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# Acupuncture for chronic pain within the research program of 10 German Health Insurance Funds—Basic results from an observational study

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## KEYWORDS

Acupuncture;  
Chronic pain conditions;  
Observational study;  
Side effects;  
Medical specialty;  
Acupuncture training

## Summary

**Objectives:** To investigate which patients receive acupuncture in the framework of statutory health insurance in Germany, how treatment was carried out, and what results were achieved.

**Design:** Basic documentation (carried out by physician) within a prospective observational study.

**Setting:** 454,920 patients with at least one of the three chronic pain conditions including headache, low back pain and osteoarthritis treated by 8727 medical acupuncturists (panel doctors) within the scope of a reimbursement program.

**Results:** Fifty-three percent of the patients were treated by general practitioners, 19% by orthopaedists and 9% by internists. Eighty percent of patients were female, mean age was 53.6 (S.D. = 15.7) years. Primary indication for acupuncture was low back pain (45%), headache (36%), and osteoarthritis (12%). Median time since the initial diagnosis was 3 years. 8.4 (S.D. = 3.0) acupuncture sessions (body acupuncture) were administered on average. In 28% a concomitant treatment was reported. Effectiveness of acupuncture was rated by physicians in 22% of the patients as marked, in 54% as moderate, in 16% as minimal and in 4% as poor (unchanged). In 8% of the patients mild adverse reactions were reported, severe side effects occurred in 13 patients (0.003%). Orthopaedists rated the effectiveness of acupuncture lower, showing shortest time for face-to-face contact with the patient. More acupuncture training did not correspond to better therapeutic effect assessed by physicians.

**Conclusions:** Acupuncture proved a highly demanded treatment option for chronic pain conditions within the German research program. Results indicate that acupuncture provided by qualified therapists is safe, and patients benefited from the treatment.

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## Background

In Germany, an estimated number of approximately 40,000 physicians are practising acupuncture. In 2000, inconsistent data from the literature with respect to evidence for the effectiveness of this treatment prompted the German Federal Committee of Physicians and Statutory Sickness Funds to limit reimbursement to the scope of a special program covered by German Social Security Code. Only a defined group of chronic pain conditions where the evidence was considered promising (chronic headache, CH; chronic low back pain, cLBP; chronic osteoarthritic pain, cOAP) was approved for this temporary project. Results from randomized trials investigating the specific effects of acupuncture are now available<sup>1–6</sup> and met a lively response even in the lay press. However, according to the legal guidelines, such reimbursement programs should serve primarily to improve the quality and the efficiency of medical care. As a consequence, we explicitly addressed this point in the scientific concept of the program initiated by 10 health insurance companies.<sup>7</sup>

While a summary of the results of this program is already published<sup>8</sup> the previous paper aims at the “basic part” of an observational study which intended to provide a comprehensive description of routine acupuncture in terms of quality profiles for patients, interventions and outcomes.<sup>9</sup> The objectives of the study were:

- to describe the ways in which German panel doctors provide acupuncture treatment in routine practice;
- to estimate the clinical effectiveness of acupuncture rated by physician acupuncturists;
- to estimate the incidence of adverse reactions and complications due to acupuncture.

First interim results of the basic documentation are yet published.<sup>10,11</sup> Methods and results of a second part of the study (“extended documentation”) which was only presented to a random sample of patients are presented in Refs. <sup>12–14</sup>.

## Methods

### Documentation

The Regulatory Authority of German Sickness Funds demanded that all treatment cases be documented for scientific analysis. Basic data like sociodemographic variables, indication for acupuncture, previous acupuncture, details of the acupuncture

sessions, concomitant treatment, physician’s global rating of therapeutic effect (following item 3.1 of “Clinical Global Impression”<sup>15</sup>), and occurrence of adverse reactions or complications of acupuncture were to be documented by the treating physician on a one-page form (printed in Ref. 10).

All patient data were recorded pseudonymously on the case report form. Merging patients’ records with the personal data from insurance company records was not permitted. Physicians sent the completed case report forms to an independent company for data capturing. Scanned paper forms were transformed to a relational database (MS-Access). Ambiguous or implausible entries were modified according to defined rules.

The project was approved by all responsible ethical review boards.

