

GERAC- The German Acupuncture Trial for Low Back Pain

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Abstract

Background: In the year 2000 the Joint Federal Committee of Physicians and Health Insurance Plans in Germany initiated a project comparing the effectiveness of acupuncture to guideline-oriented conventional therapy for chronic pain. Within this project four large, randomized studies were conducted as part of the "German Acupuncture Trials" (GERAC) testing acupuncture against sham acupuncture and guideline standard therapy in the treatment of migraine, tension headache, gonarthrosis of the knee and low back pain. The GERAC-Trial which evaluated chronic low back pain will be discussed in this paper.

Methods: All GERAC-Trials were conducted as patient- and observer-blinded randomized controlled trials. The low back pain trial involved 340 outpatient practices in Germany, including 1162 patients with a history of chronic low back pain for a mean of 8 years. Patients underwent verum acupuncture (n=387) according to principles of traditional Chinese medicine or sham acupuncture (n=387) consisting of superficial needling at nonacupuncture points or conventional therapy, a combination of drugs, physical therapy, and exercise (n=388). Five additional sessions were offered to patients who had a partial response to treatment. Primary outcome was response after 6 months, defined as 33% improvement or better on 3 pain-related items on the Von Korff Chronic Pain Grade Scale questionnaire (CGPS) or 12% improvement or better on the back-specific Hanover Functional Ability Questionnaire (HFAQ).

Results: 10 to 15 acupuncture sessions, verum as well as sham, alleviated pain more effectively than conventional therapy. At 6 months, response rate was 47.6% in the verum acupuncture group, 44.2% in the sham acupuncture group, and 27.4% in the conventional therapy group. Differences between verum vs sham was 3.4% (95% confidence interval, -3.7% to 10.3%; P=0.39) between verum vs conventional therapy was 20.2% (95% confidence interval, 13.4% to 26.7%; P<0.001) and between sham vs conventional therapy was 16.8% (95% confidence interval, 10.1% to 23.4%; P<0.001.)

Conclusions: Body needle acupuncture is an effective method to improve chronic low back pain for at least 6 months. Effectiveness of acupuncture, either verum or sham, was almost twice that of conventional therapy. On the basis of these results, acupuncture is now recognized within the German health service. However, the significance of the specific placement of the acupuncture needles strictly according to the rules of Traditional Chinese Medicine remains unexplained.

Background

In the year 2000 in Germany the reimbursement of an acupuncture-treatment has been restricted by decision of the Federal Committee of Physicians and Health Insurance Funds. From then on reimbursements of acupuncture

were only given for the indications migraine, chronic tension headache, chronic unspecific low back pain, cox- and gonarthrosis when treated within the framework of a so-called model project. It was intended to base the decision for reimbursement of acupuncture on the results of the model projects.

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The federal association of the AOK and other German health insurance associations initiated such a model project in co-operation with the University of Bochum on a scientific basis to study the quality of health care given by acupuncture treatment. The Universities of Heidelberg, Marburg and Mainz joined this agreement to build four regional trial groups that perform four different randomised clinical trials.

This model project was named German Acupuncture Trials (GERAC) and contained a cohort-study and four randomised controlled trials. The cohort-study collected data on a patient's self-assessment and the physician's assessment of the effect of an acupuncture treatment. Safety aspects were of special interest. The four randomised controlled trials compared verum acupuncture, sham acupuncture and a standard therapy with respect to efficacy and safety in four relevant indications^{1,2}. These indications were chronic tension headache, migraine, chronic gonarthrosis and unspecific low back pain (LBP). In this paper the GERAC-LBP study will be described and discussed^{3,4}.

Materials and Methods

The GERAC-LBP study was a multi-centre, randomised, controlled, 3-armed clinical trial conceived as parallel-group design with blinded assessment. Aim of the trial was to assess the efficacy with respect to pain and functionality of a standardised acupuncture in the treatment of low back pain in comparison to sham acupuncture and to a conservative standard therapy. The study was approved by local ethics committees.

