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LONG-TERM IMPROVEMENT IN PAIN COPING FOR CLBP AND GONARTHROSIS PATIENTS FOLLOWING BODY NEEDLE ACUPUNCTURE: A PROSPECTIVE COHORT STUDY*

P. Kukuk[1], M. Lungenhausen[2], A. Molsberger[3], H. G. Endres[1]

[1]Department of Medical Informatics, Statistics and Epidemiology, Ruhr University Bochum,
[2]BG Kliniken Bergmannsheil, Department of Pain Treatment, Ruhr University Bochum, Bochum,
[3]Acupuncture Research Group, Duesseldorf, Germany

Abstract

Background: Little is known about potential long-term effects of body acupuncture. The aim of the study was to determine such long-term effects 3 and 6 months after the end of a course of acupuncture treatment for chronic low-back pain (cLBP) or chronic pain caused by gonarthrosis.

Methods: Prospective cohort study with patients who had received 10 sessions of needle body acupuncture within a maximum of 10 weeks. Data source was our survey of all patients receiving acupuncture treatment in Germany. A total of 1096 eligible patients with cLBP or gonarthrosis pain were identified (68.1% female) and invited by letter to participate in the study. Ultimately 249 patients remained, with no loss of representativeness. Two telephone interviews were conducted 3 and 6 months after the last acupuncture session using standardized questionnaires, available as electronic case report forms. The primary target criteria were self-assessment of pain tolerability prior to the start of acupuncture and after the end of treatment, and pain intensity (GCPS) over time. Secondary target criteria were changes to functional impairment (HFAQ for cLBP, WOMAC for gonarthrosis), quality of life (SF12), depression (CES-D) and patient global assessment of treatment effectiveness (PGA). For the indication cLBP, pain-related fear avoidance beliefs (FABQ) were also queried.

Results: Pain tolerability before acupuncture was reported as being significantly worse than pain tolerability at the time of the two post-acupuncture interviews. The scores for all post-acupuncture questionnaires showed no significant changes over time, with the exception of treatment effectiveness for gonarthrosis. Mean scores for each of the questionnaires at the 3 and 6 month follow-up interviews were as follows:
cLBP: Pain tolerability (pre: 6.8, post: 3.4 / 3.4), pain intensity (41.8 / 42.6), PGA (2.4 / 2.6), SF12 physical (35.8 / 35.8), SF12 mental (45.3 / 46.9), CES-D (14.9 / 14.9), HFAQ (67.2 / 67.1), FABQ total (2.9 / 2.9).
Gonarthrosis: Pain tolerability (pre: 6.9, post: 3.6 / 3.9), pain intensity (42.9 / 42.8), PGA (2.6 / 2.9), SF12 physical (32.2 / 31.3), SF12 mental (45.0 / 46.2), CES-D (15.6 / 14.7), WOMAC total (34.6 / 34.0).
Conclusions: Pain tolerability was significantly improved after acupuncture and remained so up to 6 months after treatment. The mean scores of almost all questionnaires did not change significantly between 3 and 6 months. We therefore conclude that acupuncture had a long-term effect on important aspects of cognitive and emotional pain coping.

Key words: Body acupuncture; prospective cohort study; long-term improvement; pain coping; low Back; Osteoarthritis, Knee

Abbreviations: CES-D = Center for Epidemiological Studies Depression Scale, CI = confidence interval, cLBP = chronic low back pain, CRF = Case Report Form, FABQ = Fear-Avoidance Beliefs Questionnaire, GCPS = von Korff Graded Chronic Pain Scale, HFAQ = Hannover Functional Ability Questionnaire, PGA = Patient Global Assessment, SF-12 = 12-Item Short-Form Health Survey, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index

INTRODUCTION

Acupuncture is steadily gaining popularity in the West. Every week, 10% of general practitioners in Great Britain refer patients for acupuncture or perform acupuncture treatments themselves. [32] In Germany, the state health insurance plans spend roughly 250 million euros annually on acupuncture for the treat-

*On behalf of the steering committee of German Acupuncture Trials (GERAC): H.C. Diener (Department of Neurology, University of Essen, Essen, Germany), J. Kraemer (Department of Orthopedics, Ruhr-University Bochum, Bochum, Germany), J. Michaelis (Institute for Medical Biostatistics, Epidemiology and Informatics, University of Mainz, Mainz, Germany), A. Molsberger (Research Group for Acupuncture, Duesseldorf, Germany), H. Schaefer (Institute of Medical Biometry and Epidemiology, University of Marburg, Marburg, Germany), H.J. Trampisch (Department of Medical Informatics, Statistics and Epidemiology, Ruhr-University Bochum, Bochum, Germany), N. Victor (Institute of Medical Biometry and Informatics, University of Heidelberg, Heidelberg, Germany), M. Zenz (Ruhr-University Bochum, BG-Kliniken Bergmannsheil, Bochum, Germany).

ment of chronic pain, which corresponds to as many as one million patients of all ages per year. [13] In the USA, the number of one million acupuncture patients was reached in 1994. [22] Today it is estimated that 40% of Americans avail themselves of a complementary and alternative medicine (CAM) therapy, with acupuncture occupying a prominent spot. [1]

Despite the popularity of acupuncture, broadly based and reliable data concerning its effectiveness have yet to be produced. To a large extent, this is because studies purporting to test the reliability of this treatment often use methodologies that do not satisfy strict quality standards. [13, 14] Among active acupuncturists, there is a belief that acupuncture can result in clinically meaningful analgesia over a period of at least 3 – 6 months after the last acupuncture treatment. [7] Two recently published studies showed long-term effects over 3 months for cLBP [24] and even up to 3 years for chronic neck and shoulder pain. [19] So far, however, clinical studies with a high external validity of treatment effectiveness 3 and 6 months after the end of acupuncture treatment appear to be lacking.

