

Acupuncture for nasal congestion: A prospective, randomized, double-blind, placebo-controlled clinical pilot study

Serkan Sertel, M.D.,¹ Zazie Bergmann, M.D.,¹ Kerstin Ratzlaff, M.D.,¹ Ingo Baumann, M.D.,¹ Henry Johannes Greten, M.D.,^{2,3} and Peter Karl Plinkert, M.D.¹

ABSTRACT

Background: Nasal congestion is one of the most common complaints dealt with in otorhinolaryngology. Side effects of decongestants are frequently seen in patients with chronic nasal congestion. This leads to an increasing demand of alternative treatments such as acupuncture. Future studies on acupuncture should aim at objectifying effects by both physical measuring and double blinding. Therefore, we were interested in whether these effects can potentially be measured as increase in nasal airflow (NAF) in ventus ("wind") disease of traditional Chinese medicine (TCM).

Methods: Twenty-four patients with a history of nasal congestion due to hypertrophic inferior turbinates or chronic sinusitis without polyposis were additionally diagnosed according to the Heidelberg model of TCM. They were asked to score the severity of their nasal congestion on a visual analog scale (VAS). The acupuncturist was blinded according to the Heidelberg blinding assay. NAF was measured by using active anterior rhinomanometry (ARM). Specific verum acupoints according to the Chinese medical diagnosis were tested against nonspecific control acupoints. VAS and NAF were scored and measured before and 15 and 30 minutes after acupuncture.

Results: Control acupuncture showed a significant improvement in VAS and a deterioration of NAF. Verum acupuncture showed highly significant improvements in VAS and NAF. In addition, verum acupuncture improved NAF and VAS significantly over time.

Conclusion: Our control and verum acupoints fulfill the condition of a control and verum treatment, respectively. Measuring NAF by RRM and scoring VAS are possible and reflect acupuncture effects in vivo.

(Am J Rhinol Allergy 23, e23–e28, 2009; doi: 10.2500/ajra.2009.23.3380)

Key words: Active anterior rhinomanometry (RRM), acupuncture, chronic sinusitis without polyposis, Heidelberg blinding assay, Heidelberg model, hypertrophy of inferior turbinate, nasal airflow (NAF), nasal congestion, traditional Chinese medicine (TCM), visual analogue scale (VAS)

Nasal congestion is one of the most common complaints dealt with in otorhinolaryngology. Symptomatic relief of congestion can be achieved with topical or oral decongestants. Frequent use of topical decongestants, e.g., xylometazoline, often leads to significant rebound congestion when the effects of the drug wear off, causing patients to continue using the decongestant in a vicious circle of persistent, worsening congestion (rhinitis medicamentosa). Because nasal decongestants have severe side effects in long-term use, e.g., headache, bronchial spasm, or vertigo, there is a great demand for alternative treatment methods such as acupuncture. In fact, according to the World Health Organization, in many developed countries, 70–80% of the population has used some form of alternative or complementary medicine (e.g., acupuncture).¹ The report from a Consensus Development Conference on Acupuncture held at the National Institutes of Health in 1997 stated that acupuncture is being "widely" practiced—by thousands of physicians, dentists, and other practitioners—for relief or prevention of pain and for various other health conditions. According to the 2002 National Health Interview Survey—the largest and most comprehensive survey of complementary and alternative medicine use by American adults to date—an estimated 8.2 million U.S. adults had ever used acupuncture, and an estimated 2.1 million U.S. adults had used acupuncture in the previ-

ous year.² This development leads to an increasing demand of scientific proof of usefulness.

Therefore, we compared the potency of specific verum acupuncture points related to a Chinese medical diagnosis in improving nasal airflow (NAF) with nonspecific points on the body (control) as well as the use of standard medication. Acupuncture is a treatment in which vegetative reflexes are elicited in manifold pathways, influencing the patients overall vegetative functional status. Verum acupuncture is the needling of specific points based on the traditional Chinese medicine (TCM) diagnosis, in which vegetative reflexes are elicited in manifold pathways, influencing the patients overall vegetative functional status.³ In contrast, control acupuncture is supposed to be less effective because either all known verum points and meridians are avoided or the acupoints are not in accordance with the TCM diagnosis of the patient. As in western medicine, therapy in TCM is performed according to the diagnosis of the patient. In TCM, however, it is seen as an assessment of the functional vegetative status of the patient. According to the TCM diagnosis, respective curative reflexes can be elicited through specific diagnosis-related acupuncture points.⁴ The Chinese diagnosis was done according to the "Heidelberg model" of TCM.³

MATERIALS AND METHODS

Design of the Study

A prospective, randomized, double-blind, controlled clinical study was performed at the University Hospital Heidelberg, Department of Otorhinolaryngology, Head and Neck Surgery over a period of 6 months, from August 2008 to January 2009.

