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Research paper

Clinical effectiveness of the Sanfu herbal patch at acupoints for respiratory diseases including otitis media in children: A pilot before-and-after study☆

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ABSTRACT

Introduction: Many studies have demonstrated that the Sanfu herbal patch (SHP) is effective for treating asthma and allergic rhinitis. However, no studies on its effectiveness for preventing respiratory diseases were identified in searchable databases. Therefore, a prospective, before-and-after study was conducted to investigate whether it was feasible to evaluate the effectiveness of SHP when applied in summer could prevent respiratory diseases in children in winter.
Methods: This pilot study included 60 children with a history of respiratory diseases who visited Dongguk University Korean Medicine Hospital for SHP treatment during the Sanfu Days in summer 2015, and were surveyed using a questionnaire before treatment and then again in March 2016.
Results: There were improvements in the frequency and duration of the common cold and rhinitis and in the frequency of tonsillitis and otitis media after treatment ($P < 0.05$). The improvement rates for the frequency and duration of the common cold were 70% and 60%, respectively. Total and component Wisconsin Upper Respiratory System Survey (WURSS)-21 scores significantly improved after treatment ($P < 0.05$). The effectiveness rates for improvement of WURSS-21 symptom, QoL, and total score were 55.0%, 70.0%, and 66.7%, respectively.
Conclusion: The effectiveness of SHP in preventing the common cold in children seems to be encouraging, but not conclusive, because of the methodological limitations of this study. Well-designed randomized controlled trials are necessary to confirm these findings. For other respiratory diseases, further research recruiting participants separately according to each respiratory disease should be conducted to validate the effects of SHP treatment.

1. Introduction

Respiratory diseases are highly prevalent worldwide. In the Republic of Korea, respiratory diseases accounted for the highest number of outpatient visits (approximately 31.39 million of 46.67 million total) in 2014 and for the largest burden of outpatient medical costs [1]. Symptoms caused by respiratory diseases, such as upper respiratory infections (URIs), asthma, and rhinitis, disrupt sleep and daily life, reduce patients' quality of life (QoL), and carry a financial burden [2–6].

Current pediatric cough and cold medications are easily available over the counter [7], and overuse of these medications has been linked to neurological impairment, cardiovascular instability, and death in young children [8–10]. Antibiotics are often misused for the treatment of URIs with viral etiologies [11], and the injudicious use of antibiotics is associated with adverse effects, such as diarrhea and antibiotic resistance [12]. The efficacy of cold medicines and antibiotics that are commonly prescribed for URIs is not sufficiently clear [7,13], and current drug treatments for chronic respiratory diseases, such as asthma and allergic rhinitis,

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remain ineffective and have been linked to adverse events in a substantial number of patients [14,15]. Therefore, complementary and alternative treatments with fewer adverse effects have been increasingly sought out for children with respiratory diseases in China and Taiwan.

The Sanfu herbal patch (SHP), also called Sambok herbal patch in Korea, is a complementary and alternative treatment for respiratory diseases first described in the *Zhang Shi Yi Tong* text by Zhang Lu (*Qing* Dynasty, 1644–1912). The method involves applying a Chinese herbal medicine paste onto specific acupoints during the Sanfu Days. The Sanfu Days are special periods that are calculated according to the lunar calendar. They are three 10-day periods of the hottest days in the year, usually in July and August, and are considered to be periods of the greatest *Positive-qi* both in the human body and in the external environment. They are, thus, considered the optimal periods for patients to accumulate *Positive-qi* [16,17]. Applying SHP during the Sanfu Days is thought to help patients regulate bodily functions and strengthen the self-healing capacity of the body so as to prevent and treat disease because they have accumulated sufficient *Positive-qi* at this time. The acupoint herbal patch can also be applied during the Sanjiu Days. The Sanjiu Days, the three 9-day periods of the coldest days in the year, are considered to be periods of the most debilitating *Positive-qi* both in the human body and in nature, and thus, attaching the acupoint herbal patch can invigorate the circulation of *qi* and strengthen resistance against disease [18].

