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Original Research Article

Efficacy and safety of herbal steam bath in allergic rhinitis: a randomized controlled trial

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ABSTRACT

Background: Allergic rhinitis is a nasal mucosa inflammatory disorder that is induced by exposure to an allergen which results in four major symptoms, including anterior or posterior rhinorrhea, sneezing, nasal itching and nasal congestion. Allergic rhinitis may result in sleep disturbance, fatigue, depression of mood-cognitive function and quality of life impairment.

Objective: This study examined the efficacy and safety of herbal steam bath used for the reduction of allergic rhinitis symptoms, and evaluated treatment satisfaction and improvements in quality of life among participating patients with allergic rhinitis.

Design, setting, participants and intervention: A single-blind randomized controlled trial was conducted at Thai Traditional and Alternative Medicine Hospital between June and December 2016, using 64 subjects, equally divided into two groups. The treatment group received herbal steam bath and the control group received steam bath without herbs for 30 min 3 times a week for 4 consecutive weeks.

Main outcome measures: Allergic rhinitis symptoms, such as itchy nose, runny nose, sneezing, nasal congestion and watery eyes, were measured using the visual analog scale at weeks 0, 1, 2, 3 and 4. Quality of life was assessed at week 0 and week 4.

Results: The characteristics (sex, age, marital status, education, allergic rhinitis symptoms and frequency of symptoms) at the baseline were not statistically different ($P > 0.05$) between the two test groups. Anterior or posterior rhinorrhea symptoms, including sneezing, nasal itching and nasal congestion, were statistically reduced over the course of the treatment, but reductions were not significantly different between the control and treatment groups. The treatment group, however, was shown to be significantly more satisfied with the treatment than the control group ($P < 0.05$).

Conclusion: Both treatments appear to be able to significantly reduce the symptoms of allergic rhinitis. However, there was no difference in the effectiveness of steam bath with herbs and steam bath without herbs.

Trial registration: This trial was registered in the Thai Clinical Trial Registry with the identifier TCTR20170712002.

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1. Introduction

Allergic rhinitis is an inflammatory disorder of the nasal mucosa induced by exposure to allergens. The condition displays four major symptoms: anterior or posterior rhinorrhea, sneezing, nasal itching and nasal congestion. Allergic rhinitis symptoms result in

sleep disturbance, fatigue, mood depression and a decrease in cognitive function, all of which impair quality of life [1]. The incidence of allergic rhinitis is a global health problem. Allergic respiratory diseases such as asthma and allergic rhinitis are increasing worldwide [2]. In Thailand, the incidence of allergies increases every year, and is predicted to increase 300–400 percent within the next 20 years. Currently, allergic rhinitis and sinusitis account for 23–50 percent of the incidence of allergies, for which most patients were treated symptomatically [3,4], including the use of antihistamines,

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nasal irrigation and nasal spray. Thai traditional clinical practice guidelines allow for the treatment of respiratory syndromes via methods such as herbal steam bath (HSB) for allergies [5]. HSB alleviated the effects of allergies well, but some patients are unable to benefit from steam bath (SB) because of allergies to the herbs. Patients who use SB without herbs still experience good results. However, there is no research on the efficacy of HSB and SB for relieving symptoms in patients with allergic rhinitis.

2. Materials and methods

2.1. Trial design

This study was a single-blind randomized controlled trial, in which the investigator was blinded.

2.2. Study setting

This study was conducted in the Outpatient of Thai Traditional and Alternative Medicine Hospital, Bangkok, Thailand. The study protocol was reviewed and approved by the Ethics Committee of the Traditional Thai and Alternative Medicine of the Department for the Development of Thai Traditional and Alternative Medicine, under the Ministry of Public Health, Thailand (approval number: RLC0041/59). It was registered in the Thai Clinical Trial Registry (trial registration identifier: TCTR20170712002).

