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Does acupuncture improve the orthopedic management of chronic low back pain – a randomized, blinded, controlled trial with 3 months follow up

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Abstract

This prospective, randomised controlled trial, with three parallel groups, patient and observer blinded for verum and sham acupuncture and a follow up of 3 months raises the question: "Does a combination of acupuncture and conservative orthopedic treatment improve conservative orthopedic treatment in chronic low back pain (LBP). 186 in-patients of a LBP rehabilitation center with a history of LBP $\geq$ 6 weeks, VAS $\geq$ 50 mm, and no pending compensation claims, were selected; for the three random group 4 weeks of treatment was applied. 174 patients met the protocol criteria and reported after treatment, 124 reported after 3 months follow up. Patients were assorted 4 strata: chronic LBP, $\leq$0.5 years, 0.5–2 years, 2–5 years, $\geq$ 5 years. Analysis was by intention to treat. Group 1 (Verum + COT) recieved 12 treatments of verum acupuncture and conservative orthopedic treatment (COT). Group 2 (Sham + COT) recieved 12 treatments of non-specific needling and COT. Group 3 (nil + COT) recieved COT alone. Verum- and Sham acupuncture were blinded against patient and examiner. The primary endpoints were pain reduction $\geq$ 50% on VAS 3 months after the end of the treatment protocol. Secondary endpoints were pain reduction $\geq$ 50% on VAS and treatment efficacy on a four-point box scale directly after the end of the treatment protocol and treatment efficacy after 3 months. In the whole sample a pain relief of $\geq$ 50% on VAS was reported directly after the end of treatment protocol: Verum + COT 65% (95%CI 51–77%), Sham + COT 34% (95%ci 22–49%), nil + COT 43% (95%ci 29–58%) – results are significant for Verum + COT over Sham + COT ($P \leq 0.02$). The results after 3 months are: Verum + COT 77% (95%ci 62–88%), Sham + COT 29% (95%ci 16–46%), nil + Cot 14% (95%ci 4–30%) – effects are significant for Verum + COT over Sham + COT ($P \leq 0.001$) and for Verum + COT over nil + COT ($P < 0.001$). No difference was found in the mobility of the patients nor in the intake of NSAID diclofenac. Our conclusion is that acupuncture can be an important supplement of conservative orthopedic treatment in the management of chronic LBP.

Keywords: Low back pain; Pain management; Acupuncture

1. Introduction

Chronic low back pain (LBP), one of the most prevalent conditions of the western society, often shows only minor improvement when treated with conventional therapies; there is an ongoing search for additional standard or alternative treatments (Deyo et al., 2001). Basic research suggests an analgesic effect of acupuncture (Clement-Jones et al., 1980; Han and Terenius, 1982; Pomeranz, 1998). In 1997, during the NIH Consensus Conference, and more recently in systematic reviews with equivocal results focused on the question, if acupuncture can contribute to the conservative treatment of chronic LBP (Berman et al., 1998; Ernst and White, 1998; Molsberger and Böwing, 1997; Molsberger et al., 2002; van Tulder et al., 1999; NIH Consensus Conference, 1998). The common conclusion was that all studies so far conducted lack adequate design, methodology and an adequate quality of the administered acupuncture. In our three armed study, we tested the therapeutic effect of (i) needling specific acupuncture points (verum acupuncture) combined with conventional orthopedic therapy (COT) against, (ii) needling non-acupuncture points in the same region (Sham acupuncture) combined with COT, and (iii) COT alone, (nil). On the basis of ethical as well as clinical reasons (hospital setting), we decided to combine the unproven new with the

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commonly established conventional therapy. We believe that it is of higher clinical interest to test acupuncture against a widely established therapy, than to test it merely against a sham or placebo control group alone (Hammerschlag and Morris, 1997).

