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Homeopathy and Conventional Medicine: An Outcomes Study Comparing Effectiveness in a Primary Care Setting

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ABSTRACT

Background: Recent meta-analyses of randomized controlled trials in homeopathy have suggested that homeopathy is more than a placebo response.

Objective: Comparison of the effectiveness of homeopathy in primary care with conventional medicine in primary care for three commonly encountered clinical conditions.

Design: An international multicenter, prospective, observational study in a real world medical setting comparing the effectiveness of homeopathy with conventional medicine.

Participants: Thirty (30) investigators with conventional medical licenses at six clinical sites in four countries enrolled 500 consecutive patients with at least one of the following three complaints: (1) upper respiratory tract complaints including allergies; (2) lower respiratory tract complaints including allergies; or (3) ear complaints.

Main Outcome Measures: The primary outcomes criterion was the response to treatment, defined as cured or major improvement after 14 days of treatment. Secondary outcomes criteria were: (1) rate of recovery; (2) occurrence of adverse events; (3) patient satisfaction; and (4) length of consultation.

Results: Four hundred and fifty-six (456) patient visits were compared: 281 received homeopathy, 175 received conventional medicine. The response to treatment as measured by the primary outcomes criterion for patients receiving homeopathy was 82.6%, for conventional medicine it was 68%. Improvement in less than 1 day and in 1 to 3 days was noted in 67.3% of the group receiving homeopathy and in 56.6% of those receiving conventional medicine. The adverse events for those treated with conventional medicine was 22.3% versus 7.8% for those treated with homeopathy. Seventy-nine percent (79.0%) of patients treated with homeopathy were very satisfied and 65.1% of patients treated with conventional medicine were very satisfied. In both treatment groups 60% of cases had consultations lasting between 5 and 15 minutes.

Conclusions: Homeopathy appeared to be at least as effective as conventional medical care in the treatment of patients with the three conditions studied.

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INTRODUCTION

Homeopathy, a medical therapy viewed with skepticism by most medical doctors and without a scientifically plausible mechanism of action theory, has persisted for more than 200 years. Its use is growing today (Eisenberg et al., 1998; Jacobs, 1998). The most recent of two (Kleijnen et al., 1991; Linde et al., 1997) meta-analyses on treatment with homeopathy was published in 1997 and suggested that the clinical effects of homeopathy were more than a placebo response. The authors of this meta-analysis evaluated 89 randomized controlled trials and found that homeopathy was more than twice as likely to be effective than placebo. No conclusions were drawn about the effectiveness of homeopathy for specific clinical conditions. They did however suggest using prospective observational studies as a research tool, thereby separating the question of whether homeopathy is a useful tool in health care from whether or not it is a placebo response. This prospective, observational study was designed to evaluate the usefulness of homeopathy in a real world clinical setting.

This was a prospective observational study of the natural interaction between the participating physicians and their patients. It was not a part of the design for these groups to be identical, matched or comparable at baseline. This was a real-world clinical setting over which we had no control. Statistical analysis for baseline differences would not be appropriate. We tested for the influences of baseline differences on treatment outcomes in the adjusted odds ratio in the post hoc analysis.

The primary objective of the International Integrative Primary Care Outcomes Study (IIPCOS) was to use conventionally licensed health care providers and compare the effectiveness of homeopathy in primary care (Jacobs et al., 1998) with that of conventional medical treatment in primary care for three commonly seen clinical conditions. Secondary objectives studied were: (1) the rate of recovery; (2) the occurrence of adverse events; (3) patient satisfaction; and (4) the length of consultation (indirectly related to the cost of service).

METHODS

This was an international multicenter, prospective, observational study using 30 investigators with conventional medical licenses at six clinical sites in four countries. We compared the effectiveness of homeopathy with conventional medicine in a real world primary care setting. Patients were consecutively admitted into the study and treated according to the best medical practice known to the practitioner and there were no treatment restrictions placed on the participating practitioners. The conditions studied were: (1) upper respiratory tract complaints including allergies: (2) lower respiratory tract complaints including allergies: or (3) ear complaints.