2.3. Participants and intervention

The mean change between the baseline and the end of treatment was used as the main efficacy criterion. The mean difference between HSB group (μ_2) and SB group (μ_1) was assumed to be 0 (i.e., μ_2 (test) – μ_1 (control) = 0). The noninferiority margin (δ) was chosen to be 64 points and the standard deviation (σ) was estimated to be 90. By using the following formula for sample size calculation [6], setting α (significant level) = 0.05 and power at 80% ($\beta = 0.2$), Z value (standard score), n (sample size), μ (population mean), we estimated that 30 patients in each group would be the minimum. With a projected dropout rate of 15%, 34 patients per treatment group were needed.

$$n_1 = n_2 = \frac{2(Z_{\alpha} + Z_{\beta})^2 \sigma^2}{(\mu_2 - \mu_1 - \sigma)^2}$$

One hundred and thirty subjects with allergic rhinitis, based on clinicians' diagnosis at the Thai Traditional and Alternative Medicine Hospital, were selected. The inclusion criteria were as follows: male or female, aged 20–65 years, having allergic rhinitis symptoms as described in the Allergic Rhinitis with its Impact on Asthma (ARIA) guidelines (i.e., patients experience itchy nose, runny nose, sneezing, nasal congestion and watery eyes more than 4 days per week) [7], and consent to participate in the research. The exclusion criteria were pregnancy, lactation, nose surgery up

to four weeks prior to participation, fever of over 37.5 °C, dizziness, fatigue, insomnia, starvation, dermatitis, open wounds during the trial and a history of allergies to herbs, steam particles or heat.

Sixty-eight subjects fulfilled the inclusion criteria. They were randomized by a computer-generated list into two groups (34 persons each group). Allocation cards were placed in opaque, sealed and stapled envelopes by a nurse who did not participate in the research. The treatment group received HSBs and control group received SBs without herbs; baths were taken for 30 min three times a week (Monday, Wednesday and Friday) for 4 weeks. Both groups were assessed for symptoms of allergic rhinitis using the 10-mm visual analog scale (VAS; 0 = not at all bothersome, 10 = extremely bothersome) at weeks 0, 1, 2, 3 and 4. Quality of life was assessed at week 0 and week 4. Satisfaction with the treatment was assessed at week 4, as shown in Fig. 1. The herbs shown in Table 1 were steeped in water between 42 and 45 °C for use by the treatment group, but the control group used only water at the same temperature. The steam cabinet was made of pine wood and was 80 cm wide, 80 cm long and 180 cm tall. A thermostat controlled the internal temperature of the steam cabinet, and the chamber was protected by a ground fault interrupt circuit breaker. The two windows and the lamp inside the cabinet allow the health care provider to observe the patient during the treatment process. In case of an emergency, the patient can press a bell to alert the health care provider. Finally, the vent in the roof of the cabinet can be opened and closed and allows the health care provider to control how much steam is inside the cabinet. It was filled with steam and brought to the desired temperature before the patient entered (Fig. 2). Control and treatment baths were conducted in dedicated chambers to prevent exposure of the control group to the herbs.

All participants were informed about the research purposes and procedures. They signed informed consent forms and were assured that their information would be kept strictly confidential.

2.4. Outcome measures

Allergic rhinitis symptoms were measured in the subject using the 10-mm VAS for allergic rhinitis symptoms. A questionnaire was used to assess quality of life and satisfaction with the treatment. The questionnaires were from Clinical Practice Guideline of Thai Traditional Medicine [7]. All patients were asked to complete a set of questionnaires at baseline and after 4 weeks of treatment. Briefly, the questionnaires for quality of life contained 7 items

Table 1

List of herbal medicines in herbal steam bath.

Number	Scientific name	Part of use	Weight (g)
1	<i>Zingiber cassumunar</i>	Rhizome	75
2	<i>Curcuma longa</i>	Rhizome	75
3	<i>Kaempferia galanga</i> L.	Rhizome	75
4	<i>Acorus calamus</i> L.	Rhizome	20
5	<i>Tamarindus indica</i>	Leaves	15
6	<i>Cinnamomum camphora</i> (L.) Presl.	–	2.5
7	<i>Dryobalanops aromatica</i> Gaertn.	–	2.5

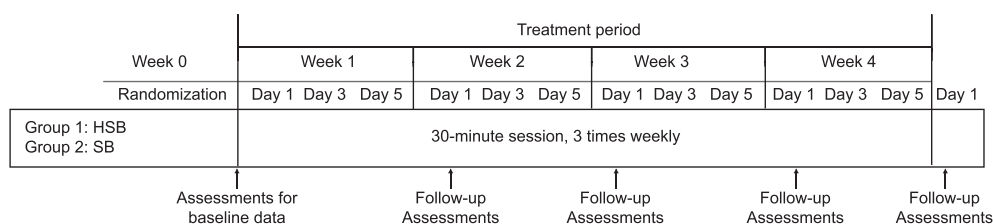


Fig. 1. Schedule of follow-up and assessment of participants HSB: herbal steam bath; SB: steam bath.



