Impact of Ao-dake-humi, a Japanese Traditional Bamboo Foot Stimulator, on Lower Urinary Tract Symptoms, Constipation, Insomnia, and Hypersensitivity to Cold in Elderly People

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Background : Ao-dake-humi (ADH) is a traditional Japanese bamboo foot stimulator that is commonly used to promote general health among the elderly in Japan. Our earlier report revealed that ADH could improve lower urinary tract symptoms (LUTS), constipation, and hypersensitivity to cold (HC). This study investigated the precise effects and mechanisms of ADH on health in elderly people.

Methods : In this multi-center, randomized, crossover trial, a simple stepping exercise (SSE) was adopted as a control to exclude the exercise effects of ADH. Elderly people over 60 years of age with clinically diagnosed LUTS, constipation, insomnia, or HC were enrolled. ADH or SSE activities were performed twice a day for 28 days. Before and at 28 days of each regimen, International Prostate Symptom Score (IPSS), Athens Insomnia Scale (a visual analogue scale for constipation and HC), and defecation frequency measurements were assessed for comparisons. After the 28 days of initial treatment, ADH and SSE activities were crossed for each other, and then a second intervention was carried out for 28 days.

Results : Of the 37 elderly people (6 male and 31 female) enrolled in the study, 25 participants (4 male and 21 female) were ultimately analyzed. IPSS results improved significantly after ADH. Moreover, ADH ameliorated insomnia and HC significantly more in comparisons with SSE. Constipation status findings were comparable between ADH and SSE.

Conclusions : ADH may have a therapeutic advantage over SSE for the management of LUTS, insomnia, and HC, possibly through the mechanism of physical foot stimulation as a neuromodulator. *Shinshu Med J 72 : 239—249, 2024*

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Key words : ao-dake-humi, lower urinary tract symptoms, constipation, hypersensitivity to cold, insomnia

Abbreviations : ADH, ao-dake-humi ; AIS, Athens Insomnia Scale ; FAS, full analysis set ; HC, hypersensitivity to cold ; IPSS, International Prostate Symptom Score ; LUTS, lower urinary tract symptoms ; OABSS, Overactive Bladder Symptom Score ; QOL, quality of life ; SSE, simple stepping exercise ; VAS, visual analogue scale

I Introduction

Ao-dake-humi (ADH) is a traditional Japanese foot stimulator consisting of a half-pipe-shaped step made of bamboo that is used to stimulate the foot by being stepping on. ADH is commonly employed to promote general health among the elderly in Japan **(Fig. 1A)**. We earlier reported that ADH displayed therapeutic effects on lower urinary tract symptoms (LUTS), constipation, and hypersensitivity to cold (HC) as a type of neuromodulator via physical stimulation of the foot[1]. Since ADH is effective, safe, portable (290 g), and low-cost (approximately 5 USD), it may have clinical use in general health promotion among the elderly at nurs-

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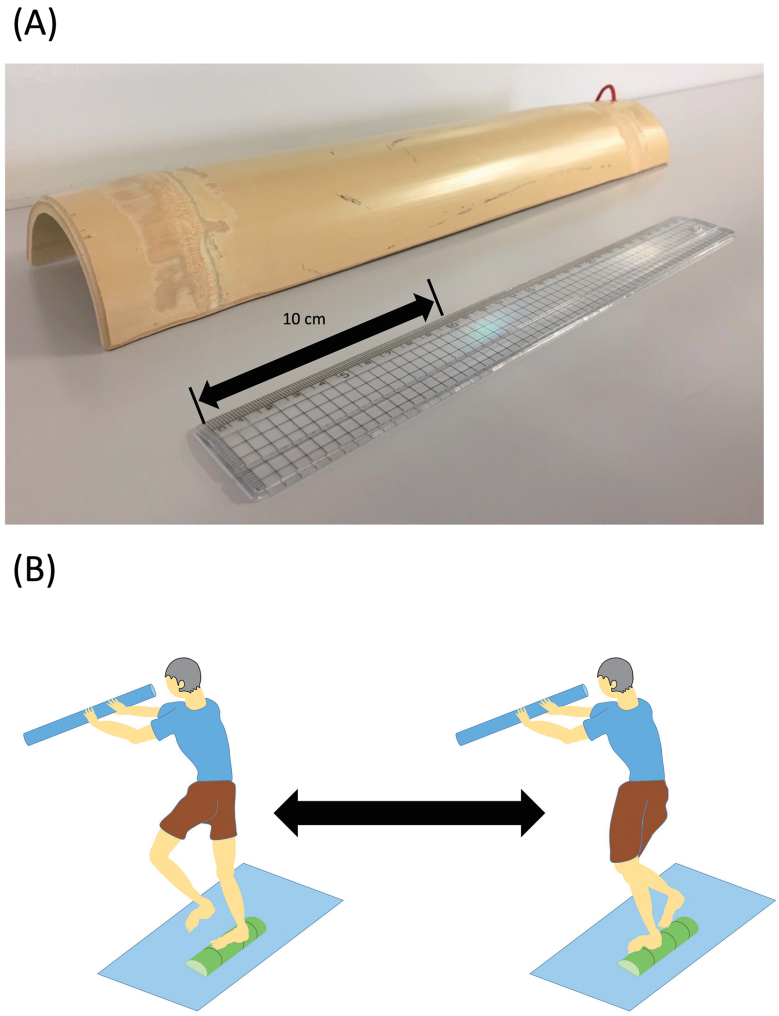

