Original Article

A preliminary study on efficacy of Prapchompoothaweep remedy for treatment of allergic rhinitis patients and their quality of life after the treatment

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Abstract

Introduction: Allergic rhinitis (AR) is an inflammatory disease of the nasal mucosa which affects patient's

quality of life. Prapchompoothaweep (PRW) remedy, listed in National List of Essential Medicine

(NLEM), was used as a drug to relieve the common cold and hay fever.

Objective: This study aimed to determine its efficacy and impact on quality of life in patients with AR.

Methods: In this preliminary study, 24 patients with AR were enrolled in this study and received PRW

remedy of 3,000 mg per day for 6 weeks. The main outcome assessments were the Total Nasal Symptom Score (TNSS) and the Rhinoconjuctivitis Quality of Life questionnaires (RCQ-36, Thai

version).

Results: After receiving PRW treatment, the TNSS score for nasal congestion and the RCQ-36 results for

rhinitis and other symptoms revealed a significant improvement (P < 0.001).

Conclusion: Piperine is a major bioactive compound of the PRW remedy. It exhibits multiple biological

properties such as anti-allergy, anti-inflammatory and anti-oxidant activities. PRW remedy can

be used to treat the symptoms of allergic rhinitis and improve patient's quality of life.

Keywords: Prapchompoothaweep, Antiallergy, National List in Essential Medicine in Thailand, Thai Traditional

medicine, Clinical Trial, Treatment

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Introduction

Allergic Rhinitis (AR) is an inflammatory condition of the nasal mucosa and can lead to asthma. Worldwide, allergic rhinitis affects between 10% and 30% of the population. National surveys show the rates of rhinitis in France and United Kingdom of 5.9% and 29%, respectively, with a mean of 16%². In Thailand, a recent study among Naresuan University students³ and Thammasat University students⁴ showed the prevalence of AR of 57.4% and 58.5%, respectively. The increasing prevalence of AR has become a burden for healthcare. AR patients suffer bothersome symptoms, such as nasal congestion, itching, rhinorrhea, sneezing, sinus pressure, snoring and other sleep problems⁵, which can severely affect their daily activities including ability to work⁶ and quality of life⁷. The management of AR consists of environmental control measures and allergen avoidance, pharmacological management, and immunotherapy. Appropriate treatment of AR can improve the symptoms, quality of life, work and school performance, and reduce the impact of the disease on future health.8

The pharmaceutical wisdom in Thai traditional medicine uses herbs with spicy taste to promote blood circulation for treatment of AR. Prapchompoothaweep (PRW) remedy is listed in National List of Essential Medicine (NLEM). Drugs listed in NLEM must be essential to prevent and resolve health problems and the medicine must have proven efficacy and safety. PRW remedy is used as a drug to relieve the common cold and hay fever. The usual dose is 750 mg to 1,500 mg 4 times a day before meals. A possible adverse side effect of PRW is a burning sensation in the throat. In a study in which PRW remedy was prescribed for patients with AR symptoms at Uthong hospital (Suphanburi province), Kapchoeng hospital (Surin province) and Wang-namyen (Sa-kaeo province),

Health Product Vigilance Center (HPVC) which supports Adverse Drug Reaction Monitoring Center (ADRMC), reported no serious adverse effect. In an in vitro study, the bioactivity of PRW 95% ethanolic extract, including anti-allergic activity based on the inhibition of β -hexosaminidase release on RBL-2H3 cell lines, and anti-inflammation activity based on the inhibition of NO production on RAW 264.7 cells, showed IC. values of 12.97 µg/ml and 22.51 µg/ml, respectively. Its anti-oxidant activity, evaluated by using DPPH radical scavenging, showed EC₅₀ of 14.26 µg/ml.⁹ These studies showed PRW 95% ethanolic extract to have excellent bioactivities; however, literature reports on PRW crude drug remedy are scarce. This study aimed to determine efficacy of PRW remedy in minimum dose (3,000 mg/day) and quality of life in patients with AR treated with PRW.