2. Materials and method

2.1. Patients

One hundred and eighty six consecutive in-patients of a rehabilitation hospital, were enrolled in the trial after satisfying the following criteria: low back pain (LBP), that is pain between the 12th rib and the gluteal fold; with pain for 6 weeks or longer; with an average pain score of 50 mm or more on a 100 mm visual analogue scale (VAS) during the last week, age between 20 and 60 years; the ability to communicate in German; no sciatica or other neurological disorders; no history of disc or spine surgery; no systemic bone and joint disorders (e.g. rheumatoid arthritis); no previous treatment with acupuncture; no overt psychiatric illness; no pregnancy; not dependent on regular intake of analgesics; no incapacity for work longer than 6 months preceding the trial and not currently awaiting decision on an application for pension or disability benefits (the latter to exclude a conflict of interest between the expected social benefit payments and possible positive treatment effects). All patients were informed about the trial and written consent was obtained. Care was taken that all patients received identical information about the trial (trial profile see Table 1).

2.2. Treatment strategies

According to randomisation (see below), all enrolled patients of the rehabilitation hospital received one of the following treatments. Patients were blinded against verum and sham acupuncture treatment, but not against standard therapy.

(a) nil + COT (conventional orthopedic therapy exclusively). These patients received the conventional conservative orthopedic treatment only. On a standardized, daily basis they received physiotherapy, physical exercise, back school, mud packs, infrared heat therapy. On demand they received 50 mg diclofenac up to three times a day. Injections or cortison application of any kind were not allowed. Other than that, information and handling of these patients was identical to those of the other two groups.
(b) Verum + COT (verum acupuncture and conventional orthopedic therapy). In addition to the conventional conservative orthopedic therapy all patients received 12 verum acupuncture treatments, three per week, each lasting for 30 min. The acupuncture therapy was carried out by an experienced medical doctor, who had studied acupuncture in China (Beijing). After a literature review on acupuncture for LBP only widely accepted acupuncture points were selected (Beijing College of Chinese Medicine, 1987; Stux and Pomeranz, 1998; Xinnong, 1987). Standard points in the lumbar region (adjacent points) were urinary bladder 23, 25, and gallbladder 30; standard points on the lower extremity (distal points)

Table 1
Trial profile[a]

Verum + COT	Sham + COT	Nil + COT
186 Randomized low back pain (LBP) inhouse patients		
$n = 65$	$n = 61$	$n = 60$
12 Verum acupuncture applications + COT	12 Sham acupuncture applications + COT	12 Conventional orthopedic applications alone
174 LBP completed treatment course		
$n = 58$ (7 Drop outs/withdrawals)	$n = 58$ (3 Drop outs/withdrawals)	$n = 58$ (2 Drop outs/withdrawals)
1 Needle phobia	1 VAS < 45 (prior to treatment)	2 VAS < 45 (prior to treat)
1 Pending compensation procedure	2 no pain intensity	
1 Death in the family		
4 VAS < 45 (prior to treatment		
124 LBP completed 3 months follow up		
$n = 47$ (11 Drop outs/withdrawals)	$n = 41$ (17 Drop outs/withdrawals)	$n = 36$ (22 Drop outs/withdrawals)
1 Treatment 'too painful' 10 unknown reasons	All reasons unknown	All reasons unknown
IIT analysis		
Primary endpoint: VAS change 3 months after treatment protocol		
Secondary endpoints: VAS change directly after end of treatment protocol, 4 score global assessment directly after and 3 months after end of treatment protocol		

[a] COT, conventional orthopedic therapy; Verum, needling of specific acupuncture points; Sham, needling of non-acupuncture points in the same region; nil, no additional acupuncture; ITT, intention to treat analysis.

were urinary bladder 40, 60 and gallbladder 34. Additionally up to four points of maximum pain 'Ahshi points' (locus dolendi, trigger points), which were often close but not necessarily identical to Bl 54, 31, 32 were needled. Depending on the site of the needle and the type of pain reported by the patient, needle insertion ranged from 1 to 10 cm and needle manipulation was mild to strong. Always a numb, warm feeling around the acupuncture point (Deqi) was achieved. During the acupuncture treatment, no additional treatment was administered.

(c) Sham + COT (sham acupuncture and conservative orthopedic therapy). In addition to the daily conservative orthopedic therapy, all patients received 12 sham acupuncture treatments, three per week, each lasting for 30 min. Sham acupuncture was standardized to ten needles applied superficially (depth of needle insertion was less than 1 cm) at defined non-acupuncture points of the lumbar region, and five needles on either side of the back. Other than the application of sham acupuncture, information and handling of these patients was identical to those of the verum group.