Methods

Participating Physicians and Patients

Overall, some 12,000 German physicians in private practice who had undergone at least 140 hours of formal acupuncture training took part in the study. [12, 13] All specialties were represented, the most common being GPs (nearly 6,000), followed by orthopedists (just under 2,200) and internists (just under 1,100). All received a letter informing them about the study, particularly the criteria for inclusion and exclusion (Table 1) and the requirement to submit a report for each patient upon completion of the acupuncture treatment. Health insurance plans reimbursed the cost of treatment only after the patient report form was received at our data centre. Symptoms had to have been present for at least 6 months in all cases, and patients could not have received previous acupuncture treatment within the past year. Only body needle acupuncture, without electrical stimulation, was allowed. Maximum number of sessions was 10. Before participating in the study, patients were required to sign an informed consent.

The reporting form contained space for personal information, indication, details of acupuncture treatment and adverse events. After the last acupuncture session (89.8% of patients completed 10 sessions) the report was faxed to our data centre. All acupuncture patients in Germany that were reported to our data centre between 15 July 2002 and 30 August 2002 were included in the initial data base. All patients had consulted their acupuncture physician for treatment of chronic pain (Table 2).

For the purposes of the present study on long-term effectiveness, only those reported patients who underwent their last acupuncture treatment within the aforementioned six-week window, and who sought acupuncture treatment for cLBP or chronic pain caused by gonarthrosis were considered. This produced a population of 6020 patients. Once the inclusion criteria for our study were applied (Table 3), 2824

Table 1. Inclusion and exclusion criteria for GERAC (German Acupuncture Trials) cohort study.

Inclusion criteria:

- No age limit
- Diagnosis of cLBP, or gonarthrosis, or coxarthrosis, or migraine, or other entities of headache, for at least half a year
- No prior acupuncture treatment within past year

Exclusion criteria for cLBP and gonarthrosis indications

- Simultaneous participation in any other clinical study
- Malignant disease, metastases
- Any systemic disease of motor apparatus (e.g. rheumatoid illnesses, Paget's disease)
- Recent spinal, hip or knee surgery
- Vertebral fractures or fractures near joints
- Malformations of the spine (clinical scoliosis, kyphosis, Gibbus deformity, spondylolisthesis)
- Acute bacterial inflammation of the affected knee
- Ongoing cortisone therapy
- Dependence on analgesics, opiates or other drugs
- Severe coagulopathy or anti-coagulant therapy
- Skin disorders that would preclude acupuncture treatment
- Epilepsy
- Psychiatric illness
- Pregnant or nursing female patient (as reported by patient)
- Language skills insufficient for clear communication

Table 2. Indications by ICD-10, as percentage of total.

ICD-10 indication	Percent
Coxarthrosis	1.4
Gonarthrosis	8.4
Back pain	**52.5**
Headache (excluding migraine)	14.9
Migraine	6.5
No indication given, no or incorrect ICD-10	7.6
More than one ICD-10 code	8.7

Table 3. Inclusion criteria for long-term effectiveness study.

- Age ≥ 18 years
- Exactly 10 acupuncture sessions
- Maximum duration of treatment 10 weeks
- Patient name, address and telephone number complete on reporting form
- Informed consent

Table 4. Comparison of data for 5771 patients (6020 in the general survey minus the 249 patients who participated in the 3-month interview) and the 249 patients of the 3-month interview (n = number of available data; Δ = difference between study population and general survey population). Study inclusion criteria: number of acupuncture session = 10, and duration of treatment ≤ 10 weeks.

	General survey (gonarthrosis)	General survey (cLBP)	3-month interview (gonarthrosis)	3-month interview (cLBP)
Number of patients	762	5009	139	110
Age in years, mean ± SD, Δ [95% CI]	67.0 ± 12.2 n = 762	57.5 ± 15.1 n = 5009	63.4 ± 11.5 Δ = -3.6 [-5.8 ; -1.4] n = 139	54.2 ± 11.9 Δ = -3.3 [-6.1 ; -0.5] n = 110
Sex distribution (%)	M: 25.6% F: 74.4% n = 761	M: 34.6% F: 65.4% n = 5002	M: 25.7% F: 74.3% n = 136	M: 35.2% F: 64.8% n = 108
Number of acupuncture sessions, mean [95% CI]	10.2 [9.2 ; 11.3] n = 754	9.6 [9.5 ; 9.7] n = 4960	10	10
Duration of treatment in days, mean ± SD	42.2 ± 22.9 n = 762	43.9 ± 25.6 n = 5009	36.3 ± 11.5 n = 136	37.9 ± 14.1 n = 108

(405 gonarthrosis, 2419 cLBP) of these remained. Incomplete name, address or telephone number information was the most common reason for excluding patients. All 405 gonarthrosis patients within the six-week window were considered eligible. A representative sample of 691 patients was drawn from the cLBP patients by establishing two shorter windows (22 July – 26 July and 31 July – 16 August). 1096 patients thus selected: 68.1% female, median age = 64, mean age ± SD = 61.6 ± 12.5, and 31.9% male, median age = 60, mean age ± SD = 58.2 ± 12.7. All were sent first-contact letters requesting their participation in the study. The letter also contained examples of the questions that would be asked in the telephone interviews. All patients who did not decline in writing (849) were called 3 months after their last acupuncture treatment (first-contact interview). Inasmuch as they still wished to participate, inclusion and exclusion criteria were verified at the same time, especially the correct indication as reported on the faxed report form. If the patient met the criteria (249 patients in all with no loss of representativeness (Table 4)), the 3-month interview was in most cases conducted immediately following the first-contact interview. At the end of the 3-month interview the patient had an opportunity to indicate his or her preferred time and date for the 6-month interview.

Target Variables and Survey Instruments

Primary and secondary target criteria were measured by means of standardized self-assessment instruments. The following parameters were captured in the two telephone interviews conducted 3 and 6 months after the end of treatment:

Self-assessment Instruments for Target Criteria Applicable to Both Indications

- *Pain tolerability*

Pain tolerability is a global score which is intended to capture, among others things, the cognitive and emotional aspects of pain coping. Patients estimated the pain tolerability immediately before acupuncture treatment (retrospectively) and at the time of the two post-treatment interviews on a scale from 0 (pain easy to tolerate) to 10 (pain intolerable).

