

Original Contribution

Cost-Effectiveness of Acupuncture in Women and Men With Allergic Rhinitis: A Randomized Controlled Study in Usual Care

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To assess quality of life and cost-effectiveness of additional acupuncture treatment for allergic rhinitis, patients were randomly allocated to 2 groups; both received usual care, but one group received an additional 10 acupuncture sessions. Quality of life (according to the SF-36 Health Survey), and direct and indirect costs, were assessed at baseline and after 3 months, and the incremental cost-effectiveness ratio of acupuncture treatment was calculated. This German study (December 2000–June 2004) involved 981 patients (64% women, mean age 40.9 years (standard deviation, 11.2); 36% men, mean age 43.2 years (standard deviation, 13.0)). At 3 months, quality of life was higher in the acupuncture group than in the control group (mean Physical Component Score 51.99 (standard error (SE), 0.33) vs. 48.25 (SE, 0.33), $P < 0.001$; mean Mental Component Score 48.55 (SE, 0.42) vs. 45.35 (SE, 0.42), respectively, $P < 0.001$). Overall costs in the acupuncture group were significantly higher than those in the control group (Euro (€; €1 = US \$1.27) 763, 95% confidence interval: 683, 844 vs. €332, 95% confidence interval: 252, 412; mean difference €432, 95% confidence interval: 318, 545). The incremental cost-effectiveness ratio was €17,377 per quality-adjusted life year (women, €10,155; men, €44,871) and was robust in sensitivity analyses. Acupuncture, supplementary to routine care, was beneficial and, according to international benchmarks, cost-effective. However, because of the study design, it remains unclear whether the effects are acupuncture specific.

acupuncture; cost-benefit analysis; economics; quality of life; rhinitis, allergic, perennial; rhinitis, allergic, seasonal

Abbreviations: CI, confidence interval; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; SF-36, Self-Rated Health Survey.

Allergic rhinitis has become a major health problem. In the past 2 decades, there has been a marked increase in the prevalence of allergic rhinitis (1). Direct yearly costs for allergic rhinitis in Europe are estimated at Euro (€; €1 = US \$1.27) 1.0–1.5 billion, whereas indirect costs are estimated at €1.0–2.0 billion (1). Two categories of costs are associated with allergic rhinitis: direct costs for treatment and indirect costs including lost productivity for medical reasons. A study in the United States showed that 55% of employees suffered from allergic rhinitis, with an average duration of 55 days per year (2). Because of allergic rhinitis, they were absent from work an average of 3.6 days per year and were unproductive 2.3 hours per day because of the symptoms. Assuming that patients with allergic rhinitis use their medication (e.g., intranasal glucocorticoids, topical

antihistamine) for up to 6 months per year, the annual costs may range between €400 and €500 per patient (3).

A remarkable number of patients are turning to complementary and alternative medicine, such as acupuncture, for relief. The lifetime prevalence of use of complementary and alternative medicine by patients with allergic rhinitis ranges from 27% to 46%, and most patients who have not yet used it intend to do so in the future (4, 5). In particular, acupuncture is used by 17%–19% of allergic rhinitis patients (4, 5). A recent study from Australia showed that acupuncture was more effective than a sham acupuncture treatment for persistent allergic rhinitis (6).

In Germany, acupuncture is mainly administered by physicians. It is a relatively resource-intensive intervention because of the time involved for physicians and patients

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alike (7). To date, there is a lack of information on costs and the cost-benefit relation of acupuncture treatment in patients with allergic rhinitis.

Therefore, the objective of the present study was to investigate quality of life, costs, and cost-effectiveness of acupuncture in addition to routine care, compared with routine care alone, among patients with allergic rhinitis. This study is part of the Acupuncture in Routine Care (ARC) studies, a large research initiative on acupuncture started and funded by the German statutory health insurance companies.

MATERIALS AND METHODS

Study design

In a multicenter, randomized controlled trial, patients (≥ 18 years of age) with a clinical diagnosis of seasonal and/or perennial allergic rhinitis and symptoms that required treatment were enrolled after initial presentation to a physician participating in this study. Exclusion criteria were all forms of nonallergic rhinitis. The patients were randomly allocated to an acupuncture group that received immediate acupuncture treatment or to a control group that received delayed acupuncture treatment after 3 months. We used a central telephone randomization procedure and a random list generated with SAS software (SAS Institute, Inc., Cary, North Carolina). Both groups were free to use conventional routine medical care supported by the German statutory health insurance companies. All study participants provided written, informed consent, and the study protocol was approved by the appropriate ethics review boards. Participating physicians were required to have received at least 140 hours of acupuncture training. The acupuncture treatments consisted of 10–15 sessions. The study period, including follow-up and availability of economic data, was December 2000–June 2004. The outcomes for allergic rhinitis-specific quality of life, measured with the Rhinitis Quality of Life Questionnaire, are published elsewhere (8).