Ethical Approval

The study was done in accordance with the ethical standards of the Helsinki Declaration of 1975, as revised in 1996. The study protocol

From the ¹Department of Otorhinolaryngology, Head and Neck Surgery, University of Heidelberg, Heidelberg, Germany, ²German Society of Traditional Chinese Medicine, Heidelberg, Germany, and ³Instituto de Ciencias Biomedicas Abel Salazar (ICBAS), University of Porto, Portugal

Presented at the 3rd Workshop on Scientific Approaches to Chinese Medicine, Huangshan, China, October 24–26, 2008

Address correspondence and reprint requests to Serkan Sertel, M.D., Im Neuenheimer Feld 400, 69120 Heidelberg, Germany

E-mail address: serkan.sertel@med.uni-heidelberg.de

Copyright © 2009, OceanSide Publications, Inc., U.S.A.

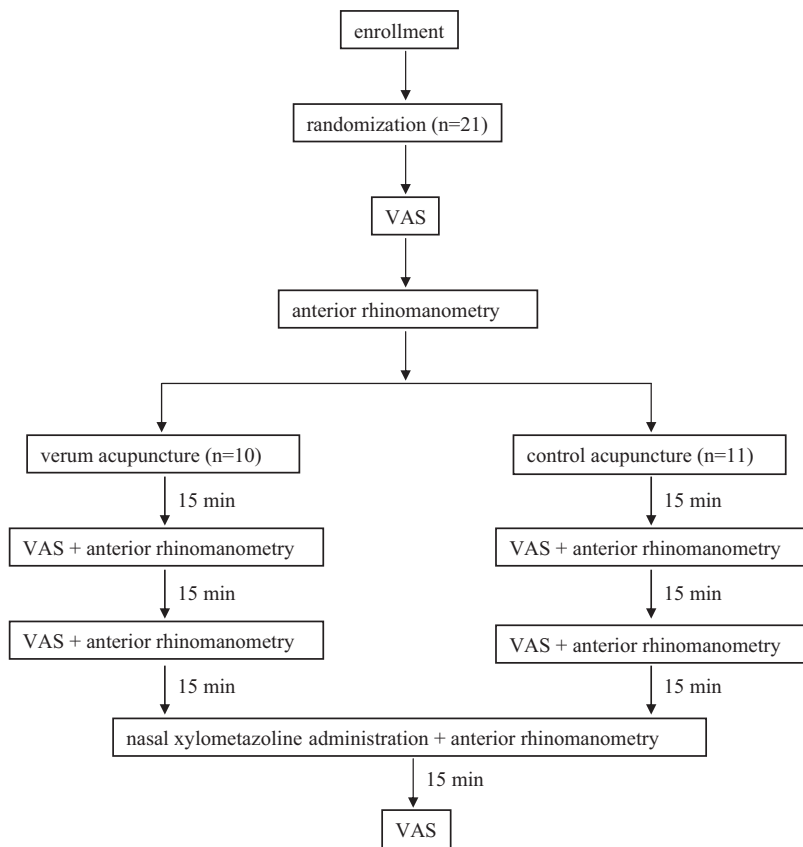


Figure 1. Flow chart of patient enrollment recruitment and study design.

was approved by the Human Ethics Committee of the medical faculty Heidelberg.

Patient Recruitment and Inclusion Criteria

Participants of the study were admitted through the outpatient clinic (Fig. 1). Patients who met the criteria for inclusion were recruited in the study. Only patients with nasal congestion due to hypertrophic inferior turbinates or chronic rhinosinusitis without polyposis were recruited in the study. Evaluation of nasal obstruction consisted of a rhinoscopy with adequate light and a nasal speculum and 0° endoscope. Age was ≥ 16 years. All patients were asked to score the severity of their nasal congestion on a 10-cm visual analog scale (VAS) with 10 = “nose is extremely blocked” and 0 = “nose is extremely clear.” Only patients with VAS values >5 were accepted for the study. Patients were given a full explanation of the study and recruited after signing a written informed consent. The exclusion criteria are listed in Table 1.