Fig. 1 Photo and use of ao-dake-humi
(A) Photo of ao-dake-humi.
(B) Use of ao-dake-humi. Ao-dake-humi can stimulate the foot by being stepping on repeatedly.

ing homes. We conducted the present trial to examine the precise effects and mechanisms of ADH on the health status of elderly people.

Ⅱ Materials and Methods

A Study design

This was a multi-center, randomized, open-label, crossover trial that was conducted at among 7 nursing homes in Japan. As the therapeutic mechanisms of ADH may include exercise in addition to stimulation akin to a foot massage or neuromodulator, simple stepping exercise (SSE) on a flat floor was employed as a control to exclude the exercise effects of ADH. The impact of ADH and SSE on health was compared using established questionnaires.

B Ethical statement

All study procedures were carried out in accordance with the standards of the Ethics Committee of Shinshu University School of Medicine, the Helsinki Declaration of 1975 (2008 revision), and the Ethical Guidelines for Clinical Studies issued by the Ministry of Health, Labor, and Welfare of Japan, which were revised in 2008 and enforced in April 2009. Permission number was 3303-2015 (accepted : November 4, 2015). Trial registration number was UMIN000023382.

C Participants

Elderly adults over 60 years of age clinically diagnosed as having LUTS, constipation, insomnia, or HC for at least 1 year or were randomized into 2 groups. Screening was done by means of questions by nurses at each institution. Participants were excluded if they could not walk by themselves or if they had dementia, performance status≧3, paralysis, bone fracture in the extremities, or severe neuropathy. Subjects with prob-

lems walking or who received regular foot massages or other forms of foot stimulation were also excluded. All participants were included in the safety analysis set (SAS) unless they withdrew informed consent. The full analysis set (FAS) included participants who performed both ADH and SSE after registration. Participants were excluded if : (i) they withdrew informed consent at any time during the trial ; (ii) they were judged as ineligible after registration ; or (iii) they were missing baseline data. Moreover, people with severe digestive diseases were excluded. In addition, change of medical management about LUTS, constipation, and insomnia were not permitted during this trial, and a participant who needed change of medical management about LUTS, constipation, and insomnia was excluded from the final analysis.

D Protocol

ADH and SSE were performed at each participating nursing home. After obtaining a consent for this trial, eligible participants were randomized at a 1 : 1 ratio into the ADH preceding group and the SSE preceding group using the envelope method. ADH and SSE were performed twice a day, in the morning and evening, for 28 days. After 28 days of the initial treatment, the ADH and SSE activities were crossed with each other and performed for another 28 days. All kinds of questionaries were obtained from all of the participants prior to the beginning of this trial and the end of each activity. Wash-out period was not set because foot stimulation may not affect for a long time. All of the self-administrated questionnaires were collected by the facility directors in the end of each term. Finally, all of the data was collected and analyzed by a single analyzer. The duration of ADH (for 28 days) was set in accordance with our previous report[1]. Moreover, 28 days may be appropriate for evaluation of short time effects of LUT therapy.

Holding something such as the wall, desk, or pillar, the participants placed the arches of both feet on the ADH instrument and made repeated steps for 2 min in a set, as shown in **Fig. 1B**. SSE was done in a comparable manner. In accordance with the conventional use of ADH, steps were made 30-60 times/min at a pace controlled by the participants themselves.

ADH used in this study was made of bamboo, 40 cm in length, 8.5 cm in width, 4.5 cm in height, and almost 290 g in weight. All of ADH was unified into the same size by Taketora Co. (Osaka, Japan).

E Questionnaires

Before and 28 days after starting ADH or SSE, International Prostate Symptom Score (IPSS), Quality of Life (QOL), and Overactive Bladder Symptom Score (OABSS) assessments were conducted to compare the impact of ADH and SSE on LUTS. Athens Insomnia Scale (AIS) was used to evaluate the efficacy of ADH on insomnia. A visual analogue scale (VAS) was employed to determine the effect of ADH on constipation (VAS-constipation) and HC (VAS-HC) in participants with constipation or HC, respectively. Defecation frequency per week was also ascertained to evaluate the impact of ADH on constipation. All of the questionaries were collected by the facility directors in the end of each term. Finally, all of the data was collected and analyzed by a single analyzer.