Owing to its simple and non-invasive nature, SHP can be used in children to prevent respiratory diseases; it has become popular in China and Taiwan in recent years. There have been a number of studies on the effects of SHP for treating single diseases, such as asthma and allergic rhinitis. In previous studies, SHP was reported to have favorable immunomodulatory effects by reducing immunoglobulin E (IgE) and to improve the symptoms of asthma and rhinitis [14,15]. However, we were unable to identify studies on the effects of SHP for preventing respiratory diseases overall in searchable databases, such as PubMed and Embase. Therefore, this pilot study aimed to investigate prospectively, using a before-and-after study design whether it was feasible to evaluate the effectiveness of SHP for preventing respiratory diseases in children, using a questionnaire that included the Wisconsin Upper Respiratory System Survey (WURSS-21) scores, a respiratory disease assessment scale.

2. Methods

2.1. Study design

This investigation was a pilot study involving 60 participants with a history of respiratory diseases who visited Dongguk University Korean Medicine Hospital, Korea for SHP treatment from July 2015 to August 2015. The aim of the study was to explore whether the use of applying SHP in summer was effective for preventing respiratory diseases in winter, based on the Traditional Chinese Medicine principle of "treatment of winter disease in summer". Thus, in this study, SHP treatment was performed during the Sanfu Days of July–August 2015. Although SHP is recommended to be applied a total of three times, once each during the first Sanfu Days (July 13–22, 2015), the second Sanfu Days (July 23–August 11, 2015), and the third Sanfu Days (August 12–21, 2015), three sessions of SHP treatment were not a prerequisite for inclusion in this study. The first survey was conducted when participants visited the hospital for the first SHP treatment. The

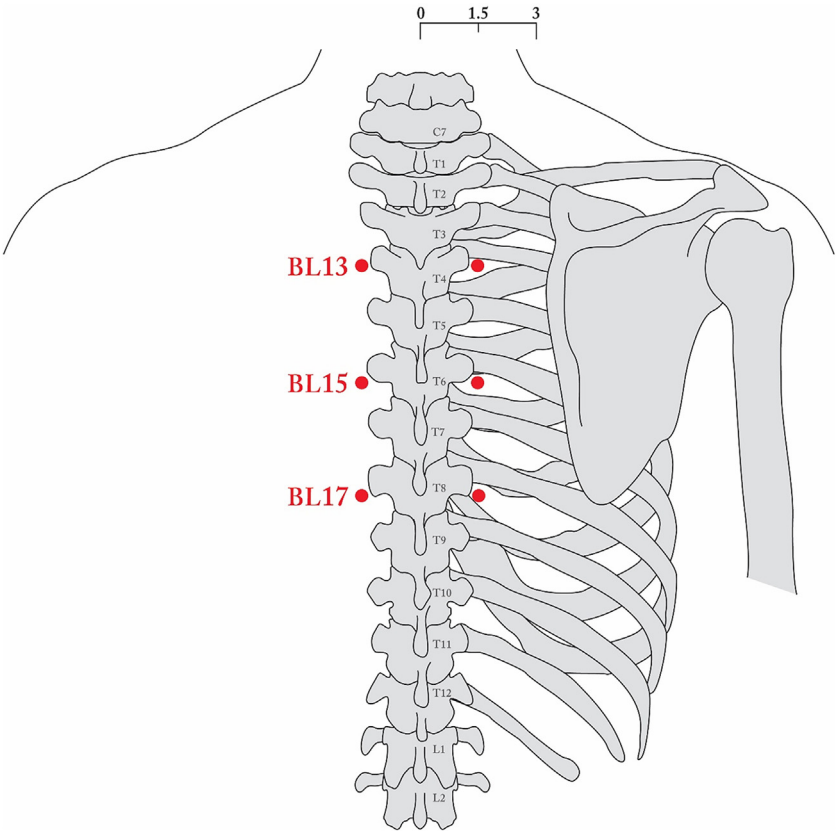

Fig. 1. Diagram of acupoints to which the Sanfu herbal patch was applied.

second survey was conducted via telephone in March 2016, after the winter had ended. This study was approved by the Institutional Review Board of Dongguk University Hospital (code 2015-05). Written informed consent was obtained from participants or their legal guardians. The study protocol was registered at the Clinical Research Information Service (CRIS), a non-profit online registration system for clinical trials to be conducted in Korea (KCT0002112; https://cris.nih.go.kr/cris/en).