Fig. 2. Therapy cabinet containing water-boiling equipment. The water is boiled to 80–90 °C and the cabinet temperature is raised to between 42 and 45 °C. Patient enters (A) and the cabinet is sealed (B). The treatment is repeated 3 times per week for 4 weeks.

(activity limitation, nose symptoms, working life, sleeping, quality of sleep, confidence when communicating with other people and irritability). The responses were given on the 5-point Likert scale (0 = no effect; 1 = very mild effect; 2 = mild effect; 3 = moderate effect; 4 = severe effect). The questionnaires contained 7 questions relating to patient satisfaction. Briefly, these questionnaires for satisfaction with the treatment covered: the SB treatment, nose symptoms, quality of sleep, conditions inside the cabinet (temperature and steam), process and service of SBs, duration of steaming and use of SBs to reduce symptoms. The responses were given on a 3-point Likert scale where 1 = neutral, 2 = satisfied, and 3 = very satisfied.

2.5. Randomization, blinding and concealment

The study was conducted over a period of four weeks. Patients who met the eligibility criteria were randomized by a computer-generated list into two treatment groups. The allocation sequence was carried out through placing the allocation cards in opaque, sealed and stapled envelopes. The envelopes were numbered in advance and opened sequentially when patients met the study's entry criteria to assign the patient to a treatment group. This research blinded only the physician because the patient could smell herbs in steam cabinet.

2.6. Statistical analysis

Data were analyzed using SPSS version 13. The findings are reported as descriptive, frequency, percentage, mean and standard deviation. In a within-group analysis, the mean values of VAS of allergic rhinitis symptoms between baseline and the consecutive weeks were compared by a one-way repeated measures analysis of variance. The comparison between groups was made using *t*-test and comparisons within groups were made using paired *t*-test and Chi-square test. *P* values less than 0.05 were considered statically significant.

3. Results

3.1. Study flow

In this study, 130 patients were enrolled and randomized into two groups. A total number of 64 participants completed the study. Two participants from each group left the study early: 2 patients from the HSB group and 1 participant in the control SB group moved to another area and 1 participant from the control SB group did not attend the follow-up evaluations (Fig. 3).

3.2. Socio-demographic data and rhinitis symptoms

As shown in Tables 2 and 3, the groups were not statistically different in terms of sex, age, marital status, education or allergic rhinitis symptoms, including itchy nose, runny nose, sneezing, stuffy nose and watery eyes.

3.3. The efficacy of HSB and SB on allergic rhinitis symptoms

As shown in Table 4, significant reductions in allergic rhinitis symptoms (runny nose, sneezing, itchy nose, nasal congestion and watery eyes) from baseline to weeks 3 and 4 ($P < 0.05$) were reported in the HSB group. The SB group showed significant reductions in allergic rhinitis symptoms: itchy nose symptom at week 3 and watery eyes symptom at weeks 3 and 4, while runny nose symptom, and sneezing symptom were significantly reduced at week 4 ($P < 0.05$). However, these results of the HSB group and the SB group were not significantly different from one another.

3.4. Safety

This study did not find any serious adverse effects. One subject in the SB group experienced itching on the skin, but the complaint resolved after 10 min.

