Feasibility of herbal steam bath on nasal allergic rhinitis symptoms: a randomized controlled trial

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Abstract

Allergy rhinitis (AR) is a chronic inflammatory disease in reversible airflow obstruction or asthma. In Thailand, the prevalence has still increased. The aim of this study is to examine the effect of herbal steam baths (HSB) and steam baths (SB) in AR patients. A single-blind randomized controlled trial was conducted. The participants received SB with or without herbs for 30 min 3 times a week for 4 consecutive weeks. The measurements used the Visual Analogue Scale (VAS) of AR symptoms, measure the other types of treatments, the factors associated with AR symptoms, the time period that symptoms occurred, and examination pale and swelling in the nasal cavity. The results showed that AR symptoms statistically reduced, but this was not significant when compared between groups. Type of treatment in both groups showed significant reductions from baseline to week 4 ($P < 0.05$).

Keywords: Allergy rhinitis, Steam baths, Herbal steam baths

ความเป็นไปได้ของการอบไอน้ำสมุนไพรต่ออาการจมูกอักเสบภูมิแพ้: การวิจัยแบบสุ่ม

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บทคัดย่อ

โรคจมูกอักเสบภูมิแพ้เป็นการอักเสบเรื้อรัง ที่ทำให้กลายเป็นการอุดกั้นทางเดินหายใจหรือโรคหอบหืดได้ ในประเทศไทยอัตราความชุกของโรคยังคงเพิ่มขึ้น โดยวัตถุประสงค์เพื่อตรวจสอบผลของการอบไอน้ำสมุนไพรและอบไอน้ำไม่มีสมุนไพรในผู้ป่วยโรคจมูกอักเสบภูมิแพ้ เป็นการวิจัยแบบสุ่มโดยการปกปิดทางเดียว อาสาสมัคร ได้รับการอบไอน้ำสมุนไพร หรืออบไอน้ำไม่มีสมุนไพร ครั้งละ 30 นาที จำนวน 3 ครั้งต่อสัปดาห์ ติดต่อกัน 4 สัปดาห์ การประเมินผลโดยมาตรวัดทางสายตา Visual Analogue Scale (VAS) การบันทึกชนิดการรักษาที่ได้รับ ปัจจัยที่มีผลต่ออาการทางจมูก และการประเมินอาการบวมและซีดในโพรงจมูก ผลการศึกษาพบว่า อาการทางจมูกลดลงอย่างมีนัยสำคัญทางสถิติ แต่ไม่แตกต่างกันเมื่อเปรียบเทียบระหว่างกลุ่ม ส่วนชนิดของการรักษาทั้งสองกลุ่มลดลงอย่างมีนัยสำคัญทางสถิติ ($P < 0.05$)

คำสำคัญ : อาการจมูกอักเสบภูมิแพ้, อบไอน้ำ, อบไอน้ำสมุนไพร

Introduction

Allergic rhinitis (AR) is an inflammatory disease which the nasal mucosa is induced by allergen exposure, resulting in triggering Immunoglobulin E (IgE)-mediated inflammation. Clinically, it is characterized by most important symptoms including runny nose, sneezing, nasal itching, and nasal congestion[1]. AR is a prevalent disease worldwide that causes a significant impact on patient quality of life, can affect multiple comorbid conditions, and is a substantial economic burden on society. Adults and children up to 40% of the population has been affected by this disease[2]. In Thailand, the incidence of allergies increases every year, the incidence of wheezing had increased from 4.2% to 18.3% and is predicted to increase 3–4 times within the next 20 years[3].

The treatment options for AR patients include environmental control, pharmacologic therapy, and allergen immunotherapy[4]. Recently, the complementary and alternative medicine (CAM) has a trend to use in AR patient in many countries[5-7]. In Thailand, Herbal steam baths (HSB) and steam baths (SB) have been reduced allergic rhinitis symptoms[8]. However, there is no study on the effectiveness of HSB and SB for relieving AR symptoms and the relation of factors that effect on AR patients. This research will focus on the 4-week improvement of AR symptoms and assessment pale and swelling in nasal cavity

Objective

The aim of this study is to examine the effect of HSB and SB in AR patients.