Inclusion/exclusion criteria

Inclusion criteria were: (1) age older than 1 month (irrespective of gender, ethnic origin, or socioeconomic status); (2) one of the three clinical conditions mentioned above; (3) onset of symptoms for 0–48 hours or 48 hours–7 days; and (4) informed consent. Patients were excluded from the study if they had histories of psychiatric disorders (psychosis, dementia, schizophrenia), spinal cord injury, stroke, renal failure, liver disease, alcohol or drug abuse, current immunosuppressive treatment, chemotherapy, or radiation treatment.

Setting

IIPCOS-1 was conducted between July 1996 and August 1997 with 30 investigators at six clinical sites in four countries. Three clinical sites were in Europe (Berlin, Germany; Bern, Switzerland; Graz, Austria) and three in the United States (Albany, CA; Ashland, OR; Santa Fe, NM). All investigators had a conventional medical license. There were 24 medical doctors (M.D.), 4 physician's assistants (P.A.), and 2 family nurse practitioners (F.N.P.). The investigators prescribing homeopathy had, in addition to their conventional medical qualifications, graduated from a homeopathic training program and had at least 5 years experience using homeopathy in their medical practices.

Initial screening

During a 3-month recruitment period (Knipschild et al., 1991) at each site consecutive patients were admitted to study if they had one of the three clinical conditions and met the inclusion/exclusion criteria. At the initial patient contact each investigator conducted a routine medical evaluation, obtained informed consent, and documented the following: demographic information, concomitant medical problems, medications taken during the previous 2 months, chief complaint, onset of symptoms, clinical diagnosis using *International Classification of Diseases, 9th* Revision (ICD-9) code, and investigator confidence in diagnosis (0–10 scale). Data were collected on the primary treatment (homeopathy or conventional medicine), adjunctive therapies, length of consultation, and follow-up recommendations. Information was collected on the general health status of all patients using the Health Status Questionnaire (HSQ-12) (Radosevich and Pruitt, 1995), an internationally validated general health status instrument. Each patient also completed a Health Complaint Questionnaire (HCQ-5); a five-item subset of the HSQ-12 developed for this study to measure the severity of their chief complaint at the time of entry into IIPCOS-1. All case report forms were translated and back-translated between English and German to check for language consistency. Investigators were free to choose any therapy for each patient.

Medications

Homeopathic medications were prepared in a 30C potency according to the *German Homoeopathic Pharmacopoeia* (HAB) and the *Homeopathic Pharmacopoeia of the United States* (HPUS) by DHU (Deutsche Hom‡opathie-Union) of Karlsruhe, Germany. Random samples of homeopathic medications used in this study were sent for independent analysis to check for the presence of contamination; none was found.

Patient follow-up

At day 14 and day 28 independent telephone interviewers trained in telephone interviewing for clinical research contacted each patient asking a series of questions: outcomes including improvement or deterioration, when improvement was noted, patient satisfaction, and adverse events. Data were also collected on compliance with prescribed treatment, use, or changes in adjunctive therapies, and willingness to use the prescribed therapy again. Twenty percent (20%) of patients reporting cure on day 14 were contacted on day 28 to verify the accuracy of their initial statements. No in-person contact by the treating physician was required after the initial patient encounter.

Outcomes criteria

The primary outcomes criterion was the response to treatment, which was defined as cured or major improvement after 14 days according to the Glasgow Homoeopathic Hospital Outcome Score (GHHOS), a nine-point outcomes scale from $+4$ to -4 using sequential questions. Secondary outcomes criteria were rate of recovery, occurrence of adverse events, length of consultation, and patient satisfaction with treatment using the Santa Fe Patient Satisfaction (SFPS) rating scale. This was a $+2$ to -2 defined as follows: $+2$ = very satisfied, $+1$ = somewhat satisfied, 0 = neutral, -1 = somewhat dissatisfied, -2 = very dissatisfied. The GHHOS and the SFPS scale have not been validated.

Monitoring

Monitoring, including source data verification was performed by an independent clinical monitor according to Good Clinical Practice (GCP) guidelines at each site. The study was approved by the Freiburg International Ethics Committee in Europe and by the Bastyr University Institutional Review Board in the United States. It was conducted in accordance with the Helsinki Declaration, GCP guidelines, and legal requirements in the participating countries.

