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Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendinitis

Julia Kleinhenz[a], Konrad Streitberger[a,*], Jürgen Windeler[b], Albert Güßbacher[c], Georg Mavridis[c], Eike Martin[a]

[a]*Clinic of Anesthesiology, University of Heidelberg, Im Neuenheimer Feld 110, 69120 Heidelberg, Germany*
[b]*Department of Biostatistics, University of Heidelberg, Im Neuenheimer Feld 305, 69120 Heidelberg, Germany*
[c]*Orthopedic Department, University of Heidelberg, Schlierbacherlandstr. 200, 69118 Heidelberg, Germany*

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Abstract

Acupuncture has gained increasing attention in the treatment of chronic pain. The lack of a satisfying placebo method has made it impossible to show whether needling is an important part of the method or whether the improvement felt by the patient is due to the therapeutic setting and psychological phenomena. Also, the effectiveness of acupuncture has not been demonstrated sufficiently. We treated 52 sportsmen with rotator cuff tendinitis in a randomised single-blind clinical trial using a new placebo-needle as control. Patients were treated for 4 weeks. The primary endpoint of the trial was the change in the modified Constant-Murley-score from the baseline. Assessment of the treatment outcome was made by experienced orthopaedists not informed of the treatment allocation. Acupuncture with penetration of the skin was shown to be more effective than a similar therapeutic setting with placebo needling in the treatment of pain. The acupuncture-group improved 19.2 Constant-Murley-score points (SD 16.1, range from −13 to 50), the control-group improved 8.37 points (SD 14.56, range from −20 to 41), ($P = 0.014$; C.I. 2.3;19.4). This study showed that needling is an important part of the acupuncture effect in the treatment of chronic shoulder pain in athletes. No conclusions can be derived from this study concerning the importance of choosing points and the rules of Traditional Chinese Medicine. Using the new placebo method as control for other ailments could improve the evidence of specific acupuncture effects beyond pain treatment.

Keywords: Acupuncture; Placebo-needle; Rotator cuff tendinitis; Athletes; Randomised controlled trial

1. Introduction

Acupuncture has gained increasing attention in the treatment of chronic pain (Patel et al., 1989). Different mechanisms have been found to explain its effects. However, the absence of a satisfying placebo method (Lewith and Machin, 1983; Vincent and Lewith, 1995), has made it impossible to prove whether needling is an important part of the method or whether the improvement felt by the patients is due to the therapeutic setting (i.e. a strong placebo effect).

Acupuncture trials have been performed with a large variety of placebo procedures. They may have different psychological and physiological effects, making meta-analyses of these trial results impossible. The simulation with the use of laser- or TENS-therapy are unreliable, as the setting differs largely from acupuncture therapy. Methods of pricking or scratching the skin by a blunt needle (Moore and Berk, 1976, Jensen et al., 1979)' can only be applied on the back, making it inconvenient for other pain sites. In most studies no attempt was made to evaluate the credibility of the placebo used. Psychological factors may be responsible for differences between groups.

Needling of non-acupoint sites is often used as a placebo. This may imply methodological problems. Piercing the skin activates different pain modulating systems to a non-quantified degree. Local effects on healing by electrical effects of skin injury (Gunn, 1978), release of vasoactive substances (Ernst and Lee, 1985), trigger point effects (Ghia et al., 1976; Lewit, 1979) as well as distant factors such as activation of a pain suppressing system in the spinal cord (Diffuse Noxious Inhibitory Controls) (Bing et al., 1990) have been described.

A placebo method which avoids the necessity of penetration of the skin but shows the same psychological impact is

* Corresponding author. Tel: +49-6221-566351; fax: +49-6221-565345.