Participants

Main inclusion criteria were as follows: age 18 years or older, clinical diagnosis of chronic low back pain for 6 months or longer, mean Von Korff Chronic Pain Grade score⁵ of grade 1 or higher and a Hanover Functional Ability Questionnaire score of less than 70%, no previous acupuncture for treatment of chronic low back pain, and signed informed consent. Primary exclusion criteria were previous spinal surgery; previous spinal fractures, infectious, or tumorous spondylopathy; and chronic pain caused by other diseases.

Interventions

Patients were randomized to receive verum acupuncture, sham acupuncture, or guideline-based conventional

therapy. All interventions comprised ten 30-minute sessions, and 5 additional sessions if patients experienced a partial reduction in pain intensity after the tenth session.

All physicians involved were required to have received a minimum of 140 hours of acupuncture training and pass a nationally recognized examination, to have had at least 2 years of clinical experience with acupuncture, and to have attended a 1-day training seminar prior to the trial on treatment protocols and documentation.

In order to assure equal attention to patients in all treatment groups, a western medical diagnosis as well as a TCM diagnosis was made before the patient was enrolled in the study and randomized to a treatment group. The TCM diagnosis included identification of one or more painful areas of the back that would help to locate Ah-shi points (*locus dolendi*), and the appropriate adjacent and distal points with respect to the affected meridians (Figure 1). It also included identification of the TCM syndrome patterns cold dampness, blood and qi stagnation, and kidney deficiency. Tongue diagnosis could be used additionally to confirm the syndrome.

For acute episodes of pain, rescue medication was permitted in all groups. This was strictly defined as nonsteroidal anti-inflammatory drugs to be taken on no

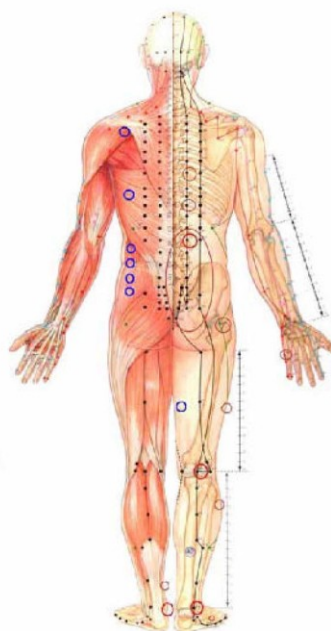


Figure 1: Acupuncture points: Verum = red, Sham = blue

more than 2 days per week up to the maximum daily dose during the therapy period and only 1 day per week during follow-up.

Verum acupuncture

Verum acupuncture points had to be selected according to defined point selection algorithms for LBP which include both obligatory and individual points. Individual points were Ah-shi points (tender points), local points, distal points chosen according to the affected channel, energetic points derived from the TCM syndromes, and mere symptomatic points.

The obligatory points which had to be needled in all patients were BL 23, BL 40, BL 60, and KI 3, with the constraint that if the GB meridian was affected exclusively, BL 40 had to be changed in GB 34 and BL 60 to GB 41 (Table 1). A maximum of six Ah-shi points had to be added, as far as they could be detected. Except for Ah-shi points all points were given bilaterally.

De qi, a sensation of heat, tingling or pressure around the needles, was accomplished by manual stimulation. Moxibustion, electrical stimulation, or cupping was not allowed. Needles had to be stimulated two to three times during treatment to achieve repeated de qi.

Sterile, stainless steel, single-use needles (gauge 0.25 to 0.35 mm) were used. The depth of insertion was 4 to 50 mm, depending on needle location. A minimum of 14 and a maximum of 20 needles per treatment were allowed. Treatment lasted 30 minutes.