- *Pain intensity and impairment as a result of pain*

A modified version of the GCPS [11, 28, 33] was used in which the questions covered 3-month instead of 6-month periods, as recommended elsewhere. [31, 33] The questionnaire captures pain intensity (questions 1-3) as well as impairment of activity as a result of pain (questions 5-7) and number of disability days in the prior 3 months due to pain (question 4). Maximum pain intensity is represented by 100 points, as is the maximum subjective impairment as a result of pain. Five graduated stages of chronicity can be formed, based on the number of points and the number of days in which normal activities could not be performed. Stages 0 to 2 represent moderate impairment with increasing levels of pain intensity, while stages 3 and 4 represent severe impairment, regardless of pain intensity.

- *Patient Global Assessment (PGA) of therapy effectiveness*

Patients' self-assessment of the effectiveness of acupuncture [9] reflects desired effects as well as undesirable events. The assessment of acupuncture effectiveness at the time of the interview was quantified us-

ing the grading scale customarily used in German schools, in which 1 = very good and 6 = fail.

• *Quality of life*

The German-language interview version of the Short-Form Health Survey (SF12) [6, 27, 35] is the 12-item short-form of the SF36 general health questionnaire. The SF12 comprises two subscales: a physical subscale and a mental subscale. The physical subscale is made up of six items from the areas "physical functioning", "physical role functioning", "pain" and "general perception of health". The mental subscale is made up of six items from the areas "vitality", "social functioning", "emotional role functioning" and "mental well-being". The subscale scores can be converted into subscale scores from 0-100. The two subscales quantify the respondent's assessment of his or her health status. Higher scores correspond to a better subjective state of health.

• *Depression*

Depression was measured with the help of the German-language version of the CES-D (Center for Epidemiologic Studies Depression Scale) [18] with 20 items scaled from 0 (rarely or none of the time) to 3 (most or all of the time) resulting in a total score from 0-60. The total score discriminates between clinically depressed (≥ 18 points) and non-depressed or mildly depressed patients.

Self-assessment Instruments for Indication-specific Target Criteria

• *WOMAC and HFAQ*

The German version of the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) [2-4] as validated by Stucki and Meier in 1996 [29, 30], and the German version of the Hannover Functional Ability Questionnaire HFAQ [17, 20, 23] were used. The 24 items in the WOMAC were grouped into three subscales to determine arthritis-specific pain (5 items) and stiffness symptoms (2 items) as well as functional impairment (17 items) from the patient's point of view, responses to which are scaled from 0 (no symptoms) to 10 (worst case) resulting in a total score of 0-240 and a mean score of 0-100 by dividing by the number of questions. The 12 items of the HFAQ pertain to the patient's ability to perform complex movements of daily life (e.g. running, getting dressed, lifting). The patient responses are scaled from 0 (not able to do, or only with assistance) to 2 (able to do without any problems at all), resulting in a total HFAQ score from 0-24, which expresses functionality within a range from 0% (0 points) to 100% (24 points). A patient with a total score of >70% is considered not impaired.

• *FABQ – Questionnaire based on the fear avoidance model of chronification of back pain*

The patients' beliefs about how physical activity and work affected their low back pain were measured using the Fear Avoidance Beliefs Questionnaire (FABQ). [26, 34] The FABQ consists of 16 questions. Patients are asked to indicate their level of agreement with statements about the relationship between back pain and work or physical activity. The answers are scaled from 0 (completely disagree) to 6 (completely agree) resulting in a total score from 0-96 and a mean score from 0-6 by dividing by the number of questions.

Data Collection

The interviews were conducted by trained telephone interviewers. Patients were informed about the nature of the interview through sample questions included in the first-contact letter. Advantages of a telephone interview are: patients are in the accustomed home environment, independence from examining physician, avoidance of interviewer bias (triggered by the appearance and behavior of the interviewer) [25], ability of patient to select date and time of interview, and higher rates of participation compared with questionnaires sent by mail. All telephone interviews were computer-assisted (Oracle®-Forms electronic case report forms (eCRFs), with direct data entry) and standardized. This means that the interviewers use the same wording for each patient. The interviewers have no access to previous answers, as the software only allows the interviewer to see the current question. Thus the interviewers are not influenced by contradictory patient responses. Because patient responses are entered directly into the Oracle® data bank, typical data entry errors produced by copying data from paper CRFs are eliminated. The patient's preferred time for the next telephone interview can also be stored in the data bank, enabling the software to generate a daily call list

Statistical Analysis

The representativeness of the sample was verified by comparing demographic data from the general survey with the corresponding data from the sample (Table 4). The significance of possible differences was analyzed either using a two-group t-test or by calculating the 95% confidence intervals. Correlation analyses of the questionnaire scores were performed where indicated. SAS® Statistical Software (Release 8.02, SAS Institute Inc., Cary, NC, USA) was used for the statistical calculations.

Results

680 (62%) of the 1096 patients in the representative sample responded to the first-contact letter. Of these, 247 (36%) declined to participate. No significant differences were found between patients who replied and those who did not with regard to age and sex distribution. Nor were any significant differences found between the indications of patients who were willing to participate in the study and those who declined. All 433 patients who were willing to participate as well as all 416 patients who did not reply to the letter were called about 3 months after their last acupuncture treatment (first-contact interview). Many cLBP patients in particular were excluded at this stage because pain could not be strictly localized in the lower back area. 249 patients (110 cLBP, 139 gonarthrosis) were identified to take part in the 3-month interview, which was generally conducted immediately after the first-contact interview. Despite the necessity of excluding a

Table 5a. Questionnaire results for cLBP patients who participated in both 3-month and 6-month interviews (Δ = 6 months – 3 months).

