromes, herpes zoster, hypertension, primary hypotension, impotency, induction, insomnia, hypoleucocytosis, low back pain, migraine, reaction of pregnancy, nausea or vomiting, peri-arthritis of shoulder, post-operative pain, premenstrual tension, nerve root pain syndrome, renal colic, arthritis pauperum, sprain or strain, dysfunction of mandibular joint, tension headache, quit smoking, trigeminal neuralgia, and urinary stones.

(2) Diseases that are claimed to be suitable for the acupuncture treatment by studies with sufficient numbers of participants, but no randomized study design:

Acute paristhmitis, acute pharyngolaryngitis, back pain, ascariasis of biliary tract, chronic pharyngitis, malposition, infantile enuresis, tennis elbow, gallstones, irritable bowel syndrome, Ménière's disease, myofascitis, children myopia, simple obesity, pain after amygdalectomy, chronic dementia, sciatica.

(3) Diseases suitable for acupuncture treatment by repeated clinic studies for a faster healing effect than conventional medicine, or there is some experimental evidence:

Constipation, hypogalactia, diarrhea, infertility, bathygastry, hiccup, urinary incontinence, painless labor, retention of urine, nasosinusitis.

According to a survey (Huang et al. 2013) in 2013 of acupuncturists in the Jiangsu province of China, the most suitable diseases for acupuncture treatment are:

Facial paralysis, stroke, low back pain, headache, neck pain, stiffness of shoulder, insomnia, stomach pain, herpes zoster, and various knee pains.

Other data (Yang et al. 2014) suggest that the suitable diseases for acupuncture treatment are:

(1) Digestive diseases: hiccups, stomach pain, diarrhea, constipation, nausea, intestinal pseudo-obstruction and hemorrhoids.

(2) Skin diseases: acne, urticaria chronica, neurodermitis. Most possible effective diseases: chloasma, corn, cutaneous pruritus. Possibly effective: pelada, eczema, psoriasis, leucoderma, bedsore.

(3) Psychiatric and behavior disorder: dementia, abstinence syndrome, mental retardation, obsession, dyssomnia, gastrointestinal neurosis, depression, alcoholism, and globus hystericus.

The category of dominant diseases for acupuncture treatment is not unchanged. Along with the efforts of acupuncturists in China, the category and the suitable spectrum for acupuncture treatment are growing. On the other side, if an acupuncturist gets just only hundreds of hours of acupuncture training and practices acupuncture according to what they learned from a textbook and only practice acupuncture on two to three patients per day, the acupuncturist may not be able to treat these diseases well, even if the acupuncturist has practiced for more than ten years. This is especially true if he/she has never treated the disease before. In this point, the so-called dominant diseases for other acupuncturists may not be the dominant disease for this given acupuncturist. Therefore, a good conceptual knowledge of acupuncture may not be sufficient to render one to become an acupuncture expert. Practice to gain sufficient experience is critical for an acupuncture expert. This is also true for a successful clinical study on acupuncture treatment.

