

Impact of Acupuncture on Vasomotor Rhinitis: A Randomized Placebo-Controlled Pilot Study

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Abstract

Objectives: Chronic rhinitis without an allergic or infectious etiology (vasomotor rhinitis) is a common disease for which there are only few and not very effective therapeutic treatment options. The current placebo-controlled, partially double-blinded pilot study evaluated the effects of acupuncture on the symptoms of vasomotor rhinitis. **Design:** A total of 24 patients with confirmed diagnosis of vasomotor rhinitis were randomly allocated to either acupuncture or sham laser acupuncture treatment. The sham laser was a deactivated laser pen beaming normal red light. The main outcome measure was the alteration of the nasal sickness score (NSS; score_{max} 27 points). Secondary outcome measures were the evaluation of a subjective symptoms score by patients' diaries and of their quality of life (SF-12 health survey). A credibility assessment regarding the respective treatment was performed. The study is registered as an International Standard Randomised Controlled Trial, number NCT00682162.

Results: NSS of patients treated by acupuncture was significantly reduced from 9.3 ± 3.89 to 4.1 ± 3.20 points ($p < 0.001$), whereas NSS declined from 5.6 ± 2.74 to 3.7 ± 2.61 points after sham treatment ($p < 0.05$). Comparison between the groups revealed a significant change of NSS (Mann–Whitney, $p < 0.01$), an analysis that also considers the significant difference between the baseline values of both groups ($p < 0.05$). Secondary outcome measures did not show significant differences between both groups. The credibility assessment was comparable for both treatments.

Conclusions: This pilot study showed significant effects of acupuncture compared to a sham treatment in the NSS on symptoms of vasomotor rhinitis. These results may justify the performance of a large randomized trial to strengthen our understanding of the therapeutic value of acupuncture in the treatment of vasomotor rhinitis.

Introduction

VASOMOTOR RHINITIS IS A NONINFECTIOUS, nonallergic form of rhinitis (NINA rhinitis) and was formerly known as nasal hyperreactivity.¹ The main symptoms are nasal obstruction, rhinorrhea, sneezing, cough induced by pharyngeal phlegm, and itching.^{1,2} In addition, patients suffer from watering eyes, headache, earsounds, or popping in the ears. Symptoms fluctuate but rarely resolve, and the degree of functional impairment is not known. In addition, the lack of a clear understanding of the pathogenic factors that lead to the symptoms, in contrast to allergic rhinitis, for example, is

strongly demoralizing for the patients, leading to a decreased daily quality of life. Vasomotor rhinitis may induce anxiety and depression.^{3–5} Lifetime prevalence of vasomotor rhinitis is described as 9% in a representative Belgian population sample.⁶ NINA rhinitis can only be diagnosed by excluding other types of rhinitis with known etiologies.⁷

Potential pathophysiologic mechanisms include neural dysfunction, immunologic inflammatory responses, or changes of the permeability of the nasal mucosa, all of which may lead to increased entrance of potential harmful nasal irritants.^{8,9} This could then lead to dysregulation of the autonomic nervous system and the nonimmunologic release of

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different irritating chemical mediators, such as vasoactive intestinal peptides, substance P, neurokinin A, and other neurotransmitters.²

Available therapeutic options for vasomotor rhinitis are poor. Present therapies are mainly directed at symptom relief, for example, by administration of sympathomimetic or immunosuppressant drugs. Nasal sprays, such as ipatropium bromide, in addition to topical glucocorticoids (e.g., budesonide), figure as the most widespread used treatments.^{1,10} Pharmacokinetic studies suggest that topical application of antihistaminic drugs has a more rapid onset of action, when compared to other ways of application of antihistamines, as well as compared to intranasal corticosteroids.¹¹ Nevertheless, neither intranasal corticosteroids nor antihistamines are effective against all symptoms of vasomotor rhinitis,¹¹ leaving a need for more adequate therapy. Clinical trials using capsaicin or botulinum toxin as therapeutic agent have shown poor outcomes. Overall, no highly efficacious first-line therapy has been found.¹²