F Sub-analysis

Participants with no or mild symptoms were excluded from the sub-analysis protocol. Moderate or severe symptoms were defined as IPSS≧8, QoL≧2, OABSS≧6, AIS≧4, VAS constipation≧1/10, and VAS-HC≧1/10, defecation frequency≦6/week. Delta (Δ) means change from the baseline value. Separately, Moderate and severe symptoms rate were calculated in the baseline values and the values after ADH and SSE conditions.

G Achievement rate and safety

Participants who felt pain could reduce their exercise frequency use from twice to once a day. The achievement rates of ADH and SSE were tracked using a diary to clarify the intervention adherence and potential harmfulness of ADH. All participants recorded ADH and SSE as “done” or “none” in the diary. The total practice rate (number of sets performed / [2 sets × 28 days]) was calculated for all participants. Adverse events were also evaluated during the trial.

All adverse events occurring after the commencement of ADH or SSE were reviewed to evaluate the safety of the activities. The occurrence and severity of such events were evaluated for each patient, with

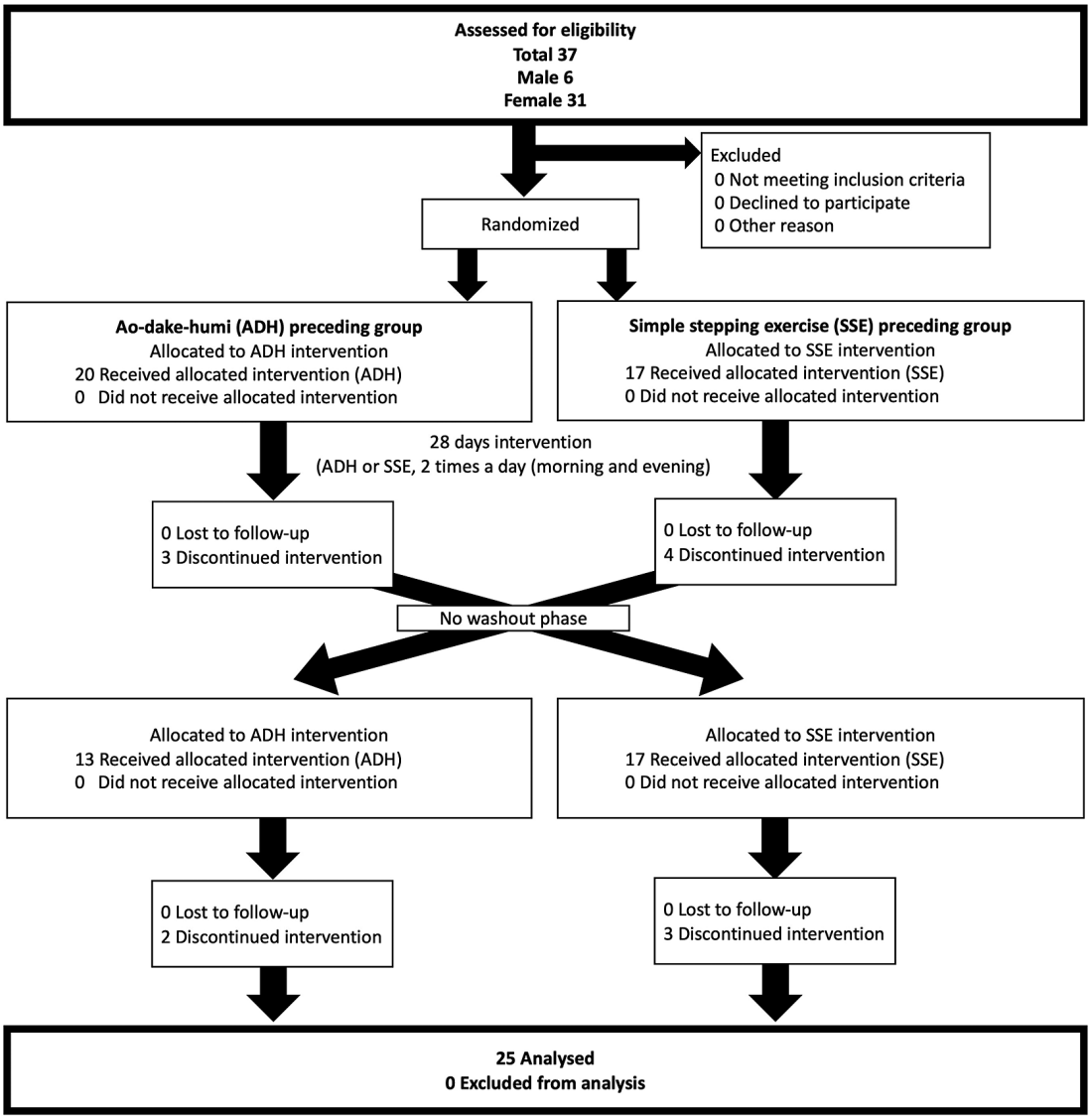

Fig. 2　Distribution of participants throughout the study
*A total of 25 participants completed all protocols of the study.

causality between ADH or SSE and the adverse event judged by investigators at the respective institution.