### Patients

Inclusion criteria for the program were (a) one of the three approved indications, (b) duration of the disease of at least 6 months, (c) being treated previously but not with acupuncture in the 6 months prior to inclusion, (d) being insured by one of the participating companies, and (e) written informed consent.

### Physician acupuncturists

Doctors on the panel who were in private practice and were certified acupuncturists with a minimum qualification according to the A-diploma (140 h education) could get approval from the Central Association of the Health Insurance Funds for the reimbursement program upon application. The modalities for providing acupuncture and payment (including the expenditures for documentation) were defined in an agreement between the insurance funds and the leading acupuncture societies.

### Interventions

Initially, six acupuncture sessions (body acupuncture of 30 min duration at least) were refundable. When supported by sound medical reasoning, applications for further treatment sessions (maximum: 15) were approved. Otherwise, the physician was fully responsible for all treatment decisions including concomitant treatments or a premature discontinuation. Patients could stop acupuncture treatment at any time. Reasons of discontinuation were supposed to be documented, if possible.

### Quality assurance and statistics

The validity of data abstraction was checked by random sample comparison of the stored data record and the original data on the form. Logically inconsistent data were identified and cleared. The analysis of the data was restricted to descriptive statistics like absolute and relative frequencies, arithmetic mean, standard deviation and median. Confidence intervals or any significance tests were found to be unhelpful since standard errors of estimated means or proportions tend to be extremely small in big sample sizes. All statistical analyses were performed by SPSS for Windows (Version 11.0).

### Results

Due to substantial modifications of the case report forms from July 2003 the presented data refer only to the first 2 years of the reimbursement program.

#### Physician acupuncture providers

At the end of the reported period, 9918 medical acupuncturists (35.6% female) had been approved as participants in the acupuncture program. The proportion of physicians with B-diploma (350h education) was 27.0%. 52.8% were general practitioners. While 19.5% of the approved physicians were orthopaedists, their representation on the panel was only 4.7% (Table 1). This means, in other words, that 35% of all eligible orthopaedists took part in the acupuncture program while the rates for other medical specialties among approved physicians were essentially lower (GPs 11.8%, anaesthetists 11.3%, internists 4.5%, neurologists 3.4%, and other specialties 3.1%).

#### Profile of acupuncture patients

During the 2-year period, we received 503,397 case reports (about 21,000 per month). In case of repeated treatments only the first treatment cycle was included into the analysis (461,109 patients). Due to missing identification numbers of the treating physicians, the sample for statistical analysis was reduced to 454,920 patients (treated by 8727 acupuncturists). 37.1% of the patients were treated by general practitioners, 42.3% by orthopaedists (Table 1). This resulted in a median of 82 patients per orthopaedist while the medians for the other specialties varied between 20 and 25 patients per doctor. The distribution of the number of patients

**Table 1** Distribution of selected medical specialties of physicians on the panel in Germany, of physicians approved for the Acupuncture Research and Reimbursement Program, and in patients database

	Number of doctors on the panel in Germany <sup>a</sup>		Number of physicians approved for the Acupuncture Program		Number of physicians represented in the database		Number of patients treated		Number of patients per doctor median	
	n	%	n	%	n	%	n	%	n	%
General practitioners	44,128	37.3	5,231	52.8	4,665	53.5	168,726	37.1	23.5	23.5
Orthopaedists	5,500	4.7	1,938	19.5	1,700	19.5	192,650	42.3	81.9	81.9
Internists	20,579	17.4	930	9.4	822	9.4	28,008	6.2	23.5	23.5
Anaesthesiologists	3,770	3.2	428	4.3	366	4.2	16,137	3.5	25.4	25.4
Neurologists/psychiatrists	5,733	4.8	196	2.0	169	1.9	6,763	1.5	24.0	24.0
Other	34,565	32.6	1,195	12.0	1,005	11.5	42,636	9.4	20.6	20.6
Total	118,263		9,918		8,727		454,920		29.0	29.0

<sup>a</sup> Source: Physicians Statistics of the National Association of Statutory Health Insurance Physicians 2003, only specialties admitted for the Acupuncture Program.

per doctor was extremely skewed; the lowest quarter had 12 or fewer patients while the uppermost quarter had 62 or more patients (maximum 1004).

cLBP was the most frequent condition (45.0%) reported as the primary indication for acupuncture. The rates for cH and for cOAP were 35.7% and 12.0%, respectively. Multiple indications were recorded in 5.0% of the patients and no indication was specified in 2.3% (Table 2). 80.2% were female, the mean age was 53.6 years (S.D. = 15.7 years).

