



Original Article

Development and validation of Sasang Urination and Defecation Inventory (SUDI) for pathophysiological symptoms of Sasang typology

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ABSTRACT

Background: The pathophysiological symptom of Sasang typology is essential for getting clinical diagnosis and analyzing treatment effects. The clinical index for examining urination and defecation related symptoms were developed and validated with established clinical measures.

Methods: Questionnaire items of six subscales of Sasang Urination and Defecation Inventory (SUDI) were developed based on previous systematic reviews, and its clinical validity was examined with clinical measures of Urogenital Distress Inventory-6 (UDI-6), Overactive Bladder Symptom Score (OBSS), and ROME 3 criteria for Irritable Bowel Syndrome (ROME3-IBS) and Functional Constipation (ROME3-FC) using 48 healthy participants. The internal consistency of six subscales of SUDI were examined with Cronbach alpha. The Pearson correlation was used to examine correlation between SUDI and Western clinical measures, and the ANOVA was adopted to investigate differences among Sasang type groups in clinical measures.

Results: The SUDI-UCHR (problematic characteristics of urine) and SUDI-ANMD (defecation anomaly discomfort) were found to represent unique concept of traditional Korean medicine, however SUDI-IRRB (irritability of bowel movement) and SUDI-FCON (functional constipation) were similar with functional gastrointestinal disease of western medicine. SUDI-URET (ability to retain urine), SUDI-UDIS (urinary discomfort) and SUDI-ANMD of So-Yang type (7.95 ± 2.16 , 14.33 ± 2.01 , and 13.10 ± 2.57) are significantly different from those of So-Eum type (9.94 ± 2.54 , 12.18 ± 2.96 , and 10.59 ± 3.47 , respectively).

Conclusion: The pathophysiological symptoms of urination and defecation in Sasang typology were systematically scrutinized, and summarized into six subscales of SUDI in this study. The SUDI would be useful for analyzing clinical symptoms of Sasang typology along with integrative collaboration of traditional Korean and Western medicine.

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1. Introduction

The Sasang typology is a unique Korean personalized medicine¹ which divides people into four Sasang types of Tae-Yang, So-Yang, Tae-Eum and So-Eum depending on their psychological temperament,² physical body shape³ and pathophysiological

characteristics,⁴ and provides type-specific intervention of medical herbs⁵ and acupuncture⁶ considering their disease susceptibility and treatment response.⁷ There have been studies to measure and analyze Sasang type-specific psychological,^{2,8,9} physical,^{3,10} clinical,⁴ biomedical⁴ and genetic¹¹ characteristics were reported.

As for the clinical perspectives, type-specific pathophysiological symptoms of digestive function, sleep, defecation and urination have been considered as pivotal clinical features for the Sasang type differentiation,^{4,12–15} since these have been used as essential objective index for analyzing treatment effects of acupuncture and herbs⁶ and identifying clinical patterns of Cold-Hot subgroups.¹⁴ However, studies on objective measures for analyzing clinical features were not satisfactory, because plenty of studies have focused on finding one or two representative symptoms and have used

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arbitrary index or questionnaire without proper validation.^{4,15} Therefore development of reliable and validated clinical measure based on type-specific pathophysiological clinical symptoms is required to tackle this issue.^{12,13}

This study collected questionnaire items from previous systematic review on Sasang type-specific excretory function of urination and defecation-related clinical symptoms,^{15–22} and organized as a Sasang Urination and Defecation Inventory (SUDI) with three subscales for urination and three subscales for defecation.^{4,15} As for the clinical validation of this newly suggested SUDI, three western clinical measures of Urogenital Distress Inventory (UDI-6), Overactive Bladder Symptom Score (OABSS), and ROME 3 criteria for Irritable Bowel Syndrome (IBS) and Functional Constipation (FC) along with two anthropometric measures of Body Mass Index (BMI) and Ponderal Index (PI) which might have correlation with digestive and metabolic functions¹⁵ were incorporated in this study. The correlation between SUDI subscales and UDI-6, OABSS, ROME 3 criteria, BMI and PI were analyzed. The differences of SUDI subscale scores among Sasang types were also examined to show whether the SUDI might be used for Sasang type differentiation together with Sasang Digestive Function Inventory^{12,14} and Sasang Personality Questionnaire.^{3,6}

This study would provide foundation for analyzing Sasang type-specific pathophysiological symptoms and developing objective and validated clinical measures for Sasang type and subgroup differentiation. And the SUDI would be useful for educating students of traditional Korean medicine and collaborating with other medical professionals in conjunction with Sasang type diagnosis in clinics.¹⁵

2. Methods

2.1. Procedures and participants

The items for Sasang Urination and Defecation Inventory (SUDI) were developed based on previous systematic review on Sasang type-specific pathophysiological symptoms of urination and defecation, and their clinical reliability and validity were examined with healthy university students.