H　Statistical analysis

The efficacy of the activities was evaluated using paired participant data between baseline and at 28 days of ADH or SSE as all end-points. Data were expressed as the mean change value from baseline ± standard deviation. Data were analyzed using the Excel-based statistical program file Excel TouKei (Social Survey Research Information Co., Ltd., Tokyo, Japan), with $p<0.05$ indicating statistical significance. Changes between before and after ADH and SSE were analyzed using paired Mann-Whitney U test. Moreover, correlation between treatment effects and age/achievement rate was evaluated considering difference of physiological function among elderly people. A correlation of 0.4 or −0.4 was treated as a moderate correlation.

Ⅲ　Results

A　Participants

The distribution of the participants throughout the study is shown in **Fig. 2**. Twenty of the participants were distributed into the ADH preceding group, and 17 participants were distributed into the SSE preceding group. A total of 37 elderly people (6 male and 31

Table 1 Characteristics of the enrolled patients in this study

	All participants	ADH proceeding group	SSE proceeding group
N	25	14	11
Gender			
Male	4	1	3
Female	21	13	8
Age	80.8 ± 8.0	80.0 ± 7.9	81.7 ± 8.0
Performance status			
0	13	8	5
1	9	5	4
2	3	1	2
Past medical history			
Hypertension	7	3	4
Diabetes melitus	3	2	1
Cerebral infarction/ bleeding	2	0	2
Heart desease (Hert infarction, angina, etc.)	1	1	0
Medication			
Drug for LUTS	3	2	1
Drug for constipation	3	2	1
Drug for insomnia	2	2	0

ADH : Ao-dake-humi, LUTS : lower urinary tract symptoms, SSE : Simple Step Excersize

Table 2 Baseline data of enrolled patients

	All patients (N = 25)			Mild-severe symptom patients				ADH proceeding group (N = 14)			SSE proceeding group (N = 11)			p value
	N	Mean	± SD		N	Mean	± SD	N	Mean	± SD	N	Mean	± SD	
IPSS total score	25	8.3	± 6.1	(IPSS ≧ 8)	12	12.9	± 5.5	14	10.3	± 7.3	11	7.7	± 4.3	0.978
IPSS voiding subscore	25	2.7	± 2.6		12	4.3	± 2.4	14	3.0	± 3.1	11	2.6	± 1.7	0.547
IPSS storage subscore	25	4.8	± 3.3		12	7	± 3.2	14	6.2	± 3.8	11	4.3	± 2.5	0.681
IPSS postvoiding subscore	25	0.8	± 1.2		12	1.7	± 1.3	14	1.0	± 1.5	11	0.8	± 0.9	0.622
QOL score	22	3.1	± 1.8	(QOL ≧ 2)	14	3.8	± 1.5	11	3.2	± 3.0	9	3.2	± 2.0	0.483
OABSS	25	3.4	± 2.4	(OABSS ≧ 6)	5	7.8	± 1.3	14	3.0	± 1.6	11	3.8	± 3.1	0.661
AIS	25	4.6	± 3	(AIS ≧ 4)	14	6.4	± 2.9	14	4.6	± 3.6	11	4.5	± 2.2	0.494
VAS-constipation	24	2	± 2.2	(VAS ≧ 1/10)	13	3.7	± 1.7	14	2.1	± 1.8	10	1.9	± 2.6	0.639
VAS-hypersensitivity to cold	23	3.6	± 3.2	(VAS ≧ 1/10)	14	5.7	± 2.2	14	3.6	± 2.9	9	3.5	± 3.6	0.208
Frequency of defecation	23	6.5	± 3.1	(≦ 6/week)	11	4.1	± 1.3	13	5.8	± 2.3	10	7.4	± 3.6	0.227

ADH : Ao-Dake-Humi, AIS : Athens Insomnia Scale, IPSS : International Prostate Symptom Score, OABSS : Overactive Bladder Symptom Score, QOL : quality of life, SD : standard deviation, SSE : Simple Step Exercise, VAS : visual analogue scale

female) were enrolled in the SAS. Six participants distributed into ADH preceding group and 6 participants distributed into SSE preceding group were excluded for protocol violation, patient decision, flu-infection, and unknown reason. Ultimately, 25 participants (4 male and 21 female, mean age : 80.8 years) were evaluated in the FAS. The clinical characteristics of the enrolled participants for both safety and efficacy analyses are shown in **Table 1**. The baseline values from questionnaires are summarized in **Table 2** along with those of the participants with moderate to severe symptoms.