Questionnaire	3 months (mean ± SD)	Δ to 6 months [95% CI]
Pain Intensity (GCPS items 1-3)	41.8 ± 20.6	+0.8 [-3.1; +4.7]
GCPS total (all items 1-7)	1.7 ± 1.0	+0.0 [-0.2; +0.2]
PGA (effectiveness)	2.4 ± 1.3	+0.2 [+0.0; +0.4]
SF12 physical	35.8 ± 10.1	+0.0 [-2.7; +2.7]
SF12 mental	45.3 ± 10.5	+1.6 [-2.8; +6.1]
CES-D	14.9 ± 6.2	+0.0 [-1.3; +1.4]
HFAQ	67.2 ± 20.5	-0.1 [-2.9; +2.7]
FABQ work	3.2 ± 1.8	-0.1 [-0.4; +0.1]
FABQ activity	4.0 ± 1.3	-0.1 [-0.4; +0.2]
FABQ prognosis	1.5 ± 1.8	+0.4 [+0.0; +0.7]
FABQ total	2.9 ± 1.4	+0.0 [-0.2; +0.3]

Table 5b. Questionnaire results for gonarthrosis patients who participated in both 3-month and 6-month interviews (Δ = 6-months – 3-months).

Questionnaire	3 months (mean ± SD)	Δ to 6 months [95% CI]
Pain Intensity (GCPS items 1-3)	42.9 ± 23.5	-0.1 [-3.3; +3.2]
GCPS total (all items 1-7)	1.8 ± 1.1	-0.1 [-0.3; +0.1]
PGA (effectiveness)	2.6 ± 1.2	+0.3 [+0.1 ; +0.5]
SF-12 physical	32.2 ± 9.5	-0.9 [-3.4 ; +1.7]
SF-12 mental	45.0 ± 11.7	+1.2 [-2.6 ; +5.0]
CES-D	15.6 ± 6.3	-0.0 [-1.4 ; +1.3]
WOMAC Total	34.6 ± 23.0	-0.6 [-3.6 ; +2.4]
WOMAC pain	31.4 ± 23.4	+0.0 [-3.0 ; +3.0]
WOMAC stiffness	35.9 ± 25.0	-0.5 [-5.0 ; +3.9]
WOMAC impairment	35.5 ± 24.3	-0.7 [-3.9 ; +2.5]

large number of patients, the patient data of the 249 interview patients were comparable to the patient data from the general survey (Table 4). The only significant difference was that the mean age of active study participants was about 3 years less than the mean age of patients in the general survey. Although patients had the opportunity to indicate their preferred time for the 6-month interview only 227 (102 cLBP, 125 gonarthrosis) were interested in taking part in the 6-month interview as well. The results of the individual questionnaires are summarized in Tables 5a and 5b.

Pain Tolerability

Mean (± SD) pain tolerability (retrospective) for the time immediately before the start of acupuncture was given as 6.8 ± 2.0 (cLBP) and as 6.9 ± 2.4 (gonarthritis) (Fig. 1a and 1b). At 3 months post-treatment, the mean tolerability score had declined significantly to 3.4 ± 2.7 for cLBP and to 3.6 ± 2.9 for gonarthritis. The mean difference [95% CI] between pre-acupuncture and 3 months post-acupuncture is 3.40 [2.77; 4.02] for cLBP, and 3.35 [2.69; 4.01] for gonarthritis respective-

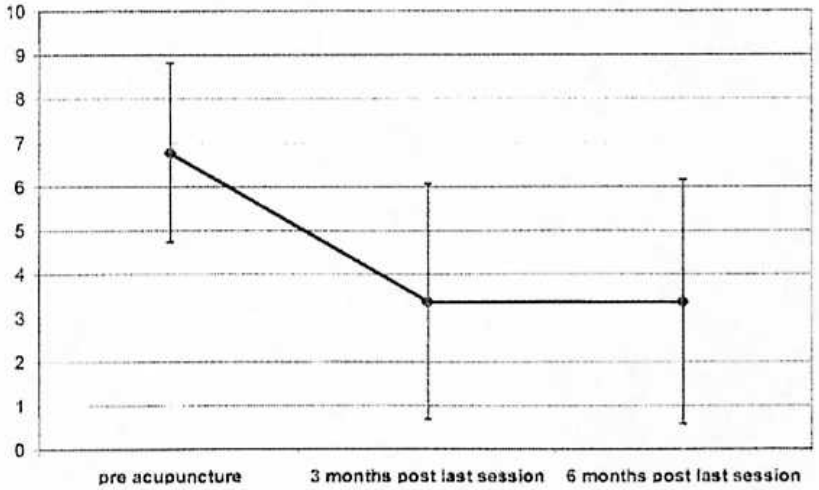

Fig. 1a. cLBP course of pain tolerability (mean ± SD) on a scale from 0 (pain easy to tolerate) to 10 (pain intolerable). Δ pre/3 months post [95% CI] = 3.40 [2.77 ; 4.02].

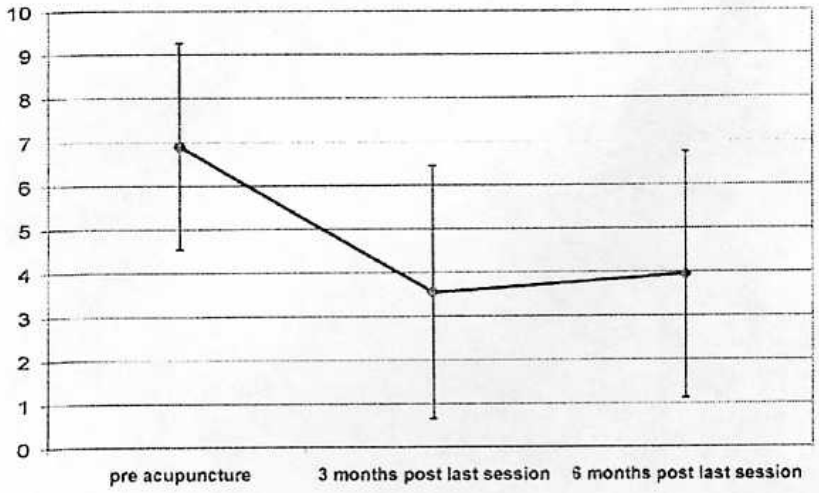

Fig. 1b. Gonarthrosis course of pain tolerability (mean ± SD) on a scale from 0 (pain easy to tolerate) to 10 (pain intolerable). Δ pre/3 months post [95% CI] = 3.35 [2.70 ; 4.01].