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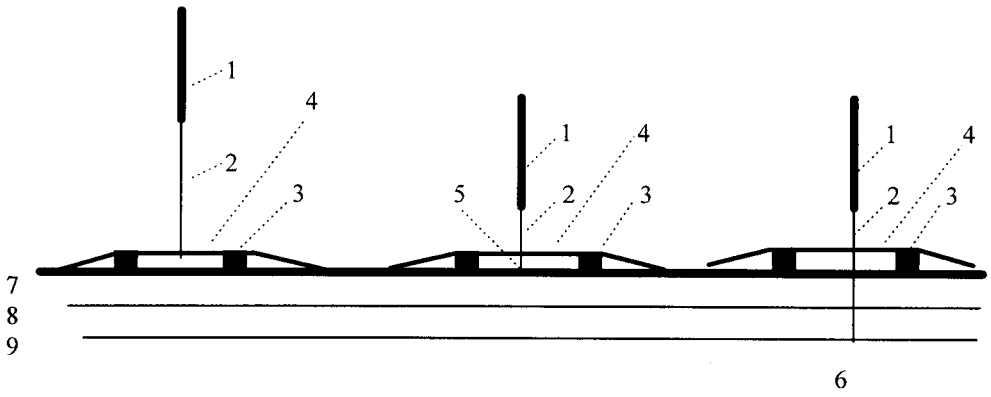

Fig. 1. Placebo-needle when touching the skin (left) and after retraction of the needle into the handle (middle), real acupuncture needle (right). Reproduction of this figure with permission of Streitberger and Kleinhenz, 1998. 1, Needle handle; 2, needle corpus; 3, plastic ring; 4, plaster; 5, blunt tip of the needle; 6, sharp tip of the needle; 7, cutis; 8, subcutis; 9, muscle.

necessary to differentiate the effects of therapeutic setting from specific effects of needling. Patients should not be able to distinguish the placebo from a real penetration of a needle. They should feel needle penetration and experience the same therapeutic setting as in acupuncture. The same anatomical points (acupoints) should be used with acupuncture and placebo to assure the same therapeutic setting.

Patients with shoulder tendinitis are often athletes with repetitive stress of the rotator cuff tendons. The natural history is said to be chronic in as much as 54% (Chard et al., 1988). Local injections with corticosteroids, lidocain or other substances as well as NSAIR drugs are used widely for pain relief and their anti-inflammatory effect. A recent systematic review found little evidence to support or refute the efficacy of any of these common interventions in managing shoulder pain (Green et al., 1998). Besides physiotherapy, rest and changing of the sport techniques is of particular importance. Acupuncture is said to have a beneficial effect in the treatment of rotator cuff tendinitis and shoulder pain (Pothmann et al., 1980; Batra et al., 1985; Wang, 1995; Zhang, 1991).

We designed a randomised, placebo-controlled, single-blind, clinical trial to ascertain whether acupuncture needling vs. placebo-needling without penetration of the skin using identical therapeutic settings for both groups is more effective.

2. Materials and methods

2.1. The placebo-needle

For this study a special 'placebo-needle' was designed by Streitberger. The needle body is not fixed inside the copper handle. Its tip is blunt and when it touches the skin, a small pricking sensation is felt by the patient, simulating the puncture of the skin. The handle of the needle moves over the needle, the needle is shortened. Patients 'see' the needle moving inside their body. For fixing the needle we used a plastic ring covered by a plaster (Fig. 1). The same procedure is used in real acupuncture to assure exactly the same therapeutic setting in both groups. In acupuncture the tip of the needle is sharp and is inserted into deeper tissue layers. No procedure differences can be realized by the patient or by third persons. This needle was tested in 60 volunteers and proved to be sufficiently credible to be used in our clinical trial as a control (Streitberger and Kleinhenz, 1998).

2.2. Patients

Athletes suffering from shoulder pain were recruited through articles in the local newspapers, by informing all sports clubs, all orthopedic and physiotherapy practices, posters at sport facilities and university bulletin boards in the Heidelberg region, F.R. Germany.

Patients were offered free treatment with acupuncture. They were informed about the study design and the use of penetrating and non-penetrating needles. Possible risks of acupuncture treatment were explained (infection, fainting, hematoma, life threatening risks in case of improper handling of the needle). They were informed that they could stop participation in the study at any time. Written informed consent was obtained by each patient eligible for the trial.

The study protocol was approved by the Ethics Committee of the Heidelberg University. The realization of the study was strictly according to the protocol.

