

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

Hypothesis / aims of study

Skin sensation, especially to cold temperature, can be related to urinary bladder function especially in elderly. This is a important characteristic to treat patients in Kampo-medicine (Japanese traditional medicine), and is called "Hie". [1] "Hie" can be translated as hypersensitivity to cold (HC), and is commonly seen in the elderly. HC induces several secondary symptoms, such as headache, back pain, diarrhea, and urinary urgency.

On the other hand, alternative medicine, such as foot-massage and reflexology, can be candidates to manage refractory LUTS, constipation, and HC. Indeed, previous study suggested that massage therapy is effective for LUTS, and constipation. [2,3] And, foot massage is commonly considered as folk therapy for HC in Japan. As the bases of foot-massage, the theory of reflexology can be apply for management of LUTS or other dysfunction of organs. The theory behind reflexology is that the specific areas of foot are match and connect to the specific organs of the body. Then, dysfunction of the specific organ can treat by stimulation on the specific areas of foot. For example, arch foot is match to urinary bladder, and can be used for management of bladder dysfunction by pushing on the area. Reflexologists use foot charts to guide them as they apply pressure to specific areas of foot (Figure 1). However, there are some limitation of massage therapy and reflexology, such as cost, manpower, and standardization of it.

In Japan, a traditional bamboo foot stimulator called ao-dake-humi (ADH) is commonly used, especially in the elderly. ADH is a home health appliance based on the theory of reflexology, which consists of a half-pipe-shaped foot-step made of bamboo cut into pieces 30-40 cm in length. ADH can be used at home to promote general health in daily use. However, the exact role of ADH has not been proven, and its efficacy has not been reported in the scientific literature. Herein, the aim of this study is to investigate the role of ADH focusing on lower urinary tract symptoms (LUTS), constipation, and HC.

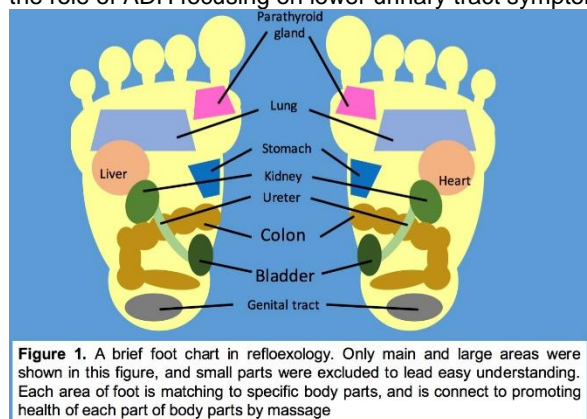


Figure 1. A brief foot chart in reflexology. Only main and large areas were shown in this figure, and small parts were excluded to lead easy understanding. Each area of foot is matching to specific body parts, and is connect to promoting health of each part of body parts by massage

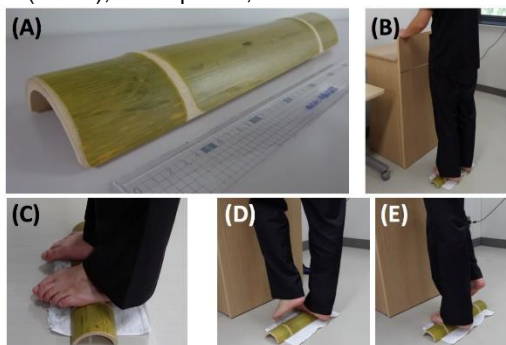


Figure 2. (A) Gross appearance of ao-dake-humi. (B,C) Putting both of arch foot on ao-dake-humi without footwear. (C, D, E) Making steps on ao-dake-humi for 2 minutes on it in a set.

Study design, materials and methods

Participants with LUTS, constipation, or HC were enrolled in this study. ADH, which is used in this study, is made of bamboo, and is 40 cm in length, 8.5 cm in wide, 4.5 cm in height, and almost 290 g in weight. Ao-dake-humi was bring back to each participant's home, and used twice a day, in the morning (after wake-up) and evening (after taking bath/shower or before going to bed) for 28 days. Holding something such as wall or a pillar, participants put both of arch foot on ADH, and then make repeatedly steps for 2 minutes on it in a set. (Figure 2) If participants feel pain, participants can make it reduce into once a day. Achievement rate of ao-dake-humi was noted during this study to evaluate exact intervention and harmfulness of ADH. Before and 28 days after starting ADH use, international prostate symptom score (IPSS), QOL score, and overactive bladder symptom score (OABSS) was measured to evaluate the efficacy of ADH on LUTS. To evaluate the objective efficacy of ADH on LUTS, a frequency-volume chart (FVC) was plotted in LUTS patients for 3 days before and after ADH. A visual analogue scale (VAS) was used to evaluate the efficacy of ADH on constipation (VAS-constipation) and HC (VAS-HC) in the participants with constipation or HC before and after ADH. The changes before and after ADH were analyzed using the paired *t*-test.