B Questionnaire results

The results of the FAS are presented in **Table 3**. ADH significantly improved the total score of IPSS, IPSS storage subscore, QOL score, OABSS, AIS, and VAS-HC, whereas SSE ameliorated QOL score only. IPSS voiding subscore, OABSS, AIS, and VAS-HC after ADH were significantly better than after SSE.

The results of the sub-analysis of participants with moderate or severe symptoms are shown in **Table 4**. ADH significantly improved the results for IPSS, QOL, OABSS, AIS, and VAS-HC, while SSE significantly ameliorated IPSS, IPSS storage subscore, IPSS postvoiding subscore, QOL, and VAS-HC results. A

Table 3 Subjective effects of ao-dake-humi on lower urinary tract symptoms, insomnia, hypersensitivity to cold, and constipation. Different before and after ao-dake-humi was shown

	N	ADH condition Mean ± SD	ADH condition *p*-value (before-after)	SSE condition Mean ± SD	SSE condition *p*-value (before-after)	*p*-value (ADH vs SSE)
Δ IPSS						
Total score	25	−2.4 ± 5.5	0.0222*	−1.5 ± 5.5	0.0985	0.0510
IPSS voiding subscore	25	−0.8 ± 2.4	0.0541	−0.4 ± 2.5	0.2391	0.0388*
IPSS storage subscore	25	−1.3 ± 3.0	0.0246*	−0.8 ± 2.9	0.0839	0.0706
IPSS postvoiding subscore	25	−0.3 ± 0.9	0.0739	−0.3 ± 1.2	0.1222	0.5000
Δ QoL score	25	−0.7 ± 1.5	0.0245*	−0.8 ± 0.9	0.0481*	0.4267
Δ OABSS	19	−1.1 ± 2.7	0.0288*	0.0 ± 2.1	0.4627	0.0379*
Δ AIS	25	−1.0 ± 2.8	0.0449*	−0.4 ± 2.4	0.2376	0.0460*
Δ VAS-hypersensitivity to cold	23	−1.2 ± 3.1	0.0435*	−0.4 ± 2.8	0.2453	0.0166*
Δ VAS-constipation	24	−0.4 ± 1.5	0.1315	0.1 ± 1.7	0.4357	0.1200
Δ Frequency of defecation	23	0.9 ± 2.6	0.0571	0.6 ± 2.4	0.1243	0.1294

*: p<0.05, **p<0.01.ADH : Ao-Dake-Humi, AIS : Athens Insomnia Scale, IPSS : International Prostate Symptom Score, OABSS : Overactive Bladder Symptom Score, QOL : quality of life, SD : standard deviation, SSE : Simple Step Exercise, VAS : visual analogue scale. Delta (Δ) means change from the baseline value.

Table 4 Subjective effects of ao-dake-humi on moderate or severe symptoms, lower urinary tract symptoms, insomnia, hypersensitivity to cold, and constipation. Different before and after ao-dake-humi was shown

	N	ADH condition Mean ± SD	ADH condition *p*-value (before-after)	SSE condition Mean ± SD	SSE condition *p*-value (before-after)	*p*-value (ADH vs SSE)
Δ IPSS						
Total score	12	−4.6 ± 6.3	0.0164*	−3.8 ± 5.9	0.0283*	0.1814
IPSS voiding subscore	12	−1.5 ± 2.7	0.0429*	−1.0 ± 2.6	0.1044	0.1281
IPSS storage subscore	12	−2.3 ± 3.3	0.0194*	−1.7 ± 3.1	0.0457*	0.1193
IPSS postvoiding subscore	12	−0.8 ± 1.1	0.0217*	−1.0 ± 1.2	0.0076**	0.0955
Δ QoL score	14	−1.1 ± 1.6	0.0147*	−1.3 ± 2.3	0.0315*	0.3043
Δ OABSS	5	−4.2 ± 3.9	0.0478*	−0.6 ± 1.2	0.1870	0.0780
Δ AIS	14	−1.6 ± 2.9	0.0326*	−1.2 ± 2.5	0.0507	0.2216
Δ VAS-hypersensitivity to cold	14	−2.6 ± 2.8	0.0027**	−1.6 ± 2.4	0.0160*	0.2313
Δ VAS-constipation	13	−0.6 ± 2.0	0.1565	−0.1 ± 2.2	0.4210	0.0409*
Δ Frequency of defecation	11	1.6 ± 3.3	0.0839	1.1 ± 3.3	0.1574	0.0881