Diagnosis was reported as confirmed by specialists in 80.3% of the patients and known for 36 months (median). A severity rating by the physician was available for two-thirds of the patients; half were judged as moderate, the other half as aggravating. In 19.8% acupuncture was documented as cause for the consultation.

Distributions of gender and age differed markedly with respect to the indication for acupuncture. Headache sufferers represented the youngest group on average and had the highest proportion of female patients. For the indications cLBP and cOAP distributions of age were asymmetrical and skewed in favour of higher age groups (Table 2).

Patients were treated by neurologists mainly because of cH (57.8%) and less because of cLBP (31.8%). Conversely, with orthopaedists, the rate of headache sufferers was clearly lower (29.6%) while

they treated the highest rates of cLBP (50.7%) and cOAP (15.4%) compared to the other medical specialties. Accordingly, differences in patient profiles with regard to medical specialty of the treating physician could be observed (Table 3). For example, patients treated by orthopaedists were older on average with a shorter duration of disease as well as a higher rate of patients with a verified diagnosis. The proportion of patients coming for consultation explicitly for the purpose of receiving acupuncture was markedly smaller (8.6%) compared to other specialties (up to 42.5% in the case of anaesthetists). Orthopaedists ranked the severity of the disease a little bit lower and the proportion of their patients getting acupuncture for the first time was highest compared to the other subgroups.

### Intervention profile

8.4 (S.D. = 2.8) acupuncture sessions were administered on average. 9.7% of the patients received fewer than 6 sessions, 28.7% exactly 6, 54.3% 7–10, and 7.4% more than 10. Summarized for all sessions, duration was 33 min in total with direct doctor–patient contact lasting 12 min on average. A mean number of 12.6 (S.D. = 5.1) needles were used per treatment session. The whole acupuncture cycle took a median of 40.9 days. 32.4% of

**Table 2** Patients profile, stratified by indication

	Indication <sup>a</sup>				Total
	cH	cLBP	cOAP	MIX	
Number of patients	162,229	204,775	54,521	22,656	454,920
%	35.7	45.0	12.0	5.0	
Female (%)	84.4	77.2	78.0	83.2	80.2
Age mean (S.D.)	47.9 (15.5)	55.7 (15.0)	61.3 (13.8)	56.7 (14.3)	53.6 (15.7)
Age >60 years (%)	22.9	41.4	57.1	42.6	36.7
Diagnosis known since months (median)	36.0	36.0	25.3	45.0	36.0
Diagnosis known since >5 years (%)	35.3	35.0	27.3	41.6	34.4
Diagnosis confirmed by specialist (%)	76.1	82.3	85.6	85.1	80.3
Acupuncture was reason for consultation (%)	22.3	18.3	17.8	22.7	19.8
Degree of severity					
Slight (%)	1.1	.9	.7	.5	1.0
Moderate (%)	52.2	52.5	47.3	44.1	51.2
Aggravating (%)	46.7	46.6	52.0	55.4	47.8
Previously acupuncture					
No (%)	76.7	78.3	80.0	70.4	77.5
Yes, for other indication (%)	8.6	9.5	11.9	9.4	9.5
Yes, for same indication (%)	14.7	12.2	8.1	20.2	13.0

cH, chronic headache; cLBP, chronic low back pain; cOAP, chronic osteoarthritic pain; MIX, multiple indications.

<sup>a</sup> Missing data: 10,739 patients (2.3%).

