RESEARCH ARTICLE

Safety and Tolerability of Shallot Oral Supplement in Patients with Allergic Rhinitis: A Randomized Pilot Clinical Trial

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Abstract

Shallot has long been suggested in Thai folk medicine to prevent allergic rhinitis (AR), but no scientific evidence on safety and tolerability is available to support the continuous use. The purpose of this study was to evaluate the adverse effects of the continuous use of oral shallot supplement in AR patients and determine the safety and tolerability by comparing the results with placebo. A prospective, randomized, double-blind, placebo-controlled, pilot study was performed in 50 AR patients. All patients received cetirizine 10 mg per day as standard treatment. An additional 3 g per day of either shallot capsules (equivalent to 1½ bulbs of fresh shallot) or placebo capsules were randomly prescribed for 4 weeks. Complete blood counts (CBC), blood urea nitrogen (BUN), serum creatinine (Cr), aspartate aminotransferase (AST), and alanine aminotransferase (ALT) levels were evaluated before and after treatment. Vital signs and physical examination were performed before starting the study and repeated every 2 weeks thereafter. Assessment of adverse events and patient's compliance were performed every 2 weeks. Patients' satisfaction was assessed via visual analog scales in an exit interview. Twenty-five patients in the shallot group and 22 patients in the placebo group completed the study. No significant differences between groups were found in terms of body weight, blood pressure, heart rate, incidence of adverse events, compliance, serum levels of CBC, BUN, Cr, AST, and ALT, and patients' satisfaction. In conclusion, the combination use of oral shallot supplement with cetirizine for 4 weeks is safe and well tolerated in AR patients.

Keywords: Safety, tolerability, allergic rhinitis, shallot, *Allium ascalonicum* L.

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ความปลอดภัยและความทนต่อยาของการรับประทานหอมแดงเสริมในผู้ป่วยโรคจมูกอักเสบจากภูมิแพ้: การศึกษานำร่องแบบสุ่ม

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บทคัดย่อ

ในทางการแพทย์แผนไทย มีการใช้หอมแดงเพื่อป้องกันจมูกอักเสบจากภูมิแพ้มายาวนาน แต่ยังไม่มีหลักฐานทางวิทยาศาสตร์ในด้านความปลอดภัยและความทนต่อยาเพื่อสนับสนุนการใช้อย่างต่อเนื่อง การศึกษานี้จึงมีวัตถุประสงค์เพื่อประเมินอาการไม่พึงประสงค์ของการรับประทานหอมแดงเสริมอย่างต่อเนื่องในผู้ป่วยโรคจมูกอักเสบจากภูมิแพ้ รวมถึงประเมินความปลอดภัยและความทนต่อยาเปรียบเทียบกับยาหลอก การศึกษาแบบไปข้างหน้า สุ่ม ปกปิดสองทาง และมีกลุ่มควบคุม ดำเนินการในผู้ป่วยจมูกอักเสบจากภูมิแพ้จำนวน 50 ราย ผู้ป่วยทุกรายได้รับยาเซทิริซีน 10 มก. ต่อวันซึ่งเป็นยามาตรฐานในการรักษา และได้รับการสุ่มเพื่อได้รับหอมแดงชนิดแคปซูล 3 กรัมต่อวัน (เทียบเท่ากับหอมแดงสด 1½ หัว) หรือแคปซูลยาหลอก เป็นเวลา 4 สัปดาห์ การประเมิน complete blood counts (CBC), blood urea nitrogen (BUN), serum creatinine (Cr), aspartate aminotransferase (AST) และ alanine aminotransferase (ALT) ดำเนินการก่อนและหลังรักษา การวัดสัญญาณชีพและการตรวจร่างกายดำเนินการก่อนเริ่มการศึกษาและหลังจากนั้นทุก 2 สัปดาห์ การประเมินเหตุการณ์ไม่พึงประสงค์และความร่วมมือในการใช้ยาดำเนินการทุก 2 สัปดาห์ ความพึงพอใจของผู้ป่วยได้รับการประเมินโดยใช้ visual analog scale เมื่อสิ้นสุดการศึกษา ผู้ป่วย 25 รายในกลุ่มที่ได้รับหอมแดงเสริม และผู้ป่วย 22 รายในกลุ่มที่ได้รับยาหลอกเข้าร่วมการวิจัยจนเสร็จสิ้น ผลการศึกษาไม่พบความแตกต่างระหว่างกลุ่มในด้านน้ำหนักตัว ความดันเลือด อัตราหัวใจเต้น อุบัติการณ์การเกิดเหตุการณ์ไม่พึงประสงค์ ความร่วมมือในการใช้ยา ระดับ CBC, BUN, Cr, AST และ ALT ในเลือด และความพึงพอใจ โดยสรุป การใช้หอมแดงร่วมกับยาเซทิริซีนเป็นเวลา 4 สัปดาห์ในผู้ป่วยโรคจมูกอักเสบจากภูมิแพ้มีความปลอดภัยและมีความทนต่อยาดี