Statistical analysis

Statistical analysis was conducted using univariate, bivariate, and multivariate statistical methods by the Institute for Numerical Statis-

tics (IFNS) in Cologne, Germany. A total of 500 patients were enrolled in the study. Forty-four patients (8.8%; 30 receiving homeopathic treatment and 14 receiving conventional treatment) were excluded from the statistical analysis. Forty-one (41) had no follow-up data and 3 had not met the inclusion/exclusion criteria. Four hundred and fifty-six (456) patient outcomes were suitable for comparison. Homeopathy was prescribed for 281 patients and 175 patients received conventional medicine. Comparisons between the effectiveness of homeopathy and conventional medicine regarding primary and secondary outcomes criteria were performed using the two-sided Mann-Whitney *U* test for rank ordered data and the two-sided Fisher's exact test for dichotomous variables (no α adjustment was made due to the exploratory character of the study). Response to treatment (the primary outcomes criterion was analyzed according the following prespecified subgroups: gender, age, whether or not the patient was known to the practitioner, practice setting, duration of consultation, clinical conditions, onset of symptoms, concomitant medical problems, adjunctive therapies for chief complaint, and initial HSQ sum score. Unadjusted odds ratios, with 95% confidence intervals, were determined for the total sample and the subgroups. In addition, multiple regression analysis was conducted to adjust for potentially confounding factors affecting response to homeopathic or conventional treatment.

RESULTS

Demographic data

The demographic data are presented in Table 1. In the group of patients receiving homeopa-

Table 1. Demographic Data

	Homeopathic treatment n = 281	*Conventional treatment n = 175*
Gender		
Male	91 (32.4%)	67 (38.3%)
Female	190 (67.6%)	108 (61.7%)
Age		
<2 years	29 (10.3%)	5 (2.9%)
2–11 years	109 (38.8%)	11 (6.3%)
12–17 years	16 (5.7%)	13 (7.4%)
18–64 years	125 (44.5%)	136 (77.7%)
≥65 years	2 (0.7%)	10 (5.7%)
Duration of consultation		
<5 minutes	23 (8.2%)	49 (28.0%)
5–15 minutes	169 (60.1%)	115 (65.7%)
16–30 minutes	71 (25.3%)	10 (5.7%)
>30 minutes	6 (2.1%)	—
Geographic region		
United States	143 (50.9%)	37 (21.1%)
Europe	138 (49.1%)	138 (78.9%)
Chief complaint		
Upper respiratory complaints	148 (52.7%)	102 (58.3%)
Lower respiratory complaints	103 (36.7%)	79 (45.1%)
Ear complaints	50 (17.8%)	8 (4.6%)
Onset of symptoms		
0–48 hours	114 (40.6%)	81 (46.3%)
48 hours–7 days	163 (58.0%)	92 (52.6%)
Concomitant medical problems		
Yes	80 (28.5%)	59 (33.7%)
No	193 (68.7%)	116 (66.3%)
Health Status Questionnaire (HSQ-12) sum score (X ± SD)	24 ± 7	24 ± 7

HSQ, Health Status Questionnaire; SD, standard deviation.

thy 49% (138) of the patients were children younger than 12 years versus 9% (16) in those receiving conventional medicine. Patients between the ages of 18 and 64 years comprised 45% (125) of the adults in the homeopathic treatment group and 78% (136) of the adults in the conventional treatment group. Upper respiratory tract complaints were the most common (>50%) in both groups followed by lower respiratory tract complaints and ear complaints. The two groups appeared similar prior to treatment as measured by the following parameters: gender, onset of symptoms (0–48 hours or 48–72 hours), HCQ-5 sum score, HSQ-12 sum score, and the number of concomitant medical problems.

Prescribed medications

The most commonly prescribed medications for both treatment groups are presented in Table 2. Eleven homeopathic medications accounted for 71.1% of all prescriptions in the group of patients receiving homeopathy and 70.9% of the patients treated with conventional medicine received antibiotics. Adjunctive therapies for the chief complaint were used in both groups. Of the group treated with homeopathy, 49.5% received adjunctive therapies. Of these 23% used herbal treatments, primarily echinacea. In this group treated with homeopathy, 16% received conventional treatment: cough and cold preparations, 5.7%; bronchodilators, 2.5%; nasal sprays, 2.1%; antibiotics, 1.8%; and analgesics, 1.4%. Acupuncture was used as an adjunctive therapy in 2.8% of patients treated with homeopathy.