Methods

Ethical approval for this study was provided by The Human Research Ethics Committee of Thammasat University No.1 (Faculty of Medicine) under the protocol number MTU-EC-ES-6-021/59. (ClinicalTrials.gov ID: NCT03640273)

Population

A preliminary study was conducted to evaluate the efficacy of PRW remedy and quality of life of the patients after the treatment. From November 2017 to June 2018, 24 patients were enrolled in this study at the ENT outpatient clinic, Thammasat University Hospital, Pathum Thani, Thailand. The inclusion criteria were patients with moderate AR (based on ARIA guideline)¹⁰ as diagnosed by physicians, aged between 18 - 70 years old and with no nasal septum perforation, nasal polyp or sinus surgery. The exclusion criteria were patients who were allergic to PRW remedy. Patients who did not complete the follow up protocol were also excluded.

Drug Preparation

Prapchompoothaweep (PRW) remedy consists of 23 herbs mixed in the w/w proportions indicated. They are: Black Pepper (Piper nigrum L.), Sea Holly (Acanthus ebracteatus Vahl.) and Honeyweed (Leonurus sibiricus L.) at 25.8% each; Hussakhunthet (Clausena excavate Burm. f.) and Clove (Syzygium aromaticum (L.) Merr. & L. M. Perry) at 2.15% each; Book-Ror (Amorphophallus saraburiensis Gagnep.), Samor-Thet (Terminalia spp.), Samor-thai (Terminalia chebula Retz. var. chebula), Scarlet Leadwort (Plumbago indica L.) and Ginger (Zingiber officinale Roscoe.) at 1.72% each; Garden Cress (Lepidium sativum L.), Dill (Anethum graveolens L.), and Thien-Kleab (Foeniculum vulgare Mill.) at 1.29% each; Black Cumin (Nigella sativa L.), Bai Zhi or Kod-Sor (Angelica dahurica (Hoffm.) Benth. & Hook. f. ex Franch. & Sav.), Cang Zhu or Kod-Kamao (Atractylodes lancea (Thunb.) DC.), Philang-kasa (Ardisia polycephala Wall. ex A. DC.), and Tape Seagrass (Enhalus acoroides (L. f.) Royle) at 0.86% each. Long Pepper (Piper retrofractum Vahl.) and Camphor (Cinnamomum camphora (L.) J. Presl) at 0.43% each; Mace (Myristica fragrans Houtt.), Nutmeg (*Myristica fragrans* Houtt.) and Siam Cardamon (Amomum testaceum Ridl.) at 0.125% each. The herbs were purchased from Chakkrawat herb store (Bangkok). The voucher specimen were referenced from the herbarium of Southern Center of Thai Medical Plants, Faculty of Pharmaceutical Science, Prince of Songkla University (Appendix A). All herbs were cleaned and grinded into powder. The powders were mixed and packed into 500 mg capsules to make PRW remedy. All drug preparation was conducted at Thai Traditional Medicine Factory, Faculty of Medicine, Thammasat University. This preparation followed the quality assessment protocols and standards of the Thai Herbal Pharmacopeia for drug quality assurance, namely ash content, including total ash less than 10% and acid-insoluble acid less than 2%, moisture content less than 10%, disintegration time less than 30 min.,

microbial contamination including bacteria less than or equal to 5×10^5 CFU/g and moulds and yeasts less than or equal to 5×10^4 CFU/g, and heavy metals including arsenic (As) less than or equal to 4 ppm, lead (Pb) less than or equal to 10 ppm and cadmium (Cd) less than or equal to 0.3 ppm.