คำสำคัญ: ความปลอดภัย, ความทนต่อยา, จมูกอักเสบจากภูมิแพ้, หอมแดง, *Allium ascalonicum* L.

Introduction

Shallot (*Allium ascalonicum* L.) is a plant in Alliaceae family, the same as garlics and onions. The major component of shallot are fats, sugars, sulfur-containing compounds, vitamins, and minerals.[1,2] Based on literature reviews, the highest total phenolic content among the Alliaceae plants is found in fresh shallot, corresponding with its anti-oxidant property.[3-6] Inhibition of gene expressions of pro-inflammatory cytokines (tumor necrosis factor (TNF)-α, interleukin (IL)-1β and IL-6) and inducible nitric oxide synthase (iNOS) by shallot extract were demonstrated.[7] The presence of flavones and polyphenolic derivatives such as quercetin and related compounds in shallot are linked to its therapeutic effect in allergic rhinitis (AR) and allergic conjunctivitis.[8] Regular consumption of shallot helps improve the AR symptoms compared to placebo, especially the itching of nose and eyes. Sixty-two percent of persistent AR patients who received oral shallot supplement in combination with cetirizine for 4 weeks had significant improvement of the overall AR symptoms compared to the patients who receive cetirizine alone (37%).[8] The additional advantages of shallots include anti-hyperlipidemia, anti-inflammatory, anticancer, and anti-fungal properties.[4-5,7,9-10]

In Indian Ayurvedic medicine and Southeast Asian traditional medicine, shallot has long been recognized for therapeutic effects in various diseases. It is a basic but essential ingredient in local foods in Southeast Asia. According to Thai traditional medicine, consumption of at least 1 bulb of shallot per day helps reduce the allergic symptoms from AR and prevent the asthmatic attacks.[11] However, the safety and tolerability of routine shallot consumption are still unknown. It is believed that the shallot intake should not exceed 3 bulbs per day because it might cause memory impairment and increased hair fall.[11] However, there is lack of scientific evidence to confirm these toxicities. The ethanolic extract of shallot was shown to be non-toxic to human dermal fibroblast cells at the concentration lower than 20 mg/mL in an *in vitro* study.[3] Despite promising efficacy, many people are reluctant to use shallot supplement because of possible side effects such as dyspepsia and bad breath or body smell. Up to present, it is elusive of how long and how many shallots can be consumed as dietary supplement with no harm.

It was the aim of this study to investigate the adverse events of the routine use of oral shallot supplement by constructing a randomized controlled trial. Since AR is one of the most common chronic illness that affects people worldwide and shallot supplement has been suggested for AR patients, this study was intentionally designed to assess the safety and tolerability of 4-week oral administration of 3 g dried shallot product, which was equivalent to one and a half bulbs of fresh shallot, in AR patients. In this pilot study, the shallot supplement were given orally as an adjunct to cetirizine, a second-generation antihistamine used as standard treatment for AR. The safety parameters including blood tests were compared between shallot and placebo groups.

Materials and Methods

This prospective, randomized, double-blinded, parallel, controlled-trial, pilot study was performed at the Department of Pharmacology, Faculty of Medicine,

Chiang Mai University, Thailand. The trial registry number was ChiCTR-IIR-17013331. The protocol was approved by the Human Research Ethics Committee of the Faculty of Medicine, Chiang Mai University, Thailand (IRB No. 254/2017). All patients gave their written informed consent prior to participation in the study. Shallot and placebo capsules were prepared at the Department of Pharmaceutical Science and Medicinal Plant Innovation Center, Faculty of Pharmacy, Chiang Mai University, Thailand, according to the Thai FDA guidelines for herbal products.