Table 6a. Correlation analysis of GCPS pain intensity (GCPS items 1-3) for cLBP patients.

Correlation with GCPS pain intensity in each case at the time of the two post-acupuncture interviews

Time post-treatment	HFAQ prognosis	FABQ	Pain tolerability pre-acupuncture	Pain tolerability post-acupuncture	SF12 physical	SF12 mental	Effectiveness PGA
3 months	r = -0.34 p < 0.001	r = 0.34 p < 0.001	none	r = 0.68 p < 0.0001	none r=-0.08 (p=0.66)	none	r = 0.41 p < 0.0001
6 months	r = 0.60 p < 0.0001	r = 0.48 p < 0.0001	none	r = 0.72 p < 0.0001	r = -0.52 p < 0.01	none	r = 0.46 p < 0.0001

Table 6b. Correlation analysis of GCPS pain intensity (GCPS items 1-3) for gonarthrosis patients.

Correlation with GCPS pain intensity in each case at the respective time of the two post-acupuncture interviews

Interview Time	WOMAC total	WOMAC pain	WOMAC stiffness	WOMAC impairment	Pain tolerability pre-acupuncture	Pain tolerability post-acupuncture	SF12 physical	SF12 mental	Effectiveness PGA
3 months	r = 0.74 p < 0.0001	r = 0.78 p < 0.0001	r = 0.56 p < 0.0001	r = 0.70 p < 0.0001	none	r = 0.64 p < 0.0001	r = -0.53 p < 0.001	none	r = 0.3 p < 0.001
6 months	r = 0.70 p < 0.0001	r = 0.75 p < 0.0001	r = 0.51 p < 0.0001	r = 0.63 p < 0.0001	none	r = 0.74 p < 0.0001	r = -0.54 p < 0.001	none	r = 0.48 p < 0.0001

ly. The 6-month values are identical or nearly identical to the 3-month values. The responses for pain tolerability showed no correlation with age or sex. The GCPS, SF12 physical, HFAQ and WOMAC scores show a strong correlation with pain tolerability, while pain tolerability pre-acupuncture does not.

Pain Intensity (GCPS Items 1-3) and Impairment

The scatter plot (Fig. 2a and 2b) of the pain intensity pairs of variates (x = 3-month values and y = 6-month values) shows that both with cLBP and gonarthrosis the changes in pain intensity with time scatter approximately equally about the line of equality (pain intensity 3 months = pain intensity 6 months). Mean pain intensity remained nearly unchanged at a score of around 42 for both gonarthrosis and cLBP at 3 and 6 months post-treatment (Table 5a and 5b). The responses for pain intensity show no significant differences as a function of age, sex, indication or time course of pain. On average only slight impairment due to pain was reported at the time of both interviews. Mean total GCPS score remained unchanged at ≤ 1.80 in both cLBP and gonarthrosis patients.

PGA (Effectiveness of Acupuncture)

At both the 3-month and 6-month interviews, retrospective PGA of effectiveness remained, on average, between 2 (good) and 3 (satisfactory), with a slight but significant worsening (shift toward 3) at 6 months (Table 5a and 5b). No correlation was found between PGA of the effectiveness of acupuncture and pain tolerability pre-acupuncture, but a moderate correlation

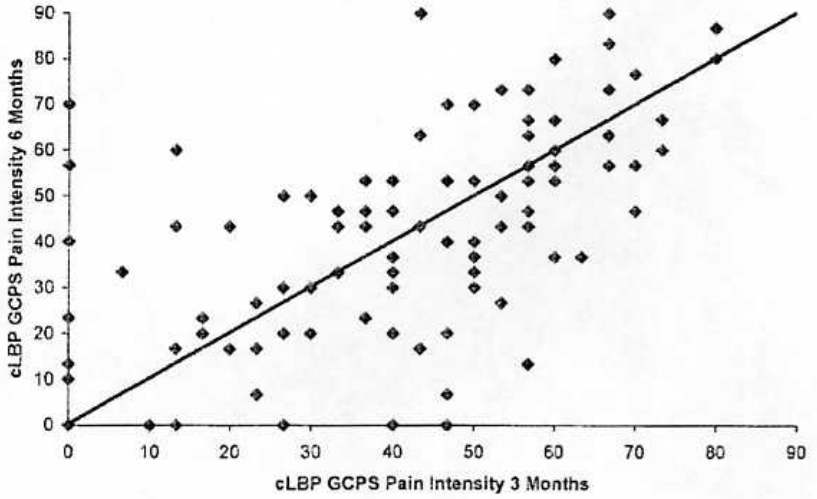

Fig. 2a. Scatter plot of cLBP pain intensity pairs of variates with x-axis = 3-month values and y-axis = corresponding 6-month values.

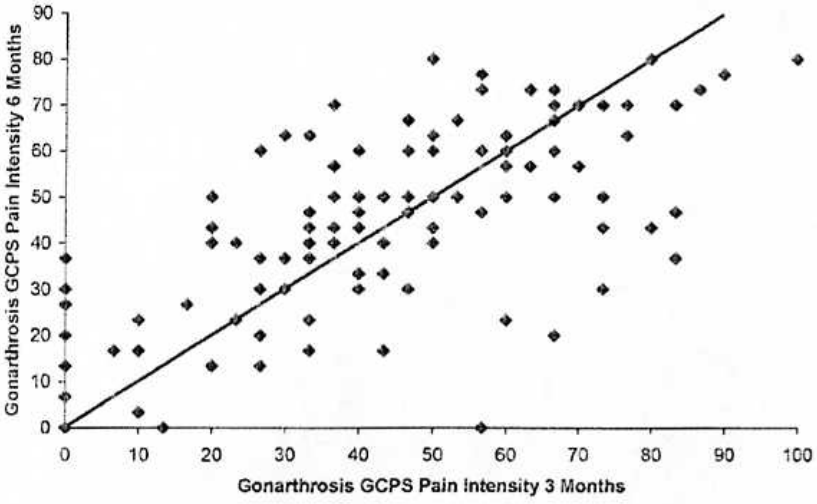

Fig. 2b. Scatter plot of gonarthrosis pain intensity pairs of variates with x-axis = 3-month values and y-axis = corresponding 6-month values.

between PGA and GCPS pain intensity was found (Table 6a and 6b). The stronger the pain intensity, the lower the PGA.