This paper focuses on the cost-effectiveness part of the study. As an effectiveness parameter, general quality of life was measured by using the Self-Rated Health Survey (SF-36) questionnaire (9), which assessed quality of life over the last 7 days, at baseline, and after 3 months.

Costs considered were those for direct health care, such as for acupuncture, physicians' visits, and hospital stays (without consideration of private individual billing), as well as prescription medication (including patients' copayments). The payment for each acupuncture session was €35. The cost perspective of the study was societal. Therefore, in addition to health insurance costs, we also assessed indirect costs caused by patients' incapacity to work. These indirect costs were determined by using the human capital approach (10) and were estimated to be €78 per sick day off from work. All cost data were provided by the statutory health insurance companies.

We calculated 1) the overall costs during the study period of 3 months after randomization, including costs not related to allergic rhinitis; and 2) diagnosis-specific costs by using codes from the *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision, to

identify costs due to allergic rhinitis and related conditions only.

Economic analyses

When higher costs and a better medical outcome was found, incremental cost-effectiveness analyses were performed. The SF-36 values were transformed into health-status utilities by using an algorithm developed by Brazier et al. (11). Only those patients for whom SF-36 data were complete could be included in the cost-effectiveness analysis. Quality-adjusted life years (QALYs) gained were calculated by adopting the area-under-the-curve method (12, 13), using the following formula:

$$QALY_{s_{\text{gained}}} = \left(\frac{\alpha_{\text{Acupuncture}} + \beta_{\text{Acupuncture}}}{2} \right) - \left(\frac{\alpha_{\text{Control}} + \beta_{\text{Control}}}{2} \right).$$

Our analysis was based on the utility values at each time point (α = baseline utility, β = utility after 3 months) and used the common assumption of a linear change over time (12). After the intervention period of 3 months, we assumed a linear decrease in the effects of acupuncture, returning to a baseline level 12 months after the start of the study.

Because the baseline values for the SF-36 and the health-status utilities could differ for subgroups in both treatment groups (particularly for male patients, where the sample size was smaller), we adjusted $QALY_{s_{\text{gained}}}$ for this baseline difference. For these purposes, we added the difference in the health-status utilities between both groups at baseline to $QALY_{s_{\text{gained}}}$, as follows:

$$\text{Adjusted } QALY_{s_{\text{gained}}} = QALY_{s_{\text{gained}}} + (\alpha_{\text{Control}} - \alpha_{\text{Acupuncture}}).$$

We calculated the incremental cost-effectiveness ratio (ICER) by using the following relation (14):

$$ICER = \frac{\text{Mean costs}_{\text{Acupuncture}} - \text{mean costs}_{\text{Control}}}{\text{Mean } QALY_{\text{Acupuncture}} - \text{mean } QALY_{\text{Control}}}.$$

The net-benefit approach (15) was used to measure the incremental cost-effectiveness against a societal threshold value λ , often described as society's willingness to pay for 1 extra QALY gained. Bootstrapped cost-effectiveness results were transformed into net-benefit values given varying threshold values and were then plotted in a cost-effectiveness acceptability curve. Under a Bayesian framework, the cost-effectiveness acceptability curve shows the probability that, for a whole range of values for λ , the incremental cost-effectiveness is below λ (16). For a given value for λ , an intervention would be considered cost-effective if its net benefit is greater than zero or, in other words, the ICER lies below λ . Thus, a new treatment should replace the existing one when the net benefit under λ is greater than zero (16).

In the United Kingdom, the National Institute for Clinical Excellence found a threshold of £30,000 per QALY to be

consistent with decisions to adopt new technologies (17). In Germany, such a threshold does not yet exist, so an arbitrary and hypothetical threshold of a maximum of €50,000 per QALY was used.

Sensitivity analyses

In our additional sensitivity analyses, we considered a variety of acupuncture cost scenarios (€15–€55 per acupuncture session) and different durations of therapeutic and economic effects (up to 5 years). As part of our calculations, we assumed that the differences in quality-of-life outcome observed between the 2 treatment groups would gradually decrease over time. For sensitivity analyses, the study situation was defined as base case. In an economic model calculation, we took into account the possibility that a variation in one specific parameter could result in modified therapeutic effect differences between the groups. Thus, we considered variations in a physician's payment alone, as well as the possibility that a decreased (or increased) physician's fee might result in reduced (or improved) clinical effectiveness. Regarding acupuncture treatment, the impact of unspecific factors on treatment results has been widely discussed in the literature (18). For example, lower fees for acupuncture sessions may reduce the intensity of the physician-patient relationship, patient expectations, or treatment satisfaction. Furthermore, some evidence suggests that different payment systems have different impacts on clinical outcomes (19, 20). Therefore, we assumed that a reduction in the cost of an acupuncture session from €35 (base case) to €15 would be associated with a 50% reduction in QALY differences, whereas an increase to €55 would result in a 50% increase in QALY differences.