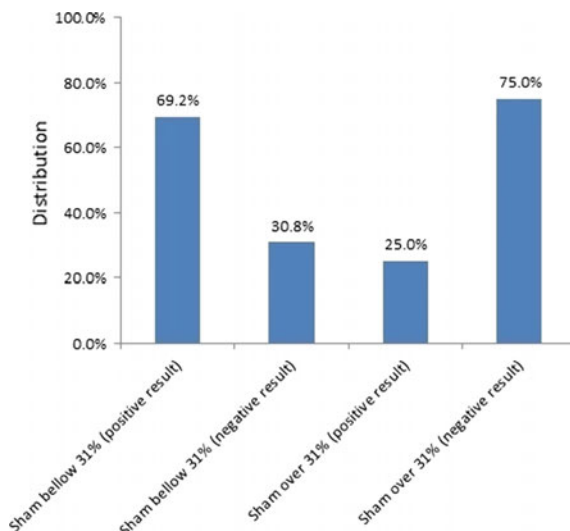
3 Sham Acupuncture Group

The susceptibility to a hint (placebo) is largely variable. The responder rate (the percentage of people who received more than 50% of symptom reduction) can be 31–45% (Peciña et al. 2015). It can be expected that the higher the responder rate is in acupuncture study (especially in sham group), the higher the healing effect of the sham group (e.g. the higher placebo effect in the sham group) would be. From the literature, the healing effect in inserted sham groups is from 2.6 to 59.1%, and that in non-inserted sham groups is from –3.8 to 55.6%, suggesting that the responder rate among studies is indeed largely variable.

We have tried to see how the level of the healing effect in a sham group relates to the final result (support or deny) acupuncture's specific healing effect. We collected data from the reviews by Colquhoun and Novella (2013), Colquhoun and Steven (2015), Linde (2009a, b), Melchart et al. (2005), Haake et al. (2007), Witt et al. (2005), and Cherkin et al. (2009). We found that (Fig. 16) when the healing effect from a sham group is more than 31, 75% of articles showed negative results. On the other hand, if the healing effect of a sham group is less than 31, 69.2% articles showed positive results supporting the specific healing effect of acupuncture. Evidently, the level of the healing effect in a sham group strongly affects the result of an acupuncture study.

The sham groups can be classified into two major categories: inserted (Smith et al. 2011; Shen et al. 2000; Wyon et al. 2004), and non-inserted (Park et al. 1999; Streit-

Fig. 16 Distribution of positive or negative results about acupuncture healing effects separating the distribution with sham effectiveness as 31%



berger and Kleinhenz 1998; Takakura et al. 2014; Zhang et al. 2015; Takayama et al. 2015). Inserted means an acupuncture needle is inserted into either acupuncture point (in shallow or in deep), or in a spot that normally does not belong to an acupuncture point (non-point). Non-inserted means a blunt needle is used on acupuncture point or on a non-point without pene the needle into the skin. Alternatively, non-inserted could mean the blunted needle is connected to an electric machine but no electricity is conducted (White et al. 2004; Vas et al. 2006), or the acupuncture point was touched by a laser probe, but no laser is emitted (Irnich et al. 2001).

We have tried to compare the placebo effect from the inserted and non-inserted sham groups, using the data from review papers of Colquhoun and Novella (2013), Furlan et al. (2010), Linde et al. (2009a, b), Madsen (2009), Vickers (2012), Azad and John (2013), Moffet (2009), and other sources (Qing et al. 2015; Cheng et al. 2009a, b; Xu and Zhang 2015; Alfredo et al. 2012; Fukuda et al. 2015; Cheing et al. 2002; Hagstroem et al. 2009; Mollasadeghi et al. 2013; Warke et al. 2006; Deng et al. 2008; Bennell et al. 2005; Cheing et al. 2003; Cheing and Hui-Chan 1999; Hawamdeh et al. 2015; Al Rashoud et al. 2014; DeSantana JM et al. 2008; Fleckenstein et al. 2009; Hopwood et al. 2008).

It was found that the sham groups showed around the same average effect level, regardless of insertion. The placebo effect of the inserted sham group was $23.0 \pm 14.7\%$ (32 published articles) and that of non-inserted sham was $22.9 \pm 16.7\%$ (35 published articles).

Yeung et al. (2011) compared the healing effect of inserted sham and non-inserted sham in the treatment of insomnia. The treatment is three times a week for a total of three weeks. The effect of non-inserted sham is 12.8% and that of inserted sham is 24.8%. The difference is very small, and both are at low levels. This result suggests that inserting a needle on a non-point without handling the needle to cause

acupuncture sensations may induce some level of healing effect, but the effect is very limited. The difference in the healing effect between the inserted and non-inserted sham groups may not be detectable with a pool of further studies for review.