Quality of Life (SF12)

Quality of life reported by patients did not change significantly between the 3-month and 6-month interviews (Table 5a and 5b). At both post-treatment interviews, the mean of the physical and mental summary scales (0-100) was clearly below the reference values for a German reference population sample. [5] The physical summary scale values were just under 36 for cLBP patients and around 32 for gonarthrosis patients (reference sample 46.3 ± 10.1, mean ± SD). The mental summary scale values were around 45 for both cLBP and gonarthrosis patients (reference sample 51.2 ± 8.8, mean ± SD). The values for the physical summary scale at both the 3-month and 6-month points correlate well with the pain intensity reported by gonarthrosis patients (Table 6b). High pain intensities cause low SF12 values. For cLBP patients, however, a good correlation with pain intensity was found only at 6 months (Table 6a). A very good correlation is found at both 3 and 6 months with the HFAQ ($r > 0.7$ und $p < 0.0001$) and with all WOMAC subscales (r frequently < -0.6 with $p < 0.001$), with the exception of stiffness. The values for the mental summary scales correlate well with the CES-D score, albeit only at 6 months for both indications ($r < -0.5$, $p < 0.001$).

Depression

There was no significant difference in symptoms of depression between gonarthrosis and cLBP patients, or between the two interview times (Table 5a and 5b). With a mean of 15.8 ± 6.4 points, the CES-D score for women was significantly higher than that for men (13.0 ± 3.6). The depression score correlated moderately with the WOMAC subscale of impairment due to pain ($r = 0.3$ und $p < 0.01$), but not with the HFAQ. It also did not correlate with patient age, pain intensity or assessment of effectiveness. There was also no correlation with the FABQ.

WOMAC and HFAQ

Neither WOMAC scores in gonarthrosis patients nor HFAQ scores for cLBP patients showed significant changes over time (Table 5a and 5b). There was also no correlation of either of these scores with sex of patients. But almost all WOMAC scores show a strong

correlation with pain intensities at both 3 and 6 months ($r \geq 0.7$, $p < 0.0001$), with the exception of stiffness with a moderate correlation $r > 0.5$, $p < 0.0001$ (Table 6b). HFAQ, however, correlates very well with pain intensity ($r = 0.6$, $p < 0.0001$) only at 6 months (Table 6a).

FABQ Total Score

The FABQ total score for cLBP patients and all FABQ subscores remained unchanged from the 3-month to the 6-month interview (Table 5a). This means that patients were generally uncertain whether physical activity or work makes the back pain worse. The FABQ does not correlate with age and only a slight correlation with sex is seen in total FABQ at 3 months ($p = 0.02$), with men being slightly more likely to see a connection between physical activity or work and their back pain. Total FABQ correlates well with the SF12 standardized physical summary scale ($r = -0.5$ with $p = 0.003$ at 3 months, and $r = -0.6$ with $p < 0.0001$ at 6 months), but correlates only moderately with the HFAQ ($r = -0.3$ with $p < 0.01$ at 3 months, and $r = -0.5$ with $p < 0.0001$ at 6 months). The FABQ subscales show similar correlation coefficients. The correlation with pain intensity is also only weak to moderate at 3 and 6 months (Table 6a).

Discussion

The data base for our study was a survey of all chronic pain patients in Germany who had consulted acupuncture-experienced physicians in private practice. The sample of cLBP and gonarthrosis patients drawn from the survey remained representative. Applying the inclusion and exclusion criteria for this study resulted in a patient group whose chronic pain had proved resistant to conventional medical treatment over an extended period of time, and who at the same time reported, for the most part, only mild to moderate pain intensity and pain-related impairment (GCPS, HFAQ, WOMAC). In this respect the data on the long-term effect of body acupuncture treatment were collected from patients for whom the unsuccessful attempts to treat the chronic pain had developed into a significant problem for the patient as well as for the physician. An aspect that needs to be considered as well is that alternative therapies such as acupuncture currently enjoy high acceptance in the population at large, as illustrated by the positive evaluations frequently expressed by patients in other studies. One would expect that these aspects of patients' positive attitude toward acupuncture would be reflected in the overall assessment of acupuncture effectiveness. In the present study, on a scale of 1 to 6 corresponding to the German school grading system, patients often graded acupuncture as good (2) or even better. It is therefore all the more important to evaluate the success of therapeutic measures by means of appropriate, psychometrically tested instruments.

As recommended in previous publications [10], our study looked at multiple dimensions of chronic pain, since it is known that in the case of chronic motor apparatus pain there is no close correlation between many questionnaire parameters, and we wanted to be sure not to overlook any therapy effects. The therapy effects were assessed exclusively by the patients themselves. The assessment took place in telephone interviews conducted by independent telephone interviewers. The relevant outcome variables measured were:

1. Direct pain-describing parameters (pain tolerability, pain intensity, overall assessment of change in pain).
2. Impact of pain (e.g. pain-related impairment in daily living, patients' health-related quality of life).
3. Depression as impairment of emotional wellbeing, a phenomenon frequently observed in chronic pain cases [21].