**Table 3** Patients profile, stratified by medical specialty of the treating acupuncturist

	General practitioner	Orthopaedist	Internist	Anaesthesiologist	Neurologist	Other
Number of patients	168,726	192,650	28,008	16,137	6,763	42,636
Female (%)	79.8	79.7	80.2	80.7	79.8	83.8
Age mean (S.D.)	50.9 (16.0)	56.4 (14.8)	54.8 (16.0)	53.0 (15.5)	51.9 (15.5)	50.8 (15.9)
Age >60 years (%)	30.8	42.9	40.4	34.1	32.5	30.7
Diagnosis known since months (median)	47.3	24.0	40.4	49.6	33.0	36.0
Diagnosis known since >5 years (%)	42.3	25.6	39.7	47.5	33.8	34.9
Diagnosis confirmed by specialist (%)	71.1	88.9	74.1	85.2	87.5	78.8
Acupuncture was reason for consultation (%)	28.6	8.6	24.7	42.5	20.8	23.8
Degree of severity						
Slight (%)	.9	1.1	.6	.8	1.1	1.2
Moderate (%)	46.2	56.0	47.3	49.1	52.8	52.9
Aggravating (%)	52.9	42.9	52.1	50.1	46.1	46.0
Previously acupuncture						
No (%)	72.8	82.7	74.9	70.6	77.6	78.0
Yes, for other indication (%)	11.0	7.9	9.9	12.6	7.7	9.0
Yes, for same indication (%)	16.2	9.4	15.2	16.8	14.6	13.0

the patients received other treatment in addition to acupuncture. In 9.4% of the patients a premature discontinuation of acupuncture was reported. Reasons were analyzed by random sample and showed that 15% were due to private reasons/problems with the appointed time, 10% each because of insufficient improvement in or relief from complaints or the occurrence of another disease. Eight percent of patients discontinued treatment because of side effects. Patients showed no clear differences in intervention profile with regard to indication.

However, comparing patients according to the specialty of the treating physician revealed clear differences (Table 4). Patients treated by orthopaedists presented a markedly diminished time on average for direct doctor–patient contact compared to patients treated by other specialists, and the complete acupuncture cycle took less time among orthopaedists than for the other subgroups. However, there was no difference in the mean number of treatment sessions. The proportion of patients with concomitant treatment was highest among neurologists reflected by greater use of pharmacological and physical measures.

### Outcome profile (assessment of clinical effectiveness by physicians)

When the acupuncture cycle was finished, the physicians rated the therapeutic effect as marked (vast improvement of complaints) in 21.8% of the patients, as moderate (decided improvement) in 54.0%, and as minimal (slight improvement) in 16.1%. Poor effectiveness (no change or deteriorated) was reported in 3.9% of the patients, and in 4.2% of the patients the physician stated “could not be judged”. Results indicated that patients suffering from headache benefited the most (78.7% marked or moderate) from acupuncture, the other indications following in decreasing order (74.6% in cLBP and 71.3% in cOAP). There was a conspicuously higher rate of poor effectiveness ratings in patients treated by orthopaedists (Table 5). This difference was greatest for patients suffering from cH and cLBP, and was less pronounced in patients with cOAP.

The effectiveness of acupuncture was nearly equally rated as marked or moderate in patients treated by acupuncturists with B-diploma (76.9%) and A-diploma (75.3%). This finding was largely reproducible for all subgroups of patients with regard to the medical specialty of the treating physician.

Excluding all patients with early discontinuation of acupuncture from the analysis, there was a clear

**Table 4** Profile of interventions within the Acupuncture Program, stratified by medical specialty of the treating acupuncturist

	General practitioner	Orthopaedist	Internist	Anaesthesiologist	Neurologist	Other
Number of patients	168,726	192,650	28,008	16,137	6,763	42,636
Number of acupuncture sessions: mean (S.D.)	8.4 (2.9)	8.4 (2.7)	8.6 (2.9)	8.9 (3.2)	8.4 (2.8)	8.4 (3.0)
Duration of acupuncture session (min): mean (S.D.)	34.6 (7.8)	31.3 (4.3)	33.5 (6.4)	35.8 (8.1)	33.8 (7.6)	34.3 (9.0)
Duration of patient–doctor contact (min): mean (S.D.)	14.8 (9.8)	9.3 (7.0)	14.2 (9.7)	18.5 (12.2)	12.4 (7.7)	13.4 (9.7)
Number of needles per session: mean (S.D.)	12.5 (5.4)	12.8 (4.7)	12.5 (5.2)	12.2 (4.9)	12.5 (4.9)	12.7 (5.5)
Duration of the acupuncture cycle (days): median	42.8	36.4	42.3	63.3	45.5	43.6
Concomitant treatment <sup>a</sup> (%)	29.9	34.5	25.0	55.7	31.7	28.3
Drug therapy (%)	18.2	20.0	16.2	38.5	23.7	15.6
Physical medicine (%)	11.6	18.8	9.4	20.1	8.8	13.7
Other (%)	4.9	5.2	3.0	9.6	2.9	5.1
Acupuncture prematurely discontinued (%)	9.2	9.4	9.0	10.0	9.4	9.7