Outcome Measures

Assessment of AR Nasal Symptoms. The Total Nasal Symptom Score (TNSS) was used to evaluate intensity of nasal symptoms (nasal congestion, sneezing, nasal itching, and rhinorrhea) using a four-point scale (0 - 3), where 0 = no symptom, 1 = mild, 2 = moderate and 3 = severe. The sum of each symptom score had a possible range from 0 (no symptom) to 12 (maximum symptom intensity). ^{11, 12}

Quality of Life. The Rhinoconjunctivitis Quality of Life Questionnaire (RCQ-36), Thai version (Prof. Chaweewan Bunnag MD, copyrighted), consisted of 36 items covering six dimensions and two independent items. Six dimensions of RCQ-36 included 17 items of rhinitis and other symptoms, 3 items of work or school performance, 3 items of activity limitation, 3 items of sleep disorders, 3 items of social quality, and 5 items of emotions. Two independent items included 1 item of overall health and 1 item of absence from work or study per month. It was scored using a scale ranging from 1 to 5 (the lower score indicated the better quality of life) except the absence from work or study question which was an open question.

Data collection and analysis

All patients received PRW crude drug capsules of 1,000 mg (500 mg per capsule) 3 times a day before meals for 6 weeks (42 days). The washout period was 7 days. Twenty four patients underwent the following clinical assessment before, and at the 3^{rd} & 6^{th} week after treatment with Prapchompoothaweep (PRW) crude drug. The data were analyzed with a computer program using mean \pm (standard deviation: SD), for demographic data (sex, N (%), age (years), and Body Mass Index: BMI (kg/m²)) using

repeated measure analysis of variance (ANOVA) at 95% confidence interval to assess the TNSS and the RCQ-36. A P - value less than 0.05 was considered statistical significance.

Results

The Prapchompoothaweep (PRW) remedy was prepared according to NLEM. The test requirements for quality control in Thai Herbal Pharmacopeia (THP) to control drug standards indicated that Prapchompoothaweep (PRW) crude

drug was within all standards, with total ash 8.81% and acid-insoluble ash 0.93%, moisture content 8.48%, disintegration time 28 minutes. There was no microbial contamination and heavy metals including lead (Pb) (0.086 ± 0.012 ppm) while arsenic (As) and cadmium (Cd) were ND (not detected).

Twenty four patients who enrolled and completed the protocol in this study consisted of 8 men and 16 women with mean age of 30.75 ± 11.81 years, and mean BMI of 21.15 ± 2.98 kg/m². (Table 1)

Table 1 Patient characteristics

Patient characteristic	Results	
Age, mean ± SD, years	30.75 ± 11.81	
Sex, N (%)		
Female	16 ± 66.67	
Male	8 ± 33.33	
Body Mass Index (BMI), mean \pm SD, kg/m ²	21.15 ± 2.98	

Abbreviation: SD, Standard Deviation; N, Number.

After 6 weeks of treatment, all symptoms in TNSS (nasal congestion, sneezing, nasal itching, and rhinorrhea) were significantly decreased (P < 0.05) (Table 2) especially for nasal congestion score which

decreased from 1.92 ± 0.83 to 0.67 ± 0.64 (P < 0.001). All of the symptoms showed significant change at the 6^{th} week of treatment.

Table 2 Changes in TNSS after receiving PRW remedy for 6 weeks

Symptoms [†]	Week 0	Week 3	Week 6	P - value
Rhinorrhea	1.75 ± 1.03	1.25 ± 1.11	0.75 ± 0.74 **	0.0030
Itchy nose	1.46 ± 0.93	0.96 ± 0.75	0.79 ± 0.66 *	0.0128
Sneezing	1.54 ± 0.88	1.08 ± 0.88	$0.79 \pm 0.59 **$	0.0066
Nasal congestion	1.92 ± 0.83	1.38 ± 0.88	0.67 ± 0.64 ***	< 0.001
Total score	6.67 ± 2.73	4.67 ± 2.68 *	3.00 ± 1.96 ***	<0.001

Abbreviation: TNSS, Total Nasal Symptom Score; PRW, Prapchompoothaweep; SD, Standard Deviation. [†] Data represent mean ± SD.

^{*} P < 0.05, ** P < 0.01, *** P < 0.001

For the RCQ-36, the scores of patients' quality of life after treatment showed a significant decrease from baseline to 6 weeks, particularly on dimensions of rhinitis and other symptoms (RS-OS) score and emotion (E) score which decreased from 39.63 ± 12.97 to 24.46 ± 7.18 (P < 0.001) and 11.88 ± 5.09 to 7.54 ± 4.63 (P < 0.01), respectively (Table 3).