2.3. Assessment prior to treatment

Personal data and details of the patient's medical history and present condition, as well as attitude towards acupuncture, were obtained during a semi-structured interview, conducted by an independent examiner, an orthopedic doctor of the clinic, not identical with the acupuncturist. The same examiner assisted the patient in evaluating his or her personal pain intensity by physical assessment. Among the obtained data were: intensity, frequency and duration of LBP, finger-to-ground distance, Schober's sign, exact location of muscle trigger points, pseudoradicular pain radiation. Pain intensity was recorded on 100 mm VAS, zero representing 'no pain at all', and 100 mm representing 'most intense pain imaginable'. Additionally, patients kept a pain diary by rating their daily pain intensity on a VAS. Necessary data for the adequate selection and manipulation of acupuncture points were taken, such as the exact location of the locus dolendi point, and the pain-quality such as pain being deep or superficial, of fixed, local or moving location, or pain being influenced by specific movements or by coldness or heat (Beijing College of Chinese Medicine, 1987; Stux and Pomeranz, 1998; Xinnong, 1987).

2.4. Assessment after treatment

Directly after the end of the 4 week in-house treatment protocol, all patients-with the help of the independent examiner, evaluated their pain intensity on a VAS (referring to the average pain level during the last 7 days) and rated the effectiveness of the treatment protocol from 'excellent, good, satisfactory to failed' on a four-point box scale (4-PBS). Schober's sign and the finger-to-ground distance were measured, too.

2.5. Follow up after 3 months

Follow up data were measured 3 months after the end of the treatment protocol. Data were taken in the same way as directly after treatment, but at that time on an outpatient basis by the patient's family doctor, who had not been informed about the assigned treatment group.

The independent examiner in the clinic and the family doctor were blinded against verum and sham acupuncture (blinded observer) but not against conservative orthopedic treatment alone (nil + COT).

2.6. Randomization

According to a computer generated randomisation list of admitted patients were randomly assigned to either of three groups: Verum + COT, Sham + COT, nil + COT. Central telephone randomisation was provided by the Department of Statistics in Medicine, Heinrich Heine University, Düsseldorf. Randomisation was stratified into four balanced strata according to the length of pain history: less than 0.5 years (stratum 1), 0.5–2.0 years (stratum 2), 2.0–5.0 years (stratum 3), and more than 5.0 years (stratum 4).

2.7. Endpoints

In pilot data, clinical experience and former acupuncture trials, we observed that the outcome of the treatment improved 3 months after the end of treatment compared to the outcome directly after the end of treatment. Therefore, the primary endpoint was defined as a reduction of at least 50% of the baseline VAS score 3 months after the end of the treatment protocol, the VA score referring to an average pain level during the last 7 days before measurement.

Secondary endpoints were a VAS change of at least 50% from baseline directly after the end of the treatment protocol and an 'excellent or good' rating of the treatment effect on the four-point box scale (4-PBS) at the end of the treatment protocol as well as 3 months later.

2.8. Hypothesis to be tested

In chronic LBP, the combined effect of verum acupuncture and conservative orthopedic treatment (Verum + COT) exceeds that of sham acupuncture and conservative orthopedic treatment (Sham + COT) or that of conservative orthopedic treatment alone (nil + COT).

2.9. Sample size

On the basis of pilot-studies and reviews of published acupuncture trials, our trial was planned to detect an effect of Verum + COT over nil + COT of at least 20%. To reach a test power of 90% with a global level of significance of $\alpha = 0.05$ (and adjustments for multiple testing and three interim analyses) the calculated sample size was 380 evaluable patients.

3. Statistical analysis

3.1. Homogeneity after randomisation and protocol adherence

To detect departures from homogeneity after randomisation, the three treatment groups were compared with non-parametric tests, the Kruskal Wallis for metrically scaled continuously distributed variables (VAS, age, duration of chronic pain, finger-to-ground distance, Schober's sign), and the chi-square contingency tables test for nominally scaled variables (attitude towards acupuncture, gender, frequencies of pain attacks, intensity of night pain).