For the base-case scenario, there was no need to discount any costs or effects because the observation period was less than 1 year. In the sensitivity analyses, we discounted the measured future QALY effects at 1.5% and costs at 3% per year. The discount rates are compatible with those published previously (21, 22).

Statistical analyses

Student's *t* test and Fisher's exact test were used to compare sociodemographic baseline characteristics. For the quality-of-life data, we used analysis of covariance and adjusted for baseline values. Furthermore, an analysis of covariance was applied with age and gender as covariates to estimate costs and cost differences between the groups 3 months before and after study onset.

To derive cost-effectiveness acceptability curves, we used nonparametric bootstrapping. The original sample was bootstrapped 1,000 times to obtain 1,000 means for cost and effect differences and the resulting ICERs. These bootstrap results were used to build the cost-effectiveness acceptability curves, as described above.

For inferential statistics, we used SPSS version 11.0 software (SPSS Inc., Chicago, Illinois). Microsoft Office Excel 2003 software (Microsoft Corporation, Redmond, Washington) was used to model cost-effectiveness analyses for

patient subgroups and to perform the additional sensitivity analyses. The significance level was $\alpha = 5\%$.

RESULTS

Baseline characteristics

A total of 981 randomized patients (487 acupuncture, 494 control) with allergic rhinitis were enrolled between December 2000 and August 2001 for this cost analysis. For all patients, sociodemographic and economic data were available (Table 1). At baseline, there were no significant differences between the 2 treatment groups, except for the use of cortisone, which was higher in the acupuncture group ($P = 0.009$). Complete quality-of-life data (SF-36), which was the basis for the QALY calculation, were available for 825 (84%) patients (418 acupuncture, 407 control). These patients were included in the cost-effectiveness analysis.

Cost analysis

The patients in the acupuncture group received on average a mean of 10.5 (standard deviation, 2.8) acupuncture sessions during the 3-month study. The mean overall cost per acupuncture patient during the study period was €763.38 (95% confidence interval (CI): 682.68, 844.07; diagnosis specific: €417.50, 95% CI: 405.21, 429.79) compared with €331.87 (95% CI: 251.74, 411.99; diagnosis specific: €52.59, 95% CI: 40.38, 64.79) for those in the control group ($P < 0.001$, Table 2). In the overall cost analysis, we observed higher indirect costs in the acupuncture group ($P = 0.03$). However, this finding was not evident in the diagnosis-specific analyses.

Overall and diagnosis-specific costs were higher in the acupuncture group compared with the control group (Table 2). The mean cost difference between both treatment groups 3 months after study entry (total overall: €431.51, 95% CI: 317.77, 545.25; diagnosis specific: €364.92, 95% CI: 347.60, 382.24) was essentially due to the actual acupuncture costs in the acupuncture group (€366.98, 95% CI: 361.01, 372.94).

When we analyzed costs excluding acupuncture, we found no significant difference in overall cost between the 2 study groups ($P = 0.28$).

Quality of life

Quality-of-life data to calculate the SF-36 component scores were available for 901 patients at baseline and for 844 patients after the 3-month study duration. At baseline, we found no significant differences for the whole study population and the female subgroup, with the exception of the subscale role-physical (Table 3). However, in the male subgroup, we found at baseline a significant difference for all subscales, showing better quality of life in the control group. At 3 months, patients in the acupuncture group had a significantly better quality of life according to all SF-36 dimensions (Table 3). This finding was mainly for the female subgroup, whereas we found nearly no significant group differences for the male subgroup (Table 3). The

Table 1. Baseline Characteristics of the Study Population of Allergic Rhinitis Patients, Germany, December 2000–June 2004