A lower score indicated a better quality of life. An adverse effect by the treatment with PRW was a burning sensation in the throat for 10 - 15 minutes. The proportion of patients who had the adverse effect was 33.33% and this symptom could be relieved after consuming food. There were no other serious adverse effects found.

Table 3 Changes in quality of life after receiving PRW remedy for 6 weeks

Symptoms [†]	Week 0	Week 3	Week 6	P - value
Rhinitis and Other Symptoms (RS-OS)	39.63 ± 12.97	30.79 ± 10.00 **	24.46 ± 7.18 ***	<0.001
Work Performance (WP)	5.75 ± 2.92	4.92 ± 2.84	3.88 ± 2.44	0.0667
Activity Limitation (AL)	4.96 ± 2.71	4.42 ± 2.10	3.67 ± 1.43	0.1196
Sleep Disorders (SD)	5.92 ± 3.46	4.63 ± 2.18	4.46 ± 2.57	0.1482
Social Quality (SQ)	5.21 ± 2.43	4.38 ± 2.83	4.04 ± 2.56	0.2871
Emotions (E)	11.88 ± 5.09	9.54 ± 4.60	7.54 ± 4.63 **	0.0099
Overall Health (OH)	2.71 ± 0.86	2.46 ± 0.59	2.13 ± 0.74 *	0.0277

Abbreviation: PRW, Prapchompoothaweep; SD, Standard Deviation.

Discussion

Prapchompoothaweep (PRW) consists of 23 herbs the main ones being Black pepper (*Piper nigrum* L.), Sea holly (*Acanthus ebracteatus* Vahl.) and Honeyweed (*Leonurus sibiricus* L.) at 25.8% each, and Hussakhunthet (*Clausena excavate* Burm. f.) and Clove (*Syzygium aromaticum* (L.) Merr. & L. M. Perry) at 2.15% each. The flavor of PRW remedy is hot and spicy. In Thai traditional medicine (TTM), herb flavor is used to indicate its suitability to cure a certain disease. Hot and spicy flavor, according to the TTM theory, is used to treat allergic rhinitis and asthma. It is also used to promote blood circulation, boost health, and keep the body warm.

The indication of PRW remedy is to take medicine before meals and the results of this study showed that the adverse effect after taking PRW remedy was a burning in the throat because of its taste and it causes some discomfort, but can be relieved after consuming food. The main bioactive compound of PRW remedy is piperine ($C_{17}H_{19}NO_3$) with a concentration of 50.85 ± 0.35 µg/g extract or 178.21 µM.¹⁵ Piperine is a major pungent alkaloid.¹⁶ It is initially tasteless, but leaves a burning aftertaste.¹⁷ Furthermore, piperine in PRW remedy revealed a potential anti-allergic activity by the inhibition of β -hexosaminidase released from RBL-2H3 cell line with an IC₅₀ value of 9.49 ± 1.00 µg/ml.¹⁵

 $^{^{\}dagger}$ Data represent mean \pm SD. * P < 0.05, ** P < 0.01, *** P < 0.001

Other Thai remedies listed in NLEM and also used as treatment for allergic rhinitis are Pra-sa-prao-hyai and Benjakul remedies and ginger, and their taste is hot and spicy as well. The anti-allergic activity of Pra-sa-prao-hyai and Benjakul remedies as determined by the inhibition of β -hexosaminidase released from RBL-2H3 cells showed that they were quite potent with IC so values of 12.83 \pm 0.84 μ g/ml and 12.69 μ g/ml respectively, while that of ginger ethanolic extract had an IC value of 40.3 μ g/ml. Pra-sa-prao-hyai remedy and ginger extract revealed a significant decrease of nasal symptoms score and improvement in quality of life as well. 22, 23