2.3. Initial assessment and assignment

The histories were taken and diagnoses of rotator cuff disease were made by two experienced orthopedic specialists in the department of sports medicine (G.A. and M.G.) according to accepted standards (Cyriax, 1982; Hawkins and Hobeika, 1983).

Ultrasound examination of the rotator cuff were performed to exclude tendon rupture (Mack et al., 1988), as well as X-rays to exclude foci of calcifications and degenerative changes within the joints. Assessments of shoulder function were made by the orthopedic specialists using the

Table 1
Items modified Constant-Murley-score

Total points for pain = 15											
Pain	None	15	Mild	10	Moderate	5	Severe	0			
Total points for activities of daily living = 20											
Training[a]	Full training	4	Training mildly reduced	3	Training moderately reduced	2	Training severely reduced	1	Training not possible	0	
Other activities of daily living	All possible	4	Activities mildly reduced	3	Activities moderately reduced	2	Activities severely reduced	1	Activities not possible	0	
Sleep	Unaffected	2	Waking up	1	Severely disturbed	0					
Positioning during daily living	Above head	10	Up to top of head	8	Up to the neck	6	Up to xiphoid	4	Up to waist	2	Not able to lift hand	0
Total points for painless range of motion = 40											
Flexion	151–180°	10	121–150°	8	91–120°	6	61–90°	4	31–60°	2	0–30°	0
Abduction	151–180°	10	121–150°	8	91–120°	6	61–90°	4	31–60°	2	0–30°	0
Internal rotation scoring:	Dorsum of hand to interscap. region	10	Dorsum of hand to D 12	8	Dorsum of hand to waist	6	Dorsum of hand to sacroiliac joint	4	Dorsum of hand to buttock	2	Dorsum of hand to lateral thigh	0
External rotation (for every position possible + 2 points)	Hand behind head with elbow held forward	+2	Hand behind head with elbow held back	+2	Hand on top of head with elbow held forward	+2	Hand on top of head with elbow held back	+2	Full elevation from on top of the head	+2		
Total points for power = 25											
Power[b]: painless abduction, internal and external rotation	Against maximal resistance	25	Against strong resistance	20	Against light resistance	15	Against minimal resistance	10	Against gravity	5	No active movement possible	0
Total points of modified Constant–Murley score = 100												

[a] Modification: original this item was 'work'. For our athletes training seemed to be the more appropriate.
[b] Modification: original power is measured from 0 to 25 kg. As most of our athletes could lift more than 25 kg in maximal power, we decided to use a clinical classification.

Table 2
Inclusion and exclusion criteria

Inclusion
Rotator cuff disease due to sport
(Stage I and II of the impingement classification of Neer)
Age over 18 years, under 50 years
Duration of disease more than 4 weeks
No acupuncture therapy during the last 6 months
Constant-Murley-score under 81 points
Written informed consent
Exclusion
Cervical or thoracic pain syndromes
Previous operation of the shoulder
Rupture of tendons
Calcification in the rotator cuff
Degeneration of gleno-humeral or acromio-clavicular joints
Pregnancy
Allergic reactions to plaster

modified Constant–Murley-score (Constant and Murley, 1987) (Table 1).

If patients did not violate the exclusion criteria and fulfilled the inclusion criteria (Table 2) central external randomisation was performed by a telephone call prior to the first session.

2.4. Masking and treatment procedure

In the pain treatment unit of the department of anesthesiology patients received eight acupuncture sessions in 4 weeks. The acupuncturists (K.J. and S.K.) were aware of the different treatments, but tried not to give any information to the patients. As the method of application in the two groups did not differ, patients were treated in the same room to keep the setting identical. Questions about acupuncture were answered using an identical 'answer-catalogue'. Before the first treatment session acupoints on the shoulder were checked to determine pain on pressure. Painful points were chosen as well as others according to the symptoms. A combination of up to 12 points was used out of a list of 20 (Table 3) which have been described as being effective (Cheng, 1987; Guillaume and Mach, 1990, Vangermeersch and Pei-Lin, 1994). This combination was used for four sessions. If no improvement was reported thereafter another examination was performed to choose alternate points for the next four sessions.