After determining the Sasang types of participants, the clinical symptoms of 48 participants were measured with SUDI, Urogenital Distress Inventory-6 (UDI-6), Overactive Bladder Symptom Score (OABSS), ROME 3 criteria for Irritable Bowel Syndrome (ROME 3 IBS) and Functional Constipation (ROME 3 FC), weight and height.²³

This study was performed under the recognition of Institutional Review Board of Pusan National University (2016_93_HR) after receiving informed consent from the participants.

2.2. Sasang type classification by clinical specialist

The Sasang type classification of the participants was made by two certified clinical specialist of Sasang medicine (YGP and NB) based on their body shape, psychological temperament, pathophysiological clinical symptoms, clinical responses to acupuncture and herbal treatments, and QSCCII test results. The certified clinical specialist of Sasang medicine should finish one year of internship and three years of residency in hospital supervised by the Ministry of Health and Welfare and Korean Medical Hospitals Association, and pass the Specialty Certification Examination.²⁴

2.3. Sasang Urination and Defecation Inventory (SUDI) and its six subscales

The questionnaire items of pathophysiological urination and defecation symptoms were developed based on previously reported studies^{15–22} and systematic review^{4,15} suggesting six

subscales, including SUDI-UCHR (problematic characteristics of urine), SUDI-URET (ability to retain urine) and SUDI-UDIS (urinary discomfort) for urination and SUDI-IRRB (irritability of bowel movement), SUDI-FCON (functional constipation) and SUDI-ANMD (discomfort from defecation anomaly) for defecation.

The preliminary items for SUDI were collected from previously reported significant clinical reports^{4,15} and books,⁷ and reorganized as six categories containing 16 items for urination and 19 items for defecation. Duplicated or inadequate items were deleted, items with multiple meanings were divided, and expression was modified for better understanding of the readers during this item development. Five point-Likert scale from one (not at all) to five (very much) was used for the score.

The item selection procedure was performed using 20 participants, and final SUDI was completed as 13 items for three urination subscales and 16 items for three defecation subscales. As a result, three subscales of SUDI-UCHR (4 items, 4–20), SUDI-URET (4 items, 4–20) and SUDI-UDIS (5 items, 5–25) were provided for the urination, and three subscales of SUDI-IRRB (6 items, 6–30), SUDI-FCON (6 items, 6–30) and SUDI-ANMD (4 items, 4–20) were assigned for the defecation.

2.4. Urogenital Distress Inventory (UDI-6)

The Urogenital Distress Inventory (UDI-6)²⁵ with six self-report items assesses clinical distress in lower urinary tract symptoms during the urination such as micturition frequency, micturition difficulty, urge incontinence, stress incontinence, and genital or lower abdominal pain. 4-Point Likert scale from 'not inconvenient' (1) to 'very uncomfortable' (4) was used for the scoring, and the high score of UDI-6 represents strongly distressed and inconvenient during the urination. The internal consistency of Korean version UDI-6 was reported as 0.661.²⁶

2.5. Overactive Bladder Symptom Score (OABSS)

Overactive Bladder Symptom Score (OABSS) is consist of four questions regarding daytime frequency, nocturia, urgency, and urgency incontinence, which is originally developed by Homma and others^{27,28} and translated into Korean in 2011.²⁹ The patient would be diagnosed as overactive bladder when urgency incontinence score is higher than 2 and the total score is higher than 3. Total score lower than 5 is regarded as mild, 6–11 as severe, and higher than 12 as most serious condition. The internal consistency of Korean version OABSS was reported as 0.73.³⁰

2.6. ROME 3 Criteria for Functional Constipation and Irritable Bowel Syndrome (ROME 3 FC and IBS)

ROME criteria is widely used in clinical evaluation and diagnosis of functional gastrointestinal diseases, and ROME 3 (2006)³¹ provides criteria for 28 diseases according to their typical clinical symptoms.³² The Korean version³³ of ROME 3 was used for this study, and its clinical usefulness for diagnosing gastrointestinal functional diseases of Koreans were previously shown.³² The sensitivity and specificity of ROME 3 criteria for upper gastrointestinal tract (59.7% and 52.9%) and lower gastrointestinal tract (80.3% and 50.0%) was also reported.³²