Of the group treated with conventional medicine, 49.7% received adjunctive therapies. Of these, 40.6% used conventional treatments (analgesics, 22.3%; cough and cold preparations, 8%; nasal sprays, 7.4%, etc.), 4.6% used herbal treatment, and 3.4% used homeopathic treatment. Acupuncture was used as an adjunctive therapy in 1.1% of patients in the group treated with conventional medicine.

Patient outcomes

The response to treatment defined as cured or major improvement after 14 days of treatment according to the GHHOS revealed that patients treated with conventional medicine noted a 68% response to treatment whereas the group treated with homeopathy noted an 82.6% response to treatment. The difference

Table 2. Treatments Prescribed

Homeopathic treatment, n = 281, most frequently prescribed medications[a]		
	n	%
Pulsatilla	35	12.5
Hepar sulphuris	21	7.5
Lycopodium	21	7.5
Sulphur	20	7.1
Belladonna	19	6.8
Ferum phosphoricum	19	6.8
Kali bichromicum	16	5.7
Mercurius jodatus ruber	16	5.7
Phosphorus	12	4.3
Rhus toxicodendron	10	3.6
Spongia	10	3.6
*Conventional treatment, n = 175, most frequently administered medications**		
	n	%
Antibacterials for systemic use	124	70.9
Cough and cold preparations	58	33.1
Antiasthmatics	11	6.3
Nasal preparations	11	6.3

[a]Multiple responses possible.

between these groups was significant ($p = 0.0058$, two-sided Mann-Whitney U test; Table 3). The unadjusted odds ratio was 2.23 (95% CI; 1.43–3.47) in favor of homeopathy. Adjustment for age as a potential confounding variable in the logistic regression model reduced the odds ratio to 2.07 (95% CI; 1.24–3.47). Further adjustment for all prespecified covariables reduced the odds ratio to 1.96 (95% CI; 1.04–3.70). Odds ratios in the prespecified subgroups of response to treatment did not favor homeopathy in the following groups: patients younger than 2 years, patients older than 65 years, and patients not previously known to the practitioner (Fig. 1). The calculation of odds ratios in the subgroups of patients less than 2 years of age and in patients older than 65 years were of limited usefulness due to the small sample size in one of the treatment groups. Odds ratios of response to treatment were essentially the same for practitioners offering both homeopathic and conventional treatment as compared with practitioners who utilized either only homeopathy or only conventional medicine.

The HCQ-5 sum score, used as an indicator for the severity of the chief complaint, decreased similarly for both groups as expected ($p = 0.3534$, two-sided Mann-Whitney U test; Table 3). The rate of recovery was different among treatment groups. Of the group receiving homeopathy, 16.4 % improved in less than 1

Table 3. Patient Outcomes and Satisfaction

	Homeopathic treatment $n = 281$	*Conventional treatment* $n = 175$
Health Complaint Questionnaire (HCQ-5) sum score (X ± SD)		
Initial contact	15 ± 4	15 ± 4
After 14 days	8 ± 3	9 ± 4
	$p = 0.3534$ (Mann-Whitney-U-Test, two-sided)	
Glasgow Homeopathic Hospital Outcomes Scale (GHOOS)		
Cured, back to normal	175 (62.3%)	91 (52.0%)
Major improvement	57 (20.3%)	28 (16.0%)
Slight/moderate improvement	32 (11.4%)	42 (24.0%)
No change	2 (0.2%)	5 (2.9%)
Deterioration	8 (2.8%)	4 (2.3%)
No remark	7 (2.5%)	5 (2.9%)
	$p = 0.0058$ (Mann-Whitney-U-Test, two-sided)	
How soon after the initial contact was improvement noted?		
	46 (16.4%)	10 (5.7%)
Less than 1 day	143 (50.9%)	90 (51.4%)
1–3 days	68 (24.2%)	47 (26.9%)
4–7 days	11 (3.9%)	20 (11.4%)
8–14 days	4 (1.4%)	4 (2.3%)
>14 days	9 (3.2%)	4 (2.3%)
No improvement/no remark		
	$p = 0.0011$ (Mann-Whitney-U-Test, two-sided)	
Santa Fe Patient Satisfaction (SFPS) Rating Scale		
Very satisfied	222 (79.0%)	114 (65.1%)
Somewhat satisfied	34 (12.1%)	39 (22.3%)
Neutral	12 (4.3%)	13 (7.4%)
Somewhat dissatisfied	8 (2.8%)	3 (1.7%)
Very dissatisfied	3 (1.1%)	6 (3.4%)
No remark	2 (.7%)	0 (0%)
	$p = 0.0010$ (Mann-Whitney-U-Test, two-sided)	

