



Hypothesis / aims of study

Ao-dake-humi (ADH) is a traditional Japanese bamboo foot stimulator consisting of a half-pipe-shaped step made of bamboo used to stimulate the foot by stepping on it, and is commonly used to promote general health among the elderly in Japan. On the other hand, reflexology is a traditional medicine to promote health via stimulation on foot and other body part. A brief foot chart in reflexology is shown in **Figure 1**. The hot spot of ADH is on urinary bladder and rectum. Then, ADH can be applied for management of LUTS and constipation. In deed, the previous report indicated the effects of ADH on lower urinary tract symptoms (LUTS), constipation, and hypersensitivity to cold (HC) in the previous report. (Ref.) The previous study was conducted in a single-center single-arm prospective study as a pilot trial. Herein, we conducted the second step trial as a multi center cross-over trial to show the exact effects and mechanisms of ADH on health-care among elder people. Simple step (SS) exercise was used as control to exclude exercise effects of ADH.

Study design, materials and methods

This study was a multicenter, randomized, open-label, cross-over trial, and was conducted at 7 nursing homes in Japan. Elder people over 60 years with LUTS, constipation, insomnia, or HC as clinically diagnosed were randomized. Patients were excluded if they cannot walk by themselves. Eligible patients were then randomized in 1:1 ratio to the ADH preceding group and the SS preceding group using envelope method. 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. (Figure 2A) The ADH was brought to each participant's nursing homes. ADH and SS was performed twice a day, in the morning (after waking up) and evening (after taking a bath/shower or before going to bed) for 28 days. Holding something such as the wall, desk, or pillar, participants placed the arches of both feet on the ADH, and then made repeated steps for 2 min in a set as shown in **Figure 2B-E**. In accordance with the usual use of ADH, steps were made 30– 60 times/min, and participants could control the rate by themselves. If participants felt pain, they could reduce use to once a day. Achievement rates of ADH and SS were counted for evaluation of harmfulness of ADH. ADH and SS were done twice a day for 28 days. Before and 28 days after starting ADH or SS, international prostate symptom score (IPSS), quality-of-life (QoL) score, overactive bladder symptom score (OABSS), Athene Insomnia Scale (AIS), a visual analogue scale on constipation (VAS-constipation), HC (VAS-HC), and defecation frequency were used for evaluation. After 28 days of initial treatment, ADH and SS were crossed each other, then ADH and SS were done for 28 days. The obtained results were compared between the baseline and the results after ADH or SS using paired t-test statistically. And, the ADH and SS were also compared statistically using unpaired t-test.

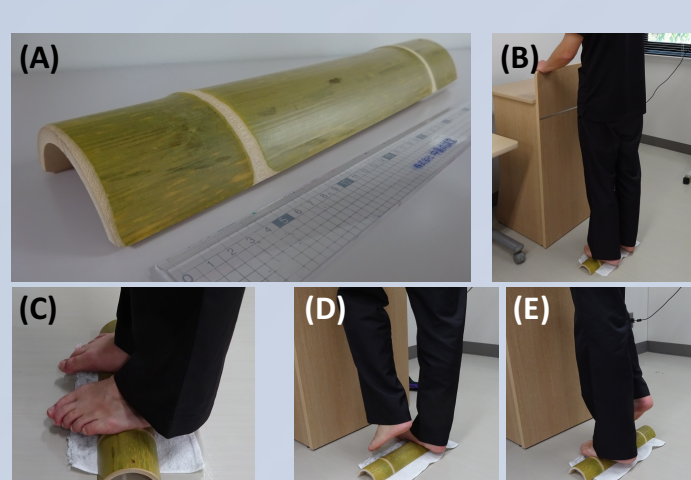
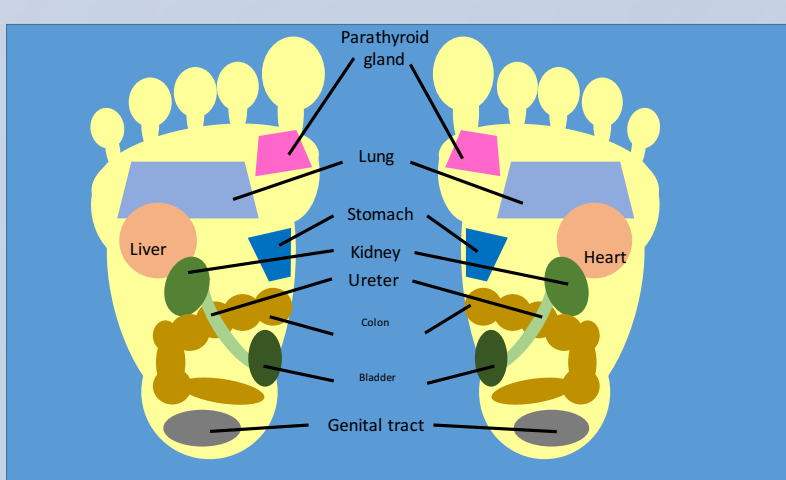