2.2. Participants

The subjects of this pilot study were 60 children who visited the Department of Pediatrics of the Korean Medicine Outpatient Clinic at Dongguk University Hospital for SHP treatment during the Sanfu period (July–August 2015). The inclusion criteria were age between 24 months and 18 years and a history of respiratory disease at least once during the preceding winter (December 2014 to February 2015). The related respiratory diseases included the common cold, influenza, rhinitis, sinusitis, tonsillitis, bronchitis, pneumonia, otitis media, and asthma. Otitis media was included because the condition often occurs as a complication of URIs [19]. The contraindications for SHP treatment were age <24 months and the presence of severe cardiac and pulmonary diseases, fever, skin hypersensitivity, or diabetes mellitus. Dropouts were defined as subjects who did not respond to the second survey via telephone.

2.3. Intervention

SHPs were applied to six acupoints commonly used for SHP treatment in Korea: Pyesu (Feishu, BL13; both sides), Simsu (Xinshu, BL15; both sides), and Gyeoksu (Geshu, BL17; both sides) (Fig. 1). One traditional Korean medicine doctor, as registered by the Korean Ministry of Health and Welfare and having more than 8 years of clinical experience, provided the SHP treatments. One patch was applied to each acupoint, and each patch weighed 1 g. The SHP was composed of Baek Gae Ja (Bai Jie Zi, *Sinapis alba*), Hyeon Ho Saek (Yan Huo Suo, Radix Corydalis Yanhusuo), Se Sin (Xi Xin, Asari herba cum Radice), and Gam Su (Gan Sui, Euphorbiae kansui Radix), corresponding to the four main herbs indicated in the *Zhang Shi Yi Tong* text in which the SHP was first described. The ratio of selected herbs was 3:3:2:2, and all these herbal powders were mixed with ginger juice and honey at a ratio of 15:9:4. All of the herbal medicines forming SHP were obtained from the Dongguk University Korean Medicine Hospital with inspection by a herbology professor (Goyang, Republic of Korea). According to the theory of Traditional Chinese Medicine, Baek Gae Ja (Bai Jie Zi, *Sinapis alba*) and Se Sin (Xi Xin, Asari herba cum Radice) warm lung and relieve cough. Hyeon Ho Saek (Yan Huo Suo, Radix Corydalis Yanhusuo) promotes flow of *qi* and Gam Su (Gan Sui, Euphorbiae kansui Radix) relieves swelling. These four herbs are also used in formulations used for treating respiratory diseases. Finally, approximately 4.5-cm × 5.5-cm adhesives (Medix Band, Q&Q Pharm) were used to attach the SHPs to the skin after they were applied to acupoints (Fig. 2). Participants or their guardians were instructed to remove the patches 4 h after application.

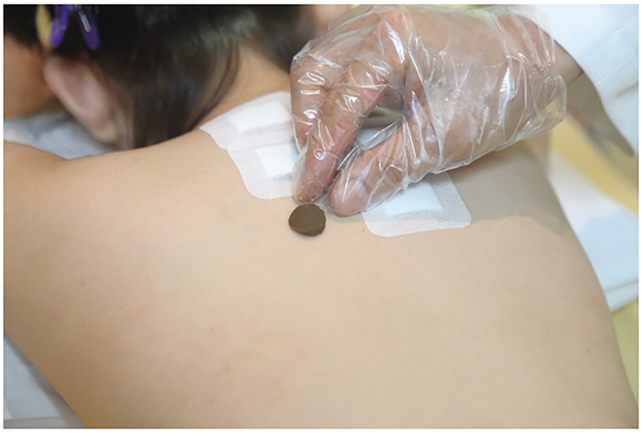

Fig. 2. Sanfu herbal patch treatment illustration.

2.4. Questionnaire

The first questionnaire contained questions about the frequency and duration of respiratory diseases during the preceding winter (December 2014 to February 2015), which were the primary outcomes. In addition, after appropriate consent had been obtained, the validated 21-item Wisconsin Upper Respiratory System Survey (WURSS-21) instrument, translated into Korean, was used to evaluate symptom severity and QoL as the secondary outcomes [20,21].

The WURSS-21 includes one item assessing global severity, 10 items assessing symptoms, nine items assessing functional impairments, and one item assessing daily changes. Because this study was not intended to observe the participants' daily changes, the last item was excluded, and 20 items were ultimately assessed. Higher scores indicated more severe symptoms, while a score of 0 indicated the complete absence of symptoms.