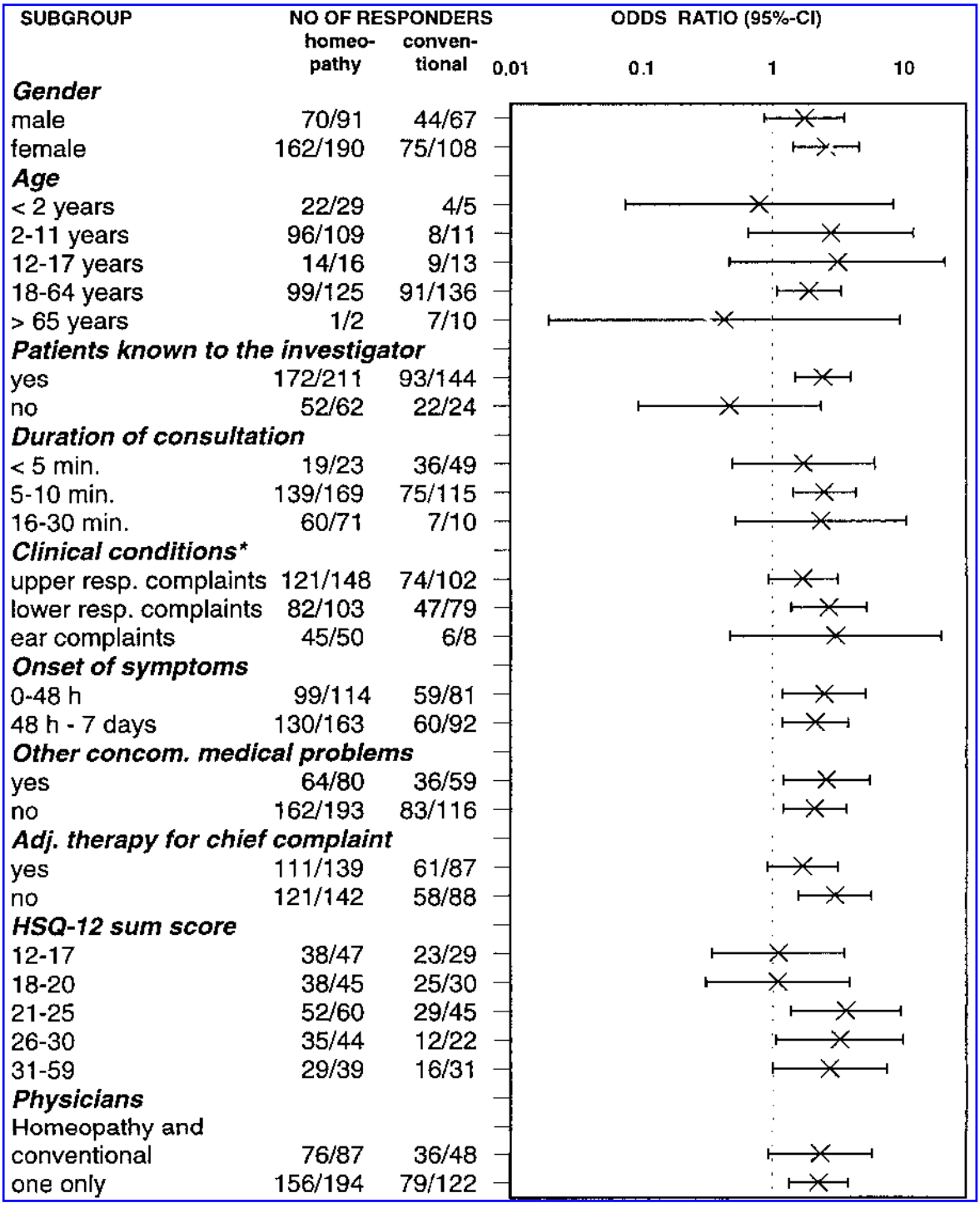

FIG. 1. Subgroup analysis. Odds ratio and 95% confidence intervals of response to treatment (cured or major improvement after 14 days of treatment) in prospectively defined patient subgroups. Odds ratio below 1 indicate that the specific patient subgroup responded better to conventional treatment. Odds ratios above 1 indicate that the subgroup responded better to homeopathic treatment.