This result suggests that the types of sham methods are not the major reason to cause the variation in the healing effects in a sham group, but that of original responder rate might be. It also suggests that perhaps the insignificant difference in healing effect between the acupuncture group and the sham group is not due to the use of an inserted sham group, but to a poor healing effect in the acupuncture group.

The variation in a population's susceptibility to a hint stimulation (placebo stimulation), e.g., the response rate in a population, is a reality. Such variation in the response rate to a hint is a background noise to all medical clinical studies, not only to acupuncture research. Since a clinical study aims to determine if acupuncture has a specific healing effect, the placebo effect in the study should be eliminated.

Currently, many acupuncture studies include a sham group and an acupuncture group. The specific healing effect of acupuncture group was determined as the difference between the total healing effect in the acupuncture group and the sham groups. This way may not be sensitive enough to detect a specific healing effect of acupuncture group. This is because the healing effect level of the sham group (the placebo effect) is largely variable among people due to personal susceptibility, and there are too many factors that can affect the level of the placebo effect in a sham group.

We may recommend eliminating the placebo effect in a clinical study by involving a wash-up phase: giving all the participants a sham treatment for some time, before starting the real treatment phase. This eliminates participants who had their symptoms reduced by more than 30% (instead of 50%). The disadvantage of this is that it will need higher numbers of participants initially, but the advantage is that it should be able to increase the chance (sensitivity) to detect the specific healing effect of acupuncture in real acupuncture groups.

Alternatively, we may recommend using the Chinese high treatment frequency, e.g. to have acupuncture once a day for 5 to 6 days per week, and for a total of 20 to 30 sessions (depending on the type of disease). As we have introduced before, upon such a treatment schedule, the healing effect of the acupuncture group tend to be higher, while that of sham group remained the same. With this high treatment schedule, it appears that there is no need to have the pre-wash up phase to eliminate the susceptible people out of the study.

4 The Ability of an Acupuncturist

Unlike pharmaceutical research in western medicine, which does not involve doctor's personal skill, any study involving personal skill, such as acupuncture, massage, chiropractic, physiotherapy (if it is manual therapy), as well as a surgery, needs to choose the highest level of practitioners to conduct the relevant part of the study.

In the review of the acupuncture studies in western countries, the impression was that anyone may act as an "acupuncturist" in the study. Some physiotherapists, chi-

ropractic, or physicians can receive an acupuncture license after taking acupuncture training courses. For example, a physician could have an acupuncture certificate after 140 h of training, and would be allowed to participate in an acupuncture study (Linde et al. 2009a, b; Haake et al. 2007; Witt et al. 2005; Brinkhaus et al. 2006; Diener et al. 2006; Endres et al. 2007; Witt et al. 2006). Sometimes, even newly graduated students can participate in the research (Joos et al. 2006; McKee et al. 2013).

Those practitioners may feel very confident to participate in an acupuncture study. They might think that they are qualified to do so if they choose the same acupuncture point(s) used by other researchers in other studies. They might believe that the outcome of the study is to the credit of the acupuncture per se, and the success or failure of the study has nothing to do with their own personal skill. However, the personal skill of acupuncture performance could greatly affect the outcome.

The ability of acupuncturists in China who participate in acupuncture studies is ensured by their published articles. Their articles would not be accepted for publication if their studies cannot improve the healing effect of current acupuncture techniques, or if their work does not allow a better understanding of acupuncture mechanisms, or any other aspect of acupuncture. However, any study on acupuncture can be published in western countries if the study meets the need of some basic requirements for the publication, such as randomization, blindness, a sham group, a waiting group, over 20–30 patients in each group, and statistical analysis of the data.

The ability of an acupuncturist is not determined by the years of that person's acupuncture license, or where the person received acupuncture training. These should not be the absolute parameters that dictate the skill of an acupuncturist. We believe that if we do not pay attention to the actual skills of an acupuncturist, no acupuncture studies, no matter the design, would ensure to reach the truth.