For a graphical check on the protocol adherence, the empirical distributions of waiting times between admission and end of treatment protocol, and between end of treatment protocol and follow-up examination were represented graphically for each group and all groups together by schematic plots.

3.2. Efficacy analysis

Nil + COT and Sham + COT were each compared to Verum + COT with a global level of significance of $\alpha = 0.05$ for the single primary endpoint (nominal level $\alpha = 0.025$), while for the three secondary endpoints nominal levels of $\alpha = 0.00625$ were used. Frequencies were compared with an approximate chi-square or an exact Fisher test, as appropriate; for quantitative variables (finger-to-ground distance and Schober's sign), the changes were compared between the respective treatment groups with the non-parametric Mann–Whitney–Wilcoxon rank test.

Nominal confidence levels are adjusted for multiple testing according to the appropriate adjustments for tests of effects in the respective comparison. All calculations were carried out with the SAS software package, version 6.12 under the operating system OS/2.

4. Results

4.1. Patients and randomisation

Due to the reorganization of the public health system in Germany, the rehabilitation clinic was closed 1.5 years after the beginning of the trial and the trial had to be stopped. At that time 186 patients were enrolled in the trial and had completed the treatment protocol. The intention to treat (ITT) analysis comprises all 186 patients as randomized, irrespective of their consistency with their compliance or adherence to the protocol specifications to either Verum + COT (65), Sham + COT (61), or nil + COT (60).

The per-protocol population (PPP, $n = 174$) analysis excluded 12 patients, who did not meet the protocol population criteria (see Table 1); group sizes then were Verum + COT (58), Sham + COT (58), nil + COT (58).

The numbers of patients per stratum (ITT) were: stratum 1-pain history less than 0.5 year, $n = 6$; stratum 2–0.5–2.0 years, $n = 27$; stratum 3–2.0–5.0 years, $n = 40$; stratum four more than 5.0 years, $n = 113$. No patient had a pain history shorter than 3 months. In the trial population (97 men, 89 women) the typical patient was approximately 50 years old, reported a moderate to severe pain (VAS score 66), with an average duration of LBP of 9.9 years. Baseline characteristics (gender, age, duration of LBP, finger-to-ground distance, Schober's sign, intensity and frequency of pain, night pain and experience in and attitude toward acupuncture, number of days in hospital) were similar across the three treatment groups (Table 2). The following analyses include all patients and are on intention to treat. The patient PPP analyses do not differ significantly.

4.2. Mean VAS scores

The mean VAS scores changed (i) in the Verum + COT group from baseline 68 to 26 directly after treatment and to 23 after 3 months; (ii) in the Sham + COT group from baseline 64 to 36 directly after treatment and to 43 after 3

Table 2
Randomisation: randomisation was successful in all categories (ITT analysis)[a]

Characteristics	Sham + COT	Verum + COT	Nil + COT	Total
	ITT	ITT	ITT	ITT
Sample sizes (number of patients)	61	65	60	186
Gender (m/w)	33/28	36/29	28/32	97/89
Age in years (mean/SD)	50/6	49/8	49/7	50/7
Duration of chronic pain in years (mean/SD)	9.9/7.7	11.5/9.2	8.1/5.7)	9.9/7.8
Pain intensity VAS (mean/SD)	64/11	68/17	67/14	66/15
Finger-to-ground distance in cm (mean/SD)	11/14	19/16	18/12	18/14
Schober's sign in cm (mean/SD)	14/1.0	14/1.0	14/1.0	14/1.0
Frequency of pain attacks (no. of 'less than daily' (no. of 'daily')	12/49	9/54	17/42	38/145
Night pain (no. of 'no or mild'/no. of 'moderate to severe')	28/32	31/28	23/36	82/96
Patients with diclofenac intake	20%	18%	15%	
Number of days in the hospital (mean/SD)	31.7/5.8	31.3/5.4	32.4/6.2	31.7/5.8

[a] Verum, verum acupuncture; Sham, sham acupuncture; COT, conventional orthopedic therapy; SD, standard deviation.