Parameter	Acupuncture Group (n = 487)		Control Group (n = 494)		P value
	%	Mean (SD)	%	Mean (SD)	
Patient characteristics ^a					
Female	63.0		65.0		0.550
Age, years		39.0 (11.5)		39.4 (12.3)	0.628
≥10 years of school	57.9		57.5		0.894
Duration of disease, years		11.9 (9.3)		12.1 (9.4)	0.657
Duration of allergic rhinitis symptoms, months/year		6.6 (3.4)		6.9 (3.6)	0.215
No. of months with allergic rhinitis symptoms/year		6.6 (3.4)		6.8 (3.5)	0.215
Concomitant asthma	25.9		24.7		0.607
Previous cortisone treatment	51.3		42.9		0.009
Previous H-blocker treatment	88.7		88.7		1.000
Acupuncture treatment in the last 12 months	11.1		11.5		0.840
	€	95% CI	€	95% CI	
Cost categories (during the 3 months before study initiation), mean Euros ^b /patient					
Overall cost perspective ^a					
Physician visits	33.55	26.13, 40.96	38.83	31.47, 46.20	0.321
Medication	79.00	58.72, 99.27	73.60	53.47, 93.72	0.711
Hospital stays	39.28	6.07, 72.50	55.90	22.92, 88.89	0.486
Indirect costs	201.90	138.26, 265.54	191.46	128.27, 254.64	0.819
Total overall costs	353.72	271.18, 436.27	359.79	277.84, 441.74	0.919
Diagnosis-specific cost perspective ^c					
Physician visits	12.94	9.20, 16.68	10.71	6.99, 14.42	0.406
Medication	20.58	15.78, 25.38	14.08	9.32, 18.85	0.060
Hospital stays					
Indirect costs	17.75	0.00, 37.99	2.28	0.00, 22.38	0.288
Total diagnosis-specific costs	51.26	30.12, 72.41	27.07	6.08, 48.06	0.111

Abbreviations: CI, confidence interval; SD, standard deviation.

^a Student's *t* test or Fisher's exact test.^b €1 = US \$1.27.^c Analysis of covariance (adjusted for age, gender).

effect size measured by Cohen's *d* for the unadjusted group differences was moderate for women (Mental Component Score 0.46, Physical Component Score 0.53) and small for men (Mental Component Score 0.08, Physical Component Score 0.08).

Cost-effectiveness analysis

More QALYs were gained in the acupuncture group compared with the control group. However, this difference was associated with additional costs (Table 4). The unadjusted ICER was 22,798 (overall) and €18,470 (diagnosis specific)

per QALY gained (Table 4). The probability that this intervention is cost-effective was approaching 100% for the threshold value of €50,000 (Figure 1). After adjustment for QALY-utility differences at baseline, the overall ICER was €17,377 and the diagnosis-specific ICER was €14,079 per QALY gained (Table 4).

Substantial differences were observed in the analysis of gender-specific cost-effectiveness. In the female study population, acupuncture was more cost-effective (the overall unadjusted ICER was €7,720 and the diagnosis-specific adjusted ICER was €10,155 per QALY gained). On the contrary, in the male subgroup, acupuncture patients gained

Table 2. Mean Costs and Cost Differences^a Related to Acupuncture Treatment in Allergic Rhinitis Patients, Germany, December 2000–June 2004

Cost Component	Mean Cost During the 3-Month Period After Study Initiation					Mean Cost Difference ^c				
	Acupuncture Group (n = 487)		Control Group (n = 494)		P value ^b	Acupuncture Group (n = 487)		Control Group (n = 494)		P value ^b
	Estimated Mean	95% CI	Estimated Mean	95% CI		Estimated Mean	95% CI	Estimated Mean	95% CI	
Overall costs										
Acupuncture	366.98	361.01, 372.94				366.98	361.01, 372.94			
Physician visits	66.00	56.43, 75.57	63.90	54.40, 73.41	0.761	32.45	21.71, 43.20	25.07	14.40, 35.74	0.339
Medication	75.60	53.99, 97.21	77.46	56.01, 98.92	0.905	−3.40	−13.84, 7.05	3.87	−6.50, 14.23	0.333
Hospital stays	47.94	9.53, 86.35	67.50	29.37, 105.63	0.478	8.66	−39.22, 56.53	11.60	−35.94, 59.13	0.932
Indirect costs	206.86	153.77, 259.95	123.09	70.38, 175.80	0.028	4.96	−56.55, 66.48	−68.37	−129.45, −7.29	0.097
Total overall costs	763.38	682.68, 844.07	331.87	251.74, 411.99	<0.001	409.65	318.35, 500.96	−27.92	−118.58, 62.73	<0.001
Overall costs without acupuncture costs	396.40	315.63, 477.17	331.87	251.74, 411.99	0.267	42.68	−48.85, 134.21	−27.92	−118.58, 62.73	0.284
Diagnosis-specific costs										
Acupuncture	366.98	361.01, 372.94				366.98	361.01, 372.94			
Physician visits	26.29	19.39, 33.19	22.72	15.87, 29.58	0.472	11.16	5.49, 16.83	12.99	7.30, 18.68	0.655
Medication	21.51	17.57, 25.44	19.97	16.06, 23.88	0.586	3.55	−1.53, 8.63	4.62	−0.48, 9.72	0.771
Hospital stays	0.00	0.00, 4.59	5.25	0.67, 9.83	0.112	−2.84	−7.96, 2.27	3.94	−1.19, 9.07	0.066
Indirect costs	2.74	0.00, 6.04	4.73	1.45, 8.01	0.402	−12.85	−28.48, 2.77	0.40	−15.28, 16.07	0.240
Total diagnosis-specific costs	417.50	405.21, 429.79	52.59	40.38, 64.79	<0.001	364.63	345.47, 383.79	21.88	2.66, 41.09	<0.001
Diagnosis-specific costs without acupuncture costs	50.52	40.00, 61.05	52.59	40.38, 64.79	0.777	−0.98	−19.51, 17.54	21.88	2.66, 41.09	0.087