Six weeks after the treatment by PRW remedy, patients' TNSS was significantly decreased (p < 0.05) and the scores in RS-OS and RCQ-36 also showed a significant decrease. The main ingredients of PRW remedy namely Black pepper (Piper nigrum L.), Sea holly (Acanthus ebracteatus Vahl.) and Honeyweed (Leonurus sibiricus L.) have also shown good anti-inflammation activity^{24 - 26} and PRW remedy showed potent activity against LPS-induced nitric oxide (NO) production with IC $_{50}$ value of 22.52 \pm 0.63 µg/ml¹⁵. In addition, Sea holly root (*Acanthus* ebracteatus Vahl.) may activate macrophage function, which plays an essential role in both innate and specific immune response.²⁴ Thus, we can infer from previous literature that PRW remedy can reduce nasal symptoms and stimulate the immune system for a better quality of life.

Piperine (10, 20, and 40 mg/kg, p.o.) showed a significantly reduced expression of IL-6, IL-1 β , and IgE (P < 0.001) and protection against nasal rubbing, redness of nose, and sneezing (P < 0.001) following nasal challenge.²⁷ Moreover, piperine has potential as an immunomodulatory agent as it modulated a significantly inhibited phytohemagglutinin-stimulated human peripheral blood mononuclear cell (PBMC) proliferation after exposure for 72 hours, with an IC₅₀ value of 100.73 \pm 11.16 µg/ml.²⁸

Because it is preliminary research on herbal medicine in the lowest dose, the next logical step forward would be a comparative study together with the control group and would likely include further investigation of the pharmacokinetics of Prapchompoothaweep remedy to elucidate the difference between taking the medicine before and after meals . In conclusion, this study shows that PRW remedy can improve nasal symptoms in TNSS (P < 0.05) and quality of life in RS-OS dimension (P < 0.001). Even though there are several other drugs that can be used to treat allergic rhinitis, PRW remedy could be an effective alternative treatment as well.

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AppendixMedicinal plants in Prapchompoothaweep remedy formulations

Scientific Name	Common name	Voucher Specimen	Part of use
Acanthus ebracteatus Vahl.	Sea Holly	SKP 001 01 05 01	All
Amomum testaceum Ridl.	Siam Cardamon	SKP 206 01 20 01	Fruit
Amorphophallus campanulatus Gagnep.	Book-Ror	SKP 015 01 19 01	Root
Anethum graveolens L.	Dill	SKP 199 01 07 01	Seed
Angelica dahurica (Hoffm.) Benth.	Bai Zhi (Kod-Sor)	SKP 199 01 04 01	Root
& Hook. f. ex Franch. & Sav.			
Ardisia polycephala Wall. ex A. DC.	Philang-Kasa	SKP 122 01 16 01	Fruit
Atractylodes lancea (Thunb.) DC.	Cang Zhu (Kod-Kamao)	SKP 199 01 04 01	Root
Cinnamomum camphora (L.) J. Presl	Camphor	SKP 096 03 03 01	-
Clausena excavate Burm. f.	Hussakhunthet	SKP 166 03 05 01	Heartwood
Enhalus acoroides (L. f.) Royle	Tape Seagrass	SKP 088 05 01 01	Root
Foeniculum vulgare Mill.	Thien-Kleab	SKP 199 06 22 01	Seed
Leonurus sibiricus L.	Honeyweed	SKP 095 12 19 01	Leave
Lepidium sativum L.	Garden Cress	SKP 160 14 19 01	Seed
Myristica fragrans Houtt.	Mace	SKP 121 13 06 01	Aril
Myristica fragrans Houtt.	Nugmeg	SKP 121 13 06 01	Seed
Nigella sativa L.	Black Cumin	SKP 160 14 19 01	Seed
Piper Nigrum L.	Black Pepper	SKP 146 16 14 01	Seed
Piper retrofractum Vahl.	Long Pepper	SKP 146 16 18 01	Fruit
Plumbago indica L.	Scarlet Leadwort	SKP 148 16 09 01	Root
Syzygium aromaticum (L.) Merr. & L. M. Perr	y Clove	SKP 123 19 01 01	Bud
Terminalia spp.	Samor-Thet	SKP 049 20 01 01	Flesh
Terminalia chebula Retz. var. chebula	Samor-Thai	SKP 049 20 03 01	Flesh
Zingiber officinale Roscoe.	Ginger	SKP 206 26 15 01	Root