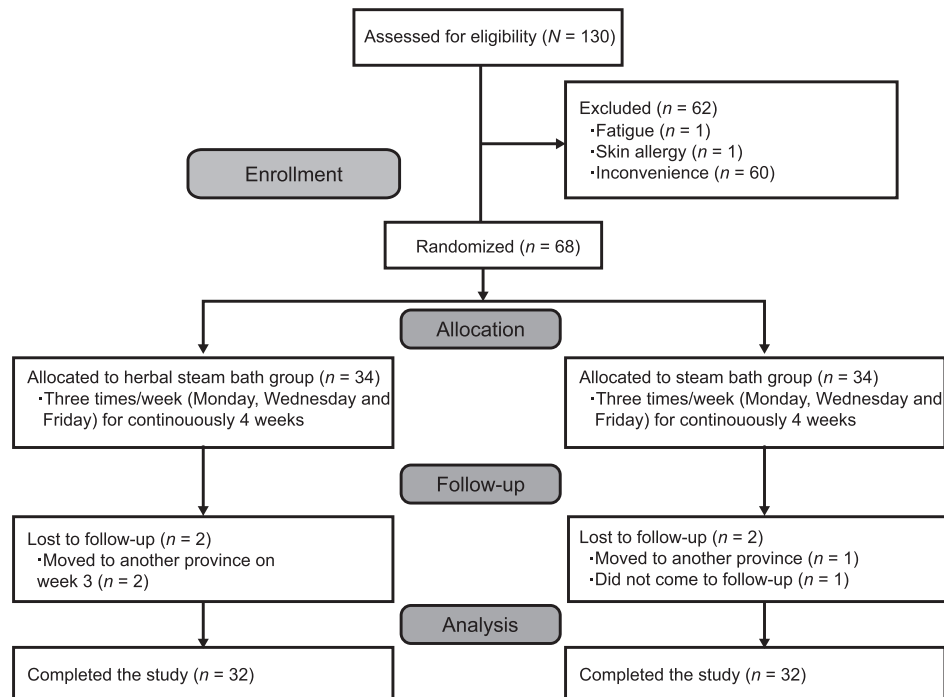


Fig. 3. Flow of participants through the trial.

Table 2
Patients' demographic characteristics.

Characteristic	HSB (n = 32)	SB (n = 32)	χ^2	P value
Sex (n, %)			0.407	0.52
Male	7 (21.9)	5 (15.6)		
Female	25 (78.1)	27 (84.4)		
Age (n, %, year)			6.750	0.08
20–29	13 (40.6)	14 (43.8)		
30–39	10 (31.3)	8 (25.0)		
40–49	5 (15.6)	6 (18.8)		
50–59	4 (12.5)	4 (12.5)		
Marital status (n, %)			2.066	0.56
Single	22 (68.8)	15 (46.9)		
Married	9 (28.1)	16 (50.0)		
Divorce	0 (0)	1 (3.1)		
Separate	1 (3.1)	0 (0)		
Education (n, %)			10.363	0.07
Primary school	6 (18.4)	5 (15.6)		
High school	3 (9.4)	5 (15.6)		
Bachelor	21 (65.7)	20 (62.6)		
Postgraduate	2 (6.3)	2 (6.3)		

Data were analyzed by Chi-square test. HSB: herbal steam bath; SB: steam bath.

3.5. Quality of life

As shown in Table 5, after treatment, the average quality of life scores of participants who received HSBs were not statistically different from those receiving SB.

3.6. Satisfaction

Comparison between the mean of baseline satisfaction and week 4 satisfaction in treatment revealed that subjects in the HSB group were significantly more satisfied with the treatment than the subjects in the SB group ($P < 0.05$).

4. Discussion

The aim of this study was to examine the efficacy and safety of using an HSB to treat patients with symptoms of allergic rhinitis,

and to investigate the quality of life improvement and patient satisfaction among patients receiving HSBs. The allergic rhinitis symptoms were significantly changed after repeating both treatments.

HSBs are a common method of treating airway diseases and promoting general health in Thailand. It has been used for a long time. The Ministry of Public Health of Thailand has established a policy to integrate Thai traditional medicine into Thai public health services and has developed the Thai Traditional Medicine Clinical Practice Guideline [5,8]. In general, HSBs are used for reducing allergic rhinitis symptoms and promoting health in postpartum women [9]. Research studies on the health benefits of steam rooms and saunas reveal limited proof of health benefits beyond promoting relaxation and providing a sense of well-being [10,11].