Abbreviation: CI, confidence interval.

^a Costs in Euros (€1 = US \$1.27) during the 3-month treatment period minus costs during the 3 months prior to study initiation per patient.^b Analysis of covariance (adjusted for age, gender).^c Negative values indicate decreased costs during the 3-month treatment period compared with the 3 months prior to study initiation.

Table 3. SF-36 Scores at Baseline and 3 Months After Randomization of Allergic Rhinitis Patients, Germany, December 2000–June 2004

SF-36 Component ^a	All Patients			Men			Women		
	Mean (SE) Score		P Value	Mean (SE) Score		P Value	Mean (SE) Score		P Value
	Acupuncture Group	Control Group		Acupuncture Group	Control Group		Acupuncture Group	Control Group	
Baseline									
Physical activity	86.02 (0.79)	86.62 (0.77)	0.585	88.03 (1.08)	91.7 (0.82)	0.006	84.84 (1.07)	83.82 (1.07)	0.499
Role-physical	69.23 (1.65)	74.14 (1.54)	0.030	71.62 (2.61)	82.62 (2.12)	0.001	67.84 (2.12)	69.50 (2.04)	0.571
Bodily pain	78.12 (1.18)	77.94 (1.19)	0.915	79.30 (1.85)	84.10 (1.69)	0.057	77.44 (1.53)	74.60 (1.55)	0.194
General health perception	58.33 (0.93)	59.00 (0.92)	0.610	58.61 (1.55)	63.89 (1.47)	0.014	58.17 (1.16)	56.29 (1.14)	0.247
Vitality	47.83 (0.84)	49.54 (0.86)	0.153	51.67 (1.32)	55.20 (1.34)	0.061	45.62 (1.06)	46.45 (1.06)	0.580
Social functioning	75.42 (1.11)	77.79 (1.03)	0.119	77.96 (1.77)	83.83 (1.38)	0.009	73.95 (1.42)	74.51 (1.36)	0.777
Role-emotional	78.53 (1.55)	79.29 (1.52)	0.726	80.91 (2.43)	87.68 (1.93)	0.030	77.13 (2.00)	74.64 (2.07)	0.386
Mental health	65.75 (0.78)	67.91 (0.80)	0.053	67.46 (1.24)	73.47 (1.05)	<0.001	64.76 (1.00)	64.88 (1.05)	0.933
Physical Component Score	48.93 (0.42)	49.27 (0.40)	0.549	49.23 (0.64)	51.51 (0.52)	0.006	48.75 (0.55)	48.01 (0.54)	0.338
Mental Component Score	45.02 (0.47)	46.05 (0.46)	0.117	46.12 (0.76)	48.71 (0.60)	0.008	44.38 (0.60)	44.55 (0.61)	0.836
3 months after randomization ^b									
Physical activity	89.97 (0.61)	83.04 (0.62)	<0.001	90.60 (0.85)	87.17 (0.88)	0.005	89.76 (0.82)	80.66 (0.83)	<0.001
Role-physical	84.87 (1.46)	66.14 (1.49)	<0.001	84.46 (2.23)	74.12 (2.33)	0.002	85.37 (1.88)	61.55 (1.90)	<0.001
Bodily pain	84.43 (1.01)	78.35 (1.03)	<0.001	83.97 (1.59)	83.36 (1.65)	0.791	84.73 (1.29)	75.59 (1.31)	<0.001
General health perception	62.25 (0.67)	59.12 (0.68)	<0.001	64.16 (1.07)	61.22 (1.11)	0.059	64.36 (0.85)	57.89 (0.86)	<0.001
Vitality	58.91 (0.79)	48.59 (0.81)	<0.001	58.49 (1.17)	54.07 (1.21)	0.009	59.25 (1.03)	45.52 (1.04)	<0.001
Social functioning	84.88 (0.97)	76.69 (0.99)	<0.001	83.49 (1.52)	81.68 (1.58)	0.412	85.82 (1.23)	73.84 (1.25)	<0.001
Role-emotional	84.78 (1.41)	77.02 (1.45)	<0.001	84.43 (2.12)	82.71 (2.21)	0.577	85.22 (1.85)	73.64 (1.89)	<0.001
Mental health	72.19 (0.68)	65.50 (0.69)	<0.001	71.91 (0.99)	69.89 (1.03)	0.161	72.53 (0.88)	62.94 (0.89)	<0.001
Physical Component Score	51.99 (0.33)	48.25 (0.33)	<0.001	51.92 (0.49)	49.94 (0.50)	0.005	52.09 (0.43)	47.26 (0.43)	<0.001
Mental Component Score	48.55 (0.42)	45.35 (0.42)	<0.001	48.09 (0.60)	47.63 (0.62)	0.591	48.89 (0.55)	44.01 (0.56)	<0.001