<sup>a</sup> Multiple responses possible.

**Table 5** Proportions of patients with unsatisfying treatment results (physician's rating of therapeutic effect "minimal" or "unchanged"), stratified by indication for acupuncture and medical specialty of the treating acupuncturist

Indication	General practitioner (%)	Orthopaedist (%)	Internist (%)	Anaesthesiologist (%)	Neurologist (%)	Other (%)
cH	13.7	21.6	14.3	16.5	15.5	15.0
cLBP	16.6	25.6	17.0	22.5	20.9	17.1
cOAP	21.5	27.7	23.9	25.9	23.0	19.7
MIX	18.3	25.2	16.6	21.8	17.2	18.9

cH, chronic headache; cLBP, chronic low back pain; cOAP, chronic osteoarthritic pain; MIX, multiple indications.

relationship between the number of treatment sessions and the physician's global rating of effectiveness. However, the difference in the mean number of acupuncture sessions between patients with the best and poorest ratings was only 1.1.

The therapeutic effect of acupuncture was graded slightly lower in patients not experienced in acupuncture (74.7% marked/moderate) compared to patients with previous acupuncture (79.4%). Effectiveness of acupuncture was rated marked or moderate in 79.0% of patients without and in 70.6% with supplementary treatment documented, respectively.

### Outcome profile (side effects and serious adverse reactions)

Physicians documented at least one of the predefined adverse reactions or complications in 7.9% of all patients. The most frequent reactions were "needling pain" (4.0%), "hematoma" (3.3%), and "bleeding" at the point of insertion (1.6%). In 0.4% of the patients the acupuncturists reported "orthostatic problems", in 0.3% "forgotten needles", and in 0.7% "other events". Of the latter category, the most frequent were "local skin irritation", "worsening of symptoms", "first aggravation", "fatigue" and "sensation of warmth".

In patients treated by acupuncturists with longer education (B-diploma) side effects were reported slightly less frequently (7.7% of the patients; A-diploma: 8.0%). With respect to the medical specialties the proportions of patients with side effects ranged between 6.3% (neurologists) and 11.0% (anaesthetists).

During the 2-year reporting period serious adverse reactions due to acupuncture were reported in 13 patients; all were followed up in detail in cooperation with the reporting physician (pneumothorax ( $n=3$ ), acute hyper- or hypotensive crisis ( $n=6$ ), erysipelis ( $n=2$ ), asthma attack ( $n=1$ ), aggravation of suicidal thoughts ( $n=1$ )). With respect to the total number of patients, this represents a ratio of 1:34,994; referring to

the total number of acupuncture sessions (about 3.84 million) the ratio accounted for 1:295,000. After receiving appropriate counteractive measures patients recovered completely from all reactions.

### Discussion

The results from the mandatory documentation of all treatment cases provide an extraordinarily expansive database for the application of acupuncture in the context of the reimbursement program. During the first 2 years about 2.6% of all people insured by the participating insurance funds (about 18 million people) took part in the program. The great demand for acupuncture continued for the full duration of the acupuncture program. More than 1.1 million treatment cases were registered by about 11,000 acupuncturists through the end of 2005.

Within the framework of this big observational study the expensive monitoring common to controlled clinical trials to warrant high data quality was not possible. The simple and unambiguous configuration of the physician's case report form as well as error-free techniques for converting the information into a database, including appropriate checks for correctness and plausibility, allowed for a credible analysis of the data. The simultaneous realization of several reimbursement programs for acupuncture with similar (but not identical) requirements for documentation<sup>16,17</sup> was a complicating factor for the staff of the private practices.