บทคัดย่อ

การศึกษานำร่องประสิทธิผลของยาปราบชมพูทวีปและคุณภาพชีวิตในการรักษาโรคจมูกอักเสบจากภูมิแพ้ ศุภสุตา เลี้ยงพานิช*, อรุณพร อิฐรัตน์*, **, ไวพจน์ จันทร์วิเมลือง***, ณิชมน มุขสมบัติ*

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- ** ศูนย์ความเป็นเลิศทางการวิจัย สถานการแพทย์แผนไทยประยุกต์ คณะแพทยศาสตร์ มหาวิทยาลัยธรรมศาสตร์

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ที่มาและความสำคัญ: โรคจมูกอักเสบจากภูมิแพ้ (Allergic Rhinitis: AR) เป็นผลมาจากการอักเสบบริเวณเยื่อบุจมูก (nasal mucosa) แม้เป็นโรคที่ไม่

ร้ายแรงถึงชีวิต แต่ส่งผลกระทบต่อคุณภาพชีวิตของผู้ป่วยเป็นอย่างมาก ยาปราบชมพูทวีปเป็นตำรับยาสมุนไพรหนึ่งที่ใช้บรรเทา อาการหวัดแพ้อากาศที่บรรจุอยู่ในบัญชียาหลักแห่งชาติ พ.ศ. 2544 มีการใช้ตามโรงพยาบาลต่างๆ มีฤทธิ์ต้านการแพ้และ

ต้านการอักเสบที่ดี ไม่พบรายงานความเป็นพิษและผลข้างเคียงร้ายแรง

วัตถุประสงค์: งานวิจัยครั้งนี้จึงศึกษาประสิทธิผลของยาปราบชมพูทวีปและคุณภาพชีวิตในการรักษาโรคจมูกอักเสบจากภูมิแพ้

วิธีการศึกษา: งานวิจัยครั้งนี้จึงศึกษาประสิทธิผลของยาปราบชมพูทวีปในการรักษาโรคจมูกอักเสบจากภูมิแพ้ในอาสาสมัคร

จำนวน 24 คน เป็นการวิจัยกึ่งทดลอง โดยให้รับประทานยาปราบชมพูทวีปวันละ 3,000 มิลลิกรัมต่อวันเป็น

ระยะเวลา 6 สัปดาห์ ประเมินประสิทธิผลด้วยคะแนนอาการทางจมูกโดยรวม (Total Nasal Symptom Score:

TNSS) และคุณภาพชีวิต (RCQ-36 ฉบับภาษาไทย)

ผลการศึกษา: ผลการศึกษาพบว่า ยาปราบชมพูทวีปสามารถลดอาการทางจมูกและส่งเสริมคุณภาพชีวิตของอาสาสมัครได้

จึงอาจสรุปได้ว่ายาปราบชมพูทวีปมีแนวโน้มในการรักษาโรคจมูกอักเสบจากภูมิแพ้ได้ดี

สรุปผลการศึกษา: สารสำคัญของยาปราบชมพูทวีปคือสาร Piperine ซึ่งมีฤทธิ์ทางชีวภาพที่หลากหลาย เช่น ฤทธิ์ต้านการแพ้

ฤทธิ์ต้านการอักเสบ และฤทธิ์ต้านอนุมูลอิสระที่ดี ดังนั้นอาจสรุปได้ว่ายาปราบชมพูทวีปสามารถใช้รักษาอาการ

ทางจมูกที่เกิดจากโรคจมูกอักเสบจากภูมิแพ้ และพัฒนาคุณภาพชีวิตของผู้ป่วยได้

คำสำคัญ: ยาปราบชมพูทวีป, ต้านการแพ้, ยาในบัญชียาหลักของประเทศไทย, แพทย์แผนไทย, การวิจัยในคน, การรักษา