Active Anterior Rhinomanometry (ARM)

ARM measures unilateral airflow of both nasal passages separately by measuring the transnasal pressure, which is the difference in pressure from the naris to the nasopharynx.⁵ In this method, a pressure probe is placed at the opening of the nostril not being tested.⁶ The nasal passage acts as an extended tube and assumes that the airway pressure of the nasopharynx equals the pressure at the naris of the nontested side. Total resistance can then be calculated from two unilateral measurements.

We used a measuring unit combination of a personal computer with a RRM (RHINOmodule Octavus+; Hortmann, Tuttlingen, Germany). Nasal obstruction was rated in inspiration with NAF measured at 150 Pa in cm^3/s . NAF was labeled as “severe nasal obstruction” with values of 100–300 cm^3/s and as “moderate nasal obstruction” with values of 300–500 cm^3/s .

Table 1 Exclusion criteria

Skin lesions near acupuncture sites
Diabetes mellitus
Viral illness
Relevant psychiatric disorder
Coagulopathy (bleeding time >4 min., thrombocytes $<50,000/\text{L}$)
Anticoagulant therapy
Poor attitude toward participation
Previous treatment with acupuncture
Addiction to analgesics, opioids, or drugs
Relevant drug allergies
Daily usage of decongestants (“privinism”), including antihistamines and steroids (intranasal or systemic)
Inability or unwillingness to follow instructions
Participation in another clinical study
Pregnancy
Traumatic nose deformity
Traumatic septum hematoma
Chronic sinusitis with polyposis
Immunotherapy (during treatment)

tion” with values of 100–300 cm^3/s and as “moderate nasal obstruction” with values of 300–500 cm^3/s .

Randomization and Blinding

A sample size of 24 patients (13 in the control-acupuncture group and 11 in the verum-acupuncture group) was calculated to reveal a clinically significant difference of 2 U on the VAS with a probability of 80%. Patients were randomized to one of the two groups: the

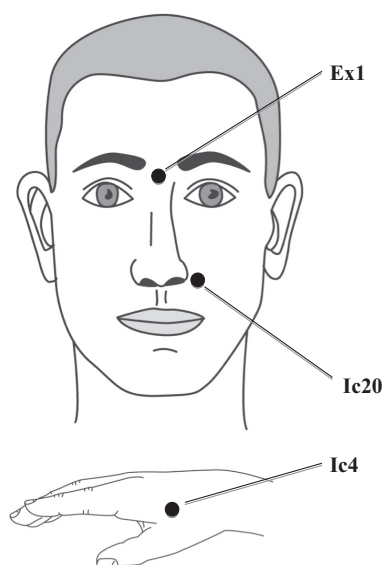


Figure 2. Specific verum acupuncture points for treatment of nasal congestion according to the Chinese medical diagnosis were Ic4, crassintestinal 4, “hegu,” is localized at the radial side, approximately in the center of the second metacarpal, in a concavity. This point has the most potent ventus dispelling effect and supports the effect of Ic20 in an additive manner. Ic20, crassintestinal 20, “yingxian,” is localized at the lateral lower border of the nostril, in a concavity of the bone. It has a direct reference on the mucosa and the sensory function of the nose. This decongestant effect is mainly established by dispelling ventus attack on the nose. It is known as the most potent acupoint in opening up the nose. Ex1, “yintang,” is localized in the center between the eyebrows. It supports the decongestant effect of Ic20 accordingly.