Sham acupuncture

For sham treatment, 6 points at the lateral part of the back (5 cm lateral from exterior bladder meridian) and 2 points of the lower limb (3 cm medially and caudally from BL 37 and on the tibial surface) were selected as marked blue in figure 1. The same type of needles and nearly the same number of needles was used as for verum acupuncture. Sessions were the same length (30 minutes), and the physician devoted the same intensity of care to the patient. Therefore sham acupuncture differed from verum acupuncture only in the location of the points needled (outside Chinese meridians), the depth of insertion (maximum 3 mm), and the absence of manual stimulation.

Standard Therapy

Patients in the conventional therapy group received a multimodal treatment program according to German guidelines. The guidelines provide the treating physician with recommendations about the treatment algorithm and assess the various therapy forms according to the degree of evidence based on a literature search and recommendations of the specialist associations. Conventional therapy included 10 sessions with personal contact with a physician or physiotherapist who administered physiotherapy, exercise, and such. Physiotherapies were supported by nonsteroidal anti-inflammatory drugs or pain medication up to the maximum daily dose during

Table 1: Specified verum acupuncture points for low back pain

Obligatory acupuncture points to be needled on both sides:

- BL 23, BL 40 (GB 34), BL 60 (GB 41) KI 3

Ah-shi and/or local points chosen from the following six points, consisting of Ah-shi points and local points, generally needled on one side only:

- BL 24-34, BL 36, BL 37, BL 52, BL 54, GB 30, GB 51, GB 34, GB 41, ST 31, ST 32, SI 3

Maximum of four points for syndrome therapy:

- Kidney yang deficiency: additionally GV4
- Kidney yin deficiency: KI 7 instead of KI 3
- Bi syndrome "damp cold": additionally SP 9, BL 20—bilaterally
- Bi syndrome "stagnation of blood and qi": additionally BL 17 on both sides

Maximum of two of Axis and meridian stimulation points before or after the actual acupuncture treatment:

- Pain on the BL and/or GV meridian: BL 60, alternatively SI 3
- Gallbladder pain: GB 34
- Symptomatic point for back pain: hand point: 1

the therapy period.

Patient communication and concealment of the treatment

In order not to influence the outcome of the trial by differing expectations, all patients receiving acupuncture treatment were informed as follows: "It has not yet been proven whether, in order for acupuncture to be effective, the needles must be inserted at certain, precisely defined locations. Therefore, in this study, a traditional Chinese form of acupuncture will be compared with a form of acupuncture developed especially for this study." To secure concealment of verum and sham acupuncture, patients were not admitted to the trial if they had ever been treated with acupuncture for LBP before or if they had received acupuncture treatment for any condition during the year preceding the trial. Physicians were instructed on how to interact with the patient in such a way that the patient could not detect from the physician's behaviour whether he or she was receiving verum or sham acupuncture. During the actual treatment session, communication with the patient was limited to a minimum of necessary explanations, so as to avoid unblinding the patient by suggestive remarks. The patient's blinding was assessed immediately after conclusion of the treatments by a blinded telephone interviewer.

Outcome Measures

Telephone interviews were conducted at baseline and at 1 1/2, 3, and 6 months. The primary outcome was treatment response 6 months after randomization, defined as 33% improvement or better on 3 pain-related items on the Von Korff Chronic Pain Grade Scale (CPGS)⁵ or 12% improvement or better on the Hanover Functional Ability Questionnaire (HFAQ).⁶ Patients who had recourse to additional treatments other than rescue medication and unblinded patients were classified as non-responders. Secondary outcomes were responder rate, scores on the 12-item Short Form Health Survey,⁷ and patient global assessment of therapy effectiveness on a scale of 1 (very good) to 6 (fail).⁸ Physicians documented medication use, acupuncture treatment, and adverse events at each session and at the final examination after 6 months.

Randomizing and Blinding

The 1:1:1 randomization was performed by a computer program balancing for chronification (>2 or <2 years),

fear avoidance belief⁹) (>4 or <4 average total points), activity (>60 or <60 minutes), patient expectations,¹⁰ and trial center. After successful completion of the baseline interview, the physician called a randomization hotline that assigned the patient to a treatment group. Patients were blinded to the type of acupuncture. Investigators could not be blinded to the method of acupuncture, but the interviewers were.