The second questionnaire, which was administered after the SHP treatment, contained the same items as the first questionnaire along with additional items regarding whether adverse effects, such as redness, warm sensation, itching, pain, blistering, or other symptoms, occurred after SHP treatment.

2.5. Outcome measurement

The primary outcome measures were changes in the frequency and duration of respiratory diseases during the winter following SHP treatment (December 2015 to February 2016) compared to the preceding winter. Frequency was defined as the number of times a person experienced symptoms associated with the respiratory conditions of interest during the winter following SHP treatment, and duration was defined as the number of days a person experienced symptoms after being diagnosed with a specific condition. The effectiveness of SHP treatment was evaluated by dividing the frequency and duration of respiratory diseases after SHP treatment with pretreatment values. In other words, a reduction in the frequency or duration of respiratory diseases after SHP treatment was defined as 'improvement'; no change in the frequency or duration of respiratory diseases after SHP treatment was defined as 'no change'; and an increase in the frequency or duration of respiratory diseases after SHP treatment was defined as 'aggravation'.

The secondary outcome measure was the change of WURSS-21 score, which assessed global severity, symptoms, and functional QoL. All items were answered in seven-point Likert-type severity scales, with a higher score indicating higher severity. In terms of criteria for effectiveness and ineffectiveness, the treatment was evaluated as effective if the WURSS-21 symptom score, QoL score, or total score decreased by ≥50% compared with pretreatment responses and as ineffective if scores decreased by <50%, were unchanged, or increased compared with pretreatment responses.

2.6. Statistical analysis

Participants' baseline characteristics were summarized by using descriptive statistics. Although changes in the frequency and duration of respiratory disease after SHP treatment were

intended to be analyzed with a paired *t*-test, they were analyzed using Wilcoxon's signed-rank test, a non-parametric method, because normality testing indicated that these variables were not normally distributed.

Two methods were used to analyze the statistical changes in WURSS-21 score after SHP treatment. Wilcoxon's signed-rank test was used to assess global severity and QoL scores because normality testing indicated that they were not normally distributed. The paired *t*-test was used to compare symptom score and total score. The binomial test was used to analyze whether differences in the effectiveness and ineffectiveness of secondary endpoints were statistically significant, with the probability parameter set at 0.50.

Statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) software (version 23) for Windows 7. In all tests, $P < 0.05$ was considered statistically significant.

3. Results

All 60 participants met the inclusion criteria, and there were no dropouts. Of these 60 participants, three (5%) received one session of SHP treatment and 57 (95%) received three sessions. The baseline characteristics of the 60 participants are summarized in Table 1. Participants had a mean age of 4.97 years, mean height of 108.93 cm, mean weight of 20.13 kg, and 70% were boys.

3.1. Primary outcomes

In comparing the frequency and duration of respiratory diseases before and after SHP treatment, there were statistically significant reductions in the frequency and duration of the common cold and rhinitis and in the frequency of tonsillitis and otitis media ($P < 0.05$) (Table 2).

The improvement rates for the frequency and duration of the common cold were 70% and 60%, respectively. The improvement rates for the other respiratory diseases, except for pneumonia and asthma, were higher than the aggravation rates (Table 3). The no change rates for the other respiratory diseases, except for the common cold, were higher than the improvement rates and aggravation rates (Table 3).

3.2. Secondary outcome

The global severity score, symptom score, QoL score, and total score were all statistically significantly decreased from pretreatment to post-treatment assessments ($P < 0.05$) (Table 4).

The effectiveness rates for improvement of WURSS-21 symptom score, QoL score, and total score were 55.0%, 70.0%, and 66.7%, respectively. The effectiveness rates for QoL score and total score, but not symptom score, were statistically significantly higher than the ineffectiveness rates (both $P < 0.05$) (Table 5.)

Table 1
Baselinecharacteristics of study participants.

Characteristic	Sanfu herbal patch recipients (N = 60)
Sex, number (%)	
Female	18 (30.0)
Male	42 (70.0)
Age, years[a]	4.97 ± 2.94
Height, cm	108.93 ± 18.60
Weight, kg	20.13 ± 9.80
Number of SHP treatments (%)	
1	3 (5.0)
3	57 (95.0)

SHP: Sanfu herbal patch
[a] Values are shown as mean ± SD, unless noted otherwise.