Figure 1. A brief foot chart in reflexology. Only main and large areas were shown in this figure, and small parts were excluded to lead easy understanding. Each area of foot is matching to specific body parts, and is connect to promoting health of each part of body parts by massage

Figure 2. (A) Gross appearance of ao-dake-humi. (B,C) Putting both of arch foot on ao-dake-humi without footwear. (C, D, E) Making steps on ao-dake-humi for 2 minutes on it in a set.

Abbreviations ADH; Ao-dake-humi, AIS; Athene Insomnia Scale, HC; hypersensitivity to cold, IPSS; international prostate symptom score, OABSS; overactive bladder symptom score, QOL; quality of life, SS; simple step, VAS; visual analogue schale

RESULTS

A total of 37 elder people (6 male and 31 female) were enrolled in this study. Finally, 25 in total (4 male and 21 female, 80.8 y.o. average) were evaluated. Disposition of patients is shown in **Figure 3**. And Characteristics and baseline values of the enrolled patients are shown in **Table 1 & 2**.

IPSS, especially storage-subscore, and OABSS decreased significantly after ADH. (Table 3) In accordance with the results of AIH and VAS, ADH improved insomnia and HC significantly. On the other hand, constipation did not change after ADH and SS. The achievement rates of ADH and SS were 92.7% and 91.7%, respectively.