The inclusion criteria were as follows: male or female, aged 18 to 65 years old, with confirmed diagnosis of AR that comprised total nasal symptom score $\geq$ 6 within prior 2 weeks and positive skin prick test of at least 1 allergen based on the common allergens in Thailand. List of allergens tested included house mites such as *Dermatophagoides farina* and *Dermatophagoides pteronyssinus*, American cockroach, careless weed, para grass, *Cladosporium* spp., dog and cat hair. All patients refrained from taking antihistamines for 2 weeks prior to the beginning of the study. The exclusion criteria were patients who had serum aspartate aminotransferase (AST) or alanine aminotransferase (ALT) elevation > 1.5 times of the upper limit of normal range or estimated glomerular filtration rate (eGFR) < 50 mL/min, severe nasal abnormality, history of hypersensitivity to cetirizine or shallot, heart diseases, pregnancy, breastfeeding, previous hepatic and renal diseases, use of oral/intranasal corticosteroids, decongestants, immunotherapy or immunosuppressant, and history of nasal surgery within 4 weeks or respiratory tract infection within 2 weeks prior to study. After enrollment, the patients were firmly instructed to avoid foods or any supplements that contained shallots, onions, and garlics until the end of study. Verbal assessment was used for reassurance at every visits. Computerized block randomization was used to allocate patients to shallot or placebo group. Every patient received a 10-mg cetirizine dihydrochloride tablet (ZERTINE®, Farmaline Ltd., Thailand) once daily for 4 weeks. The patients in the shallot group also daily received 3 g of dried oral shallot (12 capsules), which was equivalent to one and a half bulbs of fresh shallot, for 4 weeks. The patients in the placebo group received 3 g per day of placebo capsules containing starch and shallot odor.

Outcome measurement

Any adverse event that occurred during the treatment period was recorded. At the study site, surveys of adverse events were performed every 2 weeks using open- and closed-ended questions. Blood samples were collected from all patients for evaluation of complete blood counts (CBC), blood urea nitrogen (BUN), serum creatinine (Cr), AST and ALT levels before and after the treatment. Vital signs and physical examination were done prior to treatment, then repeated every 2 weeks. The left-over capsules were counted every 2 weeks of treatment to assess the patient's compliance. After 4 weeks of treatment, the exit interview was performed. A 100-mm visual analog scale was used to evaluate the patient's satisfaction toward the supplement capsules. Score of 100 (= 100 mm) meant the patient was extremely satisfied with the oral supplement while the score of 0 (= 0 mm) meant the patient was not satisfied at all. Specific questions regarding certain adverse events such as memory impairment and increased hair fall were used.

Statistical analysis

After examination of the variable distribution, the non-parametric tests were used for statistical analysis. Values were represented as median (range). Wilcoxon's signed rank test was used to determine the differences within groups of laboratory data and baseline profiles between before and after treatment. For data between groups, Wilcoxon's rank sum test (Mann-Whitney U test) was opted. Percentages of incidence of adverse events were analyzed and compared between groups by Chi-square test. *P*-value of less than 0.05 was considered significant. The statistical software used for data analysis was SPSS version 22.0 (IBM Corp., Armonk, NY, USA).

Results

Fifty AR patients participated in this pilot study were randomized equally into shallot group (n=25) and placebo group (n=25). Baseline characteristics did not differ between groups (Table 1). All 25 patients who received shallot capsules completed the study (n=25, Shallot). Two patients in the placebo group were lost to follow-up, and one patient was terminated due to the use of oral decongestant (n=22, Placebo).

Table 1. Baseline characteristics of patients participated in the study.

Characteristics	Shallot (n = 25)	Placebo (n = 22)	*P*-value
Sex, n (%)			
Male	10 (33.33)	6 (35.71)	0.888[a]
Female	15 (66.67)	16 (64.29)	
Age, years	40.0 (20.0-60.0)	33.5 (20.0-58.0)	0.137[b]
Weight, kg	62.0 (45.0-129.0)	56.5 (36.0-87.0)	0.241[b]
Height, cm	165.0 (149.0-183.0)	160.0 (150.0-175.0)	0.078[b]
BMI, kg/m^2	21.9 (17.6-39.8)	22.1 (15.8-31.4)	0.495[b]
Systolic BP, mmHg	111.0 (94.0-140.0)	110.0 (95.0-134.0)	0.236[b]
Diastolic BP, mmHg	70.0 (58.0-88.0)	64.0 (50.0-87.0)	0.066[b]
HR, beats/min	78.0 (53.0-95.0)	79.0 (53.0-95.0)	0.430[b]
Body Temperature, $^{\circ}$C	36.8 (36.1-37.3)	36.8 (36.2-37.4)	0.414[b]

Statistical analysis: [a]Chi-square test, [b]Wilcoxon's rank sum test.
BMI = body mass index, BP = blood pressure, HR = heart rate.
Age, weight, height, BMI, systolic BP, diastolic BP, HR, and body temperature values are represented as median (range).