White et al. (2012) studied acupuncture for the treatment of osteoarthritic pain. The study involved three acupuncturists. The healing effects of the three practitioners are 37, 17, and 62%. Though it was explained by the author that the highest healing effect by the third acupuncturist might be due to his impression by patients as more professional and more like an expert, it cannot exclude that his personal skill in acupuncture might be the highest. No matter what could be the reason, the huge difference in healing effects by the three acupuncturists will affect the data analysis for sure. It is possible that to compare the healing effect by the third acupuncturist with sham acupuncture, it would show a statistically significant difference (such as 63% vs. 28.4%, or 63% vs. 39.2%, as shown in the authors' paper), rather than no difference as reported.

Forbes et al. (2005) reported in their acupuncture study that when Acupuncturist A treated 12 patients with IBS, 50% patients had the symptom level reduced by 4. Acupuncturist B treated 15 IBS patients, and 33.3% of patients had the symptom level reduced by 4. The authors might combine the data from the two acupuncturists together. Their conclusion on the study may be questionable.

Another example is from the report of Deng et al. (2007) for the treatment of hot flashes with acupuncture. During the study, the acupuncturist was changed and the reduction curve of the hot flashes reversed up. They had acupuncture twice a week

for 4 weeks. The hot flashes reduced by about 30–35%, similar to that in the sham group. So, healing clearly depends on the acupuncturist.

If the personal skills among several acupuncture operators are so different, how can we trust the study involving 67 physiotherapists, (Foster et al. 2007) 122 physicians (Brinkhaus et al. 2006), or 320–340 physicians? (Peciña et al. 2015; Scharf et al. 2006).

Fregni et al. (2010) pointed out that in an international placebo symposium working group, “a great number of interventions used in PRM depend on the technician’s or clinician’s skills such as the application of acupuncture, injections, and nerve blocks. Therefore, controlling for these interventions becomes difficult with this important source of variability. This makes it even more difficult to design an appropriate placebo in these situations. To control for skills and levels of experience, it would be necessary to conduct multicentric studies with various levels of skills and experiences and perform multivariate analyses to adjust for these variables. In this scenario, a large number of patients would be necessary, increasing the difficulties to conduct such studies.”

Hawk et al. (2005) reposted their chiropractic study on chronic pelvic pain. The study involved 3 clinic locations. After 6 weeks of chiropractic treatment, the pain level reduced by 59.1, 26.9, 84.6%, in the three locations, respectively, with an average of 56.6%, while the reduction rate in the sham group is 68.5%. The healing effect of the treatment group is even less than that of the sham group. The practitioners in the 3 clinic locations were reported to have 20, 10, and 12 respective years of clinic experience. Having no alternative, the author had to admit that “The technical and personnel resources required to achieve adequate standardization of procedures at multiple sites may make a placebo-controlled trial unfeasible, given our current lack of knowledge about the active agent in manual chiropractic procedures. It might be more efficient to reverse the traditional order of experimentation used for pharmaceuticals, which begins with safety, proceeds to efficacy and finally to effectiveness. Because chiropractic—a CAM profession using manual methods for more than 100 years—can scarcely be considered in the same category as a newly developed medication, it might be reasonable to first investigate effectiveness. If chiropractic care that is provided by experienced chiropractors who are allowed to use their best clinical judgment of how to apply the procedures is documented in such studies to improve patient outcomes compared to standard medical care alone, more in-depth and controlled studies would then be warranted to identify specific aspects of that *gestalt* of care that are most responsible for the outcomes or if there are certain subpopulations of patients who benefit most from them.”

To reduce variations in acupuncture studies in personal clinic skills, we recommend a selection process for the candidates of acupuncturists.

Basic selection: the acupuncturist should have a comprehensive healing effect for most of the diseases in his/her clinic, as high as 75% (within one to two months). The comprehensive therapies include the use of acupuncture, cupping, moxibustion, bleeding therapy or whatever commonly used therapies in his/her acupuncture clinic. It should not be difficult to find such acupuncturists.