A comparison of the overall assessment of pain tolerability showed a significant improvement from pre-treatment to post-treatment. However, it is important to bear in mind that retrospective assessments entail a risk of systematic bias. As Haas [16] was able to demonstrate in a recent publication, patients with higher present pain will perceive poorer pain improvement and conversely patients with lower present pain will perceive greater improvement. Generally, participants with high present pain were found to overestimate previous pain. Since our patients reported only a constant, moderate pain intensity of around 42 at the time of the interviews, it can be assumed that the reported, significantly worse pain tolerability pre-acupuncture is real, as is the significant improvement post-acupuncture. This is further supported by the finding that pain tolerability at the time of the two post-acupuncture interviews correlates markedly with the pain intensity (Table 6a and 6b), while pain tolerability pre-acupuncture shows no correlation at all (r approaching 0.0). However, the significant improvement in pain tolerability post-treatment correlates just as markedly with the standardized SF12 physical summary scale (cLBP and gonarthrosis) and the HFAQ. An especially close correlation is found with all scales of the WOMAC. All of these scores show stable values over the entire observation period of this study. Consequently we conclude that acupuncture treatment produced a positive change for our patients, not only in terms of pain tolerability but, at minimum, in terms of all of the values for which a close correlation with pain tolerability was found.

If one defines patients who reported an improvement in pain tolerability of at least one point on a scale of 0-10 as responders to acupuncture therapy, then the responder rate for gonarthrosis patients was 73.6% and the responder rate for cLBP patients was 81.5%. There were significant differences in this regard between males and females. The response rate for patients with gonarthrosis was 71.7% for women and 78.8% for men; for patients with cLBP the response rate was 85.1% among women and 75.0% among men. This reversal of the sex ratio could be explained by the fact that the mean reported pain tolerability pre-acupuncture for cLBP patients was 7.1 for both men and women, while for gonarthrosis it was 6.6 for men and 7.9 for women ($p = 0.002$). Overall, our study demonstrates a stable, long-term effect of acupuncture up to the end of the 6-month observation period, at

least with regard to pain tolerability, pain intensity, SF12 physical summary scale, HFAQ and WOMAC. An unexpected result of our sub-group analysis was that neither stratification of patients according to pain score, nor stratification according to the total GCPS scores yielded significant differences over time in the questionnaire scores.

The stable long-term effect in our study is surprising insofar as previously published long-term studies have come to very different and often contradictory conclusions. For example, He [19] concludes an immediate effect produced after 8-10 sessions and a long-term effect for up to 3 years after the end of treatment. Other studies report a continuous decline in effect over a period of 9 weeks, until acupuncture treatment is resumed (osteoarthritis of the knee) [8], but also a steady reduction in pain for up to 3 months (cLBP) [24] and 12 months (tennis elbow) [15] after the end of treatment. Carlsson [7] found an improvement in chronic back pain as a result of acupuncture in the first month post-treatment and a stable long-term effect without further change in responder numbers at 3, 6 and 12 months after the end of treatment. However, all follow-up examinations were conducted through personal contact with the blinded observer, so that, in contrast to our study, an interviewer effect cannot be ruled out.

Conclusions

Since our study builds on a survey of all chronic pain patients in Germany who had consulted acupuncture-certified and -experienced physicians in private practice, our study reflects the situation of an "average" chronic pain outpatient. Therefore it is of special importance that we were able to demonstrate a stable, long-term effect of acupuncture up to at least 6 months after the last acupuncture session. If the use of acupuncture can successfully lower the cost of treatment of chronic pain patients, then it will play an essential role in the public health system in the future.

Declaration of competing interests: The authors declare that they have no competing interests

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LONG-TERM IMPROVEMENT IN PAIN COPING FOR CLBP AND GONARTHROSIS PATIENTS FOLLOWING BODY NEEDLE ACUPUNCTURE: A PROSPECTIVE COHORT STUDY*

P. Kukuk[1], M. Lungenhausen[2], A. Molsberger[3], H. G. Endres[1]

[1]Department of Medical Informatics, Statistics and Epidemiology, Ruhr University Bochum,
[2]BG Kliniken Bergmannsheil, Department of Pain Treatment, Ruhr University Bochum, Bochum,
[3]Acupuncture Research Group, Duesseldorf, Germany

Abstract

Background: Little is known about potential long-term effects of body acupuncture. The aim of the study was to determine such long-term effects 3 and 6 months after the end of a course of acupuncture treatment for chronic low-back pain (cLBP) or chronic pain caused by gonarthrosis.

Methods: Prospective cohort study with patients who had received 10 sessions of needle body acupuncture within a maximum of 10 weeks. Data source was our survey of all patients receiving acupuncture treatment in Germany. A total of 1096 eligible patients with cLBP or gonarthrosis pain were identified (68.1% female) and invited by letter to participate in the study. Ultimately 249 patients remained, with no loss of representativeness. Two telephone interviews were conducted 3 and 6 months after the last acupuncture session using standardized questionnaires, available as electronic case report forms. The primary target criteria were self-assessment of pain tolerability prior to the start of acupuncture and after the end of treatment, and pain intensity (GCPS) over time. Secondary target criteria were changes to functional impairment (HFAQ for cLBP, WOMAC for gonarthrosis), quality of life (SF12), depression (CES-D) and patient global assessment of treatment effectiveness (PGA). For the indication cLBP, pain-related fear avoidance beliefs (FABQ) were also queried.

Results: Pain tolerability before acupuncture was reported as being significantly worse than pain tolerability at the time of the two post-acupuncture interviews. The scores for all post-acupuncture questionnaires showed no significant changes over time, with the exception of treatment effectiveness for gonarthrosis. Mean scores for each of the questionnaires at the 3 and 6 month follow-up interviews were as follows:

cLBP: Pain tolerability (pre: 6.8, post: 3.4 / 3.4), pain intensity (41.8 / 42.6), PGA (2.4 / 2.6), SF12 physical (35.8 / 35.8), SF12 mental (45.3 / 46.9), CES-D (14.9 / 14.9), HFAQ (67.2 / 67.1), FABQ total (2.9 / 2.9).

Gonarthrosis: Pain tolerability (pre: 6.9, post: 3.6 / 3.9), pain intensity (42.9 / 42.8), PGA (2.6 / 2.9), SF12 physical (32.2 / 31.3), SF12 mental (45.0 / 46.2), CES-D (15.6 / 14.7), WOMAC total (34.6 / 34.0).