Given the relative paucity of good therapeutic options with available medications, alternative nonpharmacologic therapies could play an important role in this condition, even though large clinical trials are still lacking.¹³ In particular, there is growing evidence that acupuncture may be a promising alternative treatment for a variety of chronic conditions. Acupuncture has been shown to provide significant benefits in acute and chronic pain.^{14,15} One proposed mechanism of acupuncture analgesia is the modulation of the vegetative nervous system.^{16,17} This study investigates the use of acupuncture in the treatment of vasomotor rhinitis, as an example of a dysfunction of the autonomic nervous system.

Patients and Methods

Study design

This randomized, placebo-controlled, partially double-blinded pilot study was designed as a first step to evaluate the efficacy of acupuncture in the therapy for vasomotor rhinitis. The study took place in the Multidisciplinary Pain Centre, Department of Anaesthesiology, University of Munich, Germany. The study is registered as an International Standard Randomised Controlled Trial, number NCT00682162.

Subjects

Twenty-four (24) subjects (11 females) with vasomotor rhinitis were recruited via public announcements and included in the study. Patients eligible for inclusion in the study were over 18 years of age. Rhinitis symptoms had to be present for more than 3 months. The diagnosis of vasomotor rhinitis in participating patients was confirmed by a negative standardized allergic testing protocol (prick-testing).¹⁸ The allergic testing was performed by the Department of Otorhinolaryngology of the University of Munich, Germany. The following allergens were tested: grass, herbs, flowers, rye, dog, cat, horse, house dust mite, storage mite, different molds, and penicillin. Patients were excluded for the following reasons: nasal surgeries, polyposis nasi, early retirement by reason of rhinitis, psychologic disorders, medication or drug addiction, autoimmune diseases, severe general illness, or relative contraindications to acupuncture such as a clotting disorder and pregnancy.

Randomization and blinding

The sample size of 24 patients as well as the random sequence was generated by the Institute of Medical Information Technology, Biometry and Epidemiology, University of Munich, Germany. We prepared a series of sealed, sequentially numbered envelopes containing the treatment assignments. When a patient fulfilled the inclusion criteria, the study physician opened the lowest-numbered envelope to reveal the patient's group allocation. The patients were then randomly allocated to either acupuncture (acupuncture group) or sham laser acupuncture treatment (sham group). Patients were blinded by the following procedure: Each patient was informed individually that he or she would receive either acupuncture or a laser acupuncture treatment, that one of the treatments could be less effective, and that sham treatments could be included. Instead of the laser acupuncture, a sham laser acupuncture treatment was performed. The treating clinician was led to believe that the study was designed to compare needle acupuncture with real laser acupuncture and so was unaware that the laser pen had been deactivated.

Ethics

The study protocol and the written informed consent were approved by the Committee for Ethics of the University of Munich. Written informed consent was obtained from each patient.

Intervention

Both the acupuncture and sham laser acupuncture treatments consisted of five sessions. Acupuncture needles were kept in for 15 minutes: The rest time after treatment for the sham-laser-treated patients was 15 minutes. The sessions were administered over a period of 5 weeks (one session per week). The clinician performing the treatment was a licensed acupuncturist (>350 hours of acupuncture training). The treating clinician was the same for both groups. Outcome measures were assessed by an independent, blinded clinician.

The acupuncture treatment was semistandardized. The standard acupuncture regimen consisted of a basic pool of six body acupuncture points. Five (5) additional acupuncture body points together with auricular points formed an individual pool that could be used based on individual diagnostic considerations for each subject (Table 1).^{19–21}

The choice of the standard acupuncture regimen was made by the investigator prior to randomization based on expert opinions (JG, WS, DI) representing members of the faculty staff of one of the major German societies for medical acupuncture: German Medical Acupuncture Association (*Deutsche Ärztegesellschaft für Akupunktur, DÄGfA*). The needle acupuncture treatment followed both Traditional Chinese Medicine (TCM) and modern Western physiologic considerations.

