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Non-penetrating Sham Acupuncture

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Abstract

Most randomised-controlled trials of acupuncture use penetrating sham acupuncture as control intervention. Sham acupuncture is described as acupuncture at points which are not known as acupuncture points. Because of physiological changes due to skin penetration sham acupuncture should not be defined as placebo control. In 1998 a new placebo needle was introduced by Streitberger. This placebo needle allows patient-blinding without penetration of the skin. Since then, this placebo needle and similar devices were used frequently as non-penetrating sham acupuncture in validation studies, experimental studies and randomised controlled trials (RCTs).

This brief review will introduce the Streitberger placebo needle, the Park sham device and a simple blunt needle technique. Since 1999 more than 40 RCTs used one of these non penetrating devices. Significant better improvement in acupuncture compared to control was shown mainly in some pain conditions. However, many studies could not show a statistical significant difference between the two groups. Reasons might include a different power of placebo effects according to the condition treated, minimal effects by touching the skin with the sham needle and the fact that many studies were pilot studies with small sample sizes.

Due to the heterogeneity of these studies a conclusive statement about the clinical effects of acupuncture is not possible yet.

Especially in pain conditions further studies of acupuncture compared to non-penetrating sham acupuncture are necessary to lead to a better understanding of the importance of needle insertion. A critical discussion might allow to detect problems in existing studies and to improve protocols for further studies.

Background

A major problem in acupuncture research is the lack of adequate control groups[1].

Most randomised controlled trials (RCTs) of acupuncture use penetrating sham acupuncture as control intervention. Sham acupuncture is described as acupuncture at points which are not known as acupuncture points. Because of physiological changes due to skin penetration sham acupuncture should not be defined as placebo control.

An optimal placebo device for acupuncture should be performed in the same therapeutic setting as real acupuncture. Patients should not be able to distinguish the placebo therapy from real acupuncture therapy, they should feel needle penetration, the same acupoints should be used and the skin should not be penetrated in order to avoid physiological effects[2].

The placebo needle

In 1998 a new placebo needle was introduced by

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Streitberger[3]. This placebo needle allows patient-blinding without penetration of the skin. A blunt tip causes a small pricking sensation when it touches the skin, simulating the puncture of skin. The needle is not firmly attached inside the handle in order to allow a shortening of the needle. Patients "see" the needle moving into their body. For fixation of the needle a plastic ring is covered by a plaster (fig.1). In real acupuncture the same procedure is used and after puncturing the plaster the sharp tip of the needle is inserted into deeper tissue layers.

Before using the placebo needle in a clinical trial it was tested in a cross-over experiment with 60 healthy volunteers whether a needling with the placebo-needle is as credible as with a real acupuncture needle.

After randomisation the volunteers were needled in a cross-over design with a real acupuncture nee-

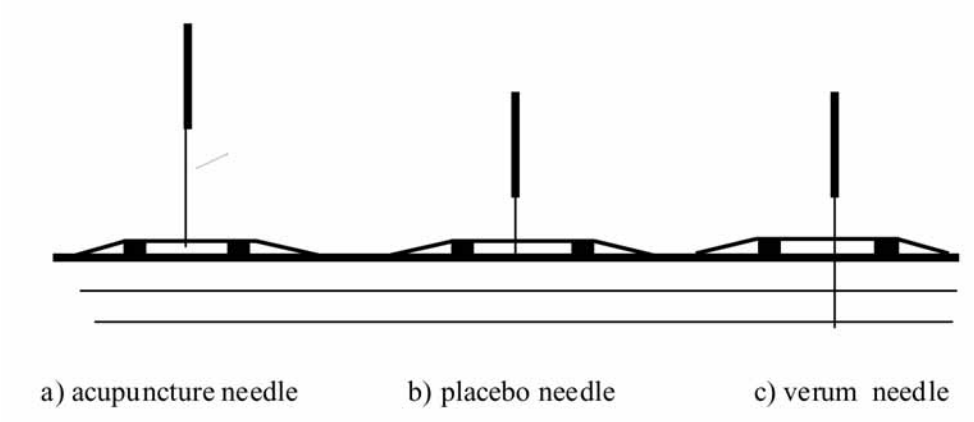

Figure 1: Placebo-needle when touching the skin (a) and after retraction of the needle into the handle (b), real acupuncture needle (c)[3]