3.3. Adverse events

During treatment, participants are expected to experience cutaneous reactions such as skin warmth, itching, pain, and blisters due to the stimulation of the SHP. These symptoms are expected reactions that may occur upon SHP treatment and are related to the principle that the treatment effects of SHP are produced through herbal absorption and acupoint stimulation. Occurrence of adverse events in participants who used SHP once was investigated in the second survey, which was conducted telephonically the following March. Occurrence of adverse events in participants who used SHP three times was investigated in the second and third visits and telephonically in the second survey.

The three children who used SHP once did not report any adverse events in the second survey. Among the 57 children who used SHP three times, one participant reported local redness, three reported itching, and three reported local discoloration in the second visit. In the third visit, one participant reported local redness, three reported itching, and three reported local discoloration. In the second survey, none of the participants reported any adverse events. However, all of these symptoms disappeared within several hours or days. There was no occurrence of adverse events requiring medical treatment.

4. Discussion

This study aimed to examine whether it was feasible to evaluate the effectiveness of SHP applied in summer could prevent respiratory diseases in children in winter. We observed promising effects of SHP for the common cold in particular among various respiratory diseases. After SHP treatment, the participants demonstrated statistically significant improvements in the frequency and duration of the common cold and rhinitis and in the frequency of tonsillitis and otitis media; however, there was no significant improvement in asthma. These findings are not consistent with those in previous reports that SHP treatment was effective in reducing the frequency and duration of asthma [22,23]. However, since the present study did not specifically recruit patients with asthma, these studies cannot be directly compared. Notably, SHP was associated with improvements in otitis media, a disease category not identified in a comprehensive bibliometric analysis of previous studies on SHP [24]. Well-designed randomized controlled trials (RCTs) are needed in the future to verify the effects of SHP on otitis media.

We found that the no change rates for the other respiratory diseases, except for the common cold, were higher than the improvement rates and aggravation rates. The reason for the high rates of no change for respiratory diseases other than for the common cold was that most subjects had not contracted the other respiratory diseases the preceding winter, except for the common cold, and also did not contract these respiratory diseases during the winter following SHP treatment. In pneumonia cases, there were only 2 participants with a history of pneumonia before the SHP treatment and 5 participants after the SHP treatment. The number of participants with a history of pneumonia was too small to evaluate the effects of the SHP treatment for pneumonia and to determine whether SHP treatment is ineffective for pneumonia. These results suggest the need for further research, in which we will recruit participants separately according to the specific respiratory diseases.

We found that the WURSS-21 global severity score, symptom score, QoL score, and total score all statistically significantly decreased after SHP treatment. The effectiveness rates for QoL

Table 2
Changes in frequency and duration of respiratory diseases after Sanfu herbal patch treatment.

Respiratory diseases		Sanfu herbal patch (N = 60)				
		Pretreatment		Post-treatment		
		mean ± SD	median (min, max)	mean ± SD	median (min, max)	*P* value[a]
Common cold	Frequency	3.55 ± 2.91	3 (0, 20)	1.62 ± 1.54	1 (0, 8)	<0.001
	Duration	6.17 ± 4.32	5 (0, 20)	4.17 ± 3.98	3 (0, 14)	<0.001
Influenza	Frequency	0.08 ± 0.28	0 (0, 1)	0.05 ± 0.22	0 (0, 1)	0.480
	Duration	0.58 ± 2.15	0 (0, 13)	0.22 ± 1.11	0 (0, 7)	0.320
Rhinitis	Frequency	1.83 ± 2.71	0 (0, 12)	0.95 ± 1.97	0 (0, 12)	<0.001
	Duration	3.23 ± 4.42	0 (0, 14)	2.12 ± 3.65	0 (0, 14)	0.005
Sinusitis	Frequency	0.47 ± 1.46	0 (0, 10)	0.17 ± 0.53	0 (0, 3)	0.081
	Duration	1.68 ± 4.40	0 (0, 21)	0.80 ± 2.31	0 (0, 10)	0.086
Tonsillitis	Frequency	0.53 ± 1.44	0 (0, 10)	0.20 ± 0.48	0 (0, 2)	0.022
	Duration	1.72 ± 4.21	0 (0, 22)	0.72 ± 1.79	0 (0, 7)	0.097
Bronchitis	Frequency	0.35 ± 0.84	0 (0, 5)	0.15 ± 0.55	0 (0, 3)	0.137
	Duration	1.37 ± 3.00	0 (0, 14)	0.63 ± 2.36	0 (0, 14)	0.065
Pneumonia	Frequency	0.05 ± 0.29	0 (0, 2)	0.08 ± 0.28	0 (0, 1)	0.527
	Duration	0.18 ± 1.03	0 (0, 7)	0.85 ± 3.20	0 (0, 20)	0.102
Otitis media	Frequency	0.28 ± 0.64	0 (0, 3)	0.07 ± 0.25	0 (0, 1)	0.003
	Duration	1.32 ± 3.22	0 (0, 14)	0.75 ± 4.01	0 (0, 30)	0.106
Asthma	Frequency	0.02 ± 0.13	0 (0, 1)	0.00 ± 0.00	0 (0, 0)	0.317
	Duration	0.17 ± 1.29	0 (0, 10)	0.00 ± 0.00	0 (0, 0)	0.317