Acupuncture treatment. The acupuncture technique used in this trial was performed in a traditional way. An expendable needle (body acupuncture 0.3×30 mm; ear acupuncture 0.2×15 mm) was used. After needle insertion, the needle was manipulated until the subject obtained the *de qi* response (a deep aching or full feeling at the needle).²² After

TABLE 1. ACUPUNCTURE POINTS (ACUPOINTS) CHOSEN FOR BASIC AND INDIVIDUAL TREATMENT

AcuPoint	Traditional name	Indication (acc. to TCM) ²⁰⁻²²
Basic pool		
CV 17	Shanzhong	Positive influence on respiration and chest Potency in psychovegetative regulation
GV 14	Dazhui	Strengthening the immunosystem
BL 13	Feishu	Helpful in chronic respiratory diseases
LI 4	Hegu	Well known for rhinitis and sinusitis treatment
LI 20	Yingxiang	To treat local diseases of the nose
ExHN 3	Yin Tang	Strong effect on disorders of the nose
Individual pool		
GV 20	Baihui	Mental stabilization
GV23	Shangxing	Local effect on rhinitis
Sp 6	Sanyinjiao	Intestinal and immunologic disorder
Lu 7	Lieqi	Lung diseases, treatment of rhinitis and sinusitis
St 36	Zusanli	Stabilization of mind, strength, and <i>qi</i>
Microsystem ear: 51 (vegetative point), 55 (Shenmen): consorting the mind		

The indications agree with Traditional Chinese Medicine (TCM) references.²⁰⁻²²

obtaining the *de qi* response, there was no further manipulation of the needle.

Sham treatment. Sham laser acupuncture was applied at the same points as the acupuncture treatment, using a laser pen, which had been deactivated by the manufacturer (Seirin, 3B Scientific GmbH, Hamburg, Germany). Only red light was emitted. To strengthen the power of this sham procedure, visual and acoustic signals accompanied the red light emission. The patients were treated 30 seconds without skin contact. No warming of the skin was observed. Every point was treated for 30 seconds.

Main outcome measure

The main outcome measure was the nasal sickness score (NSS). Patients were asked to answer standardized questionnaires before their first and after their last treatment. NSS was recorded with a specific nine-item questionnaire, based on the Health-Related Quality of Life,²³ covering the nine major symptoms of vasomotor rhinitis: nasal obstruction, rhinorrhea, sneezing, pharyngeal phlegm, itching, watering eyes, headache, ringing in the ears, or popping sensation in the ears (maximum score 27), each evaluated by its severity on a fourfold scale (0 indicating no symptoms, 1 = somewhat, 2 = moderate, and 3 indicating extreme symptoms). The NSS

is a symptom-specific and not a disease-specific score. The main objective of the study was to evaluate the change score in the NSS.

Secondary outcome measures

At each treatment session, a subjective symptoms score (patients disease diary score or PDDS) was evaluated out of a diary in which patients answered a 10-item questionnaire concerning their medical conditions once a day.

Quality of life was evaluated using the 12-item Short-Form Health Survey (SF-12), with calculation of the SF-12 Physical Component Summary score (PCS) and SF-12 Mental Component Summary score (MCS).²⁴

A clinical examination including measurement of nose patency was completed before and after every treatment session. The nose patency measurement was performed in both nostrils with acoustic rhinometry (Rhinoklack RK 1000, IfM GmbH, Wettenberg, Germany). Results were expressed as cross-sectional area in square centimeters.²⁵

At the endpoint of the study, we assessed their feeling of well-being on a 10-point numeric scale.