*: p<0.05, **p<0.01. ADH : Ao-dake-humi, AIS ; Athens Insomnia Scale, IPSS ; international prostate symptom score, OABSS ; overactive bladder symptom score, QOL ; quality of life, SSE : symple step excercise, VAS ; visual analogue scale. Moderate or severe symptoms were defined as IPSS ≧8, QoL ≧2, OABSS ≧6, AIS ≧4, VAS constipation ≧1/10, and VAS hypersensitivity to cold ≧1/10, defecation frequency ≦6/week. Delta (△) means change from the baseline value.

significant difference was seen for VAS-constipation among the conditions. Comparing moderate and severe symptoms rate, the values after ADH condition were generally less than those after SSE condition besides QOL **(Fig. 3)**.

C Achievement rate and safety

The achievement rate for ADH and SSE was 92.7 % and 91.7 %, respectively, according to participant diaries. During the study period, 5 participants suffered influenza infection and dropped out the protocol. Those events were not considered adverse ef-

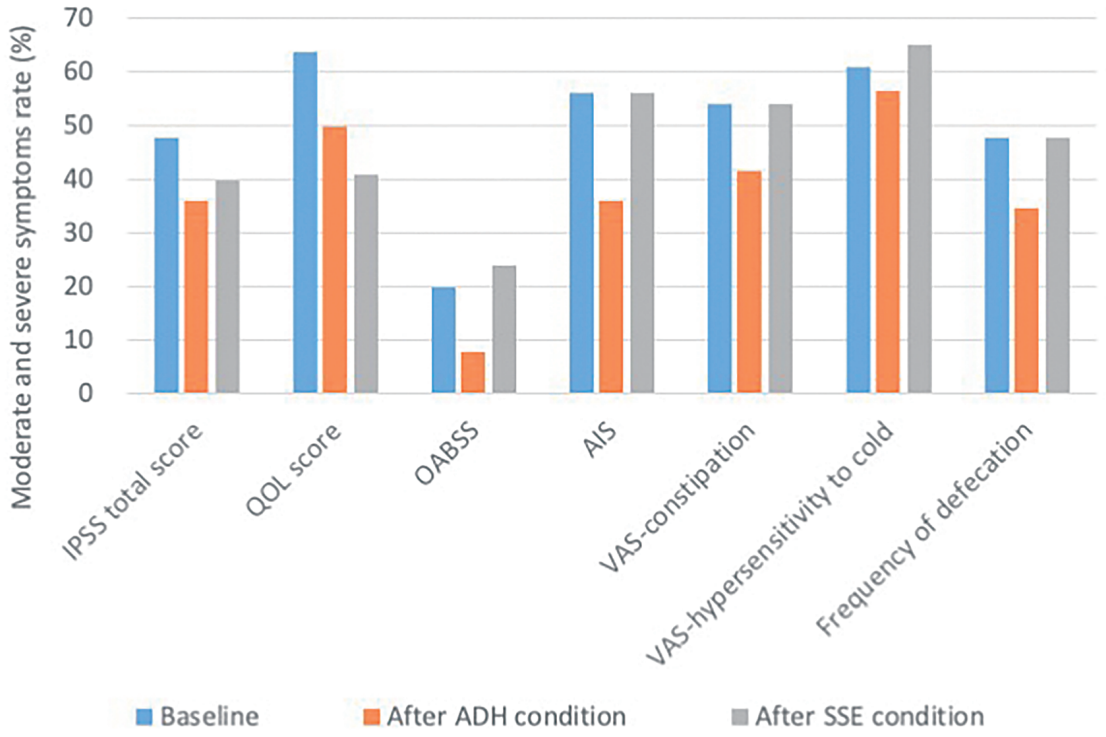

Fig. 3 Moderate and severe symptoms rate. Percentage of participants number with moderate and severe symptoms were shown. Moderate or severe symptoms were defined as IPSS≧8, QOL≧2, OABSS≧6, AIS≧4, VAS constipation≧1/10, and VAS hypersensitivity to cold≧1/10, defecation frequency≦6/week. Delta (Δ) means change from the baseline value.

Table 5 Correlation between treatement effects and age/achievement rate

	Effects & Age				Effects & Achievement rate			
	ADH condition		SSE condition		ADH condition		SSE condition	
	r	p	r	p	r	p	r	p
IPSS total	−0.082	0.400	−0.014	0.483	0.288	0.818	−0.063	0.422
QOL sco	−0.324	0.094	−0.053	0.435	0.077	0.618	0.105	0.659
OABSS	0.466	0.809	−0.191	0.372	0.737	0.956	0.311	0.708
AIS	0.315	0.862	0.495	0.962	−0.013	0.483	−0.115	0.354
VAS-con	−0.103	0.370	−0.052	0.433	−0.170	0.308	−0.734	0.004
VAS-hyp	−0.042	0.444	−0.449	0.056	−0.476	0.059	−0.166	0.303
Frequency of defecation	0.501	0.944	0.479	0.934	0.280	0.771	0.285	0.775

ADH : Ao-Dake-Humi, AIS : Athens Insomnia Scale, IPSS : International Prostate Symptom Score, OABSS : Overactive Bladder Symptom Score, QOL : quality of life, SD : standard deviation, SSE : Simple Step Exercise, VAS : visual analogue scale

fects of ADH or SSE. No other adverse events were recorded among the participants.