Table 3
Classification of acupoints used for treatment[a]

Local points (chosen when painful on pressure)		
Tianliao TE 15	Bingfeng SI 12	Jianwaishu SI 14
Shentang B 44	Tianzong SI 11	Jianzhen SI 9
Jianliao TE 14	Jianyu LI 15	Jianquan (extra)
Taijian (extra)	Binao LI 14	
Distant points according to local points (same meridian)		
Quchi LI 11	Yanglao SI 6	Houxi SI 3
Zhongzhu TE 3	Yanglingquan G 34	
Symptomatic point		
Tiaokou S 38		
Points according to the eight criteria in Traditional Chinese Diagnostics		
Yunmen L2	Jiquan H1	Tianquan P2

[a] Meridian-Abbreviation: TE, Triple Energizer; SI, Small Intestine; B, Bladder; LI, Large Intestine; G, Gallbladder; S, Stomach; L, Lung; H, Heart; P, Pericard.

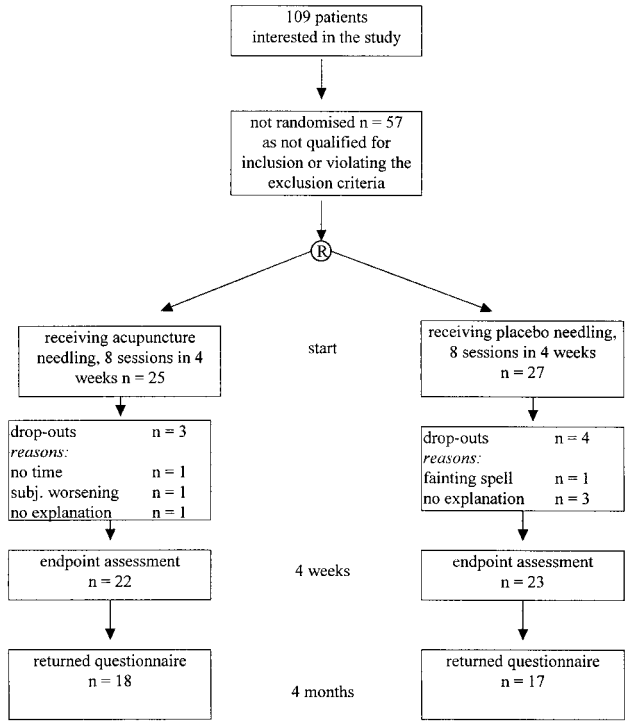

Fig. 2. Trial profile.

Treatment itself started with disinfection with alcohol, application of a plastic ring fixed with plaster. In the case of acupuncture the needles were inserted through plaster and skin into deeper tissue layers. For the control-group the blunt needle tip only touched the skin. Needles were retained for 20 min in both groups, without further electrical or manual stimulation.

After the first session patients were asked questions proposed by Vincent and Lewith (1995) to ascertain the credibility of the therapeutic setting. Treatment with physiotherapy was allowed to be continued during the study. Drug intake and injections were not allowed during the trial. All adjuvant therapies were to be reported on a special form.

2.5. Endpoint

The primary outcome variable was the change from baseline in the modified Constant–Murley score after eight acupuncture sessions. Assessment was made at least 2 days after the last treatment by the same orthopedist of the initial assessment who had not been informed about the treatment of the patients.

2.6. Postal follow-up

Three months after the end-point assessment, letters were sent to the patients to gain some impression about long-term effects. The questionnaires contained the first subjective items (35 points) of the modified Constant–Murley score. Patients were also asked about treatment necessity after the trial and overall judgement of acupuncture treatment. (Trial profile (see Fig. 2)).

2.7. Analysis and planned study population

In a pilot study of seven patients not part of this study score differences pre- and posttreatment were 20.86 points (SD 12.06). Five patients reported a treatment success, each having a difference of at least 20 score-points. Two patients not being satisfied with the result showed a difference of 2 and 14 points, respectively. To detect a difference in the change from baseline of 10 points between groups, 23 patients were needed in each treatment group to give a power of 0.8 (unpaired t-test, two-sided, $\sigma = 12$). The level of significance was defined as $\alpha = 0.05$.