Results

A total of 24 participants were enrolled in this study. Twenty-one participants had LUTS, 11 had constipation, and 17 participants had HC. The characteristics of the enrolled patients are described on Table 1. The results of subjective evaluation were demonstrated on Table 2. IPSS, especially storage-subscore, decreased significantly after use of ADH. QOL score and OABSS also decreased after ADL use statistically. And, the results of objective evaluation (FVC) were demonstrated on Table 3. The use of ADH increased maximal bladder capacity, resulting in a significant decrease in urinary frequency as determined from the FVC. In accordance with the results of VAS-constipation and VAS-HC, both constipation and HC were significantly relieved after ADH use. In this study, only 3 participants complained slight pain at the induction of ao-dake-humi, 98.5 % of achievement rate was taken in average of participants, and all of participants wished to continue ADH after this study spontaneously. And, there were no severe adverse events among the participants.

N	24	LUTS (N = 21)	Change from baseline	p value
Sex		IPSS Total	-3.8	0.0002 **
Male	13	Voiding subscore	-1.0	0.0592
Female	11	Storage subscore	-2.1	0.0000 **
Age (y.o.)	65.2 ± 16.3	Postvoiding subscore	-0.7	0.0060 **
Body mass index (kg/m ²)	21.8 ± 2.2	QOL score	-1.2	0.0000 **
Distribution of LUTS, constipation, and HC		OABSS	-1.1	0.0070 **
LUTS	21	<hr/>		
Constipation	11	Constipation (N = 11)		
HC	17	VAS-constipation	-31.8	0.0073 **
Only LUTS	5	<hr/>		
Only Constipation	0	HC (N = 17)		
Only HC	1	VAS-HC	-21.9	0.0158 *
LUTS and constipation	2	<hr/>		
LUTS and HC	7	Table 2. Subjective effect of ao-dake-humi on lower urinary tract and constipation and hypersensitivity to cold. Different before and after ao-dake-humi was shown. *: p < 0.05, ** p < 0.01		
Constipation and HC	2	LUTS; lower urinary tract symptoms, IPSS; international prostate symptom score, QOL; quality of life, OABSS; overactive bladder symptom score, HC; hypersensitivity to cold, VAS; visual analogue scale		
LUTS, constipation, and HC	7	<hr/>		

Table 1. Characteristics of the enrolled patients in this study.
LUTS; lower urinary tract symptoms, HC; hypersensitivity to cold

	Before	After	p value
LUTS (N = 20)			
Total urine volume (ml/day)	1684.7 ± 788.5	1669.1 ± 691.2	0.4543
Mean voided volume (ml)	169.7 ± 52.8	187.0 ± 67.0	0.0538
Maximal voided volume (ml)	331.5 ± 140.3	373.0 ± 139.0	0.0424 *
Minimal voided volume (ml)	58.3 ± 31.4	72.8 ± 50.2	0.0948
Total urinary frequency (/day)	10.9 ± 3.5	9.8 ± 2.7	0.0065 **
Day-time urinary frequency (/6-22 o'clock)	8.9 ± 2.7	7.9 ± 1.7	0.0162 *
Night-time urinary frequency (/22-6 o'clock)	2.0 ± 1.7	1.8 ± 1.6	0.1898

Table 3. Objective results of ao-dake-humi on LUTS. One of 21 patients did not make flow-volume chart.
LUTS; lower urinary tract symptoms. *: p < 0.05, ** p < 0.01

Interpretation of results

This is the first report to describe the clinical effects of ADH on LUTS, constipation, and HC. The obtained results indicate that ADH has therapeutic effects on chronic functional dysfunction such as LUTS, constipation, HC. ADH can increase functional bladder capacity, and lead the decrease of urinary frequency, which was consistent with improvement of storage subscore of IPSS and OABSS. Although this study was conducted as a single-arm trial as a pilot study, the results of this study indicate the possibility of ADH as therapeutic option for LUTS, constipation, and HC.

Concluding message

The results of this prospective pilot study demonstrate that ADH is safe and has therapeutic efficacy in cases of LUTS, constipation and HC.

References

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Disclosures

Funding: None **Clinical Trial:** Yes **Registration Number:** UMIN000019333 (UMIN-CTR) **RCT:** No **Subjects:** HUMAN **Ethics Committee:** The protocol of this study was approved by the ethics committee of Shinshu University School of Medicine (Permission No. 2184, 2012). **Helsinki:** Yes **Informed Consent:** Yes