2.7. Anthropometric measures of Body Mass Index (BMI) and Ponderal Index (PI)

The weight (kg) and height (cm) of participants were measured, and the Body Mass Index (BMI) and Ponderal Index (PI) were calculated. The Body Mass Index (BMI, kg/m²) is the weight (kg) divided by the square of the height (m²), and the Ponderal Index (PI, kg/m³)

is the body weight (kg) divided by the three time of the height (m^3).¹⁰ The BMI is an anthropometric index for growth hormone and obesity measure, and the PI is used as a corporal index for thyroid hormone and lean body mass.³ Previous study showed that the PI is more clinically useful for the Sasang type classification than BMI.³

2.8. Statistical analysis

The demographic features of the participants were shown with descriptive statistics. The differences among Sasang types were examined with χ^2 test in sex distribution, and ANOVA and Bonferroni or Dunnett T3 post hoc analysis in age, body weight, height, Body Mass Index (BMI) and Ponderal Index (PI).

The internal consistency of SUDI six subscales was tested with Cronbach alpha. As for the nonstructural validity, the correlation between SUDI and well-validated clinical measures of UDI-6, OABSS, ROME 3 FC and IBS were observed with Pearson correlation. The differences of SUDI subscale scores among ROME 3 criteria and OABSS diagnosis were attested with *T*-test and ANOVA.

As to show the clinical validity of SUDI, scores of six SUDI subscale of each Sasang type groups were examined with ANOVA. The ROME 3 criteria and OABSS diagnosis among Sasang types were attested with χ^2 test.

As for the statistical analysis IBM SPSS 20.0 (IBM, Armonk, NY) were used, and the results were described as mean with standard deviation or frequency (%). The statistical significance was determined at the level of $p < 0.05$, $p < 0.01$, and $p < 0.001$.

3. Results

3.1. Demographic features of the participants in this study

The OABSS, UDI-6, ROME 3 criteria, SUDI and Sasang type differentiation of 48 participants were performed. There were 21 So-Yang type (44%), 20 Tae-Eum type (21%) and 17 So-Eum type (35%) in this study, and there were no significant differences among three Sasang types groups in sex distribution and age (Table 1).

There were no significant differences among Sasang type groups in weight and height, however not in BMI and PI. The BMI and PI of Tae-Eum type (25.00 ± 2.38 and 14.66 ± 1.31 , respectively) were significantly ($p < 0.01$) higher than those of So-Yang type (21.30 ± 3.13 and 12.66 ± 1.39) and So-Eum type (21.36 ± 2.53 and 12.53 ± 1.22). Considering that the BMI is a measure for obesity and PI for lean body mass,^{3,10} these results reaffirm the description of Longevity and Life Preservation⁷ that the Tae-Eum type is bigger than other types.

3.2. Development of six SUDI subscales

As for the urination-related three SUDI subscales (Table 2), the high score of SUDI-UCHR represents dark or yellowish color, high turbidity, strong odor, and foamy characteristics of urine which is problematic and unwanted in clinical situation. The SUDI-URET means fewer (or infrequent) urination during day and night and seldom nocturia, decreased total volume of urine, and fewer urinary urgency. The SUDI-UDIS measures urination-related discomfort such as hesitancy, staining and residual urine sense, and clinical symptoms of decreased volume and dark color when in bad shape.

Table 1
Demographic features of the participants in this study

	So-Yang	Tae-Eum	So-Eum	Total	Statistical analysis
Sex (m/f)	21 (9/12)	10 (7/3)	17 (12/5)	48 (28/20)	$\chi^2 = 3.680, p = 0.159$
Age	30.67 ± 4.26	32.70 ± 4.45	30.56 ± 3.95	31.06 ± 4.19	$F = 0.968, p = 0.388$
Weight	60.76 ± 14.46	73.20 ± 11.06	62.57 ± 13.07	64.05 ± 13.97	$F = 3.074, p = 0.057$
Height	167.71 ± 8.52	170.70 ± 7.92	170.33 ± 8.84	169.22 ± 8.43	$F = 0.609, p = 0.548$
BMI [*]	21.30 ± 3.13	25.00 ± 2.38	21.36 ± 2.53	22.12 ± 3.14	$F = 6.770, p = 0.003, TE > SY \& SE$
PI ^{**}	12.66 ± 1.39	14.66 ± 1.31	12.53 ± 1.22	13.05 ± 1.55	$F = 9.487, p < 0.001, TE > SY \& SE$