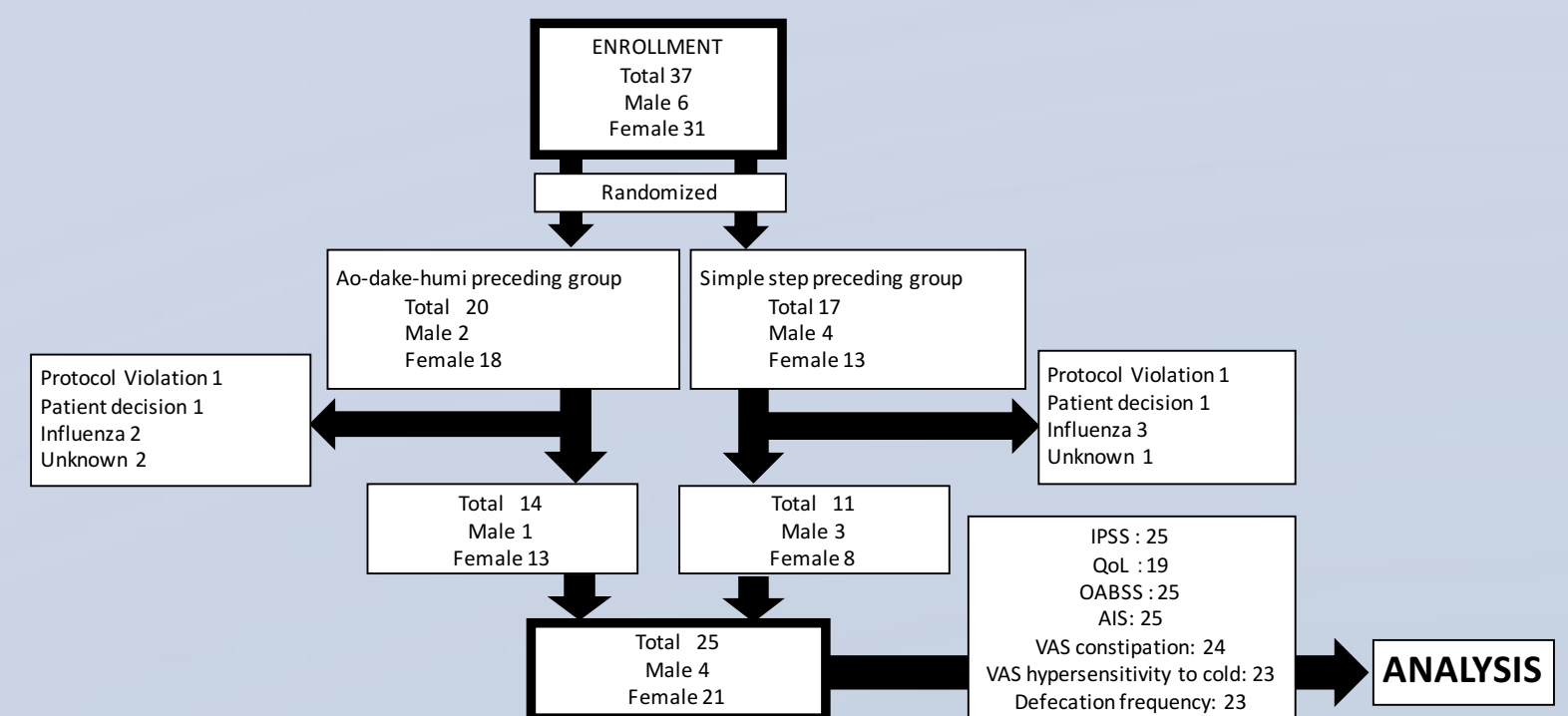


Figure 3. Disposition of patients through the study. *A total of 25 patients completed all of the protocols of the study.

	All patients	Simple step preceding group	Ao-dake-humi preceding 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 mellitus	3	2	1
Cerebral infarction/ bleeding	2	0	2
Heart disease (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

Table 1. Characteristics of the enrolled patients in this study.

LUTS; lower urinary tract symptoms

	All patients	
	N	Mean ± SD
IPSS total score (N =)	25	8.3 ± 6.1
IPSS voiding subscore	25	2.7 ± 2.6
IPSS storage subscore	25	4.8 ± 3.3
IPSS postvoiding subscore	25	0.8 ± 1.2
QoL score	22	3.1 ± 1.8
OABSS	25	3.4 ± 2.4
AIS	25	4.6 ± 3.0
VAS-constipation	24	2.0 ± 2.2
VAS-hypersensitivity to cold	23	3.6 ± 3.2
Frequency of defecation	23	6.5 ± 3.1

Table 2 The baseline data of enrolled patients

	N	Ao-dake-humi		Simple step		p-value (Ao-dake-humi vs Simple step)
		Mean ± SD	p-value (before-after)	Mean ± SD	p-value (before-after)	
ΔIPSS						
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
ΔQoL score	25	-0.7 ± 1.5	0.0245 *	-0.8 ± 0.9	0.0481 *	0.4267
ΔOABSS	19	-1.1 ± 2.7	0.0288 *	0.0 ± 2.1	0.4627	0.0379 *
ΔAIS	25	-1.0 ± 2.8	0.0449 *	-0.4 ± 2.4	0.2376	0.0460 *
ΔVAS-hypersensitivity to cold	23	-1.2 ± 3.1	0.0435 *	-0.4 ± 2.8	0.2453	0.0166 *
ΔVAS-constipation	24	-0.4 ± 1.5	0.1315	0.1 ± 1.7	0.4357	0.1200
ΔFrequency of defecation	23	0.9 ± 2.6	0.0571	0.6 ± 2.4	0.1243	0.1294

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. *: p < 0.05, **: p < 0.01

INTERPRETATION OF RESULTS & CONCLUSION

ADH is a Japanese traditional foot stimulator to promote general health. However, we did not know what the effect is, and how to use it. This study showed that ADH has a better therapeutic effect than SS on LUTS, constipation, HC, and insomnia. These results indicated that ADH is not only an exercise equipment, but also a physical neuromodulator. The achievement rate was high, and indicate that ADH is not a harmful even in elder people. To the best of our knowledge, the present study is the first investigation showing the effect of ADH on LUTS and other aging problems using a randomized trial. The mechanisms of ADH on general health has been unknown. However, we suppose ADH is a kind of neuromodulator using physical stimulation on foot.

In conclusion, the results of this study indicated that ADH has therapeutic efficacy in cases of LUTS, insomnia, and HC more than SS. The possibility of ADH as physical neuromodulator was shown comparing SS exercise.

REFERENCES

Minagawa T, Saitou T, Suzuki T, et al. Impact of ao-dake-humi, Japanese traditional bamboo foot stimulator, on lower urinary tract symptoms, constipation, and hypersensitivity to cold: a single-arm prospective pilot study. *BMC Complement Altern Med* 16: 513. 2016