Credibility assessment

Expectations about outcome are the main modifying variables of the placebo effect according to Strauss-Blasche.²⁶ Patients were therefore asked to evaluate whether their satisfaction and expectations were met through a specific questionnaire according to Vincent²⁷ comprising four items: (1) (EWV) How confident do you feel that this treatment can alleviate your complaint?; (2) (EWTH) How confident would you be in recommending this treatment to a friend who suffered from similar complaints?; (3) (EWLO) How logical does this treatment seem to you?; (4) (EWAB) How successful do you think this treatment would be in alleviating other complaints?²⁷ Patient satisfaction was measured with a 10-point visual analogue scale at the end-point of the study (EWTZU).

Statistical analysis

Statistical analysis was done with the SPSS statistical software system (SPSS Inc., Chicago, IL; version 15.0). Data were expressed as mean $\pm$ standard deviation. Nonparametric tests were used to compare pretreatment and post-treatment data. Intragroup comparisons were performed with paired *t*-tests or the Mann-Whitney *U* Test. Two-sided *p* < 0.05 were considered statistically significant.

Results

Subjects' characteristics

A total of 24 patients (13 male, 11 female; age 32.8 years, range 21–64 years) with confirmed diagnosis of vasomotor rhinitis were allocated to either acupuncture (acupuncture group; age 30.7 years; 6 female) or sham laser acupuncture treatment (sham group; age 35.0 years; 5 female). All medications previous to this study had been prescribed by general practitioners on the basis of the respective symptoms. Detailed characteristics are given in Table 2 No adverse events were recorded in either group.

TABLE 2. SUBJECTS' CHARACTERISTICS

	Sham group (n = 12)	Acupuncture group (n = 12)
Age (years)	35.0	30.7
Gender		
Female	0.42	0.5
Male	0.58	0.5
Term of sickness		
> 2 years	0.75	0.67
0.5–2 years	0.17	0.33
3–6 months	0.8	0
Medication		
Sympathomimetics	0.25	0.08
Corticoids	0.08	0.00
None	0.66	0.92
Number of GPs visited		
before		
> 2	0.08	0.08
2	0.42	0.33
1	0.5	0.58

Descriptive data of both study groups (acupuncture and sham group) is given. Age is represented by mean. Parameters figure the intergroup distribution in decimal ratios. Combination of medication was allowed.

GP, general practitioner.

Nasal sickness score (NSS)

A specific questionnaire was used to rank each of the nine main symptoms mentioned above. From this follows a sum score, range 0–27.²³ The mean NSS before therapy was 9.3 ± 3.89 in the acupuncture group and 5.6 ± 2.74 in the sham group, and after therapy 4.1 ± 3.20 and 3.7 ± 2.61 , respectively. Change scores were -5.24 ± 2.89 (t -test, $p < 0.001$) in the acupuncture and -2.0 ± 2.57 (t -test, $p < 0.05$) in the sham group. There was a significant difference between the two groups in the mean baseline NSS score (t -test, $p < 0.05$). The between-group comparison of the change of NSS was significant, taking into account the baseline difference before therapy (Mann–Whitney U test, $p < 0.01$, Fig. 1).

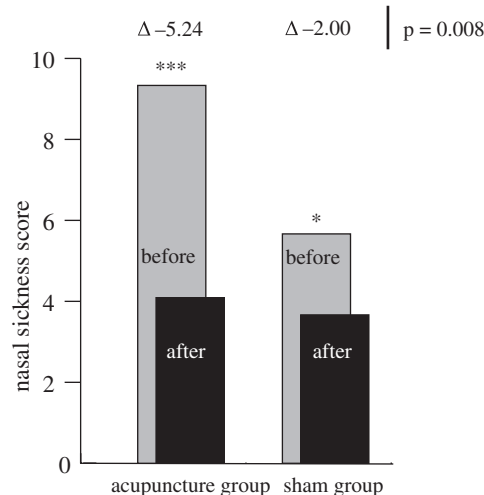


FIG. 1. Nasal sickness score (NSS) (as assessed by the specific questionnaire). Gray bars represent the NSS at timepoint 0, whereas black bars correspond to NSS after 5 weeks of treatment. Within- and between-group comparisons at time points week 0 and week 5 were determined statistically. Reduction of nasal sickness score for the acupuncture in comparison to the sham group was significantly better ($p = 0.008$). (*) and (***) express the different levels of significance ($p < 0.05$ and 0.001), respectively, in between needle- and sham-treated subjects.