day and 50.9% noted improvement in 1 to 3 days. For the group treated with conventional medicine, 5.7% noted improvement in less than 1 day and 51.4% first noted improvement between days 1 and 3. This difference between treatment groups for patients with improvement in less than 1 and in 1 to 3 days was significant and is consistent with the response to

treatment at 14 days ($p = 0.0011$, two-sided Mann-Whitney U test; Table 3).

Adverse events and patient satisfaction

Adverse events were significantly lower in the group treated with homeopathy; 7.8% versus 22.3% ($p < 0.0001$, Fisher's two-sided exact test; Table 4). The adverse events in the group treated with conventional medicine appear to be side effects–related to antibiotic therapy. The adverse events in the group treated with homeopathy were primarily headaches.

Patient satisfaction was high in both groups. Seventy-nine percent (79.0%) of patients treated with homeopathy were very satisfied and 12.1% were somewhat satisfied. Of patients treated with conventional medicine, 65.1% were very satisfied and 22.3% were somewhat satisfied. This difference between treatment groups for those very satisfied was significant ($p = 0.0010$, two-sided Mann-Whitney U test; Table 3). Further analysis of the correlation between adverse events and the response to treatment as well as patient satisfaction revealed that as anticipated patients without adverse events had a better response ($p = 0.0172$, two-sided Mann-Whitney U test) and reported a higher rate of satisfaction ($p < 0.0001$, two-sided Mann-Whitney U test) than patients who experienced adverse events.

Length of consultation

Both treatment groups had consultations lasting between 5 and 15 minutes in approximately 60% of cases. Longer consultation times were more common in the homeopathic treatment group (25% versus 5%) and shorter consultation times were more common in the conventional treatment group (28% versus 8%).

DISCUSSION

This study illuminates aspects relating to the clinical practice of homeopathy and its use in primary care. It is the first observational study using conventionally licensed health care practitioners to compare the effectiveness of homeopathy in primary care with that of conventional medicine. In this study, 84% of patients in the group treated with homeopathy received no conventional medications, suggesting that homeopathy is used as a stand-alone treatment modality in primary care, even by conventionally licensed practitioners. We were surprised that 11 homeopathic medicines covered approximately 70% of the prescriptions in the group treated with homeopathy. Despite the individualized nature of homeopathic treatment, it appears that clinical pathways to a specific prescription exist. This suggests that homeopathy can be evaluated in clinical trials.

Table 4. Adverse Events

	Homeopathic treatment n = 281	*Conventional treatment n = 175*
# of Patients with AEs (%)	7.8	22.3
thereof with[a]		
Headache	2.1	4.0
Diarrhea	0.0	5.1
Fatigue	0.4	2.3
Abdominal pain	0.4	2.3
Nausea	0.0	2.9
Dyspepsia	0.4	1.1
Pruritus	0.0	1.1
Rash	0.0	1.1
Dizziness	0.0	1.1
Somnolence	0.0	1.1
Allergic reaction	0.0	1.1
Gastrointestinal disorder	0.0	1.1

[a]Multiple responses possible.
AEs, adverse events.

We also noted that homeopathic prescribing for acute illnesses was possible within the time constraints associated with a conventional medical consultation. These two points suggest that homeopathy could be integrated into the primary care setting.

The wide difference in the rate of adverse events in this study between treatment groups was significant ($p < 0.0001$) and of importance given the concern about drug safety and side effects. Nyquist and coworkers (1998) recently documented the use of antibiotics in children for colds (44%), upper respiratory tract infections (46%), and bronchitis (75%), all conditions that typically do not respond to antibiotics, all conditions seen in this study. A recent meta-analysis of prospective studies evaluating adverse drug reactions reported a high incidence of adverse events among hospitalized patients receiving conventional medicine (Lazarou et al., 1998). The potential side effects of antibiotics could have been responsible for the high rate of adverse events in the conventional treatment group and may have blunted the effectiveness of conventional medicine. An alternative explanation is that homeopathy is effective for the three conditions seen in this study.