Statistical analysis

The primary analysis included all randomized patients on the intent-to-treat basis. Patients in all groups who missed the 6-month-assessment were classified as non-responders.

Response rates were tested for differences using the 2-sided Fisher exact test. Two tests comparing verum acupuncture with the 2 control groups at a level of 2.5% each were performed as a first step.⁴ If this global test ruled out the null hypothesis of no difference among the 3 treatments, then all 3 pairwise comparisons were performed at a level of 5%. The study was powered to detect a change of 10% in response rates (verum acupuncture 60%; conventional therapy 50%; and sham acupuncture 40%), with 95% power for the global test. Exploratory analyses were performed for all secondary end points. Sensitivity analyses included comparisons with grouping by treatment, dropping patients who missed the 6-month assessment, and best and worst imputation of missing data at 6-month assessment in all pairwise comparisons.

Results

Of 1802 screened patients with low back pain 1162 were randomized between March 2002 and December 2004. Baseline data showed no difference between the groups (Table 2). Twenty-three patients in the intent-to-treat population in the conventional therapy group missed the 6-month telephone assessment and were, thus, classified as non-responders.

A total of 13 475 treatment sessions were conducted (verum acupuncture, 4821 [mean, 12.5 per patient]; sham acupuncture, 4590 [mean, 11.9 per patient]; conventional therapy, 4064 [mean, 10.5 per patient]). The therapies given in the conventional group were physiotherapy (n=197), massage (n=180), heat therapy (n=157), electrotherapy (n=65), back school (ie, a practical education in the management of back pain) (n=36), injections

(n=48), and guidance (n=56). Pharmacologic treatment in the conventional therapy group consisted of analgesics in 95% of patients (n=183). At the end of the study, patients rated the credibility of both acupuncture forms positively. Blinding seems to have been maintained: most patients did not correctly identify or did not know which form they had received. Primary outcome at 6 months could be assessed in 96.1% of all randomized patients.

Clinical outcomes

Table 3 and Figure 2 show the response rates and between-group differences at 6 months. Almost half of patients in the acupuncture groups but only one-fourth of patients in the conventional therapy group benefited. The P value of the comparison of verum acupuncture and conventional therapy as well as the P value of the comparison of sham acupuncture and conventional therapy is less than 0.001. Verum acupuncture was not superior to sham acupuncture, with an observed difference of 3.4% (P=0.39). Before application of the non responder criterion, success rates were about 30% greater; that is, in

any group, about 25% of patients were classified as non responders because they had recourse to additional therapies. Patients in both acupuncture groups also had clinically meaningful better results for all secondary outcome measures, including medication use (Table 4).

During the 6 months after randomization, 40 serious adverse events were documented, 12 each in the verum and sham acupuncture groups and 16 in the conventional therapy group. All were deemed unrelated to the intervention. In addition, 476 clinically relevant adverse effects were reported by 257 patients (22.6%), with no significant difference between therapy groups (P=0.81).

Discussion

The GERAC-LBP-Study shows that both verum and sham acupuncture improve pain and functionality in patients with low back pain more than conservative therapy. The effect was assessed by success rates based on the von Korff Chronic Pain Grade Scale and the Hanover Functional Ability Questionnaire. The study yielded further surprising results. Almost half of the patients in

Table 2: Baseline

	Verum	Sham	Standard
Number of patients	387	387	388
Pain history (y)	8.1	7.7	8.1
Age (y)	49.6	49.2	51.3
CPGS (Baseline)	67.7	67.6	67.8
HFAQ (Baseline)	46.3	46.3	46.8

GCPS = Von Korff Chronic Pain Grade Scale
HFAQ = Hanover Functional Ability Questionnaire