Methodology

1. Study design

This study was a single-blind randomized controlled trial, in which the investigator is blind. This study was conducted with outpatient of Traditional Thai Hospital and Alternative Medicine, Bangkok, Thailand. The study protocol was reviewed and approved by the Ethical Committee of the Traditional Thai and Alternative Medicine of Department for the Development of Thai Traditional and Alternative Medicine under the Ministry of Public Health, Thailand (approval number: RLC0041/55).

2. Participants

The sample size calculation was based on the assumptions that mean change from the baseline and the end of treatment was used as the main efficacy criterion. The mean difference

between HSB ($\mu 2$) and SB ($\mu 1$) was assumed to be 0 (i.e., $\mu 2$ (test) $-\mu 1$ (control) = 0.64). The standard deviation (σ) was estimated to be 0.94 by using the following formula for equality trial the required sample size to achieve an 80% power (β = 0.2) at α = 0.05 for detecting such difference was 30 patients. With a projected dropout rate of 10%, so thirty-three participants per treatment group were needed. One hundred and thirty participants based on physician' diagnosis at the Thai Traditional and Alternative Medicine Hospital, were selected. Patients that met the following criteria were eligible for this study: (1) both sex aged 20–65 years, (2) has AR symptoms as show in the Allergic Rhinitis with its Impact on Asthma (ARIA) guidelines[1], meaning patients experience itchy nose, runny nose, sneezing, nasal congestion more than 4 days per week, and consent to participation in the research. Patients were excluded from the study if they met one of the: (1) pregnancy, lactation, (2) nose surgery up to 4 weeks prior to participation, (3) fever of over 37.5 °C, dizziness, fatigue, diarrhea, insomnia, starvation, dermatitis, open wounds during the trial and had a history of allergies to herbs, steam particles and heat.

Sixty-six participants achieved the inclusion criteria. The participants were randomized by a computer-generated list into two groups (33 participants per each group). The allocation sequence was carried out through placing the allocate cards in opaque, sealed, and staple envelopes to preserve concealment by a nurse who did not participate in this research.

3. Intervention

The trial was informed by researcher in the private room of the hospital. The study divided 2 groups, group 1 received HSB and group 2 received SB without herbs for 30 min three times a week for 4 weeks; (Day1, Day 3, and Day 5). The steam cabinet was separated to prevent the smell from herbs. List of herbal medicine in HSB consist of 7 herbs such as *Zingiber cassumunar*, *Curcuma longa*, *Kaempferia galanga* L, *Acorus calamus* L., *Tamarindus indica, Cinnamomum camphora* (L.) Presl, and *Dryobalanops aromatica* Gaertn. All of herbs were steeped in water until boiled for use by treatment group, but control group use only boiled water. The temperature in steam cabinet was controlled 42-45 °C in both groups. All participants were informed research project and signed informed consent before start the experiment. Figure 1 showed the flow chart of selection of the participants, study designs, and interventions

4. Outcome instruments

In this study, the overall AR symptoms were measured in the subject using the 10-cm VAS in AR symptoms in term of itchy nose, runny nose, sneezing, nasal congestion, (0 = not at all bothersome, 10 = extremely bothersome). All participants were asked to complete a set of questionnaires at baseline and after 4 weeks of treatment. The physician also examined the nasal cavity to assess pale and swelling at baseline and after 4 weeks of treatment (severe=3, moderate=2, and mile =1). In addition, briefly, the questionnaires about the types of treatment, the correlation of overall nasal AR symptoms on daily life in term of stop working, not concentration, obstacles to the work, obstacles to meet other people. The factors associated with overall nasal AR symptoms, effect on daily life and time period that AR symptoms occurred.