Table 3
Mean pain intensity on VAS[a]

Time of measurement	Sham + COT	Verum + COT	Nil + COT
	Mean (SD)	Mean (SD)	Mean (SD)
Baseline	64/11	68/17	67/14
Directly after treatment protocol	36/19	26/21	39/21
3 months follow up	43/23	23/20	52/19

[a] Verum, verum acupuncture; Sham, sham acupuncture; COT, conservative orthopedic treatment; SD, standard deviation. For all VAS measurements patients were asked to evaluate the average pain intensity during the last week. According to the trial protocol a statistical analysis on significance was not carried out for these values

months; (iii) in the nil + COT group from baseline 67 to 39 directly after treatment and to 52 after 3 months (Table 3).

4.3. Primary endpoint

4.3.1. Pain relief on VAS after 3 months

After 3 months, a pain relief of at least 50% was reported by 77% (95%CI 62–88%) in the Verum + COT group ($n = 47$), 29% (95%CI 16–46%) in the Sham + COT group ($n = 41$), 14% (95%CI 4–30%) in the nil + COT group ($n = 36$). Results are significant for Verum + COT versus Sham + COT ($P < 0.00003$) and for Verum + COT versus nil + COT ($P < 0.00001$) after appropriate adjustments for multiple testing (Table 4, Fig. 1).

4.4. Secondary endpoints

4.4.1. Pain relief on VAS directly after treatment protocol

A pain relief of at least 50% was reported by: 65% (95%CI 51–77%) in the Verum + COT group ($n = 60$), 34% (95%CI 22–49%) in the Sham + COT group ($n = 58$), 43% (95%CI 29–58%) in the nil + COT group

Table 4
Primary and secondary endpoint analyses of patients (ITT)[a]

Characteristics	Sham + COT	Verum + COT		nil + COT	Total
Sample sizes ITT [PPP	61 [58]	65 [58]		60 [58]	186 [174]
Primary endpoint analysis					
3 months VAS assessment					
Good outcome	12	36		5	53
Bad outcome	29	11		31	71
n	41	47		36	124
n.a.	20	18		24	62
P		< 0.00003	< 0.00001		
Secondary endpoint analysis					
VAS assessment directly after treatment protocol					
Good outcome	20	39		23	82
Bad outcome	38	21		30	89
n	58	60		53	171
n.a.	3	5		7	15
P		0.013	> 0.05		
Treatment efficacy after 3 months					
Good outcome	23	36		11	70
Bad outcome	19	13		26	58
n	42	49		37	128
n.a.	19	16		23	58
P		> 0.05	0.0006		
Treatment efficacy directly after treatment protocol					
Good outcome	41	52		31	124
Bad outcome	20	10		24	54
n	61	62		55	178
n.a.	0	3		5	8
P		> 0.05	0.016		

[a] Good outcome: VAS pain reduction of at least 50% in VAS assessment; 'excellent or good' treatment efficacy on the 4-point box scale. n, number of assessed patients; n.a., number of patients not available, *P* value is adjusted for multiple testing according to trial protocol. Verum, verum acupuncture; Sham, sham acupuncture; COT, conventional orthopedic therapy. PPP analyses does not differ significantly.

