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Efficacy and Effectiveness of Acupuncture in Patients with Chronic Low Back Pain - A Summary of the Acupuncture in Routine Care Study (ARC) and the Acupuncture Randomized Trial (ART)

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Abstract

Objective: To evaluate the effectiveness and efficacy of acupuncture for low back pain

Material and Methods: In the ARC study patients were randomly allocated to one of two groups, either to receive up to 15 acupuncture sessions over three months or to a control group receiving no acupuncture. Patients who declined randomization were followed in a prospective observational study. All study participants were allowed to receive additional conventional medical care. The patients participating in the ART were randomized in to three groups, either treatment with semi-standardized acupuncture or minimal acupuncture (superficial needling at non acupuncture points) or to a waiting list control. Both acupuncture groups received 12 sessions over 8 weeks. The focus of this paper is on two comparisons: 1) additional acupuncture compared to routine care only and 2) acupuncture compared to sham-acupuncture.

Results: In the ARC study 2841 patients were analyzed. After three months back function improved by 12.1 ±0.4 (mean SE) to 74.5 ± 0.4 points in the acupuncture group and by 2.7 ± 0.4 to 65.1 ± 0.4 points in the control group (difference 9.4 (95% CI 8.3, 10.5); p<.001).

In the ART a total of 219 patients received acupuncture treatment (146 acupuncture, 73 sham-acupuncture). Between baseline and week 8, pain intensity decreased by 28.7 ± 30.3 mm in the acupuncture group and 23.6 ± 31.0 mm in the minimal acupuncture group (difference 5.1 mm (95% CI -3.7 to 13.9; p = 0.26)).

Conclusion: Routine medical care plus acupuncture was more effective than routine medical care alone. However, no significant difference was observed between acupuncture and sham-acupuncture.

Key words: *Acupuncture, low back pain, randomized controlled trial, efficacy, effectiveness*

Introduction

In 2000 the German Federal Committee of Physicians and Health Insurers proposed that large research initiatives on acupuncture could be conducted by health insurance companies for several pain syndromes[1].

As one of these research initiatives, we designed among others, the present model project with the aim of evaluating efficacy, effectiveness, safety and cost of acupuncture treatment in patients with one of the following chronic medical complaints: pain due to osteoarthritis of the knee or hip, low back pain, neck pain or headache[2-8].

The following article outlines the concept and methodology of two studies on low back pain[9,10], the main results are provided, and important implications are discussed. Based in part on the results of this model project, the German Federal Committee of Physicians and Health

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Insurers proposed in April 2006 that acupuncture will be provided as a routine medical option for the treatment of chronic low back pain.

Methods

In order to evaluate the efficacy, effectiveness, and costs of acupuncture the model project consisted of three modules[2]. Within this project two studies were performed on chronic low back pain, one of them focusing on effectiveness (Acupuncture in Routine Care Study, ARC) and the other focusing on efficacy (Acupuncture Randomized Trial, ART).

Acupuncture in Routine Care Studies (ARC): In a randomized controlled study with an additional cohort study, the effectiveness of acupuncture was evaluated when administered in addition to usual care compared to usual care alone[9]. Patients visiting their physician due to chronic low back pain and who agreed to randomization were randomized into an acupuncture or a control group. Patients who declined randomization were included in a third non-randomized group, this paper focuses on both randomized groups solely.

To be included in the study, a patient had to meet the following criteria: clinical diagnosis of chronic low back pain with disease duration of more than 6 months; aged 18 years and above; and the provision of written informed consent. The exclusion criteria were: protusio or prolapse of one or more intervertebral discs with concurrent neurological symptoms; prior vertebral column surgery; infectious spondylopathy; low back pain caused by inflammatory, malignant, or autoimmune disease; congenital deformation of the spine, except for slight lordosis or scoliosis; compression fracture caused by osteoporosis; spinal stenosis; and spondylolysis or spondylolisthesis. The patients in the acupuncture groups received an average of 10 sessions of needle acupuncture. To represent usual care, the decision on which acupuncture points were chosen and how many needles were required was left up to the physician. The patients in the control group did not receive acupuncture until after three months. All patients were allowed to receive usual medical care. The patients completed standardized questionnaires at baseline, three and six months. The primary outcome measure was back function at three months, as assessed by the validated Hannover Functional Ability Questionnaire (HFAQ; in German, Funktionsfragebogen Hannover Rucken)[11].

The HFAQ rates back function on a scale from 0 to 100, with 100 representing perfect back function. Additionally, all patients completed a questionnaire on their general, health-related quality of life (short form: SF 36). The physicians documented the medical history, diagnoses and adverse effects.

In addition, we evaluated overall the cost-effectiveness from a social perspective (cost data was provided by German statutory health insurance companies). The quality adjusted life years (QALYs) were calculated from the SF 36 data[12]. The incremental cost-effectiveness-relationship (cost per QALY gained) was expressed in euro per QALY and resulted from the difference of the mean costs (direct and indirect, of both acupuncture and control groups), divided by the difference between the mean QALYs of both groups three months after the study began.