5. Statistical analysis

The findings were reported via descriptive, frequency, percentage, mean and standard deviation. In a within-group analysis, the mean value of VAS of AR symptoms between baseline and the consecutive weeks were compared by one-way analysis of variance with repeated measurement. The comparative between groups was made using t-test and the comparative within groups was made using pair t-test and Chi-square tests. The P-value < 0.05 were considered statically significant.

Results and Discussion

Patient demographics by primary diagnosis.

As shown in Tables 1 and Table 2, both groups were not statistically different in demographic data, factors, such as general environment, home environment, and type of problems that effect daily life, and the time period that AR symptoms occurred. This study was continuous study. Previous paper found that SB had the efficacy and safety to use in AR participants[8]. The main objective of previous study was examined the efficacy and safety of HSB. In addition, previous study also evaluated satisfaction and improvement of quality of life. On the other hand, the objective of this study was to examine the effect of HSB and SB without herbs adjunctive treatment in reduced overall nasal AR symptoms in term of rhinorrhea, nasal itching, nasal congestion, and sneezing and examination of the nasal cavity to assess pale and swelling and to investigate the reduction of using the other treatment. This study, we asked all on types of drug, times of use per day and the duration used continuously, the correlation of AR

symptoms on daily life, the factors associated with AR symptoms, time period that AR symptoms occurred at baseline and after 4 weeks of treatment.

The effect of HSB and SB on AR symptoms (VAS)

As shown in figure 2, the effect on overall nasal AR symptoms (rhinorrhea, nasal itching, nasal congestion, and sneezing) were significant reductions from baseline to week 4 ($P<0.05$) in both groups. However, the HSB group and the SB group were not significantly different between groups. The allergic diseases of the airway especially, allergic rhinitis is on the increase in Thailand and their prevalence shows no signs of reduction. In Thailand, the clinical practice guidelines for allergic rhinitis which is comparable to the international guidelines like ARIA[3].

The reduction of the types of treatments in allergic rhinitis participants

As shown in Table 3, in both groups were shown significant reductions of type treatments from baseline to weeks 4 ($P < 0.05$, $^{**}P< 0.01$). However, these results of the HSB group and the SB group were not significantly different. Many kinds of pharmacotherapy are on the National List of Essential Drugs. Yet due to the restricted number of expert allergists, many patients are seen by general doctors, and often, the suitable diagnostic tests and treatments are not provided. Additionally, the financial problem for quality health care may be expensive for those without private health insurance for some Thai citizens. Therefore, the traditionally intervention such as SB is still useful for allergic rhinitis patient in Thailand. In addition, the medication for allergic rhinitis especially, antihistamine, many research found a variety of negative central nervous system symptoms, including irritability, frustration, fatigue, reduced productivity, and poor concentration[9-11]. Due to concerns over probable side effects, many Thai people with allergies are looking at relieve symptoms naturally.

The results of examination of the nasal cavity to assess pale and swelling by a doctor

As shown in Table 4, the results shown that swelling and pale inside the nasal cavity in both groups were decreased but there was no difference. In addition, the participants felt relief in the nose and easier breathing. SB or steam inhalation are a commonly method of treating airway diseases and promoting general health worldwide[12]. For example, the steam inhalation was alleviated of cold symptoms and was increased nasal patency in a significantly higher percentage of patients with the common cold[13]. In addition, Elevation of intranasal temperature resulted in amelioration of rhinitis symptoms of patients compared to the placebo-treated group[14]. In

Thailand, there have some evidence about steam bath to improve AR symptoms. For example, the steam inhalation significantly improved nasal obstruction in AR patients[15]. Recently, previous study revealed that not only HSBs, but also SBs significantly reduce the symptoms of AR[8]. Interestingly, this study and previous study found that patients decrease in nasal congestion after inhaling hot and humid air for 30 min which have therapeutic benefits for reduce swelling, pale, relief in the nose and easier breathing[16]. Previous study found that sauna baths can caused elevation of systolic blood pressure and reduce of thermoregulation mechanisms resulting in more resistance to winter infections, reduction of toxins with perspiration and relaxation[17]. Moreover, sauna bathing has potential health benefits such as mediated vasodilation of brachial artery and plasma volume changes (calculated from hemoglobin readings) in AR patients[18]. In addition, previous research determined that pale nasal mucosa may be a sign of eosinophil infiltration of the nasal mucosa which lead to central airway limitations in asthmatic children[19]. In this study, we found that the SB also reduced a pale nasal mucosa in AR patients. Therefore, SB could be another way to improve central airway of AR patients.