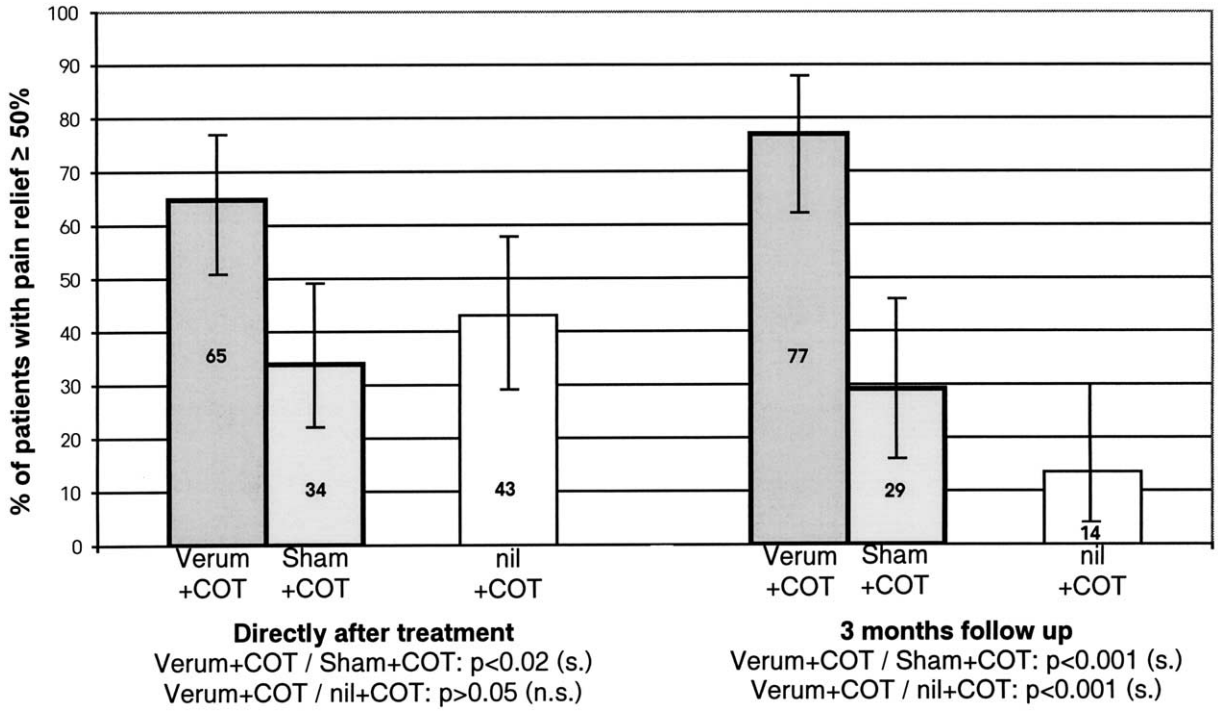

Fig. 1. Pain relief ≥ 50% directly after treatment protocol (secondary endpoint) and 3 months after (primary endpoint). Verum + COT and Sham + COT were patient and observer blinded, nil + COT was not blinded. Verum, verum acupuncture, Sham, sham acupuncture, COT, conventional orthopedic therapy.

($n = 53$). Results are significant for Verum + COT versus Sham + COT ($P = 0.013$) and are not statistically significant for Verum + COT versus nil + COT ($P > 0.05$) after appropriate adjustments for multiple testing (Table 4, Fig. 1).

4.5. Treatment effect on 4-PBS directly after treatment protocol

An excellent or good effect was reported by: 84% (95%CI 72–92%) in the Verum + COT group ($n = 62$), 67% (95%CI 54–79%) in the Sham + COT group ($n = 61$), 56% (95%CI 42–70%) in the nil + COT group ($n = 55$). Results are significant for Verum + COT versus nil + COT ($P = 0.016$) and are not statistically significant for Verum + COT versus Sham + COT ($P > 0.05$) after appropriate adjustments for multiple testing.

4.6. Treatment effect on 4-PBS after 3 months

An excellent or good improvement was reported by: 73% (95%CI 58–85%) in the Verum + COT group ($n = 49$), 55% (95%CI 38–70%) in the Sham + COT group ($n = 42$), 30% (95%CI 15–47%) in the nil + COT group ($n = 37$). Results are statistically significant for Verum + COT versus nil + COT ($P = 0.0006$) and are not significant for Verum + COT versus Sham + COT ($P > 0.05$) after appropriate adjustments for multiple testing (Table 4).

4.7. Analyses of endpoints only for patients with a pain history of at least 6 months (Stratum 2–4)

Significant and not-significant results do not change when patients with a LBP pain history of less than 6 months (stratum 1, $n = 6$) are excluded from analysis.

4.8. Schober's sign, finger to ground distance and diclofenac intake

In the values of Schober's sign, finger-to-ground distance and diclofenac intake no significant changes were found. Before treatment 18% patients of the Verum + COT group took diclofenac versus 20% of the Sham + COT and 15% of the nil + COT group. After end of treatment protocol patients diclofenac intake decreased/stayed stable/increased in: Verum + COT, 11%/82%/7%; Sham + COT, 7%/84%/9%; and nil + COT, 11%/75%/14%. After 3 months patients diclofenac intake decreased/stayed stable/increased in: Verum + COT, 7%/82%/11%; Sham + COT, 10%/80%/10%; and nil + COT, 9%/68%/23%. No important adverse events or side effects in either of the intervention groups were observed.