Acupuncture Randomized Trials (ART): This study determined the efficacy of acupuncture compared to sham-acupuncture, and to no acupuncture (waiting list contro[1,13]) for patients with chronic low back pain. In this paper the focus is on the acupuncture group compared to sham-acupuncture group only. The waiting list group will not be reported here.

The inclusion criteria were as follows: clinical diagnosis of chronic low back pain with a disease duration of more than six months (further diagnostic results were not required), aged 40 to 75 years, average pain intensity of 40 or more on a 100-mm visual analog scale during the last seven days, use of oral non-steroidal anti-inflammatory drugs only for pain treatment in the four weeks prior to treatment, and written informed consent. The main exclusion criteria were as follows: protrusion or prolapse of one or more intervertebral discs with concurrent neurological symptoms; radicular pain; prior vertebral column surgery; infectious spondylopathy; low back pain caused by inflammatory, malignant, or auto-immune disease; congenital deformation of the spine (except for slight lordosis or scoliosis); compression fracture caused by osteoporosis; spinal stenosis; spondylolysis or spondylolisthesis; patients with Chinese medicine diagnoses warranting treatment with moxibustion (determined by trial physicians); and any acupuncture treatment during the past 12 months.

Treatment for the acupuncture group involved deep needling of specific points following the principle of Chinese Medicine; for the non-acupuncture group it involved superficial needling of non-acupuncture points

(for each group a total of 12 treatments over a period of two months). The treatment was developed in a consensus process with national and international experts. 13 Patients were informed about acupuncture and minimal acupuncture in the study as follows: "In this study, different types of acupuncture will be compared. One type is similar to the acupuncture treatment used in China. The other type does not follow these principles, but has also been associated with positive outcomes in clinical studies." The primary outcome variable was the change in low back pain intensity from baseline to the end of week eight, as determined on a visual analog scale (range, 0-100 mm). Secondary outcome parameters were for example back function (HFAQ), quality of life (SF 36) and the pain disability index (PDI).

Further details including statistical analysis of the ARC and the ART study are described in the primary publications[9,10].

Results

In the ARC study 2841 were included, 1390 patients received usual care only and 1451 additional acupuncture treatment. In ART a total of 219 patients received acupuncture (146 acupuncture, 73 sham-acupuncture)). The baseline characteristics of both trials are displayed in table 1.

Effectiveness - Acupuncture in Routine Care Studies (ARC) The patients who received acupuncture in addition to usual care showed significantly greater improvement (p<0.001) in the primary outcome measure after three months compared to those who only received usual care. The improvement in the acupuncture group after three months persisted at six months. After a three month waiting period, the patients of the control group received acupuncture and showed similar improvement after six months compared with that of the acupuncture group. The health-related quality of life was significantly higher in the acupuncture group compared to the control group (p<0.001) after three months.

From baseline to three months, we observed significant differences in overall and diagnosis-specific costs between the acupuncture and control groups (1,062.46 (SD 1,539.74) vs. 782.36 (SD 1,728.80) (p < 0.001) and 557.15 (SD 872.94) vs. 251.91 (SD 1,065.41) (p < 0.001), respectively). The mean difference between the two treatment groups (280.10 (95 percent CI: 148.42, 411.78) vs. 305.24 (95 percent CI: 226.79, 383.68)) was essentially due to the costs of acupuncture (366.95 (SD, 84.90) in the acupuncture group, whereas no significant differences were observed for other cost components. After three months, QALY utility values were higher in the acupuncture group than in the control group (0.65 QALYs (SD, 0.10) vs. 0.62 QALYs (SD, 0.10); p < 0.001). The incremental cost-effectiveness ratios were estimated to be 10,526 per QALY gained (overall cost perspective).

Efficacy - Acupuncture Randomized Trials (ART):

Table 1: Baseline characteristics of study population

Parameter	ARC		ART	
	Acupuncture n = 1,451 mean (SD)/(%)	Control n = 1,390 mean (SD)/(%)	Acupuncture n=146 mean (SD)/(%)	Sham-acupuncture n = 73 mean (SD)/(%)
Female	837 (57.7%)	791 (56.9%)	93 (64%)	55 (75%)
Age (years)	53.1 (13.5)	52.6 (13.2)	59.1 (8.8)	58.9 (9.5)
> 10 years of school	25.8%	29.2%	20 (15%)	13 (19%)
Duration of disease (years)	7.2 (8.0)	7.2 (7.8)	14.7 (11.0)	13.6 (10.5)
Back function (HFAQ)	61.8 (21.0)	63.3 (20.8)	57.1 (18.6)	57.2 (17.3)
Quality of life (SF-36)				
Physical Component Score	34.3 (9.0)	34.6 (9.6)	32.8 (8.2)	31.8 (8.3)
Mental Component Score	43.3 (10.3)	43.5 (10.1)	48.5 (10.7)	48.0 (11.1)