Conclusions

The results of this study indicate that HSB and SB are both effective treatments for AR symptoms, particularly in the reduction of nasal symptoms, reduction other type medication and improve nasal cavity from pale and swelling in AR patients.

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Table 1 Patient demographics by primary diagnosis

Variables	HSB (n=33)	SB (n=33)	Chi-square	P-value
Sex (n)			0.407	0.523
Male	7	5		
Female	26	28		
Age (year)			1.148	0.284
21-40	25	21		
41-60	8	12		
Weight (kg)			0.696	0.706
40-50	11	8		
51-60	10	12		
>61	12	13		
Marital status			0.063	0.082
Single	19	20		
Married	14	13		
Education			0.665	0.415
Primary–secondary				
School	11	8		
Bachelor degree				
Post-graduation	22	25		
Regular exercise			0.557	0.757
No	9	11		
Yes	24	22		
Alcohol and smoke consumption			4.940	0.085
No	15	22		
Yes	15	11		
Stop smoking	3	0		

Table 2 Patient allergic history

Variables	HSB (n = 33)	SB (n = 33)	Chi-square	P-value
Experience of HSB or SB			1.521	0.218
No	15	20		
Yes	18	13		
The time period that AR symptoms occurred			1.992	0.574
Morning (6.00 - 12.00 am)	15	12		
Afternoon (1.00 - 6.00 pm)	5	4		
Evening (7.00 - 12.00 pm)	6	11		
Others	7	6		
Underlying disease			0.287	0.592
No	24	22		
Yes	9	11		
Drug allergy or food allergy			1.438	0.230
No	28	31		
Yes	5	2		
Allergic history			0.262	0.609
No	22	20		
Yes	11	13		
AR symptoms effect on daily life			1.929	0.748
Sleep disturbance	9	9		
Distracting concentration in work	8	9		
Stop working / school	0	1		
Irritated	9	10		
Fatigue	7	4		