Adverse events that occurred during shallot and cetirizine treatments, from the highest to the lowest incidence, were somnolence, fatigue, dizziness, dyspepsia, diarrhea, abdominal pain, headache, rash, dry mouth, increased hair fall, and polyuria. The severity of these adverse events were mild to moderate degree. All of them were self-limited. Spontaneous recovery was found within 15 days after

cessation of the AR therapy. No serious adverse event was reported. The number and percentage of patients who experienced adverse events did not differ between the shallot and placebo groups (Table 2). None of the patients in the shallot group quit the study due to intolerable side effects.

There was no significant change in post-treatment body weight, heart rate, and blood pressure compared to the baseline values in both groups (Table 3), although a slight decrease of median diastolic blood pressure was observed in the shallot group. The median (range) change in diastolic blood pressure from baseline was -3.0 (-17.0-8.0) mmHg in the shallot group and 0.0 (-21.0-13.0) mmHg in the placebo group. Regarding the systolic blood pressure, the median (range) change from baseline was -1.0 (-17.0-16.0) mmHg in the shallot group while that was +3.0 (-19.0-21.0) mmHg in the placebo group (p=0.110). At the end of week 2, the median (range) numbers of left-over supplementary capsules were 8.0 (0.0-48.0) in the shallot group and 2.0 (0.0-84.0) in the placebo group (p=0.948). After completion of the study (week 4), the remaining oral supplements counted from the shallot and placebo groups were 4.0 (0.0-30.0) and 11.0 (0.0-70.0) capsules (p=0.155).

For laboratory investigations, serum levels of CBC, BUN, Cr, AST, and ALT at post-treatment did not significantly change from the baseline values and did not differ between groups (Table 4). Overall patients' satisfaction was slightly higher in the placebo group. The median (range) satisfaction scores were 80.0 (49.0-100.0) and 86.5 (60.0-100.0) in the shallot and placebo groups (p=0.17).

Table 2. Summary of adverse events reported for shallot or placebo group.

Adverse events*	Shallot % (n = 25)	Placebo % (n = 22)	*P*-value
No adverse events	48.0 (12)	40.9 (9)	0.452
Central nervous system (CNS)			
Somnolence	44.0 (11)	54.5 (12)	0.475
Fatigue	24.0 (6)	22.7 (5)	0.919
Dizziness	16.0 (4)	9.1 (2)	0.484
Headache	4.0 (1)	13.6 (3)	0.243
Skin and mucous membrane			
Increased hair fall	4.0 (1)	9.1 (2)	0.481
Dry mouth and throat	4.0 (1)	9.1 (2)	0.481
Rash	4.0 (1)	4.5 (1)	0.927
Gastrointestinal system			
Dyspepsia	16.0 (4)	18.2 (4)	0.844
Diarrhea	16.0 (4)	13.6 (3)	0.822
Nausea	4.0 (1)	13.6 (3)	0.243
Abdominal pain	8.0 (2)	9.1 (2)	0.895
Kidney and urinary bladder			
Polyuria	4.0 (1)	0 (0)	0.348

*More than one adverse events occurred in some patients. Statistical analysis: Chi-square test

Table 3. Body weight, blood pressure, and heart rate of patients at week 0 and 4.

Vital signs	Shallot (n = 25)		*P*-value	Placebo (n = 22)		*P*-value
	Week 0	Week 4		Week 0	Week 4	
Body weight (kg)	62.0 (45.0-129.0)	62.0 (45.5-129.5)	0.251	56.5 (36.0-87.0)	57.0 (36.0-87.0)	0.574
Systolic BP (mmHg)	111.0 (94.0-140.0)	112.0 (95.0-131.0)	0.263	110.0 (95.0-134.0)	112.0 (82.0-136.0)	0.289
Diastolic BP (mmHg)	70.0 (58.0-88.0)	67.0 (50.0-88.0)	0.074	64.0 (50.0-87.0)	65.0 (48.0-80.0)	0.637
HR (beats/min)	78.0 (53.0-95.0)	80.0 (56.0-96.0)	0.205	79.0 (53.0-95.0)	81.0 (55.0-109.0)	0.127

Values are represented as median (range). Statistical analysis: Wilcoxon's signed rank test.