Four of the symptoms assessed in the NSS subscores—rhinorrhea, nasal obstruction, pharyngeal phlegm, and sneezing—turned out to be the most severe symptoms, with an individual symptom severity in between somewhat and moderate. Other symptoms were not very disturbing to the patients, according to the score.

Patients disease diary score (PDDS)

A weekly sum score was built out of an accompanying diary subjects had to answer daily. Ten (10) items asked about daily influence of symptoms. The within-group reduction of the PDDS from week 1 to week 5 from 2.35 to 1.54

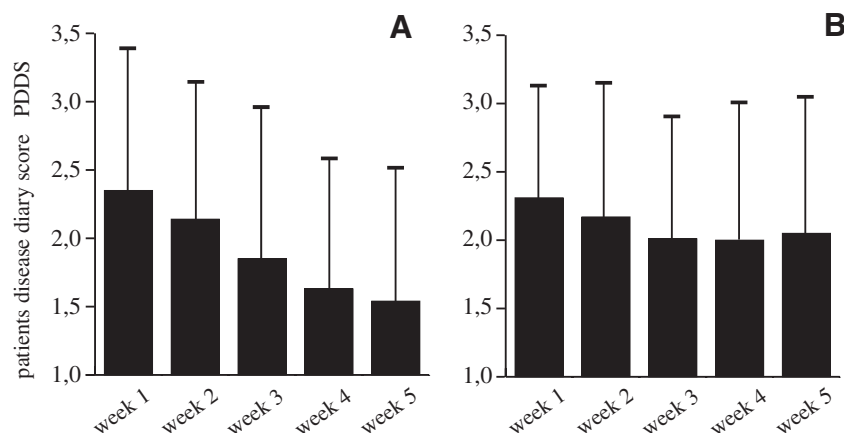


FIG. 2. Patients Disease Diary Score (PDDS). Weekly scores for the acupuncture (A) and the sham group (B) (as assessed by an accompanying subjects' diary). Neither reduction in the change score for the acupuncture ($\Delta = 0.81$) nor the sham group ($\Delta = 0.26$) was significant.

in the acupuncture group and from 2.31 to 2.05 in the sham group was not significant. The between-group comparison of the change scores of the acupuncture group (3.75 ± 6.5) and the sham group (1.77 ± 5.36) was also not significant (Mann-Whitney *U* test, $p = 0.621$, Fig. 2, Table 3).

Quality of life

Quality of life was evaluated using the SF-12 with calculation of the PCS and MCS. MCS for the acupuncture group increased by 5.1 ± 7.6 from 48.6 to 53.7, (Mann-Whitney *U* test, $p = 0.091$), whereas for the sham group the change of 0.8 ± 6.2 from 52.1 to 52.9 was not significant (Mann-Whitney *U* test, $p = 0.926$). There was a trend toward significance in the between-group comparison (Mann-Whitney *U* test, $p = 0.09$). The within-group change score in the PCS for both the acupuncture group from 51.1 to 51.2, change score 0.1 ± 5.6 , and the sham group from 50.4 to 51.0, change score 0.6 ± 6.2 , were not significant (Mann-Whitney *U* test, $p = 0.926$, Table 3).

Nose patency

Nose patency was measured in both left and right nostrils. Mean value between both cross-sectional areas (CSA) was calculated. The CSA before first treatment was $0.83 \pm 0.37 \text{ cm}^2$ in the acupuncture and $0.71 \pm 0.28 \text{ cm}^2$ in the sham group. The

CSA after last treatment was $0.78 \pm 0.25 \text{ cm}^2$ in the acupuncture and $0.81 \pm 0.39 \text{ cm}^2$ in the sham group. Within-group and between-group comparisons were nonsignificant (Mann-Whitney *U* test, $p = 0.47$, Table 3). There was no trend to significant changes of CSA in any of the two groups.