D Correlation

Moderate correlations with age were found in OABSS and frequency of defecation after ADH condition, and AIS and frequency of defecation after SSE condition **(Table 5)**. However, statistical significance was not revealed in all of the conditions. Moreover, correlation with treatment effects was revealed about OABSS and VAS-HC after ADH without statistic significant, whereas VAS-constipation after SSE with statistic significant.

Ⅳ Discussion

This trial was conducted as a randomized study to clarify the impact of ADH on general health in elderly people using SSE as a control. With a mean age over 80 years, the cohort comprised very advanced age participants and had a female preponderance.

Concerning results on LUTS in the FAS, ADH significantly improved total IPSS, IPSS storage subscore, QOL score, and OABSS, whereas SSE ameliorated QOL score only. The change in values after ADH was statistically different for IPSS voiding subscore and OABSS between ADH and SEE conditions. In the sub-analysis of participants with moderate or severe LUTS symptoms, ADH significantly improved total IPSS, all IPSS subscores, QOL score, and OABSS, with significant gains in total IPSS, IPSS storage subscore, IPSS postvoiding subscore, and QOL score seen for SSE. ADH was significantly superior to SSE for the recovery of voiding symptoms and OABSS. These results indicate that ADH may improve the storage function of the urinary bladder in addition the effects of SSE exercise. On the other hand, moderate and severe symptoms rate decreased after ADH conditions, especially in OABSS. These results indicated that ADH can attenuate these symptoms more than SSE.

No significant differences were seen before and after ADH or SSE regarding constipation in the FAS. In the sub-analysis of participants with constipation, the change in VAS-constipation after ADH was statistically greater than after SSE. The frequency of defecation did not change in any condition. Thus, the role of ADH on constipation was not confirmed in this trial. Although ADH was effective to manage constipation in our previous report, therapeutic effects of ADH were not revealed in this trial. This discrepancy may come from the patient background in this trial. Elderly people were aimed in this trial on the assumption that constipation is commonly troubled among elderly people. Actually, constipation is not so common and severe in this trial. That may be cause on the results about effect of ADH about constipation.

Insomnia is also a common problem among the elderly, who tend to suffer from fragmented, shallow sleep and early morning awakening[2)3)]. In the FAS and the sub-analysis of participants with insomnia, ADH significantly improved AIS results. We suspect that ADH may have an indirect effect on insomnia via a decrease in nocturnal frequency, although further investigation is needed on the exact role of ADH on sleep.

HC has been identified as an aging problem in Japanese traditional "Kanpo" medicine. For example, skin sensation, especially to cold temperatures, can be related to urinary bladder function and is called "Hie-Shou" in Kampo medicine. Hie-Shou can be translated as HC. HC induces several secondary symptoms, including urinary urgency[4)5)]. HC was evaluated as a therapeutic target of ADH in our earlier report. VAS-HC was improved after ADH in all subjects, and was also ameliorated in the participants with HC in the FAS of the present trial[1)]. Since SSE also improved VAS-HC in participants with HC, however, it might be considered that this symptom can be improved by exercise, with additional effects elicited by ADH.

In the sub-analysis, statistical difference was demonstrated only in VAS-constipation among the participants with moderate or severe symptoms. Considering the therapeutic effects of ADH on IPSS voiding sub-score, OABSS, AIS, VAS-HC more than SSE among FAS (n＝25), ADH may not have sufficient effects on patients with moderate or severe symptoms. Even if ADH do not have strong therapeutic effects, ADH may have several benefits, such as cost and safety, for elderly people with chronic organ disorders.

Moreover, we found inconsistent results about correlation between treatment effects and age/achievement rate. These results indicate achievement rate of both of ADH and SSE may increase the effects of treatment on some symptoms. However, the obtained results are not consistent among the analytical methods. The further investigation should be arranged considering age and achievement rate dependency. Considering change of physiological function among elder people, negative correlation was assumed prior to this trial. However, correlation with significance

was not found among age and treatment effects. Sample size might affect the results, and further investigation should be done to confirm aging effects on ADH and SSE conditions.

