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

W. Weidenhammer\textsuperscript{a,}\textsuperscript{*}, A. Streng\textsuperscript{a}, K. Linde\textsuperscript{a}, A. Hoppe\textsuperscript{a}, D. Melchart\textsuperscript{a,\textsuperscript{b}}

\textsuperscript{a} Centre for Complementary Medicine Research, Department of Internal Medicine II, Technical University Munich, Kaiserstr. 9, 80801 München, Germany
\textsuperscript{b} Division of Complementary Medicine, Department of Internal Medicine, University Hospital Zurich, Switzerland

Available online 30 October 2006

**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.

© 2006 Elsevier Ltd. All rights reserved.

\textsuperscript{*} Corresponding author. Tel.: +49 89 726697 0; fax: +49 89 726697 21.
E-mail address: Wolfgang.Weidenhammer@lrz.tum.de (W. Weidenhammer).
Results from study of acupuncture for pain in research of German Health Insurance Funds

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 available1–6 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.7

While a summary of the results of this program is already published8 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.9 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.10,11 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. 12–14.

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”15), 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 (350 h 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>
<thead>
<tr>
<th>Number of doctors on the panel in Germany, of physicians approved for the Acupuncture Research and Reimbursement Program, and in patients database</th>
<th>Number of physicians represented in the database</th>
<th>Number of physicians approved for the Acupuncture Program</th>
<th>Number of patients treated</th>
<th>Number of patients per doctor median</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioners</td>
<td>44,128</td>
<td>37.3</td>
<td>5,231</td>
<td>52.8</td>
</tr>
<tr>
<td>Orthopaedists</td>
<td>5,500</td>
<td>4.7</td>
<td>1,938</td>
<td>19.5</td>
</tr>
<tr>
<td>Internists</td>
<td>20,579</td>
<td>17.4</td>
<td>930</td>
<td>9.4</td>
</tr>
<tr>
<td>Anaesthesiologists</td>
<td>3,770</td>
<td>3.2</td>
<td>428</td>
<td>4.3</td>
</tr>
<tr>
<td>Neurologists/psychiatrists</td>
<td>5,733</td>
<td>4.8</td>
<td>196</td>
<td>2.0</td>
</tr>
<tr>
<td>Other</td>
<td>34,565</td>
<td>32.6</td>
<td>1,195</td>
<td>12.0</td>
</tr>
<tr>
<td>Total</td>
<td>118,263</td>
<td>100.0</td>
<td>9,918</td>
<td>100.0</td>
</tr>
</tbody>
</table>