Most of the herbs used in HSBs are fragrant, and are both familiar to and generally liked by Thai people. However, little research has explored reducing symptoms of rhinitis. Notwithstanding, one study of the crude ethanol extract of *Zingiber cassumunar* Roxb (5–100 µg/mL), found that this compound significantly inhibited the total mucin production associated with various chronic airway diseases [12]. Research on HSBs in patients with allergic rhinitis has not yet been produced, but some studies exploring the use of sauna therapy have been conducted. One study investigated the effect of six weeks of sauna used on the condition of the autonomic nervous system, peak nasal inspiratory flow and lung function among Thai allergic rhinitis patients. The authors found a significant increase in sympathetic activity, nasal inspiratory peak flow and lung function in the 13 allergic rhinitis patients who received sauna treatment [10]. Allergic rhinitis patients always suffer from sneezing, nasal itching and nasal congestion that affect daily life. The results in this study showed all symptoms were significantly reduced. Previous studies showed a decrease in nasal congestion after inhaling hot and humid air for 30 min. Steam heat can have therapeutic benefits for thinning mucus, making it easier for some individuals to cough up phlegm [10,13].

The present study did not find serious side effects. One subject in the SB group experienced skin irritation, but this disappeared after 10 min. This itching could have been caused by the expanding

Table 3
Allergic rhinitis symptoms.

Allergic rhinitis symptom	HSB (n = 32, %)	SB (n = 32, %)	χ^2	P value
Allergic rhinitis symptoms (answer more than one question)			0.407	0.52
Itchy nose	25 (78.1)	27 (84.4)		
Runny nose	23 (71.9)	23 (71.9)		
Sneezing	25 (78.1)	23 (71.9)		
Nasal congestion	26 (81.3)	23 (71.9)		
Watery eyes	19 (59.4)	10 (31.3)		
Time duration (answer more than one question)			0.930	0.79
6.00–10.00 am	23 (71.9)	24 (75.0)		
11.00 am–2.00 pm	4 (12.5)	8 (25.0)		
3.00–6.00 pm	12 (37.5)	12 (37.5)		
Others	10 (31.3)	9 (28.1)		
Frequency			1.839	0.07
4 days per week	14 (43.8)	21 (65.6)		
4–5 days per week	2 (8.3)	1 (3.1)		
5–6 days per week	5 (15.6)	6 (18.8)		
>4 weeks per year	11 (34.4)	4 (12.5)		

Data were analyzed by Chi-square test. HSB: herbal steam bath; SB: steam bath.

Table 4
VAS assessment of allergic rhinitis symptoms.

Variable	Group	n	VAS score				
			Baseline	Week 1	Week 2	Week 3	Week 4
Runny nose	HSB	32	1.55 ± 0.60	1.11 ± 0.75	1.12 ± 0.57	0.86 ± 0.28**	0.80 ± 0.37**
	SB	32	1.56 ± 0.63	0.83 ± 0.47**	1.08 ± 0.71	1.06 ± 0.72	0.98 ± 0.62*
Sneezing	HSB	32	1.63 ± 0.71	1.05 ± 0.56	1.05 ± 0.62	0.91 ± 0.48*	0.83 ± 0.51**
	SB	32	1.50 ± 0.69	0.97 ± 0.59	1.09 ± 0.76	1.12 ± 0.73	0.81 ± 0.47**
Itchy nose	HSB	32	1.82 ± 0.82	1.11 ± 0.56	0.80 ± 0.43**	0.81 ± 0.41**	0.77 ± 0.37**
	SB	32	1.75 ± 0.79	1.15 ± 0.69	1.31 ± 0.58	0.95 ± 0.65*	1.16 ± 0.67
Nasal congestion	HSB	32	1.65 ± 0.71	1.27 ± 0.55	1.23 ± 0.66	0.96 ± 0.50*	0.98 ± 0.34*
	SB	32	1.69 ± 0.68	1.11 ± 0.67	1.23 ± 0.72	1.32 ± 0.76	1.27 ± 0.74
Watery eyes	HSB	32	1.27 ± 0.65	0.89 ± 0.51	0.55 ± 0.27**	0.63 ± 0.28**	0.59 ± 0.28**
	SB	32	1.67 ± 0.71	0.93 ± 0.66	0.89 ± 0.56*	0.82 ± 0.60**	0.73 ± 0.62**

Data are represented as mean ± standard deviation. * $P < 0.05$, ** $P < 0.01$, vs baseline. VAS: visual analog scale; HSB: herbal steam bath; SB: steam bath.