Several factors could have contributed to the higher response rate in the group treated with homeopathy. Patient satisfaction or dissatisfaction with treatment appears to be related to the growing interest in alternative medicine (Campion, 1993; Sutherland and Verhoef, 1994; Hentschel et al., 1996). A survey in the United Kingdom found that patients consulting a physician using homeopathy cited the fact that the physician incorporated homeopathy into their medical practice as the main reason for seeing that physician (Vincent and Furnham, 1996). Another factor in this survey was the belief that complementary therapies would be effective in treating their complaints and that patients appreciated being treated as a whole person and playing an active role in their own health. This survey also documented that the perceived side effects of conventional medicine as well as communication between patient and physician were important to patients in their choice of practitioners. Astin (1998) recently noted that "the majority of alternative medicine users appear to be doing so because they find complementary and alternative medical therapies to be more congruent with their own values, belief, and philosophical orientations toward health and life."

Other reasons may favor success with conventional medicine. Homeopathic philosophy tends to emphasize self-healing and patients using homeopathy appear to regard their practitioners and the treatments they prescribe as having less influence on their health than patients treated with conventional medicine (Kaiser, 1997). In addition homeopathy claims more success in the treatment of chronic as opposed to acute illness.

A study with this level of complexity has limitations. One of the potentially confounding variables was that investigators could enroll patients in a particular treatment group. Other potentially confounding factors such as age of the patients differed considerably between the treatment groups; these differences may be expected in a nonrandomized trial. However, baseline difference did not affect the outcomes as demonstrated by the fact that the adjusted odds ratios showed that these potentially confounding variables had no significant effect on the overall results of the study.

It is challenging to evaluate the treatment of acute illnesses where it may be difficult to distinguish among spontaneous recovery and the results of a therapeutic intervention. Expectation bias is another potentially confounding variable. Patients often try please their physicians (Bischoff and Zeitler, 1997) and practitioners may overestimate the effect of treatment (König and Nemeth, 1994). We used independent telephone interviewers in order to minimize expectation bias on the part of the patient and the practitioner (Jhni, 1994). Finally practice pattern variations are a confounding variable in all of primary care and complicate clinical research, particularly in a real world medical setting (Horton, 1999). Even with these limitations we believe that the practice of medicine in the United States and Europe has many things in common, not the least of which is the growing use of alternative medical therapies.

CONCLUSION

Regardless of evidence about the safety of homeopathy or its potential usefulness in primary care, the lack of a testable mechanism of action theory contributes to the scientific skepticism about this medical therapy (Sampson, 1995) and the controversial nature of these results (Horton, 1998; Belon et al., 1999). Nevertheless, an estimated 75% of the world's population use alternative medicine and the use of homeopathy is growing in the United States (Eisenberg et al., 1998) and Europe. There may be aspects of the way homeopathy is used in primary care that offers insights into what it means to be an effective practitioner in this setting. Its usefulness should continue to be evaluated with further practice-based research; exploring issues such as practitioner preference, and prescribing patterns (including dosing frequency). We believe that the information from this study will improve clinical trial design in the real world medical setting and offer a better understanding of how homeopathy and other alternative medical therapies are and can be integrated into the practice of medicine.

CONTRIBUTORS

D. Riley conceived and coplanned the study, was a principal investigator, supervised the data collection, participated in the interpretation of the data analysis, wrote the first draft of the manuscript, participated in all of the manuscript revisions, and wrote the final version of the manuscript. M. Heger coplanned the study, was a principal investigator, supervised the data collection, participated in the interpretation of the data analysis, participated in the manuscript revisions, and approved the final version of the manuscript. M. Fischer in Cologne, Germany, was responsible for the data extraction and statistical analysis, wrote the statistical analysis section, and approved the final draft of the manuscript. B. Singh participated in the data analysis and interpretation, participated in the manuscript revisions, and approved the final version of the manuscript. M. Haidvogl supervised the data collection in Austria, participated in the interpretation of the data analysis, participated in the manuscript revisions, and approved the final version of the manuscript.

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