The indication for the treatment was essential to be accepted for the acupuncture program. With a sample of patients following a more elaborate procedure for diagnostic classification ("extended documentation"), there were some deviations concerning the frequency of the indications. But, since this sample did not prove to be fully representative for the population of patients participating in the acupuncture program,<sup>12</sup> it is not possible to draw conclusions on the precision of the physician's declaration in the basic documentation. However,

we know from individual cases that physicians may occasionally not have complied fully with the pre-conditions of the program so as to enable patients to be refunded for the costs of acupuncture.

Moreover, patients from the acupuncture program under investigation did not fully reflect German conditions. The cooperating health insurance companies primarily insure clerks (white-collar employees), and so substantial segments of society are inevitably under-represented. The proportion of females insured is slightly higher (58%<sup>18</sup>) what partially explains the high rate of 80% female patients in the acupuncture program. Additional factors are the increased prevalence of specific pain conditions in women (headache 1.3-fold, low back pain 1.1-fold<sup>19</sup>) and the finding that more women make use of acupuncture than men.<sup>20,21</sup>

The stepwise approval procedure had an impact on the number of acupuncture sessions which had been effectively performed. A clear relationship between the number of necessary treatment sessions and the effectiveness of the treatment as a whole could not be derived from the presented study. The prolongation of the treatment often was dependent on the success until that point, and a rating of the effectiveness was not scheduled after each single session. Similarly, a direct correlation between concomitant treatment administered to one third of the patients and the success of treatment is misleading. Such supplementary measures seemed to be indicated mainly when the treatment course had not been beneficial.

When acupuncture was terminated the physicians stated a marked or moderate relief from complaints in about three quarters of all patients. This favourable finding was confirmed by results from standardized pain questionnaires that were completed by a sample of patients indicating that headache sufferers benefited most from acupuncture.<sup>14</sup> Patients with previous acupuncture experience showed marginally better effects than patients were new to the treatment. More acupuncture training did not correspond to physician self-rated clinical effectiveness. Based on subjective patient data, the effectiveness did not differ relevantly (after statistical controlling for baseline differences) with regard to treatment being provided by acupuncturists with less or more training.<sup>22</sup>

The disproportionate number of patients treated by orthopaedists is undoubtedly related to the larger number of patients in the practice in general as well as to the prevalence of low back pain and arthritic pain indications in orthopaedic settings. But it remains unclear whether these points alone explain the four-fold number of patients per orthopaedist as compared to the average number in

the acupuncture program. Interestingly, the mean amount of time which orthopaedists spent face-to-face with their patients was noticeably shorter compared to all other specialists. The results indicate that fewer patients demanded for acupuncture with orthopaedists compared to GP's, for example. Relations between patients' expectations and self reported outcome are known<sup>23</sup> but there is no conclusive explanation how these factors interact with the less favourable physician's rating of effectiveness among orthopaedists. However, indication and degree of severity of the medical problem were not able to explain this finding. Orthopaedists might use a different reference system for their assessment which tends to result in a lower rating in general.

The results confirm the findings from literature<sup>24,25</sup> that acupuncture, in the hands of qualified therapists, is safe. In 7.9% of the patients, non-serious adverse reactions were documented. However, the variation in reporting indicated that German physicians differ greatly in their opinions of what constitutes a minor event. Less disagreement should occur for severe reactions. We observed an incidence of 0.003% per patient which was even lower than that derived from an interim analysis.<sup>11</sup> Although it was mandatory for all physicians to report such observations underreporting cannot be excluded completely.

The systematically collected data on the routine use of acupuncture provided a unique database thus far. This groundwork has enabled the creation of profiles that describe the patients who demand for acupuncture, the way physicians perform the treatment and evaluate its outcomes, and thus filling the gap between a 'real world' perspective and the 'experimental world' of controlled trials. The extraordinary big sample size allowed not only estimates of the prevalence of extremely rare side effects but also subgroup analyses addressing several stratifying factors simultaneously. However, international comparisons are limited due to several different context factors like the smaller proportion of medical acupuncturists in many other countries.<sup>26</sup> In the end, after termination of the reimbursement program and the legally binding decision of the federal committee modified regulations for acupuncture in routine practice will be installed in Germany.

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