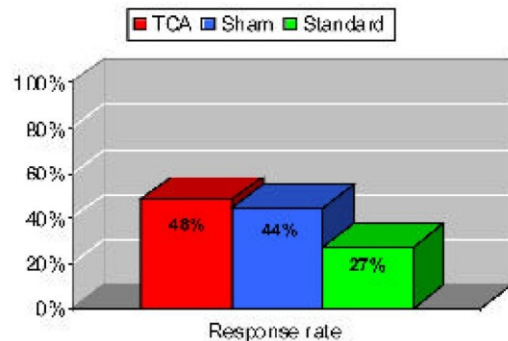


Figure 2: Results Main outcome: Response rate (33% success)

Table 3: Response rate (33% success)

	Verum-ACU	Sham-ACU	Standard
	47.6%	44.2%	27.4%
Differences	% [95%CI]		
• Verum-ACU - Standard	20.2%	[13.4; 26.7%]	p<0.001
• Verum-ACU - Sham	3.4%	[-3.7; 10.3%]	p=0.39
• Sham-ACU - Standard	16.8%	[10.1; 23.4%]	p<0.001

both acupuncture groups were responders. They experienced clinically relevant improvement in pain intensity or back-specific disability without having recourse to concomitant therapies. On the other side only one-fourth of the patients receiving conventional therapy, consisting of a multimodal combination of pharmacologic and non-pharmacologic treatments, responded to treatment. However, there was essentially no difference between the results for verum and sham acupuncture.

A recently published meta-analysis of acupuncture for low back pain¹¹⁾ concluded that "Current preliminary data suggest that acupuncture may be more effective than ineffective controls for providing short-term relief of chronic low back pain."¹²⁾ In contrast, the GERAC-LBP study shows superiority over an active control group. The non superiority of verum over sham acupuncture found in this study is in agreement with a recently published study¹³⁾ that was conducted at the same time.

To our knowledge, the GERAC-LBP study is the largest reported randomized, controlled trial on the efficacy and safety of acupuncture in patients with low back pain. Blinding between verum and sham acupuncture was successful, the number of patients who left the study was kept low, and homogeneous treatment groups could be created with respect to demographic characteristics and baseline values. However, the study has several limitations. Adherence to the predefined acupuncture schemes could not be monitored. The recruited patients assumedly had an interest in acupuncture, possibly introducing a selection effect.

Because complete blinding was impossible, this study does not allow us to determine whether the observed effectiveness of verum and sham acupuncture was due to placebo effects, intensity of provider contact, or a physiologic effect of needling. An effect of needle insertion (deep or minimal), more intensive practitioner-patient contact (placebo effect of a "healing ritual"), or patients'

Table 4: Results for Secondary Endpoints

Secondary EndPoint	Verum Acupuncture	Sham Acupuncture	Conventional Therapy
Treatment response			
6 wk	60.7 (387)	59.2 (387)	56.1 (387)
3 mo	55.0 (387)	51.9 (387)	41.9 (387)
Disability, HFAQ			
Baseline	48.3 ± 14.7 (387)	46.3 ± 15.3 (387)	46.7 ± 14.5 (387)
6 wk	54.0 ± 21.1 (370)	61.3 ± 20.8 (375)	56.3 ± 20.8 (361)
3 mo	55.4 ± 22.9 (373)	61.3 ± 22.7 (375)	56.0 ± 22.0 (361)
6 mo	55.8 ± 23.1 (377)	62.2 ± 23.0 (375)	55.7 ± 22.7 (364)
Quality of life, SF-12 physical scored			
Baseline	31.8 ± 8.8 (385)	31.5 ± 8.9 (388)	31.6 ± 8.9 (394)
3 mo	40.3 ± 10.1 (370)	39.2 ± 9.7 (372)	36.1 ± 8.9 (361)
6 mo	41.6 ± 10.5 (373)	39.5 ± 10.1 (372)	35.8 ± 9.5 (364)
Quality of life, SF-12 mental scored			
Baseline	48.8 ± 12.3 (385)	48.8 ± 11.5 (388)	47.1 ± 11.3 (384)
3 mo	50.5 ± 11.1 (370)	50.2 ± 11.0 (372)	40.8 ± 11.3 (361)
6 mo	50.7 ± 11.1 (373)	50.0 ± 10.8 (372)	49.2 ± 11.9 (364)
Patient global assessment			
6 wk	2.8 ± 1.2 (380)	3.1 ± 1.4 (375)	3.5 ± 1.3 (380)
3 mo	2.8 ± 1.3 (371)	3.1 ± 1.4 (376)	3.3 ± 1.3 (359)
6 mo	2.8 ± 1.3 (376)	3.0 ± 1.4 (375)	3.5 ± 1.3 (362)
Study cessation, No. (%)			
	34 (8.8)	39 (10.1)	50 (12.9)