4.9. Handling of missing data

After 3 months data could be obtained from 124 (67%) patients of an ITT population of 186 randomized patients. In accordance with the guidelines of the EMEA in a second analysis we counted all patients missing after 3 months as

Table 5
Primary endpoint analysis including missing patients (ITT)[a]

Characteristics	Sham + COT	Verum + COT		nil + COT	Total
Primary endpoint analysis in ITT sample					
3 months VAS assessment					
Sample sizes ITT	61	65		60	186
Good outcome	12	36		5	53
Bad outcome	29	11		31	71
n	41	47		36	124
Not available	20	18		24	62
P		< 0.00003	< 0.00001		
Worst case assumption					
Good outcome	12	36		5	53
Bad outcome	49	29		55	133
P		0.0001	< 0.0001		
Best case assumption					
Good outcome	32	54		29	115
Bad outcome	29	11		31	71
P		0.0005	0.0001		
Mixed worst–best case assumption					
Good outcome	32	36		29	97
Bad outcome	29	29		31	89
P		> 0.05	> 0.05		

[a] Good outcome: VAS pain reduction of at least 50% in VAS assessment; n, number of assessed patients; n.a., number of patients not available; *P* value is adjusted for multiple testing according to trial protocol. Verum, verum acupuncture; Sham, sham acupuncture; COT, conventional orthopedic therapy.

failures (worst case assumption) or as successes (best case assumption, EMEA, 2001). Results of Verum + COT versus Sham + COT and Verum + COT versus nil + COT remain statistically significant in the worst-case (adjusted $P = 0.0001$, $P = 0.00000002$) and best case analysis (adjusted $P = 0.000528$, $P = 0.00011$).

For statistical reasons, we also performed a mixed worst/best case assumption analysis where all patients were considered as failures when missing in Verum + COT, and as successes when missing in either Sham + COT or nil + COT which lead to no statistically significant differences (Table 5). This is the least favourable assumption for Verum + COT regarding missing values.

5. Discussion

The trial had to be stopped early after 1.5 years for external reasons[1]. Although it was not possible to reach the originally planned sample size, the statistically significant results are not compromised. The trial gives evidence that acupuncture can be an effective add-on-treatment in chronic LBP lasting longer than 3 and 6 months. Together with conservative orthopaedic standard therapy acupuncture as described in the trial helps to decrease pain intensity directly after treatment and patients rating of the acupuncture treatment regimen is significantly better than that of the standard therapy alone. Our data suggest that the therapeutic effect of the acupuncture treatment lasts for at least 3 months after the end of treatment, slightly improving in the Verum + COT group. We have observed the phenomenon clinically and described it before (Molsberger and Böwing, 1997).

Any needling of any point raises beta-endorphin levels and its clinical effect does exceed that of a mere suggestive therapy (placebo-control) (Pomeranz, 1998; Vincent and Richardson, 1986). In sham acupuncture which is also called 'minimal acupuncture' or 'dry needling' afferent stimulation does occur. Contributing to the ongoing discussion on sham and verum acupuncture the trial also gives strong evidence that for chronic LBP needling verum acupuncture points (specific Chinese acupuncture points) surpasses the effect of needling sham acupuncture points (non-acupuncture points), even when sham acupuncture points are administered in the same LBP region as the verum acupuncture needles. In fact, we found a higher pain relief in the Sham + COT group than in the nil + COT (not significant) after 3 months but not directly after the end of treatment.

With the German public health rehabilitation system providing an in-house treatment for chronic LBP patients, it was possible to enforce the trial protocol in this single center trial; treatments and examinations were applied strictly and consistently during the 4 weeks treatment interval. After discharge, however, patients were without supervision by the investigating doctor and not accessible but through their family doctors once at the end of the 3 months follow-up.

Patients with pending compensation claims were not accepted into the trial, in order to exclude a possible conflict of interest between positive treatment effects and expected

[1] As a result of the reorganisation of the German public health system the in house treatment of the hospital had to be stopped during the time of the trial.

benefits payments influencing unduly the outcome of the trial. Still, a mean VAS pain score of 66, an average age of 50 and an average duration of the disease of 9.9 years describes a LBP patient population which is comparable to other trial populations (Cherkin et al., 2001).