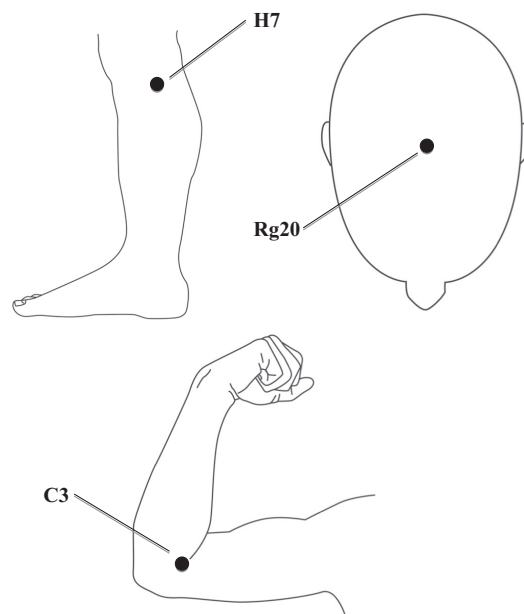


Figure 3. Nonspecific control acupuncture points with no relation to the Chinese diagnosis of the patient. Rg20, regens 20, “bailu,” is localized in the center of the top of the skull, in the vertex of hair, hence approximately 7 cun (7 Chinese inches, equivalent to the width of the interphalangeal joint of the thumb of the patient) from the posterior and 5 cun from the anterior border of hair. C3, cardial 3, “shaohai,” is situated medially in the crease of the elbow, at the medial epicondylus humeri. H7, hepatic 7, “xiguan,” is localized at the knee, behind and below the medial condylus of the tibia.

verum-acupuncture group, received acupuncture according to the Chinese medical diagnosis; the control-acupuncture group, treated with nonspecific points with no relation to the TCM diagnosis of the patient. The randomization was performed by the Institute of Medical Biometry and Informatics at the University of Heidelberg.

All acupuncture treatments were performed by one blinded acupuncturist, who was only educated in the technique of acupuncture and the two acupuncture methods (verum and control acupuncture) using the same type of needles and depth of skin penetration. The acupuncturist performed acupuncture according to randomization. Patients were blinded as to which acupuncture treatment they received. To avoid suggestive influence, communication with the patient was limited to a standardized minimum.

Acupuncture Needles and Acupuncture Points

We used standard disposable sterile acupuncture needles (Viva 0.25 × 40 mm; China Purmed GmbH, Karlsruhe, Germany). Acupuncture was performed bilaterally on each patient. Altogether, five acupuncture needles were used (two for each side and Rg20 or Ex1). They penetrated the skin to a depth of 1 cm and were kept in place for 15 minutes. The acupuncture points are listed and described in Figs. 2 and 3.

Treatment Protocol

After examination of participants, inclusion and exclusion criteria were checked before enrollment in the study. Then, patients were randomized. Participants scored their subjective nasal congestion on a VAS before and 15 and 30 minutes after acupuncture treatment, and 15 minutes after nasal application of xylometazoline at the end of each trial. All patients were asked to rate the severity of their nasal congestion on a 100-cm VAS with the extremes labeled as 10 = “nose is

Table 2 Patient characteristics

	Verum Acupuncture Group	Control Acupuncture Group
No. of patients	11	13
Mean age (yr)	38.4	48.1
Range of age (yr)	22–66	23–82
Sex (F/M)	4/7	8/5

extremely blocked” and 0 = “nose is extremely clear.”⁷ RRM was performed to determine NAF, respectively. Before verum acupuncture the functional Chinese diagnosis was done according to the “Heidelberg model” of TCM.³ In addition, possible side effects of acupuncture were recorded.

Statistical Analysis

The sample size ($n = 24$) was calculated based on a previous pilot study. Because of these results a number of 12 patients per group had a power of 80% to detect a standardized difference of $\Delta = 1$ with statistical significance (type I error) of 5%. Sample size calculation was performed using nQuery Advisor Version 6.0.1 (Statistical Solutions, Ltd., Cork, Ireland). For statistical analysis of results SAS 9.1WIN (SAS, Inc., Cary, NC) was used. Quantitative data were summarized by means of the following summary statistics: the number of observations, the arithmetic mean, SD, minimum, median, and maximum. The change of VAS and NAF after 15 and 30 minutes were analyzed using multivariate analysis of variance (MANOVA) with repeated measurements. Boxplots were used to visualize the findings.

RESULTS

Patient Characteristics

A total of 24 patients participated in our study (12 male and 12 female patients). Eleven patients were randomized to the verum-acupuncture group and 13 were randomized to the control-acupuncture group. The male/female ratio in the verum and control acupuncture group is mirror inverted. In contrast to the control group, mean age of the verum group is lower (Table 2). No dropouts were noted.

Side Effects

In this study no significant side effects were noted. In rare cases, small hematomas appeared at the side of puncture.

Control Acupuncture

Control acupuncture showed a significant improvement in VAS and a deterioration of NAF (in 75% of cases; see Table 4). In addition, it showed a constant behavior in both parameters between 15 and 30 minutes (Tables 3 and 4). It fulfilled the condition of a control treatment.

Verum Acupuncture

Verum acupuncture showed highly significant improvements in VAS and NAF. It fulfilled the condition of a verum treatment. In addition, verum acupuncture improved NAF and VAS significantly over time (Tables 3 and 4). Furthermore, the mean values of change of NAF after 30 minutes and after nasal xylometazoline application are similar, but variation is higher after xylometazoline application (see Fig. 5).