Condition of well-being

Nine (9) subjects in the acupuncture group (75%) compared to 4 patients in the sham group (33%) reported improved well-being after treatment (*t*-test, $p < 0.01$, Fig. 3).

Credibility assessment

Checking for the four different items of expectation at timepoint 0 demonstrated that there were no baseline differences between the two groups. In addition, this lack of difference between the groups with regard to expectations did not change after completion of the treatment sessions (Table 3). However, between-group comparison of subject satisfaction was strongly significant in favor of the acupuncture group (Mann-Whitney *U* test, $p = 0.015$, Table 3).

Discussion

This pilot study shows that patients who received a semi-standardized acupuncture treatment significantly improved

TABLE 3. SIDE PARAMETERS: INTRAGROUP COMPARISON SHAM VS. ACUPUNCTURE GROUP

	Sham group				Acupuncture group				<i>p</i> -value Intragroup comp.	Intragroup week 0 versus week 5
	n	Mean	SD	CI	n	Mean	SD	CI		
Patients Disease Diary Score (PDDS)										
PDDS week 0	10	2.35	0.94	1.67–3.03	10	2.30	1.33	1.34–3.26	0.152	
PDDS week 5	10	2.30	0.95	1.62–2.98	10	1.30	1.16	0.47–2.13	0.413	0.621
Quality of Life SF-12										
MCS week 0	12	52.31	9.27	46.07–58.54	12	48.60	9.50	42.56–54.63	0.288	
MCS week 5	12	52.87	11.97	44.83–60.91	12	53.73	6.69	49.48–57.99	0.880	0.090
PCS week 0	12	50.36	6.87	45.74–54.98	12	51.08	4.65	48.13–54.03	0.976	
PCS week 5	12	51.03	9.77	44.46–57.59	12	51.21	6.14	47.31–55.11	0.786	0.926
Nose patency										
Week 0	12	0.71	0.30	0.51–0.91	12	0.83	0.37	0.58–1.07	0.178	
Week 5	11	0.81	0.39	0.54–1.07	12	0.79	0.26	0.61–0.97	0.928	0.470
Credibility assessment										
Expectations										
EWV week 0	12	6.58	2.71	4.86–8.31	12	7.07	2.39	5.55–8.58	0.648	
EWV week 5	12	6.16	3.60	3.87–8.44	12	8.45	0.81	7.93–8.97	0.340	0.324
EWTH week 0	12	7.64	3.46	5.45–9.84	12	8.69	1.79	7.56–9.83	0.360	
EWTH week 5	12	7.35	3.27	5.27–9.42	12	9.18	0.92	8.59–9.76	0.139	0.762
EWLO week 0	12	6.62	3.59	4.34–8.90	12	7.13	2.44	5.59–8.68	0.684	
EWLO week 5	12	6.33	3.38	4.18–8.48	12	6.71	3.40	4.55–8.87	0.665	0.477
EWAB week 0	12	8.54	2.91	6.69–10.39	12	8.63	1.73	7.53–9.73	0.924	
EWAB week 5	12	7.60	3.26	5.53–9.67	12	8.58	1.59	7.58–9.59	0.582	0.349
Satisfaction										
EWTZU week 5	12	6.39	3.27	4.31–8.47	12	9.33	0.70	8.89–9.78	0.015	

Side parameters were evaluated statistically. Data are expressed as mean $\pm$ standard deviation (SD) and the 95% confidence interval (CI) is given.

The *p*-values represent either the intragroup comparison at week 0 or week 5 (left column) or the between-group comparison of change values (week 0 compared to week 5).

SD, standard deviation; CI, confidence interval; MCS-SF-12. Mental Component Summary; PCS, SF-12 Physical Component Summary; EWV, EWTH, EWLO, EWAB, EWTZU, see text.