Table 1: Results of the validation study for the Streitberger needle[3]

	group 1	group 2	total
number of volunteers	30	30	60
female	15	14	29
mean age in years	27.3	27.8	27.6
VAS			
acupuncture	12.4 (SD 9.0)	14.4 (SD 11.9)	13.4 (SD 10.6)
placebo	9.1 (SD 10.1)	8.6 (SD 10.9)	8.9 (SD 10.6)
difference	3.3 (SD 13.2)	5.8 (SD 9.6)	4.5 (SD 11.6)
95%-confidence interval	-1.5; 7.9	2.4; 8.1	1.6; 7.4
penetration felt			
in acupuncture	28	26	54
in placebo	21	26	47
DEQI felt			
in acupuncture	17	17	34
in placebo	5	9	13

dle and with the placebo-needle at acupoint "Large Intestine 4". The volunteers were asked if they felt the needle penetration through the skin, how painful the penetration of the needle was (on a Visual Analogue Scale = VAS), and if they felt a dull pain (DEQI-feeling). Baseline data and results are shown in table 1.

Concerning the comparative feeling of needle penetration 43 of 60 volunteers (72%, 95%-confidence interval: 59%; 83%) felt no difference. 12 volunteers felt penetration only with acupuncture (20%), 5 only with placebo (8%). As most important none of the volunteers suspected that the skin had not been punctured in one of both procedures. Therefore in this experiment the placebo-needle proved to be sufficiently credible to be used as a placebo in single blind conditions.

Since then, this placebo needle and similar devices were used frequently as non-penetrating sham acupuncture in validation studies, experimental studies and RCTs[4].

The Park sham device and other techniques

Shortly after the description of the Streitberger needle a similar device with the same principle of a blunt telescopic needle but using a different applicator was introduced and evaluated by Park (fig 2)[5,6]. Also studies with more simple concepts like sticking a blunt needle into a foam applicator were described[7,8].

Randomized controlled trials

Acupuncture studies using non-penetrating sham acupuncture as control were identified by a systematic search covering the period from 1998 onwards in MEDLINE. Database searches were supplemented by screening of reference lists of systematic reviews and eligible primary studies. Participant blinded RCTs were described qualitatively in tables. Yet, the methodological quality of the studies was not analysed in detail.

Since 1999 at least 40 RCTs used one of those non penetrating devices (table 2). Significant better improvement in acupuncture compared to control was shown 15 trials, mainly in some pain conditions. However, 25 studies could not show a statistical significant difference between both groups in the main outcome criterion. Using multiple testing in 11 of these studies at least in one secondary criterion a significant better result for acupuncture could be detected.

From 20 studies including more than 50 patients only 6 showed a clearly significant effect in the main outcome criteria (table 3). Only 2 of 8 studies which included more than 100 patients proved a significant effect.

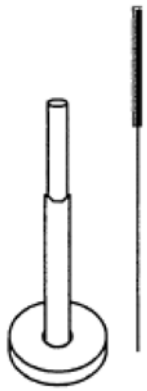

Figure 2: The Park Sham Device[5]

Table 2: RCTs with non-penetrating devices (n=40)

	s	n	s(s)
Shoulder and arm pain	2	2	1
Knee pain	2	1	
Low back and neck pain	3	2	1
Acute and experimental pain	3	4	2
Headache	2	4	3
Nausea and vomiting	0	3	1
Stroke	0	3	1
Other			
-Rheumatoid arthritis	0	1	
-Dental anxiety	1	0	
-Alcohol dependance	0	1	1
-Postmenopausal hotflashes	0	1	1
-Hypertension	1	0	
-Irritabile Bowel Syndrome	0	1	
-Straight leg raise	0	1	
-Local circulation	1	0	
-In Vitro Fertilization	0	1	
Together	15	25	11

s: significant

ns: non significant

s(s): partially significant

Table 3: RCTs with non-penetrating devices including >50 patients (n=20)