Comparison of p Values

The analysis shows highly significant differences in VAS between groups ($p = 0.0004$) and significant changes over time ($p = 0.038$), but no significant interactions between time and group ($p = 0.150$; Table 4). NAF shows similar results in difference between groups ($p = 0.0041$), change over time ($p = 0.016$), and no significant interaction between time and group ($p = 0.058$; Table 4).

DISCUSSION

Increasing clinical implementation of acupuncture in western medicine leads to an increasing demand of scientifically objectifying its effects. In one of our first studies, we could show that additional use of acupuncture to nonsteroidal anti-inflammatory drugs effectively reduced posttonsillectomy pain.⁸ Diseases in otorhinolaryngology offer a wide range of appliance of TCM.

Previously, there was no controlled, double-blinded acupuncture study concerning the issue of nasal congestion and effects of acupuncture points in the literature. This is the first study to compare the decongestant efficacy of specific verum acupuncture to nonspecific control acupuncture and a nonacupuncture standard medication group for the improvement of nasal breathing. Takeuchi *et al.* investigated the effect of nasal massage of one single acupuncture point "yinxing" on NAF and VAS in patients with nasal congestion associated with acute upper respiratory tract infection.⁹ No correlation could be found between the changes in objective and subjective measures of nasal congestion. Massaging of yinxing significantly improved VAS but not NAF. There are evident and important differences to our study. In contrast, we applied the technique of acupuncture with acupuncture needles, which turned out to be much more effective than massage of acupuncture points. Furthermore, we proved the existence of a specific verum and nonspecific control acupuncture treatment, respectively. In addition to the western diagnosis, we considered the Chinese medical diagnosis of the patient in the treatment and by this recruited highly selected patients for the study to show the direct cause-and-effect correlation of acupuncture.

Concerning the interactions between time and treatment groups, NAF and VAS show the same tendency over time. In this respect, the effect of verum acupuncture improved in both parameters, indicating that acupuncture has not only short-time effects (Figs. 4 and 5).

Interestingly, the mean values of change of NAF after 30 minutes and after xylometazoline application are similar, but variation is higher after xylometazoline application (Fig. 5). These results emphasize that verum acupuncture has a measurable decongestant effect but less than xylometazoline.

Limitations

Limitations of this study include the difficulty in determining nasal congestion on the VAS. ARM as a surrogate measure for nasal con-

Table 3 Change of value to baseline

Parameter	n	Group	Time (min)	Mean Value	Change of Value to Baseline				
					Mean	SD	Minimum	Median	Maximum
VAS	13	Control	0	7.2					
			15	7.0	-0.3	0.5	-1.2	-0.2	0.5
			30	6.8	-0.4	0.6	-1.3	-0.6	0.9
			45	6.0	-1.3	1.2	-4.0	-1.4	1-5
VAS	11	Verum	0	8.1					
			15	6.8	-1.2	0.8	-2.7	-1.1	-0.1
			30	6.2	-1.9	1.2	-4.5	-1.8	0.0
			45	5.0	-3.1	2.0	-6.3	-3.1	0.6
NAF	13	Control	0	321.0					
			15	275.5	-45.5	61.8	-183.0	-20.0	21.0
			30	283.4	-37.6	99.5	-259.0	-9.0	143.0
			45	383.4	62.4	138.7	-282.0	92.0	227.0
NAF	11	Verum	0	289.8					
			15	323.9	34.1	100.6	-216.0	46.0	117.0
			30	382.6	92.8	76.3	-94.0	107.0	175.0
			45	422.4	132.5	128.9	-53.0	116.0	317.0

*Xylometazoline application.

VAS = Visual analog scale.

Table 4 Comparison of *p* values (conducted with MANOVA test)

Group	Difference between Groups*	Change over Time#	Interaction between Time and Group§
VAS	<i>p</i> = 0.0004	<i>p</i> = 0.038	<i>p</i> = 0.150
NAF	<i>p</i> = 0.0041	<i>p</i> = 0.016	<i>p</i> = 0.058

*Control versus verum.

#Change of values (VAS and NAF) of both treatment groups between first measurement (baseline) and third measurement (30 min).

§Interaction of values (VAS and NAF) of both treatment groups between first measurement (baseline) and third measurement (30 min).