[a] *P* values obtained from Wilcoxon's signed-rank test. SD, standard deviation. Frequency refers to the number of times that patients experienced symptoms of the respiratory disease, and duration refers to the number of days that patients experienced symptoms after being diagnosed with a specific disease.

Table 3
Effectiveness of the Sanfu herbal patch for reducing the frequency and duration of respiratory diseases.

		Sanfu herbal patch (N = 60)		
Respiratory diseases		Aggravation, n (%)	No change, n (%)	Improvement, n (%)
Common cold	Frequency	2 (3.3)	16 (26.7)	42 (70.0)
	Duration	4 (6.7)	20 (33.3)	36 (60.0)
Influenza	Frequency	3 (5.0)	52 (86.7)	5 (8.3)
	Duration	3 (5.0)	52 (86.7)	5 (8.3)
Rhinitis	Frequency	1 (1.7)	41 (68.3)	18 (30.0)
	Duration	4 (6.7)	43 (71.7)	13 (21.7)
Sinusitis	Frequency	4 (6.7)	47 (78.3)	9 (15.0)
	Duration	4 (6.7)	47 (78.3)	9 (15.0)
Tonsillitis	Frequency	3 (5.0)	46 (76.7)	11 (18.3)
	Duration	5 (8.3)	44 (73.3)	11 (18.3)
Bronchitis	Frequency	5 (8.3)	44 (73.3)	11 (18.3)
	Duration	5 (8.3)	44 (73.3)	11 (18.3)
Pneumonia	Frequency	5 (8.3)	53 (88.3)	2 (3.3)
	Duration	5 (8.3)	53 (88.3)	2 (3.3)
Otitis media	Frequency	1 (1.7)	47 (78.3)	12 (20.0)
	Duration	2 (3.3)	48 (80.0)	10 (16.7)
Asthma	Frequency	–	59 (98.3)	1 (1.7)
	Duration	–	59 (98.3)	1 (1.7)

score and total score were significantly higher than the corresponding ineffectiveness rates. The WURSS-21 is a commonly used instrument for the daily assessment of acute URIs. In the present study, which was based on the concept of receiving a treatment in the summer to prevent diseases in the winter, daily assessment was not feasible, and the WURSS-21 questionnaire was

Table 4
WURSS-21 score before and after Sanfu herbal patch treatment.

WURSS-21 score	Pretreatment		Post-treatment		*P* value
	mean ± SD	median (min, max)	mean ± SD	median (min, max)	
Global severity score[a]	4.63 ± 1.31	5.00 (1, 7)	2.40 ± 1.80	2.00 (0, 7)	<0.001
Symptom score[b]	27.92 ± 9.42	29.50 (12, 49)	13.30 ± 8.79	12.00 (0, 35)	<0.001
QoLscore[a]	22.98 ± 14.63	24.00 (0, 51)	7.12 ± 10.36	2.00 (0, 46)	<0.001
Total score[b]	55.53 ± 20.60	55.00 (17, 96)	22.82 ± 18.62	17.00 (0, 81)	<0.001

WURSS-21: Wisconsin Upper Respiratory System Survey 21, QoL: quality of life; SD, standard deviation.
[a] *P* value obtained from Wilcoxon's signed-rank test.
[b] *P* value obtained from paired *t*-test.

Table 5
Effectiveness of Sanfu herbal patch treatment based on the change in WURSS-21 score.