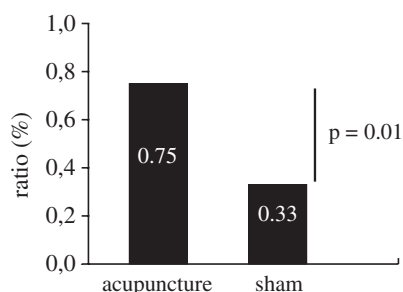


FIG. 3. Condition of well-being. After 5 weeks of treatment, patients were asked for the subjective improvement of their condition of well-being. Seventy-five percent (75%) of patients in the acupuncture compared to 33% in the sham group ($p = 0.01$) reported that their condition improved.

in the severity of nasal symptoms (NSS) when compared to placebo.

To our knowledge, our study is the first randomized, controlled, partially blinded study to investigate the impact of acupuncture therapy. Strengths of our trial include a strictly concealed randomization, an assessment of the credibility of interventions, blinded evaluation of diaries, and interventions based on expert consensus provided by qualified and experienced medical acupuncturists. The credibility of acupuncture and sham laser acupuncture was rated very similarly by patients, which supports the validity of our blinding procedures.

Although the groups were comparable with regard to sociodemographic characteristics at baseline, limitations regarding the external validity were found to exist on the differences of the NSS in spite of randomization. Given the small sample size of our study, the baseline differences regarding the NSS between acupuncture and sham group is likely based on our randomization method. The small number of subjects is justified as this study was determined to be a pilot study. In future, a larger study group such as stratification of subjects based on the severity of baseline symptoms possibly led by the differences in the NSS should be envisaged.

Future studies are necessary to confirm the symptom-based effects of needle acupuncture and to disprove that the shown effect was either due to a statistical regression to the mean or related to a bias of psychologic factors. Nevertheless, already this relatively small study showed that the NSS score changes significantly in both groups and that the improvement of symptoms was significantly higher in the acupuncture group. The predominance of only four of nine characteristic symptoms—rhinorrhea, nasal obstruction, pharyngeal phlegm, and sneezing—explain why the scores at baseline only reached 9 points of 27 possible points in the acupuncture group and only 6 points in the sham group, respectively. In the acupuncture group, the severity of symptoms was more pronounced than in the sham group, with a mean severity of “moderate” when concerning the four major symptoms.

The mean symptom severity of the four main symptoms in the acupuncture group was “moderate,” and we could show that the severity decrease was clinically significant. This clinical effect was only notable in the acupuncture group.

Unfortunately, the sample size is too small to statistically relate the observed improvement to either the disease-specific

fluctuation of symptoms,^{4,5} or to a combination of fluctuation and acupuncture-specific effects.

The number of treatments (five) is small when compared to the traditional Chinese setting of acupuncture treatments. This was due to different reasons: (1) ethical reasons, since the sham group in our trial did not receive any rescue medication; and (2) this pilot study was performed in order to explore whether there were any favorable effects. Confirmatory trials should follow TCM requirements with at least 10–12 treatments.

The study was designed as a pilot study; therefore, a follow-up of patients did not form part of the study protocol. A confirmatory trial intending to strengthen these results should include an adequate follow-up.

The use of medications was slightly different in both the acupuncture and sham group, making the influence of effective co-interventions possible. The majority of patients did not use drugs. We did not expect changes of the medication reported in patients. All patients were chronically suffering from vasomotor rhinitis, and we advised them at study entry to continue their medication as usual. Influences of patients' medications on the outcome of this clinical trial seem limited but cannot be ruled out.