No differences were found in Schober's sign and in the finger-to-ground distances, suggesting that either acupuncture in fact is a mere pain treatment without effect on body movement functions or that these measurements are not as sensitive as the VAS for pain or the 4-PBS for treatment efficacy. Only 15–20% of the patients took diclofenac. For patients suffering from LBP for more than 9 years that is not a surprising finding, since those patients refrain from long-term drug intake causing side effects. We did not detect significant differences of drug intake between the groups before and after treatment either because there is none or the trial population was to small.

Since, after 3 months, follow-up data were collected by the family doctor on an outpatient basis the trial is compromised by a loss of about 30% of the trial patients at that time (having changed their doctor, not showing up in the office any more e.g.) (Table 5). We undertook two analyses according to the guidelines of the EMEA (European agency for the evaluation of medicinal products)(EMEA, 2001). In a first analysis, we imputed all missing patients as failures, in a second analysis all missing patients as successes; in both cases the significant differences are reproduced. Additionally we undertook a third mixed worst–best analysis, counting missing patients in the test group (Verum + COT) as failures and missing patients in the control groups (Sham + COT, nil + COT) as successes; in this case the differences were not significant for the 3 months data. However, this third least favourable assumption biases the test treatment downwards and the control treatment upwards and we did not detect any inhomogeneity in the baseline values of the missing patients, supporting the clinical relevance of this analysis.

Discussing the results of this trial one should also consider:

- the contradictory results of two recent major reviews/ metaanalysis of acupuncture in LBP by Tulder and Ernst- one stating that there is no evidence that acupuncture is more effective than placebo, the other stating that in contrast acupuncture is superior to various control interventions, with both authors agreeing only, that former LBP trials are of too low quality to rely on (Ernst and White, 1998; van Tulder, 1999);
- The inconsistent results of three back pain trials of high methodological quality just recently being published – one showing massage being superior to acupuncture in LBP (Cherkin et al., 2001), the second showing acupuncture being superior to massage but not to sham procedure in neck pain (Irnich et al., 2001) and the third showing acupuncture being superior to physiotherapy but not to sham acupuncture in chronic LBP (Leibing et al., 2002).

Main differences of our trial to those discussed in the reviews of Tulder and Ernst are the bigger sample size of 186 versus 17–100 (mean 50) patients, and the number of treatments with 12 versus 1–10 (mean 6) treatments and furthermore the clearly defined verum, sham and control treatments (Carlsson and Sjölund, 1993; Coan et al., ; Edelist et al., 1976; Fox and Melzack, 1976; Garvey et al., 1989; Gunn et al., 1980; Lehmann et al., 1983; Macdonald et al., 1983; Mendelson et al., 1983; Thomas and Lundberg, 1994).

In comparison to the acupuncture versus massage trials again one important difference is the number of acupuncture treatment sessions in a given time. On the basis of clinical experience and pilot data we applied 12 treatments within 4 weeks in contrast to five treatments within 3 weeks (Irnich et al., 2001) and eight treatments within 10 weeks (Cherkin et al., 2001). Additionally, in our trial acupuncture was carried out by an orthopedic doctor whereas in the massage-LBP trial acupuncture was done by non medical doctors.

In the LBP trial by Leibing et al. for methodological reasons the selection of individual acupuncture points such as Ahshi points (locus dolendi-, trigger points) was forbidden (Leibing et al., 2002). This might explain the different outcome of this study compared to ours.

Taken together all discussed trial outcomes support the hypothesis that acupuncture for musculosceletal pain syndromes of the back yields positive results,

- when acupuncture is combined with conservative orthopedic treatment, and
- when 12 treatments are applied within 4 weeks, and
- when individual acupuncture points (Ahshi points) are identified and needled possibly by an anatomically trained medical doctor.

Next to apparent questions e.g. diseases suited for acupuncture treatment, comparison of acupuncture to standard therapy-future research should focus on the ideal number of treatments needed to treat chronic diseases sufficiently and should expand the follow up time to 6 months or 1 year.

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