expectations (a "meaning response," according to Moerman and Jonas) may explain the observations. The absence of a specific effect of verum acupuncture is surprising: Specificity of needling points, depth of needling with stimulation, and deqi sensation do not result in marked effects. The verum acupuncture scheme used in this study was based on different acupuncture schools. We cannot be completely sure, however, that there are no active points outside this scheme and that no active point was included in the sham acupuncture scheme. The results raise the question of whether there is a single optimal point selection and whether deep needling with stimulation and deqi sensation is superior to shallow needling.

It has to be considered that in all GERAC trials the point selection was semistandardized and not completely free. Because syndrome diagnosis varies among practitioners as described, some might have chosen other syndromes for point selection. Only manual needle acupuncture was tested. Electroacupuncture, moxibustion, or cupping therapy was not allowed. Similar to surgical treatments and in contrast to drug therapy, quality of acupuncture treatment is highly dependent on the practitioner. With more than 300 treating physicians, investigators controlled treatment quality by requiring a predefined standard of acupuncture training and clinical experience and providing specific instructions before the trial, but it is obvious that it is not possible to observe and record every single treatment. In short, a literature- and expert-based consensual acupuncture applied in a randomized controlled trial setting is not necessarily the best acupuncture possible. Still the authors believe they succeeded in testing a widely used form of acupuncture mirroring Traditional Chinese acupuncture very closely as understood by most practitioners in Germany.

Another consideration with respect to an invasive sham control is that shallow insertion of the needle might in itself have clinical effects and therefore should be avoided. A well-accepted placebo device is the Streitberger needle, which creates the impression, that acupuncture is being performed without penetrating the skin.¹⁴⁾ However, in a multicenter trial in an ambulatory environment involving several hundred physicians, use of the Streitberger needle is too time-consuming and might be susceptible to error. Furthermore a positive outcome for verum acupuncture in such a trial design might be attributed solely to penetration of the skin.

Therefore an invasive sham technique was chosen to test also the specificity of the Traditional Chinese acupuncture procedure compared to shallow needling of non-acupuncture points. All sham points were located close to but outside of the regular acupuncture regions. One might argue that the non-acupuncture points selected for this study might be considered effective in other acupuncture systems. However, according to the authors' literature research and expert discussions, none of these sham points would have been chosen according to any Traditional Chinese Medicine textbook acupuncture style.

The results for conventional therapy were significantly poorer than those in the 2 acupuncture groups. This raises questions about qualitative and quantitative aspects of conventional therapy. The number and duration of patient therapist contacts were designed to be as similar as possible to those in the acupuncture groups. A comparison of the conventional therapy as delivered in our study with several studies of routine care in Germany¹⁵⁾ shows that the treatment in this study was superior in both quality and quantity. We, therefore, assume an efficient level of care for the conventional therapy arm.

Conclusion:

Body needle acupuncture is an effective method of pain reduction in LBP. Because of the results in GERAC, the Joint Federal Committee of Physicians and Health Insurance Plans (G-BA) has recommended that acupuncture for both indications be treated as a covered benefit under German public health insurance plans.

Further investigation is necessary to determine whether the mechanism of the observed effect of acupuncture is due to physiologic effects of needling, intensity of provider contact, or placebo effects.

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