Our previous study, which was the first to report on the therapeutic effects of ADH, was conducted as a prospective trial in refractory LUTS participants with or without constipation or HC[1]. However, it was a single-center, single-arm, prospective pilot trial with insufficient evidence to address the mechanisms of ADH. Therefore, the present investigation was designed as a crossover controlled trial, which employed simple exercise as a control to exclude its effects on LUTS and other pathological conditions. We hypothesized that ADH might represent a form of neuromodulation. Neuromodulation incorporates electrical stimulation of specific nerves that control LUTS and an overactive bladder. The mechanism of neuromodulation for LUTS is reportedly reflex inhibition of detrusor contraction by the activation of afferent fibers[6]. Generating stimulation includes electrical stimulation, interferential therapy, and magnetic stimulation for afferent fiber activation[6)-13]. However, if the source of neuromodulation is not stimulation, but rather rhythmic and repeated stimulation of afferent fibers, such forms of physical or mechanical stimulation like acupuncture, reflexology, and foot massage may constitute a source of neuromodulation. In fact, improvements in overactive bladder and constipation by reflexology have already been reported[14)-16]. ADH can therefore be used for rhythmic, repeated, weight-dependent physical stimulation of the feet without any additional equipment. Indeed, Sasaki et al. earlier reported that "Aotake", which was identical to ADH, improved lower-extremity function as compared with walking exercise[17]. Those results indicated that ADH might impart additional effects for promoting physical ability in the elderly than SSE. ADH may represent a type of neuromodulation based on its superior therapeutic role over SSE, as evidenced in this trial. On the other hand, therapeutic mechanisms of ADH still have been unknown yet. However, the classical foot massage effectively decreased insomnia and anxiety symptoms in the previous report via parasympathetic nerve activation[18)19]. In this view point, ADH can be treated as a kind of self-foot-massage equipment. Therefore, ADH may affect peripheral vasodilator action and mental relaxation from parasympathetic nerve system, and improved sensitivity to cold and insomnia. These mechanisms should be clarified using nerve and vascular monitoring in further investigations. Moreover, ADH can be used in a private space, and the rhythm, duration, and frequency can be controlled by the user. ADH also appears adequate for extended treatment as a neuromodulator. However, the exact role of ADH has still been unknown well including endurance after interruption of ADH and timing to show the effects of ADH. Therefore, further investigation should be done to clarify the effects of ADH in detail.

The effect of exercise should be considered when speculating on the mechanisms of ADH as moving the leg muscles may promote blood supply and lymph circulation in the pelvic organs. In this study, we used SSE as a control to exclude the exercise effects of ADH. ADH showed significantly superior effects versus SSE for several parameters apart from constipation. Although attention is needed for a possible placebo effect, the results of this trial highlighted a role of ADH in neuromodulation or additional effects to exercise via neural stimulation.

To the best of our knowledge, the present study is the first randomized trial demonstrating the impact of ADH on LUTS, constipation, HC, and insomnia in elderly people. However, it contained several limitations that must be considered when interpreting the results. First, the number of enrolled participants was limited. Especially, the effect of ADH on constipation may be clarified using a larger cohort, although significant differences were observed. Such findings will support the role of ADH on promoting general health in the elderly. Moreover, this trial was conducted to explore for adequate study design to investigate the role of ADH on elderly people. The difference of therapeutic effect of ADH may not be much more than SSE. Therefore, more than 150 participants might be required in each pathological condition to conduct the next step considering the previous reports and power

calculation after this trial[20)-22)]. Second, subjective evaluation in the form of questionnaires were used to evaluate the impact of ADH. In our previous report, bladder diaries, uroflowmetry, and residual urine volume were adopted for objective assessment.[1)] The current trial was conducted among elderly people averaging over 80 years old in nursing homes. The mean age of participants in this trial was very high more than that expected in the designing of this trial. That may also affect on the results of the results. Nevertheless, obtaining objective findings in randomized trials are needed. In addition, considering ADH as a handy physical therapy, wash-out period was not set in this trial design. Moreover, we did not suppose a therapeutic role of SSE for each pathological condition. As the results, prolonged effects of ADH should be considered, and SSE may have therapeutic effects also. These findings are serious limitation to interpret the obtain results of this trial, and indicated adequate study design as a further step about ADH research. Additional investigations that address the aforementioned limitations are warranted.

ADH has several key advantages, including safety, portability, low cost, and efficacy as evidenced by our trial. In contrast, the possible disadvantages of ADH are slight foot pain and restriction to individuals who can walk by themselves, with virtually no other demerits. Even with its limitations and a yet undefined mechanism of action, ADH shows promise as useful health-promoting equipment.

V Conclusions

ADH displayed superior therapeutic efficacy for the management of LUTS, insomnia, and HC over SSE. Physical foot stimulation may be the underlying mechanism of ADH on general health improvement.

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