Author	Year	Condition	N	Control	Result
Smith[13]	2005	analgesia d. electromyography	51	park at AP-point	ns
Kleinhenz[14]	1999	rotator cuff tendinitis	52	streitberger at AP-point	s
Knight[15]	2001	nausea of pregnancy	55	cocktail stick	ns
David[16]	1999	rheumatoid arthritis	56	needle introducer	ns
Huguenin[17]	2005	straight leg raise	59	streitberger at AP-point	ns
Sim[18]	2002	postoperative pain	60	blunt needle at non AP-point	ns (s)
Karst[19]	2007	dental anxiety	67	blunt needle at non AP-point	ns (s)
Jubb[20]	2008	osteoarthritis of the knee	68	streitberger at AP-point	s
Karst[21]	2001	tension type headache	69	blunt needle at AP-point	(s)
Streitberger[22]	2003	nausea during chemotherapy	80	streitberger at AP-point	ns
Kennedy[23]	2008	acute LBP	94	park at AP-point ns	(s)
Vas[24]	2004	osteoarthritis of the knee	97	streitberger at AP-point	s
Elden[25]	2008	pelvic girdle pain in pregnant	115	streitberger at AP-point	ns
Park[26]	2005	recovering from stroke	116	park at AP-point	ns
Goldman[27]	2008	arm pain	123	streitberger at AP-point	ns
Facco[28]	2008	migraine	127	blunt needle at AP-point	s
G. de Hoyos[29]	2004	shoulder pain	130	park at AP-point	s
Streitberger[30]	2004	PONV	220	streitberger at non-AP-point	ns (s)
Smith[31]	2006	IVF	228	streitberger at non-AP-point	ns
Foster[32]	2008	osteoarthritis of the knee	352	streitberger at AP-point	ns

IVF = in vitro fertilization; PONV = Postoperative nausea and vomiting; AP = Acupuncture; Result of main outcome criterion: s = significant; ns = non significant; (s) = partially significant (multiple testing, one of different outcome measures significant)

Discussion

Due to the heterogeneity of the studies a conclusive statement about the clinical effects of acupuncture is not possible yet.

Reasons for the inconclusive results might include a different power of placebo effects according to the condition treated, minimal effects by touching the skin with the sham needle and the fact that many studies were pilot studies without a clear definition of a main outcome criterion.

Especially in pain conditions further studies of acupuncture compared to non-penetrating sham acupuncture are warranted to lead to a better understanding of the importance of needle insertion. A critical discussion might allow to detect problems in existing studies and to improve protocols for further studies.

Double blinding remains a problem. Recently a device for double blinding acupuncture trials was introduced. The evaluation of the device seems to be promising to keep patient and acupuncturist blinded. However, as a matter of fact the quality of verum acupuncture depends on the experience and skill of the acupuncturist. In case of a negative result it could be argued that the acupuncture treatment was not appropriate. Furthermore using the double blinding device control of adverse effects like nerve injury or hematoma might be a problem. Another concern in placebo acupuncture might be that even touching the skin might have physiologic effects. The physiologic activity of placebos is difficult or impossible to assess empirically and is normally determined on theoretical grounds[9,10]. Despite much experimental work on the physiological mechanisms of acupuncture, it is not known which aspects of the acupuncture treatment, such as the mode of stimulation or location of the acupuncture point, are specific to produce these physiological effects[11]. If placebo needles are applied at acupuncture points, it is possible that manual stimulation by the blunted tip of the placebo needle may lead

to acupuncture-like effects. It seems preferable therefore to apply the placebo needle away from acupuncture points. The sensations of pricking or pressure, which are important to convince the patient that they are receiving a credible treatment, will at least have no physiologic impact specific to acupuncture points[12].

Further empirical research is necessary on both the psychological and physiological effects of non-penetrating sham acupuncture techniques.

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