Table 4. Laboratory investigations of patients at week 0 and 4.

Laboratory	Shallot (n = 25)		*P*-value	Placebo (n = 22)		*P*-value
	Week 0	Week 4		Week 0	Week 4	
Hemoglobin (Hb) (g/dL)	13.0 (11.4-15.6)	12.8 (11.0-15.5)	0.330	12.9 (9.8-15.1)	13.0 (9.6-15.4)	0.661
Hematocrit (Hct) (%)	39.3 (34.8-48.6)	40.2 (33.5-47.7)	0.936	39.2 (31.1-45.3)	39.8 (30.2-47.6)	0.745
Platelet (Plt) (10^3/μL)	271.4 (193.0-526.0)	287.0 (187.0-462.1)	0.333	279.5 (146.0-440.1)	288.2 (154.4-440.0)	0.516
White blood cell (10^3/μL)	6.3 (4.8-10.3)	6.5 (3.8-9.0)	0.979	6.4 (3.1-14.0)	7.0 (4.0-11.3)	0.615
Neutrophil (%)	54.0 (31.0-69.0)	51.0 (37.0-70.0)	0.617	57.0 (38.0-72.0)	57.5 (40.0-77.0)	0.897
Lymphocyte (%)	36.0 (18.0-61.0	34.0 (5.0-55.0)	0.775	31.5 (21.0-48.0)	31.0 (19.0-43.0)	0.767
Monocyte (%)	6.0 (3.0-9.0)	6.0 (3.0-13.0)	0.511	6.0 (3.0-9.0)	6.0 (2.0-9.0)	0.953
Eosinophil (%)	3.0 (1.0-9.0)	3.0 (1.0-15.0)	0.459	4.5 (0.0-12.0)	4.0 (1.0-11.0)	0.401
Basophil (%)	0.0 (0.0-1.0)	1.0 (0.0-1.0)	0.257	1.0 (0.0-2.0)	1.0 (0.0-1.0)	0.157
BUN (mg/dL)	12.0 (5.0-22.0)	12.0 (6.4-18.0)	0.421	12.0 (6.0-20.0)	11.0 (8.0-20.0)	0.631
Cr (mg/dL)	0.8 (0.6-1.0)	0.8 (0.6-1.6)	0.277	0.7 (0.7-1.2)	0.8 (0.6-1.2)	0.508
AST (U/L)	17.0 (14.0-37.0)	19.5 (12.0-34.0)	0.862	17.5 (13.0-36.0)	19.0 (13.0-33.0)	0.177
ALT (U/L)	17.0 (9.0-74.0	16.5 (5.0-61.0)	0.268	14.5 (6.0-64.0)	14.5 (8.0-37.0)	0.985

Values are represented as median (range). Statistical analysis: Wilcoxon's signed rank test.

Discussion

It is true that allergen avoidance is the safest and most successful method to cease the AR symptoms. However, many patients are allergic to various indoor and outdoor allergens which are difficult to avoid. The principle of pharmacological use for AR is a stepwise approach upon the severity and duration of AR symptoms.[12] For moderate-severe intermittent, mild persistent, and moderate-severe persistent AR, combination of medications such as oral second-generation H_1-antihistamines, intranasal corticosteroids, and leukotriene receptor antagonists (or cromone), with or without decongestants are recommended for continuous use for at least 2 weeks. After that, these drugs should be adjusted and continued for one more month even though the symptoms are improved. In some cases, inappropriate drug use can lead to treatment failure and adverse events, for example, epistaxis from intranasal corticosteroids, sedation from H_1-antihistamines, as well as insomnia and tachycardia from oral decongestants.[13] Long-term use of anti-allergic medications is not desirable in many patients; therefore, the use of complementary medicine has been an alternate choice. In addition to saline nasal irrigation, herbal supplement is one of the most common complementary and alternative medicine that are widespread used.[14]