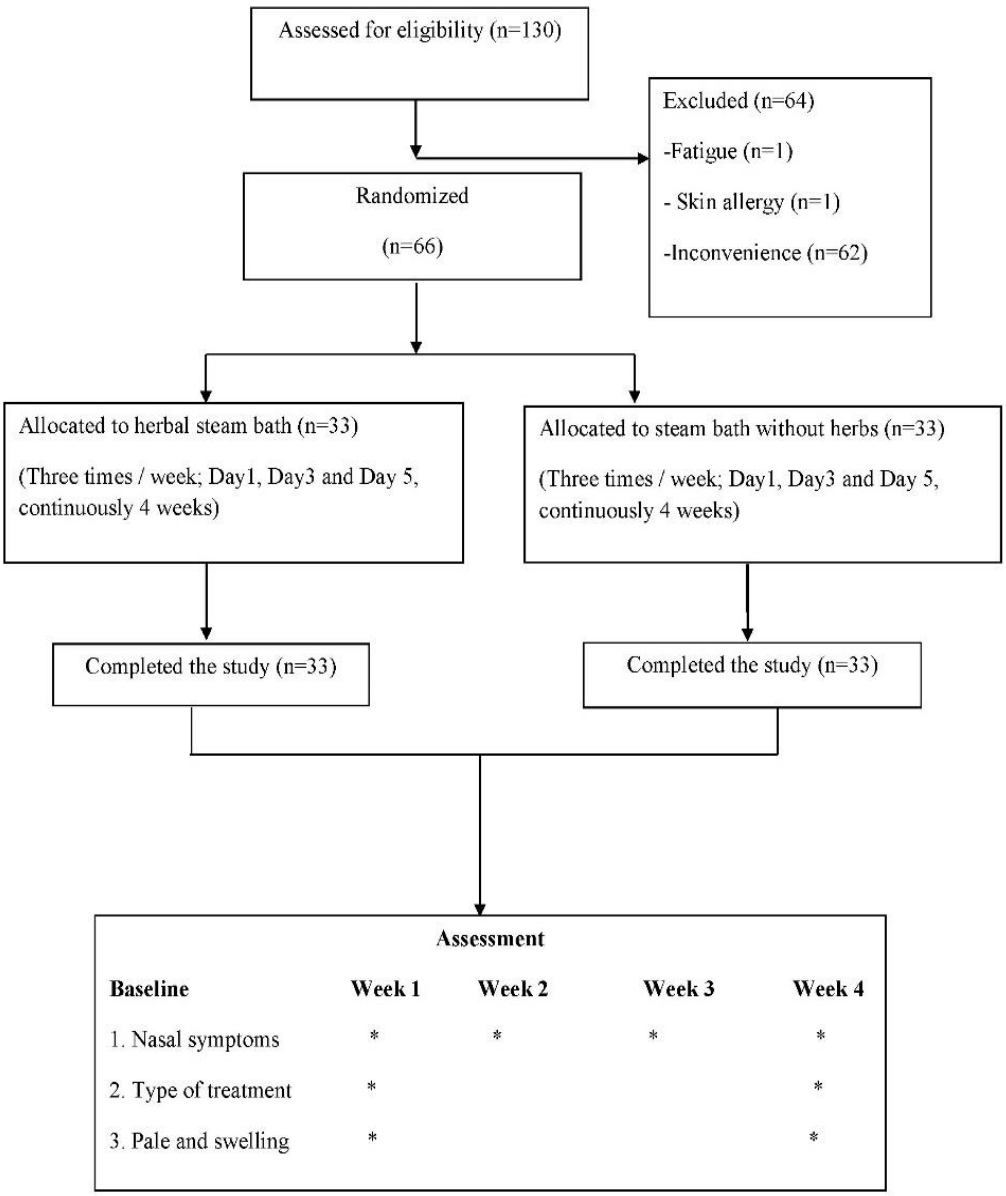
Table 3 The types of treatment in participants

Groups (n)	**Week 0** **n (%)**	**Week 4** **n (%)**
HSB (33)	Chi-square	P- value
	17.10	0.001
Oral medicine	15 (54.45)	4 (12.13)
Nasal spray	2 (6.06)	1 (03.3)
See a doctor	4 (12.13)	0 (0)
No treatment	12 (36.36)	28 (84.85)
SB (33)	Chi-square	P -value
	12.98	0.005
Oral medicine	19 (57.58)	7 (21.22)
Nasal spray	1 (3.03)	1 (3.03)
See a doctor	2 (6.06)	0 (0)
No treatment	11 (33.33)	2 (75.76)

Data represent percent of participants' treatment compared with baseline and week 4 by using Chi-square test

Table 4 The examination of the nasal cavity to assess pale and swelling by a physician

Groups (scores)	**Week 0 (n=33)** **n (%)**	**Week 4 (n=33)** **n (%)**
HSB		
Severe (3)	8 (24.24)	0
Moderate (2)	16 (48.48)	20 (60.60)
Mild (1)	9 (27.27)	13 (39.39)
SB		
Severe (3)	10 (30.30)	2 (6.06)
Moderate (2)	14 (42.42)	20 (60.60)
Mild (1)	9 (27.27)	11 (33.33)



Assessment				
Baseline	**Week 1**	**Week 2**	**Week 3**	**Week 4**
1. Nasal symptoms	*	*	*	*
2. Type of treatment	*			*
3. Pale and swelling	*			*

Figure 1 Flow of participants through to stage of randomized trial

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