Introducing a placebo needle into acupuncture research

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Summary

Background A problem acupuncture research has to face is the concept of a control group. If, in control groups, non-acupoint needling is done, physiological acupuncture effects are implied. Therefore the effects shown in this group are often close to those shown in the acupuncture group. In other trials, control groups have received obviously different treatments, such as transcutaneous electrical nervous stimulation or TENS-laser treatment; it is not clear if the effects of acupuncture are due only to the psychological effects of the treatment.

Methods We developed a placebo acupuncture needle, with which it should be possible to simulate an acupuncture procedure without penetrating the skin. In a cross-over experiment with 60 volunteers we tested whether needling with the placebo needle feels any different from real acupuncture.

Findings Of 60 volunteers, 54 felt a penetration with acupuncture (mean visual analogue scale [VAS] 13·4; SD 10·58) and 47 felt it with placebo (VAS 8·86; SD 10·55), 34 felt a dull pain sensation (DEQI) with acupuncture and 13 with placebo. None of the volunteers suspected that the needle may not have penetrated the skin.

Interpretation The placebo needle is sufficiently credible to be used in investigations of the effects of acupuncture.

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Introduction

Acupuncture has long been used in the treatment of pain, although proof of its effects is uncertain. Since no satisfactory placebo to acupuncture has previously been developed,[1–3] it has not been possible to differentiate the effects of the therapeutic setting from specific effects of acupuncture needling. To measure such effects, a placebo method of needling with the same psychological impact as actual needling is required. Comparison of acupuncture with other treatments or transdermal electric nervous stimulation are unsatisfactory as the setting is largely different from acupuncture. Pricking or scratching the skin with a blunt needle[4,5] can only be applied, blind, on the back. In most studies no attempt has been made to evaluate the credibility of the placebo used; psychological factors may be largely responsible for differences between groups.

A widely used placebo method is sham-acupuncture or comparison of the effects of needling indicated and non-indicated acupoints. Every penetration of a needle through the skin, be it at an acupuncture point or not, produces physiological effects. These are partly due to activation of a pain-suppressing system in the spinal cord, diffuse noxious inhibitory controls (DNIC),[6,7] which can be activated by stimuli such as ice massage,[8] heat,[9] and vibration.[10] Acupuncture has shown the same effect on the DNIC systems as thermal stimulation.[11] Needling at trigger points other than acupoints has remarkable physiological effects.[12,13]

With an effective placebo for acupuncture, patients should not be able to distinguish the placebo from the real penetration of a needle, and they should feel placebo penetration in the same therapeutic setting as in acupuncture. DEQI should be felt more often with acupuncture than with placebo. The same acupoints should be used with acupuncture and placebo and the skin should not be penetrated by a placebo treatment.

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Methods

Placebo needle

We designed a placebo needle. The needle is not fixed inside the copper handle. Its tip is blunt, and when it touches the skin a pricking sensation is felt by the patient, simulating the puncturing of the skin. The needle moves inside the handle, and appears to be shortened. To place the needle we used a plastic ring covered with plastic sheet (figure 1); a procedure we also used in real acupuncture to ensure the same treatment setting. In acupuncture the tip of the needle is sharp and is inserted into deeper tissue layers. This may cause a DEQI feeling. No differences between real and placebo acupuncture could be seen.

Protocols

29 women and 31 men volunteers, recruited from hospital staff, aged 21–40 years were included. None had acupuncture experience, they had no sign of disease, and felt healthy. People with acute or chronic pain, those taking analgesics or psychotropic drugs, and those with skin disease at the site of the acupoint, or who were pregnant were excluded. The study was approved by the Ethics Commission of the University of Heidelberg.

Volunteers were told that we were testing a new needle to see if it was more or less painful than a traditional needle. After randomisation by sealed envelopes, they were needled in a cross-over design with acupuncture and placebo at acupoint Hegu (large intestine 4). 30 volunteers were first punctured with real acupuncture, 30 others with the placebo needle. The point was disinfected with alcohol, then marked with the plastic ring which was covered with plastic sheet. After puncturing the plastic the needle was depressed; in the case of the real acupuncture approximately 0·5 cm through the skin, in the case of placebo acupuncture until the needle touched the skin, and the shortening of the needle appeared the same as in real acupuncture.