MANOVA = multivariate analysis of variance; NAF = nasal airflow; VAS = Visual analog scale.

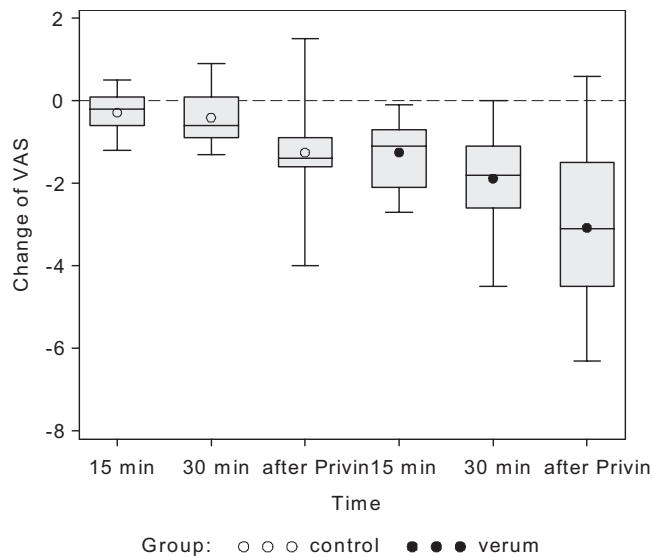


Figure 4. Change of visual analog scale in respective treatment groups. T1 = 15 minutes after acupuncture, T2 = 30 minutes after acupuncture, and T3 = last measurement after nasal xylometazoline application (30 minutes after T2).

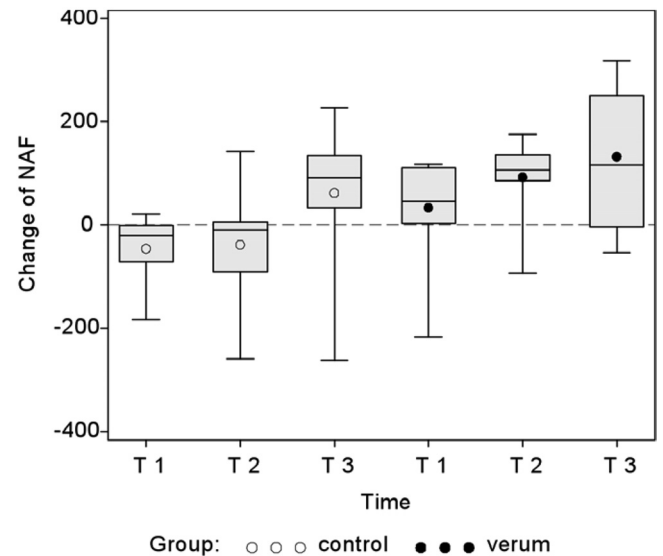


Figure 5. Change of nasal airflow at 150 Pa in ccm/s during inspiration through both nostrils in respective treatment groups. T1 = 15 minutes after acupuncture, T2 = 30 minutes after acupuncture, and T3 = last measurement after nasal xylometazoline application (30 minutes after T2).

gestion is discussed controversially in literature. Although, ARM is commonly used in providing valuable information to support clinical decisions, a recent study shows that ~25% of symptomatic patients with functionally relevant nasal structural deformity could not be detected by ARM. It is also stated that a negative test outcome of ARM does not exclude a functionally relevant nasal stenosis.¹⁰

ARM is routinely used to measure respiratory resistance in the nasal passage. However, its application faces problems. First of all, measurements can not be performed continuously, meaning that measurements have to be interrupted to present allergens and/or drugs to the nasal epithelium. This interruption changes conditions of measurement, which may lead to more variance in the obtained measures. Artifacts are produced if the patient mistakenly breathes through the mouth or if the facemask does not fit tightly. Measurements *via* RRM are not possible in cases of septal perforation or in totally obstructed noses. In addition, swelling of the nasal mucosa is only detected indirectly *via* nasal airway resistance. Furthermore, correlations between the subjects' ratings and ARM results have not been proven; therefore, the clinical value of ARM is controversial. In contrast, the subjects' ratings of nasal congestion correlated to a higher degree with the results from optical rhinometry than with those from ARM.¹¹

Another limitation is the short measurement period of 30 minutes after acupuncture. Because patients were recruited through the daily outpatient clinic, patients' presence was limited from the outset. In the context of a pilot study this setting seems reasonable and needs to be adjusted in additional studies.