Table 5
Comparison of quality of life at baseline and week 4 and satisfaction between HSB group and SB group.

Group	n	Quality of life		Satisfaction score at week 4
		Week 0	Week 4	
HSB	32	2.09 ± 0.68	1.19 ± 0.53*	2.75 ± 0.44
SB	32	1.84 ± 0.67	1.31 ± 0.47*	1.64 ± 0.64 [△]

Data are represented as mean ± standard deviation. * $P < 0.05$, vs baseline; [△] $P < 0.05$, vs SB group. HSB: herbal steam bath; SB: steam bath.

of blood vessels as the skin was heated. Steam rooms and dry saunas cause the blood vessels in the skin to dilate, which accounts for the warm glow appearance afterward. The blood flow out of the heart has been reported to increase by 2 or more times after a 10- to 15-minute steam room or sauna exposure [14]. A similar study reviewed the benefits and risks of sauna bathing on the cardiovascular system. Skin temperature increased rapidly to about 40 °C. Sweating began quickly and reached its maximum after about 15 min with an average total secretion of 0.5 kg. During this exposure, skin blood flow was increased by 5%–10% [12]. In addition, this research found that the patients who received HSBs were very satisfied with the treatment. Both herbal and standard SBs can improve the quality of life of patients with allergic rhinitis. A similar previous study found that heat exposure through a dry sauna or steam sauna created a sense of muscle relaxation and a reduction in the sense of stress and anxiety. Many people use steam rooms and saunas to improve their sleep [12].

However, sauna bathing holds high risk for pregnant women and for patients with unstable angina pectoris, recent myocardial infarction and severe aortic stenosis. Decompensated heart failure and cardiac arrhythmia are also risks relative to the severity of the symptoms experienced by the patient. Blood pressure may decrease after sauna use, sometimes resulting in syncope. Alcohol intake while sauna bathing can create serious health risks and should be avoided [12,14].

The room temperature during the study was 42–45 °C [5]. Recommended temperature of the basic modern sauna is 80–100 °C. In addition, a good sauna has efficient ventilation. In Thai hospitals, the usual routine consists of two short stays in the SB, of 10–15 min each, which are broken-up by a 5-minute rest outside of the steam room, accompanied by oral intake of 1 to 2 glasses of warm water to prevent dehydration [5]. The Thai traditional medicine theory suggests that after leaving the steam room, patients should rest until their body temperature returns to normal before taking a bath [9]. Harvard Medical School recommends that participants stay in the sauna no more than 15–20 min at a time, cool down gradually after sauna use and avoid rapidly going from a hot environment to a cold environment, as this considerably increases the physiological stress on the body [10]. This study is different from previous studies in terms of duration of time and temperature. The duration of time is 10–15 min, while other studies used 5–20 min. The room temperature of our study is 42–45 °C, while other studies maintain room temperature at 37 °C. The results showed that more heat and water delivery to the nasal mucosa may cause a greater increase in nasal mucosal temperature and more dilution and reduction in the osmolality of nasal secretions, resulting in a larger inhibitory effect on the allergic response [15,16].

SBs and HSBs are similar to steam rooms and saunas and can be used as an alternative treatment for relieving symptoms in allergic rhinitis patients. However, allergic rhinitis patients have to be cautious of factors which trigger symptoms. In Thailand, the results of skin prick testing have indicated the leading sources of indoor (house-dust mites, house dust, cockroaches, dogs and cats) and outdoor allergens (pollen from Bermuda grass, para grass, sedge, and careless weed) [3]. A similar previous study of allergic rhinitis in the United Arab Emirates showed that symptoms were aggravated by dust (59%), grass/pollens (44%) and proximity to animals (21%) [17]. Therefore, prevention by avoiding exposures is important for the patient.

The current study has its limitations, including no biomarkers for allergic rhinitis symptoms such as IgE, and no records of factors in daily life such as dust, food or supplements that affect participants' symptoms of allergic rhinitis. These limitations should be addressed in future studies.

5. Conclusion

The results of this study indicate that HSBs and SBs without herbs are both effective treatments for allergic rhinitis symptoms, particularly in the reduction of symptoms as shown by the VAS score at week 4.

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Conflict of interest

The authors confirm that this article content has no conflicts of interest.

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