After 2 min the needles were removed and the volunteers were asked if they felt the needle penetrate the skin, if the penetration of the needle was painful on a visual analogue scale (VAS), and if

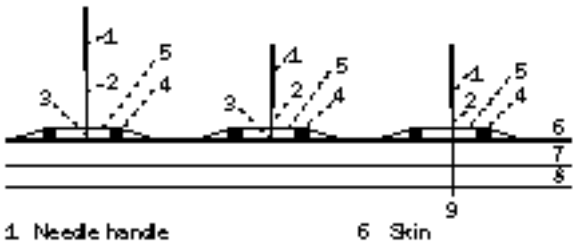

Figure 1: **Placebo needle**

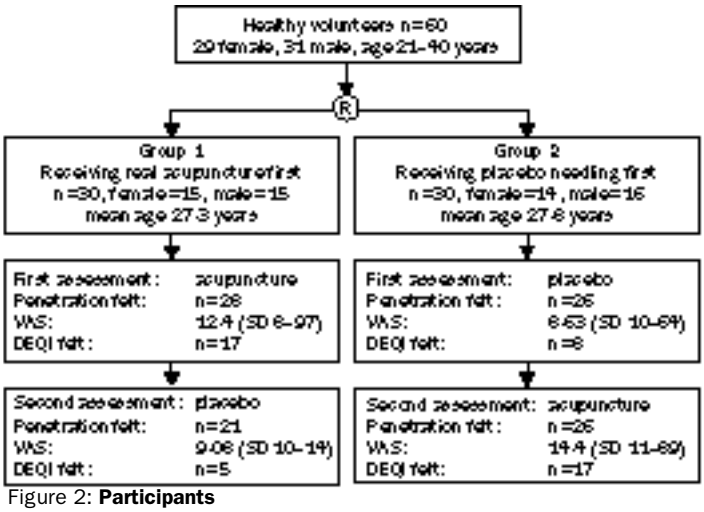

Figure 2: **Participants**

they felt a dull pain. Between 1 h and 1 week later, volunteers were tested with other methods.

Results

Distribution of sex and mean age did not differ between the two groups of 30 volunteers (figure 2). The penetration of the needle was felt by 54 of the volunteers in the acupuncture group and in 47 of the placebo group. Penetration through the skin was felt in both acupuncture and placebo needling by 42 volunteers. Five felt the penetration using placebo needling, but did not feel penetration in the case of acupuncture. Twelve volunteers felt penetration of acupuncture but not with placebo. One did not feel penetration with either. VAS ratings and differences between groups are shown in the table.

DEQI was felt by 11 volunteers with acupuncture and placebo needling. Two felt the DEQI with placebo needling, but did not feel DEQI with acupuncture. 23 felt DEQI with acupuncture but not with placebo, 24 did not feel DEQI with either.

Discussion

Acupuncture seems to be a little more painful than placebo needling. The difference in VAS between acupuncture and placebo is small (4·15) with a large SD (11·57) and a large range (0–51) showing the individual range of pain perception. The differences in the VAS rating between the two needles is too small to reveal which was the placebo.

Seven volunteers felt no penetration with the placebo after having felt it first with acupuncture; none suspected that the skin had not been punctured, and some said they would prefer the less painful needle used in acupuncture treatment. DEQI was felt by some volunteers with placebo needling, but in real acupuncture needling it was felt more often. DEQI in placebo needling could be caused by the pressure of the ring and plastic cover, by psychological influences, or by pain by direct pressure on a pain receptor in the skin.

	Acupuncture	Placebo	Difference
A before P	12·4 (SD 8·97)	9·08 (SD 10·14)	3·25 (SD 13·17)
P before A	14·4 (SD 11·89)	8·63 (SD 10·94)	5·77 (SD 9·56)
Total	13·4 (SD 10·58)	8·86 (SD 10·55)	4·15 (SD 11·57)

A=acupuncture. P=placebo needing.

Pain perception in acupuncture and placebo: VAS scores

The double-blind placebo-controlled clinical trial is said to be the gold standard for showing that a treatment has a specific effect over placebo.[14] Double-blind designs have not been possible in acupuncture research because the acupuncturist has to be aware of the method applied. To avoid bias, investigators must be blinded. Effects of acupuncture are based on different proposed mechanisms and it has not previously been possible to differentiate specific from non-specific effects. Acupuncture treatments undoubtedly involve placebo effects.[15] The personality of the acupuncturist, time spent with the patient, and manual contact during the search for the acupoints may all enhance the effect of the treatment-setting.

We believe that the most important specific effect of acupuncture for relieving pain is based on the penetration of the needle through the skin at acupuncture points. Our placebo-needle does not penetrate the skin while the patient feels that it has done so. With this needle it is possible to treat people in exactly the same settings with acupuncture and placebo.

Contributors

Julia Kleinhenz: design, acupuncture and placebo needling, analysis, and writing up. Konrad Streitberger: invention of placebo needle, design, acupuncture and placebo needling, analysis, and writing up.

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