WURSS-21 score	Sanfu herbal patch (N = 60)		
	Ineffectiveness, number (%)	Effectiveness, number (%)	*P* value[a]
Symptom score	27 (45.0)	33 (55.0)	0.519
QoL score	18 (30.0)	42 (70.0)	0.003
Total score	20 (33.3)	40 (66.7)	0.013

WURSS-21: Wisconsin Upper Respiratory System Survey 21, QoL: quality of life.
[a] *P* values obtained from binomial test.

administered twice over a long time interval, once each before and after SHP treatment. If the WURSS-21 questionnaire had been more frequently administered between the first survey in July 2015 and the second survey in March 2016, changes in WURSS-21 score over time may have been identified. In view of the fact that this pilot study was intended to analyze the comprehensive effects of SHP for respiratory diseases rather than for single diseases such as asthma and rhinitis, it was difficult to identify a more appropriate symptom scale. The results of this study demonstrating that WURSS-21 score was improved by SHP treatment are considered to represent a basis for further investigation into the therapeutic effects of SHP in children with URIs.

Various studies on the effects of SHP according to different patient groups, prescriptions, and treatment methods have been conducted in China and Taiwan [14,24]. Most research has predominantly focused on respiratory diseases, including asthma, chronic bronchitis, allergic rhinitis, chronic obstructive pulmonary disease, and recurrent respiratory tract infection [24]. Although the effects of SHP for treating single diseases such as asthma and rhinitis have been demonstrated in previous studies [17,22,23,25], we were unable to find any high-quality studies on the effects of SHP on a broad range of respiratory diseases using widely recognized symptom assessment tools. To the best of our knowledge, the present study is the first to evaluate the effects of SHP on preventing respiratory diseases overall, including URIs and otitis media as well as asthma and rhinitis, with a standardized symptom assessment tool. The WURSS-21 scale used as an instrument to assess respiratory symptoms in this study has the advantage of containing information on QoL and is simpler than the WURSS-44, but with a similar reliability and validity [20].

This study has several limitations that should be taken into consideration. First, because three sessions of SHP treatment were not a requirement, 3 participants who received one session of SHP treatment were also included in this study, in addition to 57 who received all three sessions. If the participants were divided according to the number of treatment sessions, the sample sizes of the two groups would be too small to compare the effects of SHP. A larger sample size is needed to examine how the effects of SHP differ according to the number of treatments. As reported in a study by Zhu et al. [17], there is also a method to compare effects between 1 year and 2 years, with 3 sessions of SHP per year as a course of treatment. Second, this study has recall bias, because the participants or their parents were required to rely on their memory to complete the questionnaire. The questionnaire used in this study addressed whether SHP treatment given to the participants in the summer was effective in preventing respiratory diseases during the following winter. Therefore, respondents had to compare their conditions in the preceding winter before SHP treatment with those in the winter after SHP treatment, which may have been limited in accuracy. Third, our analysis was based on the participant-reported outcomes and did not include any medical records such as hospital visits and use of medication for respiratory diseases. Therefore, the results might tend to be subjective rather than objective. Fourth, the characteristics of participants were heterogeneous regarding their history of respiratory diseases and specific information about their respiratory illness was not shown as subgroups. In further research, we will divide participants into specific disease groups according to their history and analyze the groups separately. Finally, there was no control or placebo group, only an SHP treatment group. Chen et al. [26] has proposed a protocol for a three-armed RCT examining the efficacy and safety of SHP for allergic rhinitis, and if studies of the common cold as well as rhinitis are conducted with reference to that study protocol using appropriate scales, high-quality study results can be obtained that should overcome the current methodological limitations. Although the present study has a number of limitations, this pilot study has provided a direction for further research evaluating the effectiveness of SHP treatment for respiratory diseases.

5. Conclusion

The results of this study indicate that SHP might be effective in the prevention of the common cold in children. SHP treatment appeared to be effective in improving and preventing symptoms of the common cold based on its improvement rate and improvements in WURSS-21 score. SHP treatment did not cause serious adverse effects requiring medical treatment. However, considering the limitations of this study, such as recall bias, possibility of subjectivity of the participants' answers, and lack of a controlled study design, a definitive conclusion cannot be drawn from our results. Further well-designed randomized controlled trials recruiting participants with the common cold are necessary to confirm these findings. For other respiratory diseases, further research recruiting participants separately according to each respiratory disease should be conducted to validate the effects of SHP treatment.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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