Specific selection: the acupuncturist should have at least 75% of the average healing effect (as published data from China, for example) for the disease/symptom to be studied. Moreover, only the acupuncture therapy, not other therapies, such as cupping or moxibustion, is used in a pilot study. The average healing effect of acupuncture is different for different disease/symptom. For example, if an average healing effect for non-specific lower back pain in China is average of 55%, the healing effect of the candidate acupuncturist in the western countries for the same types of pain should be more than 41% ($55\% \times 75\% = 41\%$). If the candidate acupuncturist cannot reach such level in acupuncture treatment, he/she should not be regarded as “qualified” acupuncturist in an acupuncture study.

The reason for the comprehensive basic selection is that if the acupuncturist cannot reach such levels of comprehensive healing effects with their own natural and practical ways of acupuncture treatment, it would be impossible for them to create a positive result in a western style of acupuncture study in which only acupuncture is allowed, while moxibustion, cupping, or any other kind of therapies, are not. There is no point in creating significant amounts of negative data through untrustworthy ways of studies.

The reason for the special selection is that even if the acupuncturist passes the basic selection, it still does not guarantee that the acupuncturist is able to treat the disease to be studied. For example, if an acupuncturist never treated coma patients (due to stroke), it would be hard to believe that the acupuncturist can treat such patients in a study. The specific selection allows the study to use an acupuncturist that has experience with the specific disease to be treated.

If there is no acupuncturist that can pass the specific selection, it means that the conditions for an acupuncture study are not met. The study should not be started, similar to how a surgeon should not perform a craniotomy without anesthesia.

5 Suggestions for Acupuncture Studies

Evidently, the study of acupuncture is more complex and difficult than a drug clinical study. For a drug, its concentration or content can be easily standardized. The same tablet can be used at the same time to thousands of participants. Even sham pills or sham tablets can be produced in the exact same shape, color, and same size as the true pills or tablets. It is hard for participants to recognize the difference between taking a true or sham pill.

However in acupuncture studies, the effect of acupuncture treatments can be affected by improper selection and number of the acupuncture points, insufficient stimulation doses in each session, poor treatment frequency, not enough numbers of treatment sessions, and more. It is also hard to standardize the personal skill in acupuncture treatment among practitioners, even if the same acupuncture treatment procedures are requested to be followed since the stimulation of acupuncture in each session is also hardly the same for the same acupuncturist. The sham acupuncture process is also hard to standardize as blind to the participants. Additionally, the sham

acupuncture procedure (inserted or not), may have enhanced placebo effects compared to sham pills (Thomas et al. 1991). All of these factors make the acupuncture studies easy to fail.

Based on our discussion above, we recommend acupuncture studies to pay attention to the following:

5.1 Wash-Out Phase

There should be a wash-out phase.

Give all patients a sham treatment for 3–4 weeks with the same treatment frequency as in the true study phase. It is better to have the sham acupuncture once a day, 5 days per week, for 3–4 week (Knipschild et al. 1991; Pablos-Méndez et al. 1998; Dutilleul et al. 2014; Ramsay 1997; Trial Designs 2013; Lembo et al. 2009). After the sham period, exclude the patients who had symptoms reduced by more than 30%. These patients are excluded from the latter study because they belong to placebo-sensitive patients and they are not good candidates to test the healing effect of any therapy (inducing new drugs, surgery, chiropractic, or physiotherapy, etc.).

Patients that did not have more than a 30% reduction in their symptoms can be treated with true or sham acupuncture in study phase (acupuncture phase).

5.2 No-Treatment Group

Depending on the aim of the study, this group may be omitted.