HFAQ = back pain questionnaire (Hannover Functional Ability Questionnaire); † = lower values indicate less pain
Exploratory p-values from two-sided t-tests or Chi2 tests

The primary outcome was the difference reported between the group receiving acupuncture vs. the minimal acupuncture group, the resulting difference was 5.1 mm (95% CI, -3.7 to 13.9 mm; P=.26). Also, at 26 (P=.96) and 52 (P=.61) weeks, pain did not differ significantly between the acupuncture and sham-acupuncture groups. Overall, after eight weeks, there were significant differences in 6 of 12 outcomes between the acupuncture and minimal acupuncture groups.[9]

The results of both trials could be compared for back function, because both trials used the HFAQ (the primary outcome in the ARC study and the secondary outcome in the ART study). Patients participating in the more experimental ART study had greater reduced back function at baseline than patients in the pragmatic ARC study (Figure 1). Furthermore, the difference between the group receiving additional acupuncture to the usual care group alone were larger that between the acupuncture and the sham-acupuncture group.

Discussion

In patients with chronic low back pain acupuncture in addition to routine care was more effective than routine care alone. However, there was no significant difference between acupuncture and sham-acupuncture.

One of the main advantages of this project is the fact that both randomized parts of the study (ART and ARC) complemented each other with respect to the content and method. ART focused on determining - with high internal validity - the specific efficacy of acupuncture. The aim of the ARC studies, on the other hand, was to evaluate - with high external validity - the effectiveness of acupuncture in usual medical care. Limitations were that blinding in the ARC study was not possible, and that subjective parameters were used as primary outcome measures in both trials, although they were based on internationally validated questionnaires.

In ART there was no significant difference between treatment groups for our main outcome measure (the change in pain intensity from baseline to week eight). We assume that one of the main reasons for the non-significant result for the primary outcome variable between acupuncture and minimal acupuncture is the par-
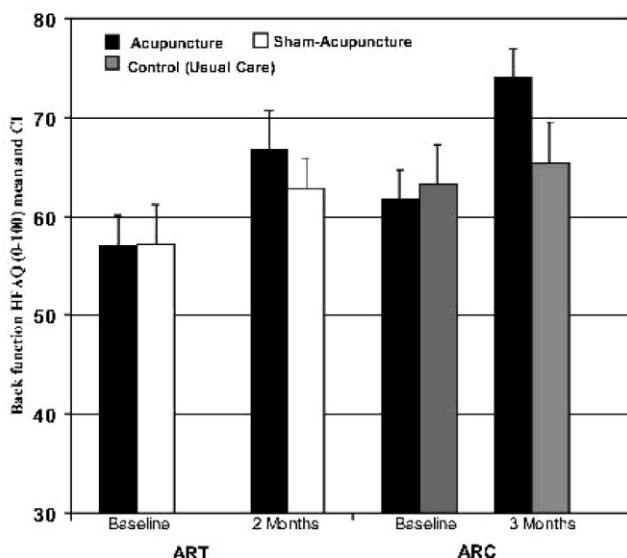
Figure 1: Back function (HFAQ) at baseline and after treatment for both studies (ARC and ART) (mean and CI). ART: HFAQ after 2 months no significant difference between acupuncture and sham-acupuncture p=0.17; ARC: HFAQ after 3 months significant difference between acupuncture and control (<0.001).

ticularly strong response to sham-acupuncture. We performed sensitivity analysis and found that comparing the means instead of the differences would have resulted in a significant difference (p=0.03). However, when we adjusted the means for baseline values in a covariance analysis, the difference was not significant but showed a trend (p=0.06). This seems to be due to the fact that the baseline values differed slightly between the groups. The comparison between acupuncture and sham-acupuncture indicates a high proportion of unspecific effects (e.g. by skin penetration, characteristics of the therapy setting and the role of patient expectations) are part of the overall effect of acupuncture. The size of the non-specific effect was much higher than expected and resulted in a smaller difference between groups than assumed in the sample size calculation.

Combining the results of both studies (ART and ARC) indicated that patients in experimental studies such as ART differ from those in usual care. Pre-post improvements in the acupuncture groups were comparable in both studies, whereas pre-post comparisons for the controls showed a higher effect in the sham-acupuncture group compared to usual care group. Acupuncture is a relatively resource-intensive intervention because of the time involved for physicians and patients alike. Our study showed that acupuncture was associated with additional costs but was cost-effective according to international threshold values (e.g. 30,000 GBP in UK).

In conclusion, our study showed that acupuncture, in addition to routine care, resulted in a clinically relevant benefit and was cost-effective among patients with chronic low back pain from primary care practices in Germany. Non-specific effects of acupuncture play a more prominent role than expected. However, acupuncture should be considered a viable option in the management of patients with chronic low back pain.

Conflict of Interest Statement

The author declares no conflict of interest.

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