Moreover, blinding of the investigator performing the acupuncture might become a potential source of bias in a larger patient population, as repetitive positive experience with one of both acupuncture methods can produce prior expectations in effect. This problem could be overcome by changing the blinded acupuncturist by another.

CONCLUSION

Based on the results, three important implications arise from our study. First, our control and verum acupuncture points fulfill the condition of a control and verum treatment, respectively. Second, measuring NAF by ARM and scoring VAS are possible and reflect acupuncture effects *in vivo*. Third, acupuncture appears to be a potential therapeutic strategy for nasal congestion, particularly in cases of inefficiency, drug resistance, or atrophic rhinitis.

Our results prove that acupuncture is capable of a measurable improvement in NAF and shows good clinical implications for nasal congestion without side effects. Improving of NAF, measured with the VAS and ARM, was significant because of verum acupuncture. Control acupuncture also showed an improving effect in VAS and a deterioration of NAF (in 75% of cases). Nevertheless, the effects of verum acupuncture on patients' subjective sensation on nasal breathing tend to be stronger. This supports the concept of verum acupuncture points having a subjective and objective change in nasal congestion. In addition, this study emphasizes that acupuncture, specifically addressing the demands according to the Chinese diagnosis of the patient, has a measurable decongestant effect but less than xylometazoline. Overall, we present a pilot study with some suggestion of

potential effectiveness of acupuncture in relieving nasal congestion that needs additional study.

Future studies in this area would include: (I) survey of duration of acupuncture's decongestive effect with a longer analysis time frame, (II) comparison of the correlation between ARM and other methods, e.g., acoustic rhinomanometry or optical rhinometry in the detection of changes in nasal congestion after acupuncture, and (III) investigating the effects of acupuncture on nasal ciliary beat frequency.

ACKNOWLEDGMENTS

The authors thank Merdhad Nouri for performing the acupuncture and Adriana Pieterek for doing the rhinomanometry measurements. They also thank Reinhard Schwab and Dr. Thomas Bruckner from the Institute of Medical Biometry and Informatics at the University of Heidelberg for invaluable assistance during statistical analysis of the study.

REFERENCES

1. World Health Organization. Traditional medicine. Fact sheet 134, revised December 2008. Available online at www.who.int/mediacentre/factsheets/fs134/en/; last accessed January 10, 2009.
2. National Institutes of Health, National Center for Complementary and Alternative Medicine. Acupuncture: An introduction. Available online at www.nccam.nih.gov/health/acupuncture/introduction.htm; last accessed January 10, 2009.
3. Greten HJ. *Kursbuch Traditionelle Chinesische Medizin*, 1st ed. Stuttgart-New York: Thieme Publishing House, Stuttgart, Germany. 1–50, 2003.
4. Porkert M. Introduction to TCM. In *Chinese Medical Diagnostics: The Comprehensive Textbook*. Phainon Editions & Media GmbH, Dinkelscherben, Germany. 1–40, 1997.
5. Bailey B. *Head and Neck Surgery: Otolaryngology*, 2nd ed. New York: Lippincott-Raven, 335–344, 1998.
6. Cummings CW, Haughey BH, Thomas JR, et al. Rhinology. In *Otolaryngology: Head and Neck Surgery*. St. Louis, MO: Mosby Year-Book, 801–806, 816, 820, 1999.
7. Huskisson EC. Measurement of pain. *Lancet* 2:1127–1131, 1974.
8. Sertel S, Herrmann S, Greten HJ, et al. Additional use of acupuncture to NSAID effectively reduces post-tonsillectomy pain. *Eur Arch Otorhinolaryngol* 266:919–925, 2009.
9. Takeuchi H, Jawad MS, and Eccles R. The effects of nasal massage of the “yingxiang” acupuncture point on nasal airway resistance and sensation of nasal airflow in patients with nasal congestion associated with acute upper respiratory tract infection. *Am J Rhinol* 13:77–79, 1999.
10. Bermuller C, Kirsche H, Rettinger G, et al. Diagnostic accuracy of peak nasal inspiratory flow and rhinomanometry in functional rhinoplasty. *Laryngoscope* 118:605–610, 2008.
11. Wustenberg EG, Zahnert T, Huttenbrink KB, et al. Comparison of optical rhinometry and active anterior rhinomanometry using nasal provocation testing. *Arch Otolaryngol Head Neck Surg* 133:344–349, 2007. □

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.