If the primary aim is to test whether the acupuncture group is better than a sham group, the no-treatment group can be omitted. However, if the aim is to know exactly how much of an effect of a placebo has in a sham group, the no-treatment group must be included. This is because the healing effect in a sham group is not only contributed by a possible placebo effect but also contributed by some other factors, such as natural turn-over, regression-to-normal. These latter two factors are the main reasons for the healing effect measured in a non-treatment group. The healing effect in a sham group, if any, cannot be credited to the placebo effect directly without exclusion as these latter effects.

5.3 Sham Group

The difference between true acupuncture and sham groups should be that there is acupuncture stimulation in the former but not at all in the latter. The acupuncture group be treated the same as one in a clinical environment, without the use of moxibustion, cupping, or other remedies.

Current data strongly suggest that the failure of acupuncture study is due to the poor healing effect in the acupuncture group, rather than the types of sham groups used. Therefore either inserted or non-inserted sham groups can be used under the condition that the acupuncture and the sham acupuncture are performed in higher treatment frequency, such as once a day, 5 days per week, for more than 20 sessions. The schedule can be variable depending on the disease to study. For example, for the treatment of post-operation nausea, the total number of treatment session may not need such high.

The advantage of the insert sham group (shallowly inserted needle on non-points or other-points) over non-inserted sham groups is that the procedure mimics the true acupuncture procedure. Even patients with previous experience in acupuncture can hardly tell if they are receiving a sham treatment, so there is no need to find acupuncture naive participants, or the need to blind the patient vigorously.

5.4 Acupuncture Group

This group only uses acupuncture, without moxibustion, cupping, bleeding therapy, massage, or Tuina. If the primary aim of the study is to test whether acupuncture works for a given kind of disease, the acupuncturist is allowed to select the basic acupoints or special acupoints, the number of the acupoints during each session, the frequency of the treatment, and length of each session. If the primary aim is to test whether one or more specific acupoints or specific acupuncture technique works for a given kind of disease, the above parameters should, of course, be fixed.

The acupuncture should be performed once a day, 5-6 days per week, for a total of 20–30 days (referring to the method used by acupuncturists in China). Allow the acupuncturists to keep the same way of communication with the patients as in an actual acupuncture clinic (Witt et al. 2006).

One of the characteristics of Chinese medicine (acupuncture or herbal therapy) is individual treatment (Jindal 2008). Traditional Chinese medicine regards patients individually. This is quite opposite to western medicine, which tends to standardize everything to all patients. Failure of many acupuncture studies may be due to a western medicine approach, by not allowing the change of a treatment plan based on each patient's condition. This could also be one of the reasons for a high fall-off rate in acupuncture studies in western countries. For example, if a patient cannot tolerate 10 needles each time, or cannot tolerate the intensity of the needle stimulation, but the acupuncturists insist to perform acupuncture treatment as for all the patients in the study group, the patient may escape from the study.

The stimulation of acupuncture in each session is also very important, but it is hard to standardize the stimulation dose to each session and among acupuncturists. We recommend using electrical acupuncture, or even better, the warm acupuncture, to standardize the intensity of stimulation from session to session and among large numbers of acupuncturists (especially in large scale acupuncture studies).

6 Conclusions and Perspectives

From our clinical experience and bench research, we believe that there are many factors that affect the outcome of acupuncture, whereas these factors are not well recognized by clinical and research community in the western countries. In fact, there is no standard protocol up to now for all acupuncturists to follow in the same way. The personal skill of acupuncturists greatly affects the outcomes of acupuncture. Therefore, clinical acupuncture study is easy to fail due to the disturbance by one or more influencing factors.

We recommend the acupuncturists in western countries to carefully check the methodology of acupuncture in China and use compatible methods in their practice and research since acupuncture origins from China with many acupuncture studies being done there. It is important to well consider all influencing factors, improve the design of research, make informative measurements with advanced approaches and adopt appropriate statistical analysis for reliable conclusions without bias (Asakawa and Xia 2012). It is our belief that significant improvements in the design and methodology of clinical acupuncture will eventually lead to better and more reliable outcomes.

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