Abbreviations: SE, standard error; SF-36, Self-Rated Health Survey.

^a All scales range from 0 to 100; higher values indicate improved quality of life.^b Adjusted for baseline.

fewer QALYs than controls did (difference between groups: mean -0.023 QALYs (standard error, 0.112)), which resulted in a negative ICER. After adjustment for QALY baseline differences, there was a QALY difference in favor of the acupuncture group (0.015 (standard error, 0.006))—the adjusted ICER was €44,871 per QALY gained—and the probability of reaching the cost-effectiveness level was approximately 60% according to an international threshold value of €50,000 (Figure 2).

Sensitivity analysis

Changing the parameter “physician payment rate” by itself (i.e., without considering any effect this change might have on treatment effects) led to major changes in the cost-effectiveness of acupuncture (Table 5). When the acupuncture

fee was reduced to €15 per session, the overall ICER was €9,329, whereas a higher fee of €55 led to an ICER of €25,208 per additional QALY. Similarly, changing the parameter “effect duration” by itself had a marked influence on the cost-effectiveness of acupuncture treatment. The overall ICER ranged from €17,337 in the base case to €7,389 in the hypothetical scenario of an effect within a 5-year period.

Subsequently, we investigated whether a decrease in the effectiveness of acupuncture treatment due to a reduction in the physician payment rate (or, conversely, an improvement in the effectiveness of acupuncture treatment due to an increase in the payment rate) might affect the cost-effectiveness of acupuncture treatment. However, our calculations showed that neither scenario would lead to major changes in the cost-effectiveness of acupuncture treatment, which confirms the robustness of our findings.

Table 4. Cost-Effectiveness Analyses: Mean QALY Differences, Mean Overall and Diagnosis-specific Cost Differences, and Resulting ICERs for Acupuncture Patients vs. Controls After the 3-Month Study Duration, Germany, December 2000–June 2004^a

	Overall Cost-Effectiveness Analyses			Diagnosis-specific Cost-Effectiveness Analyses		
	All Patients (Acupuncture Group: <i>n</i> = 418; Control Group: <i>n</i> = 407)	Men (Acupuncture Group: <i>n</i> = 153; Control Group: <i>n</i> = 141)	Women (Acupuncture Group: <i>n</i> = 265; Control Group: <i>n</i> = 266)	All Patients (Acupuncture Group: <i>n</i> = 418; Control Group: <i>n</i> = 407)	Men (Acupuncture Group: <i>n</i> = 153; Control Group: <i>n</i> = 141)	Women (Acupuncture Group: <i>n</i> = 265; Control Group: <i>n</i> = 266)
QALY differences (mean (SE))	0.020 (0.007)	−0.023 (0.112) ^b	0.043 (0.009)	0.020 (0.007)	−0.023 (0.112) ^b	0.043 (0.009)
Adjusted QALY differences ^c (mean (SE))	0.026 (0.004)	0.015 (0.006)	0.033 (0.005)	0.026 (0.004)	0.015 (0.006)	0.033 (0.005)
Cost differences, Euros ^d (mean (SE))	457.43 (63.21)	682.64 (120.34)	332.71 (71.80)	370.61 (9.83)	380.062 (19.19)	365.33 (11.01)
ICER, Euros	22,798	−29,194 ^c	7,720	18,470	−16,254 ^e	8,477
Adjusted ICER, ^c Euros	17,377	44,871	10,155	14,079	24,982	11,150

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years; SE, standard error.

^a Sample size: *n* = 825 (294 men, 531 women).

^b Acupuncture was less effective compared with control.

^c Adjusted for QALY-utility differences at baseline.

^d €1 = US \$1.27.

^e The ICER was negative because the outcome was better in the control group.

Discounting the monetary costs and benefits by up to 10% as well as varying the discount rates for effects between 0% and 5% did not change the major findings of our study.