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**

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

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

*Missing data: 10,739 patients (2.3%).
<table>
<thead>
<tr>
<th></th>
<th>General practitioner</th>
<th>Orthopaedist</th>
<th>Internist</th>
<th>Anaesthesiologist</th>
<th>Neurologist</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>168,726</td>
<td>192,650</td>
<td>28,008</td>
<td>16,137</td>
<td>6,763</td>
<td>42,636</td>
</tr>
<tr>
<td>Female (%)</td>
<td>79.8</td>
<td>79.7</td>
<td>80.2</td>
<td>80.7</td>
<td>79.8</td>
<td>83.8</td>
</tr>
<tr>
<td>Age mean (S.D.)</td>
<td>50.9 (16.0)</td>
<td>56.4 (14.8)</td>
<td>54.8 (16.0)</td>
<td>53.0 (15.5)</td>
<td>51.9 (15.5)</td>
<td>50.8 (15.9)</td>
</tr>
<tr>
<td>Age &gt;60 years (%)</td>
<td>30.8</td>
<td>42.9</td>
<td>40.4</td>
<td>34.1</td>
<td>32.5</td>
<td>30.7</td>
</tr>
<tr>
<td>Diagnosis known since months (median)</td>
<td>47.3</td>
<td>24.0</td>
<td>40.4</td>
<td>49.6</td>
<td>33.0</td>
<td>36.0</td>
</tr>
<tr>
<td>Diagnosis known &gt;5 years (%)</td>
<td>42.3</td>
<td>25.6</td>
<td>39.7</td>
<td>47.5</td>
<td>33.8</td>
<td>34.9</td>
</tr>
<tr>
<td>Diagnosis confirmed by specialist (%)</td>
<td>71.1</td>
<td>88.9</td>
<td>74.1</td>
<td>85.2</td>
<td>87.5</td>
<td>78.8</td>
</tr>
<tr>
<td>Acupuncture was reason for consultation (%)</td>
<td>28.6</td>
<td>8.6</td>
<td>24.7</td>
<td>42.5</td>
<td>20.8</td>
<td>23.8</td>
</tr>
<tr>
<td>Degree of severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slight (%)</td>
<td>.9</td>
<td>1.1</td>
<td>.6</td>
<td>.8</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Moderate (%)</td>
<td>46.2</td>
<td>56.0</td>
<td>47.3</td>
<td>49.1</td>
<td>52.8</td>
<td>52.9</td>
</tr>
<tr>
<td>Aggravating (%)</td>
<td>52.9</td>
<td>42.9</td>
<td>52.1</td>
<td>50.1</td>
<td>46.1</td>
<td>46.0</td>
</tr>
<tr>
<td>Previously acupuncture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (%)</td>
<td>72.8</td>
<td>82.7</td>
<td>74.9</td>
<td>70.6</td>
<td>77.6</td>
<td>78.0</td>
</tr>
<tr>
<td>Yes, for other indication (%)</td>
<td>11.0</td>
<td>7.9</td>
<td>9.9</td>
<td>12.6</td>
<td>7.7</td>
<td>9.0</td>
</tr>
<tr>
<td>Yes, for same indication (%)</td>
<td>16.2</td>
<td>9.4</td>
<td>15.2</td>
<td>16.8</td>
<td>14.6</td>
<td>13.0</td>
</tr>
</tbody>
</table>
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 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

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

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), erysipelas (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 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, 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 pro-
gram under investigation did not fully reflect Ger-
man conditions. The cooperating health insurance
companies primarily insure clerks (white-collar
employees), and so substantial segments of soci-
ety are inevitably under-represented. The propor-
tion of females insured is slightly higher (58%18)
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-fold19) and the finding that more
women make use of acupuncture than men.20,21

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 ses-
sions 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 treat-
ment is misleading. Such supplementary measures
seemed to be indicated mainly when the treatment
course had not been beneficial.

When acupuncture was terminated the physi-
cians 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.14 Patients with previous acupuncture
experience showed marginally better effects than
patients were new to the treatment. More acupunc-
ture training did not correspond to physician self-
rated clinical effectiveness. Based on subjective
patient data, the effectiveness did not differ rele-
antly (after statistical controlling for baseline dif-
fferences) with regard to treatment being provided
by acupuncturists with less or more training.22

The disproportionate number of patients treated
by orthopaedists is undoubtedly related to the
larger number of patients in the practice in gen-
eral as well as to the prevalence of low back pain
and arthritic pain indications in orthopaedic set-
tings. 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 indi-
cate that fewer patients demanded for acupuncture
with orthopaedists compared to GP’s, for example.
Relations between patients’ expectations and self
reported outcome are known23 but there is no con-
clusive explanation how these factors interact with
the less favourable physician’s rating of effective-
ness 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
literature24,25 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.11 Although it was manda-
tory for all physicians to report such observations
underreporting cannot be excluded completely.

The systematically collected data on the rou-
tine 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 fill-
ing the gap between a ‘real world’ perspective and
the ‘experimental world’ of controlled trials. The
extraordinary big sample size allowed not only esti-
mates of the prevalence of extremely rare side
effects but also subgroup analyses addressing sev-
eral stratifying factors simultaneously. However,
international comparisons are limited due to sev-
eral different context factors like the smaller pro-
portion of medical acupuncturists in many other
countries.26 In the end, after termination of the
reimbursement program and the legally binding
decision of the federal committee modified regu-
lations for acupuncture in routine practice will be
installed in Germany.

Acknowledgements

The research program on acupuncture is funded
by the following German statutory sickness
funds: Deutsche Angestellten-Krankenkasse (DAK),
Hamburg; Barmer Ersatzkasse (BEK), Wuppertal;
References

15. AMDP and CIPS (Hrsg.). Rating scales of psychiatry. 2.7. CGI. Weinheim: Beltz; 1990.