Interpretations of the presented results have been carried out on the basis of the control procedure used. Assumed laser acupuncture was chosen for the sham treatment to avoid nonspecific physiologic effects and to maintain expectation and motivation of both the clinicians and study subjects.²⁸

We are aware that there is still a great deal of controversy regarding how to choose an adequate placebo control in acupuncture trials.^{27,29–31}

First, the use of superficial or deep needle insertions at locations distant from acupuncture points, also known as minimal or sham acupuncture control, cannot be considered an inert placebo, given the nonspecific physiologic effects of needle stimulation via activation of A β - and C-fibers.^{27,30,31} Even small, nonspecific perturbations around singular points can have important systemic effects.³² The superficial needle procedures are more likely to evaluate needling effects regarding the depth or the site of needle insertion. Physiologic antinociceptive effects of needle insertion cannot be avoided using these methods.

The development of so-called placebo needles represented substantial progress in acupuncture research methodology on mechanisms of acupuncture.³¹ In contrast, their application in clinical trials implicates methodological problems (e.g., artificial setting, loss of credibility in acupuncture experienced patients), and continual activation of A β -fibers, which by itself can activate pain-inhibitory systems.^{33,34} Second, sham laser acupuncture presents the possibility of blinding both physicians and patients.

Belief in the sham treatment modality enhances the objectivity of the study methodology.^{26,27,35} Our setting implied that both clinician and patient believe that a modern laser acupuncture treatment was used. Physicians trained in acupuncture are used to localize the specific acupuncture points. Acupuncturists may therefore lose their belief in therapeutic success when treating at nonspecific points or applying a sham method in the context of clinical trials.^{28,29} Patients were blinded as they were told that they would receive either acupuncture or a laser acupuncture treatment. It was mentioned that one treatment could be less effective and that sham

treatments could be included. This way we tried to consider the ethical responsibility toward the patient. The Ethics Committee at the University of Munich, Germany approved the suitability of this approach.

The weakness of this blinding consists of the fact that the therapist is aware of the difference between needle versus laser. Thus, the individual confidence of the therapist in the laser acupuncture technique may influence the placebo effect as well. In addition, technical devices are not directly comparable to acupuncture and are able to evoke different beliefs in treatment effects.³⁶

Given that the resolution to this controversy remains in doubt, the use of the sham laser methodology in this partially double-blinded study design avoids these mentioned concerns while still providing a valid control. Assessment of expectations (Table 2) demonstrated the high level of belief in the sham laser acupuncture arm, supporting our contention.^{26,28}

Therefore, we conclude that our results indicated the needling effect, since it maintained the special environment of an acupuncture setting in the verum and the sham group for both the physician and the patient.

In conclusion, the results of this pilot study suggest that verum acupuncture significantly improves the symptoms of vasomotor rhinitis when compared to a sham treatment, seen on the NSS in our population. In addition, there may be important positive effects on subjects' quality of life. Larger studies are necessary to strengthen our understanding of the effect of acupuncture on this condition, and this pilot study can therefore provide the basis for better statistical estimates of the number of subjects that would be required to sufficiently power a large randomized controlled study. In future studies, there would also be value to confirming the effects on nasal symptoms and to strengthen the outcome by significant effects in secondary outcome measures such as quality of life and disability parameters. There would also be value to comparing the effects of acupuncture to other treatment approaches. Based on the first results and given the lack of therapeutic options for symptoms of vasomotor rhinitis sufferers, acupuncture may be a safe and effective treatment of vasomotor rhinitis in therapy-resistant patients.

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Authors' Contributions

JF performed the statistical analysis and drafted the manuscript. CR performed the recruitment of the patients and their treatment, and helped in drafting the manuscript. Parts of the presented results are topics of her thesis. JG participated in the design of the study and carried out the acupuncture and sham regimen. PO participated in the recruitment and the assessment of the patients at the Department of Otorhinolaryngology. GR participated in the design of the study and recruited and assessed patients at the Department of Otorhinolaryngology. WS participated in the design of the study and carried out the choice of the acupuncture and sham regimen. DI conceived of the study, participated in its design and coordination, and drafted the manuscript. All authors read and approved the final manuscript.

Disclosure Statement

The authors declare that they have no competing interests.

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