DISCUSSION

For patients with allergic rhinitis, acupuncture in addition to routine care compared with routine care alone was associated with a better quality of life as well as higher costs. This cost increase was essentially due to the acupuncture costs themselves and was not compensated for by savings associated with other health-care components during the study period. The overall ICER, adjusted for baseline values, was €17,377 per QALY and proved robust in additional sensitivity analyses. When we adopted a threshold of €50,000 per QALY gained, acupuncture, in addition to routine care, was therefore relatively cost-effective. We observed relevant gender differences. Acupuncture was more cost-effective for women than for men (ICER €10,155 vs. €44,871).

The strengths of our study are that it was performed in a setting that reflects the situation of usual care in Germany; it used a large sample size that allowed for robust estimation of costs, a validated and internationally accepted quality-of-life questionnaire, and a modern state-of-the-art cost-effectiveness analysis including the first known calculation of ICERs for acupuncture treatment in patients with allergic rhinitis; and, to our knowledge, it incorporated the first calculation of ICERs for patients with allergic rhinitis based on QALYs. Use of the Brazier algorithm to calculate QALYs tends to generate relatively higher ICERs compared with other approaches (23). Therefore, our analysis is based on a conservative approach.

This pragmatic study cannot answer whether the effects observed may be due, at least in part, to the “placebo”

effect. A further limitation of our study design is that the treatment group received acupuncture as a form of add-on treatment, whereas the control group received routine care alone. As a result, there was no control for the add-on acupuncture group; therefore, our positive findings must be interpreted with caution. A recent study found a significant difference between acupuncture and sham acupuncture (6), but 2 recently published reviews on the efficacy of acupuncture in allergic rhinitis yielded inconsistent results (24, 25).

In addition, our study design and methodology did not enable us to distinguish between patients with seasonal allergic rhinitis and those with perennial allergic rhinitis. However, because of the randomization procedure, an equal distribution of both types of allergic rhinitis could be

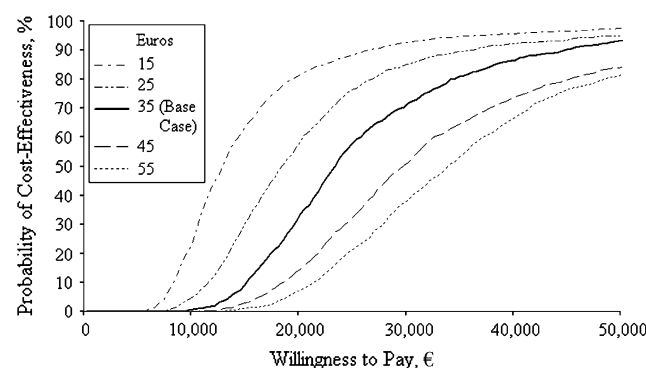


Figure 1. Probability, based on cost per quality-adjusted life years, that acupuncture treatment is cost-effective (against different threshold values of society's willingness to pay in Euros; €1 = US \$1.27) with regard to acupuncture payment rate, Germany, December 2000–June 2004.

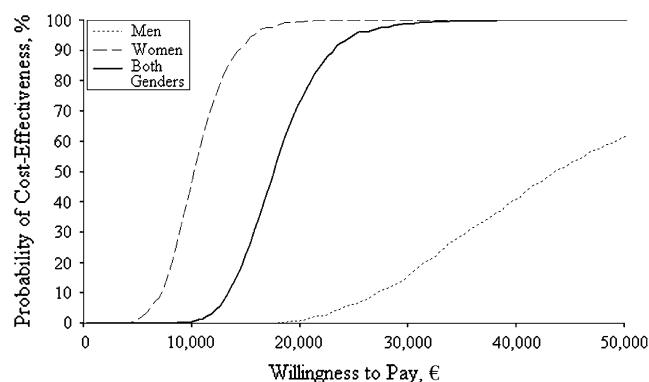


Figure 2. Probability, based on cost per quality-adjusted life years, that acupuncture treatment is cost-effective (against different threshold values of society's willingness to pay in Euros; €1 = US \$1.27) with regard to gender (values adjusted for quality-adjusted life years–utility differences at baseline), Germany, December 2000–June 2004.

assumed. It seems unlikely that type of allergic rhinitis relevantly influenced the overall effect size of treatment.