The statistical method used for the analysis of the primary endpoint was the unpaired t-test. Additionally 95%-confidence-intervals are reported. Data were analysed on an intention to treat basis including all randomised patients. For patients who did not show up for the final evaluation, initial assessment data were used (change from baseline of 0 points).

3. Results

3.1. Recruitment and baseline characters

Between 30 May 1996 and 31 January 1997, 109 patients applied for inclusion in the study. Fifty-seven patients did not qualify for inclusion or violated the exclusion criteria. Fifty-two patients were randomly assigned to the treatment groups after the initial assessment. Twenty-five patients were assigned to the acupuncture treatment group, 27 to the control group. Baseline characteristics have been subjected to statistical analysis and revealed no relevant differences (Table 4).

Seven patients dropped out and they did not show up for end-point assessment after treatment. In the acupuncture-group one patient reported a worsening after three sessions, one reported having no time, one stopped participation without any explanation after the first session. In the control-group one patient dropped out after one, one patient after two, and one patient after four sessions without explanation. Another patient in the control-group could not continue treatment because of a fainting spell. In these seven patients a score difference = 0 was used for the end-point assessment.

Additional treatment with ice during the study were reported by two patients, and two patients received physiotherapy, all four being in the control-group. The others did not have any additional treatment during the 4 weeks trial period.

Table 4
Demographic and other characteristics of acupuncture and control-group at initial assessment

Characteristic	Acupuncture group $n = 25$	Control group $n = 27$
Age (years)	33.72 (SD 7.91)	37.37 (SD 10.08)
Sex female	12 (48%)	9 (33%)
Left handed individuals	4 (16%)	4 (15%)
Left shoulder afflicted	7 (28%)	12 (44%)
Sports		
Ballsports with repetitive acceleration-trauma of the shoulder (handball, volleyball)	10 (40%)	11 (41%)
Tennis	6 (24%)	7 (26%)
Sports with stress against resistance (bodybuilding, weight lifting, gymnastics, swimming, kayak)	6 (24%)	7 (26%)
Sports without direct shoulder stress (running, soccer)	3 (12%)	2 (7%)
Level of sport activity		
Recreational sport	9 (36%)	14 (52%)
Competitive sport	16 (64%)	13 (48%)
Training hours per week	5.44 (SD 2.74)	5.93 (SD 4.92)
Working stress		
No shoulder stress	12 (48%)	12 (44%)
Shoulder stress (lifting weights)	7 (28%)	7 (26%)
Desk work	6 (24%)	8 (30%)
Pain duration (months)	29.04 (SD 34.86, range 1–170)	26.52 (SD 35.13, range 1–156)
Previous therapy		
None	7 (28%)	6 (22%)
Physiotherapy alone	6 (24%)	12 (44%)
Physiotherapy and medication	1 (4%)	1 (4%)
Physiotherapy and local injections	9 (36%)	6 (22%)
Local injections alone	2 (8%)	2 (8%)
Initial Constant–Murley score	60.4 (SD 12.28)	53.93 (SD 14.03)

3.2. Outcome

3.2.1. Primary endpoint: modified Constant-Murley-score

The mean change from baseline of modified Constant-Murley-scores were 19.2 points (SD 16.1, min −13, max 50) for the acupuncture-group and 8.37 points (SD 14.56, min −20, max 41) for the control-group (P = 0.014; C.I. for difference between groups: 2.3; 19.4) (Table 5).

3.2.2. Subjective ratings

Subjective patient evaluation after the last treatment as expressed to the acupuncturists was positive (i.e. acupuncture did help) in 17 patients (68%) of the acupuncture-group

Table 5
Modified Constant–Murley score at initial assessment and after 4 weeks of treatment

	Initial assessment	End-point (after eight acupuncture sessions/4 weeks)	Difference
Acupuncture ($n = 25$)	60.4 (SD 12.3)	79.6 (SD 17.1)	19.2 (SD 16.1)
Placebo ($n = 27$)	53.9 (SD 14.0)	62.3 (SD 17.9)	8.4 (SD 14.6)

and 14 patients (52%) of the control group (P = 0.27, Fisher's exact test).