Conclusions: Pain tolerability was significantly improved after acupuncture and remained so up to 6 months after treatment. The mean scores of almost all questionnaires did not change significantly between 3 and 6 months. We therefore conclude that acupuncture had a long-term effect on important aspects of cognitive and emotional pain coping.

Key words: Body acupuncture; prospective cohort study; long-term improvement; pain coping; low Back; Osteoarthritis, Knee

Abbreviations: CES-D = Center for Epidemiological Studies Depression Scale, CI = confidence interval, cLBP = chronic low back pain, CRF = Case Report Form, FABQ = Fear-Avoidance Beliefs Questionnaire, GCPS = von Korff Graded Chronic Pain Scale, HFAQ = Hannover Functional Ability Questionnaire, PGA = Patient Global Assessment, SF-12 = 12-Item Short-Form Health Survey, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index

INTRODUCTION

Acupuncture is steadily gaining popularity in the West. Every week, 10% of general practitioners in Great Britain refer patients for acupuncture or perform acupuncture treatments themselves. [32] In Germany, the state health insurance plans spend roughly 250 million euros annually on acupuncture for the treat-

*On behalf of the steering committee of German Acupuncture Trials (GERAC): H.C. Diener (Department of Neurology, University of Essen, Essen, Germany), J. Kraemer (Department of Orthopedics, Ruhr-University Bochum, Bochum, Germany), J. Michaelis (Institute for Medical Biostatistics, Epidemiology and Informatics, University of Mainz, Mainz, Germany), A. Molsberger (Research Group for Acupuncture, Duesseldorf, Germany), H. Schaefer (Institute of Medical Biometry and Epidemiology, University of Marburg, Marburg, Germany), H.J. Trampisch (Department of Medical Informatics, Statistics and Epidemiology, Ruhr-University Bochum, Bochum, Germany), N. Victor (Institute of Medical Biometry and Informatics, University of Heidelberg, Heidelberg, Germany), M. Zenz (Ruhr-University Bochum, BG-Kliniken Bergmannsheil, Bochum, Germany).

ment of chronic pain, which corresponds to as many as one million patients of all ages per year. [13] In the USA, the number of one million acupuncture patients was reached in 1994. [22] Today it is estimated that 40% of Americans avail themselves of a complementary and alternative medicine (CAM) therapy, with acupuncture occupying a prominent spot. [1]

Despite the popularity of acupuncture, broadly based and reliable data concerning its effectiveness have yet to be produced. To a large extent, this is because studies purporting to test the reliability of this treatment often use methodologies that do not satisfy strict quality standards. [13, 14] Among active acupuncturists, there is a belief that acupuncture can result in clinically meaningful analgesia over a period of at least 3 – 6 months after the last acupuncture treatment. [7] Two recently published studies showed long-term effects over 3 months for cLBP [24] and even up to 3 years for chronic neck and shoulder pain. [19] So far, however, clinical studies with a high external validity of treatment effectiveness 3 and 6 months after the end of acupuncture treatment appear to be lacking.

Methods

Participating Physicians and Patients

Overall, some 12,000 German physicians in private practice who had undergone at least 140 hours of formal acupuncture training took part in the study. [12, 13] All specialties were represented, the most common being GPs (nearly 6,000), followed by orthopedists (just under 2,200) and internists (just under 1,100). All received a letter informing them about the study, particularly the criteria for inclusion and exclusion (Table 1) and the requirement to submit a report for each patient upon completion of the acupuncture treatment. Health insurance plans reimbursed the cost of treatment only after the patient report form was received at our data centre. Symptoms had to have been present for at least 6 months in all cases, and patients could not have received previous acupuncture treatment within the past year. Only body needle acupuncture, without electrical stimulation, was allowed. Maximum number of sessions was 10. Before participating in the study, patients were required to sign an informed consent.

The reporting form contained space for personal information, indication, details of acupuncture treatment and adverse events. After the last acupuncture session (89.8% of patients completed 10 sessions) the report was faxed to our data centre. All acupuncture patients in Germany that were reported to our data centre between 15 July 2002 and 30 August 2002 were included in the initial data base. All patients had consulted their acupuncture physician for treatment of chronic pain (Table 2).

For the purposes of the present study on long-term effectiveness, only those reported patients who underwent their last acupuncture treatment within the aforementioned six-week window, and who sought acupuncture treatment for cLBP or chronic pain caused by gonarthrosis were considered. This produced a population of 6020 patients. Once the inclusion criteria for our study were applied (Table 3), 2824

Table 1. Inclusion and exclusion criteria for GERAC (German Acupuncture Trials) cohort study.

Inclusion criteria:

- No age limit
- Diagnosis of cLBP, or gonarthrosis, or coxarthrosis, or migraine, or other entities of headache, for at least half a year
- No prior acupuncture treatment within past year

Exclusion criteria for cLBP and gonarthrosis indications

- Simultaneous participation in any other clinical study
- Malignant disease, metastases
- Any systemic disease of motor apparatus (e.g. rheumatoid illnesses, Paget's disease)
- Recent spinal, hip or knee surgery
- Vertebral fractures or fractures near joints
- Malformations of the spine (clinical scoliosis, kyphosis, Gibbus deformity, spondylolisthesis)
- Acute bacterial inflammation of the affected knee
- Ongoing cortisone therapy
- Dependence on analgesics, opiates or other drugs
- Severe coagulopathy or anti-coagulant therapy
- Skin disorders that would preclude acupuncture treatment
- Epilepsy
- Psychiatric illness
- Pregnant or nursing female patient (as reported by patient)
- Language skills insufficient for clear communication

Table 2. Indications by ICD-10, as percentage of total.

ICD-10 indication	Percent
Coxarthrosis	1.4
Gonarthrosis	8.4
Back pain	**52.5**
Headache (excluding migraine)	14.9
Migraine	6.5
No indication given, no or incorrect ICD-10	7.6
More than one ICD-10 code	8.7

Table 3. Inclusion criteria for long-term effectiveness study.

- Age ≥ 18 years
- Exactly 10 acupuncture sessions
- Maximum duration of treatment 10 weeks
- Patient name, address and telephone number complete on reporting form
- Informed consent