Another limitation arises from the duration of the study. The cost and effectiveness data were compared between the 2 groups for 3 months after baseline since patients in the waiting-list control group were also subsequently offered acupuncture after 3 months. Therefore, we could not investigate possible long-term health economic effects. In addition, patients were not blinded, which could have affected treatment outcome. Because we aimed to perform a cost-effectiveness analysis on the basis of QALYs (i.e., a cost-utility analysis), it was not possible to use a more disease-specific quality-of-life questionnaire (e.g., Rhinitis Quality of Life Questionnaire). The advantage of cost-utility analyses is that quality of life as an outcome parameter includes both treatment benefits and side effects. A further limitation might be the fact that the only sources of costs were the companies' statutory health insurance databases.

Therefore, private expenses, such as over-the-counter medication, could not be included.

Because the statutory health insurance databases were used, all patient contacts within the German health care system were captured apart from the purely "private" ones paid for exclusively by the patients. Patients insured by one of the approximately 300 statutory health insurance companies in Germany (87.8% of the population) (26) have free choice of physicians, and their visits are (almost without exception) covered by the statutory health insurance company. Thus, costs for private visits to physicians were considered negligible.

Since, during the present study, acupuncture was not routinely reimbursed by the statutory health insurance companies in Germany, costs of the acupuncture session were determined arbitrarily. Additional sensitivity analyses were performed according to varying assumptions, including modeling of the effect duration of 1–5 years and the projection of different acupuncture session costs of €15–€55. One might argue, however, that a reduction in physicians' payment could perhaps result in lower treatment effects, leading to a less favorable ICER and a decreased probability of cost-effectiveness.

We found noticeable and relevant gender differences. Acupuncture was shown to be beneficial for women, whereas we found no benefit for men. That acupuncture in usual care is more beneficial for female patients than for male patients was also found in another study from our group of patients with chronic neck pain (27). It is well known that more female than male patients seek complementary medicine (28). However, this difference does not explain why they have better treatment outcomes. Other studies by our group showed a higher expectation of a better treatment outcome in acupuncture patients suffering from pain (29). In the present study, the patients were not blinded, and expectation could have influenced the outcome. It might be possible that women have higher expectations than men do. This possibility was not assessed in our study but should be taken into account in further studies.

Table 5. Adjusted ICERs^a in Sensitivity Analyses: Isolated Variation in Physician Acupuncture Payment Rate, Length of Acupuncture Effect, and Combined Variation in Acupuncture Payment Rate and Dimension of Group Effect Difference, Germany, December 2000–June 2004^b

	Overall Cost-Effectiveness Analyses			Diagnosis-specific Cost-Effectiveness Analyses		
	All Patients (Acupuncture Group: <i>n</i> = 418; Control Group: <i>n</i> = 407)	Men (Acupuncture Group: <i>n</i> = 153; Control Group: <i>n</i> = 141)	Women (Acupuncture Group: <i>n</i> = 265; Control Group: <i>n</i> = 266)	All Patients (Acupuncture Group: <i>n</i> = 418; Control Group: <i>n</i> = 407)	Men (Acupuncture Group: <i>n</i> = 153; Control Group: <i>n</i> = 141)	Women (Acupuncture Group: <i>n</i> = 265; Control Group: <i>n</i> = 266)
Cost of acupuncture (€15–€55)	9,329–25,208	23,970–64,870	5,463–14,737	4,908–23,250	17,808–27,374	7,677–18,431
Length of effect (1–5 years ^c)	17,377–7,389	44,871–18,941	10,155–4,337	14,079–1,791	24,982–3,590	11,150–1,616
Cost of acupuncture (€15–€55) and effect difference (–50% to 50%)	9,997–6,519	25,568–16,732	5,883–3,822	9,816–15,500	17,808–27,374	7,677–12,308

^a Incremental cost-effectiveness ratio (ICER) in Euros (€1 = US \$1.27) adjusted for quality-adjusted life year–utility differences at baseline.

^b Sample size: *n* = 825 (294 men, 531 women).

^c Discounted (effects 1.5%; costs 6.0%).

In the current study, the cost differences between the acupuncture and the control groups were twice as high for male patients than for female patients, indicating that men had used more conventional treatments. However, in the male subgroup, there were quality-of-life baseline differences between the acupuncture group and the control group, indicating a lower quality of life in the acupuncture group, which could have caused higher resource use in the acupuncture group. Nevertheless, in our analysis, we adjusted the ICER for the quality-utility differences at baseline, and even though the ICER for the male subgroup was not as negative after adjustment, the large difference in cost-effectiveness between men and women remained. For further studies on acupuncture, it could be helpful to stratify randomization for gender.

In conclusion, our study showed that using acupuncture in addition to routine care to treat patients with allergic rhinitis resulted in a benefit and was, according to international benchmarks, cost-effective. Acupuncture was more cost-effective for women than for men. However, because of the study design, it remains unclear whether the effects are acupuncture specific.

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on design, data collection, analysis, interpretation, and publication were left completely to the discretion of the researchers.

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