There was also no difference in the credibility of the treatment-setting in both groups after the first and the last treatments. All items were responded positive by all patients but one. Even a negative treatment outcome was attributed to an individual treatment failure and acupuncture was continued to be judged as effective. Only one of the patients would no longer recommend this treatment to friends after having been treated in the control-group without improvement.

3.3. Postal follow-up

Eighteen patients from the acupuncture-group and 17 patients from the control-group returned the questionnaire (35 = 67%)). After the trial seven patients of the acupuncture-group received further treatment, six with physiotherapy, one with medication. Ten patients from the control-group were treated further, nine had physiotherapy and one received local injections. Subjective elements of the modified Constant-Murley-score were compared with the ratings after 4 weeks for these 35 patients. In the acupuncture-group there was no difference between the score values for pain intensity after 4 weeks (10.00 Constant-Murley-points, SD 4.54) and 4 months (8.89 C-M-points, SD 4.04). Control-group showed further improvement from 4 weeks (6.47 C-M-points, SD 3.86) to 4 months (9.41 C-M-points, SD 4.64). The other subjective items of the C-M-score revealed no differences between groups.

3.4. Adverse effects

Two patients fainted during the treatment, both in the control-group. Headaches were reported in five patients (three in acupuncture, two in placebo). Dizziness was reported by two patients in the acupuncture-group, one in the control-group. Increased muscle tension was reported once in the control-group, loss of strength in the legs and inflammatory reaction were reported once each in the acupuncture-group.

4. Discussion

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 although the patient feels that it has done so. With this needle it is possible to create exactly the same setting in acupuncture and placebo. A small acupressure effect may be induced by the method. Acupressure itself has not been proven yet scientifically, as well as the pressure needed for appropriate stimulation has not been determined. Nevertheless, we could prove in the treatment of rotator cuff disease that needling is more effective than the placebo-needling method, suggesting that the acupressure effect might not have been very big.

The statistical analysis of the results showed a significant difference in the Constant–Murley score between the groups ($P = 0.014$). Acupuncture with penetration of the skin is more effective than placing the needles on similar sites. This only demonstrates the effectiveness of the needling procedure in rotator cuff tendinitis. No evidence can be obtained by this trial concerning the specificity of acupuncture points and the rules of Traditional Chinese Medicine. This demands another study, where groups treated with 'indicated' vs. 'non-indicated' acupuncture points should be compared. If both groups are to receive real acupuncture, the number of patients should be very large. This is a particular difficulty as most acupuncture trials (like this one) are not subsidised.

The acupuncture therapeutic setting fulfils most criteria described for harnessing placebo effects (Chaput de Saintonge and Herxheimer, 1994). The personality of the acupuncturist, time spent with the patient, manual contact during the search for the acupoints may all enhance the effect of the treatment-setting.

Consequently patients from the control-group also improved. Side-effects did not exceed those already published in the literature (Norheim, 1995). There was no difference between acupuncture and placebo. This supports the credibility of the placebo-method.

Follow-up after 3 months suggested that the control-group improved to similar results as the acupuncture-group with further treatment after the trial. The pain rating in the acupuncture-group did not worsen with time, suggesting a long-term effect. As only 67% of the patients returned their questionnaires these long-term results should be regarded as preliminary.

Subjective ratings by patients towards the acupuncturist did not correspond to the objective rating by the orthopaedist not knowing the randomisation. Patients of the control-group rated the result more positive than expected by the score results as the treatment establishes a close relationship between doctor and patient. As this concerns all alternative 'soft' treatment protocols stress should be laid in any trial on

external assessment of the treatment results to avoid bias. Even in negative personal treatment outcome patients did not loose their faith in the effectiveness of acupuncture treatment.

To prove the effectiveness of acupuncture in other diseases trials with the new placebo method are needed.

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