Mast cell stabilizers such as disodium cromoglicate, ketotifen, nedocromil sodium, and cromolyn are used in AR and asthmatic patients while cromolyn, ladoxamide and pemirolast are used in allergic conjunctivitis. However, systemic cromones are generally less effective than antihistamines and leukotriene receptor antagonists. The topical cromones have lower efficacy than topical corticosteroids and are not available in Thailand.[13] Searching for new mast cell stabilizers from natural sources is needed because the mast cells have heterogeneity and multiple daily dosing is required. Many mast cells stabilizing agents are found in natural sources such as coumarins, terpenoids, and flavonoids. Flavonoids can be subdivided into several classes including flavones, flavonols, flavonones, isoflavones, flavonol-3-ols, and anthocyanidins. Quercetin is the derivative from flavonoid in flavonol class.[15] Herbal medicine with high flavonoids such as butterbur, elderberry, *Nigella sativa*, grape seed extract, rosemary, spirulina, Lingzhi muhsrooms, onions, and shallots have been recommended for AR patients to reduce or prevent allergic symptoms.[8,14,16] Our recent study showed that shallot extract exhibited higher anti-allergic activity than onion despite similarly containing quercetin compounds.[8] The recommended dose for oral shallot supplement is at least 1 bulb per day.[11] The enriched quercetin in shallot may prevent the release of histamine by blocking mast cells degranulation, competitively inhibiting IL-8, reduce IL-6, and inhibiting an increase of cytosolic calcium level.[17] The efficacy of a daily use of one and a half bulb of oral shallot combined with 10 mg of generic cetirizine was already shown in previous study.[8] Results from the present study confirmed that the oral shallot supplement was well tolerated by most AR patients. None in the shallot group quit the study due to intolerable side effects. No serious adverse event was found.

All adverse events occurring in the AR patients receiving oral shallot supplement were similar to those who received placebo, which included drowsiness, dizziness, fatigue, headache, rash, dry mouth and throat, nausea, and dyspepsia. Dry mouth and throat could be the result of antihistaminergic action of cetirizine.

Similarly to the CNS side effects, drowsiness could be the sedative effect caused by cetirizine. Despite being the second-generation antihistamine, the occupancy of brain H_1 receptor of cetirizine ranges between 10 and 30%, whereas the H_1-receptor occupancy of a classified non-sedative antihistamines is less than 20%.[18]

A daily intake of one and a half bulb of shallot was opted in this study because the patients' safety was the primary concern. Scientific evidence of safety and tolerability of continuous shallot consumption has never been reported. Due to variation in size of fresh shallots, a daily administration of 12 capsules (containing 3 g of dried shallot which is equivalent to one and a half bulbs of fresh shallots) was used in this study. According to Thai traditional medicine, taking shallots more than 3 bulbs per day can cause side effects such as memory loss and decreased strength of hair roots.[11] However, the results from this study had shown otherwise. Neither incidence of memory impairment nor incidence of increased hair fall in the shallot group differed from that of the placebo group when one and half bulbs of shallots were taken every day for 4 weeks. Surprisingly, regular ingestion of shallots did not cause bad breath or body smell in our patients even when the closed-ended questions were asked. Nevertheless, we cannot confirm that the unpleasant breath from high sulfur composition in shallot did not occur. The patients might gradually develop tolerance perception to the sulfur smell following chronic consumption.

Additionally, it was clearly demonstrated that the 4-week ingestion of shallot capsules did not compromise liver or kidney function. On the contrary, it has been revealed that administration of shallot extract (1 g/kg) for 3 weeks has protective effect against cyclosporine A-induced nephrotoxicity in rats, presumably from the antioxidative activity.[5] Regarding blood pressure change, our findings were consistent with those of the study by Sobenin et al. which demonstrated the hypotensive effect of Alliaceae plants.[19] Oral garlic supplement can lower aprroximately 2.5±0.6 mmHg (95% CI: 1.1-3.8) of diastolic blood pressure in hypertensive patients. In our study, the median (range) change in diastolic blood pressure from the baseline after 4 weeks of shallot consumption was -3.0 (-17.0-8.0) mmHg in normotensive patients. Although postural hypotension was not presented in our patients, it should be cautioned when larger amount of shallot and longer duration are expected to be consumed.

Conclusions

Current findings suggest that oral administration of one and a half bulbs of shallot in combination with cetirizine for 4 weeks is safe and well tolerated in AR patients. Further study with larger sample size and longer duration should be performed to verify long-term safety of shallot consumption.

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