SUDI, Sasang Urination and Defecation Inventory; SUDI-UCHR, SUDI-characteristics of urine; SUDI-URET, SUDI-ability to retain urine; SUDI-UDIS, SUDI-urinary discomfort; SUDI-IRRB, SUDI-irritability of bowel movement; SUDI-FCON, SUDI-functional constipation; SUDI-ANMD, SUDI-defecation anomaly discomfort; BMI, Body Mass Index; PI, Ponderal Index; UDI-6, Urogenital Distress Inventory with 6 items; OABSS, Overactive Bladder Symptom Score; ROME 3 FC, Rome 3 criteria for Functional Constipation; ROME 3 IBS, Rome 3 criteria for Irritable Bowel Syndrome

* $p < 0.05$

** $p < 0.001$

Table 2
Operational Definition and Internal Consistency of SUDI Subscales

Subscale	Cronbach α	Item #	Contents
Urination			
SUDI-UCHR (problematic physical characteristics of urine)	0.717	4	Dark or yellowish color, high turbidity, strong odor and foamy features of urine
SUDI-URET (decreased frequency and volume in urination)	0.554	4	Infrequent urination (day and night) and nocturia. Relatively decreased total volume of urine. Experiencing less urinary urgency
SUDI-UDIS (urinary discomfort or discomfort micturition)	0.625	5	Frequent experience of hesitancy, straining and residual urine sense (feeling of incomplete urination). Dark color and decreased volume when in bad shape.
Defecation			
SUDI-IRRB (irritability of bowel movement)	0.803	6	Frequent changes in bowel habits (constipation or diarrhea) from spicy, oily, dairy and flour-based food. Frequent diarrhea. Defecation urge from food intake. Hard to hold the defecation urge.
SUDI-FCON (functional constipation)	0.730	6	Frequent use of dietary supplements and laxatives for easy defecation. Hard stools. Increased frequency of constipation and decreased frequency of defecation. Tenesmus (feeling of incomplete evacuation) and residual feeling after defecation. Full and tight feeling and bloating (gas swelling) in lower abdomen.
SUDI-ANMD (defecation anomaly discomfort or regularity of bowel movement)	0.700	4	Discomfort from defecation rhythm anomaly or regularity (fixed time every day) of bowel habit. Rapidity of feces dumping.

Three items questioning urinary incontinence, painful micturition and slowing micturition velocity from aging were deleted based on preliminary study, since these were related with specific disease not Sasang type-specific pathophysiological symptoms. As a result 13 items from original 16 items were selected for urination-related three subscales of SUDI.

As for the defecation-related three SUDI subscales (Table 2), SUDI-IRRB, SUDI-FCON and SUDI-ANMD were finalized after deleting five ambiguous questionnaire items, adding one more uneasiness measuring items to SUDI-ANMD, dividing one item questioning changes of defecation habit into two items and modifying two items in SUDI-IRRB, which made final 16 items for defecation-related three subscales of SUDI based on results of preliminary study.

SUDI-IRRB represents irritability of bowel movement showing frequent changes of bowel habits from environmental influences, and SUDI-FCON measures functional constipation, residual feeling after defecation, decreased frequency of defecation, increased use of laxatives and tight feeling in lower abdomen. The high score of SUDI-ANMD means high regularity of bowel movement and increased discomfort from irregular bowel movement.

3.3. Internal consistency of six SUDI subscales

The Cronbach alpha for measuring internal consistency of six SUDI subscales was shown in Table 2. The internal consistency for SUDI-UCHR, SUDI-URET, SUDI-UDIS, SUDI-IRRB, SUDI-FCON and SUDI-ANMD was 0.717, 0.554, 0.625, 0.803, 0.730, and 0.700, respectively.

3.4. Correlation among six subscales of SUDI

The correlation coefficients among six subscales of SUDI were shown in Table 3. There were significant correlation between SUDI-URET and SUDI-UDIS ($r = -.334, p < 0.05$) as for the urination, and

between SUDI-IRRB and SUDI-ANMD ($r = 0.306, p < 0.05$) as for the defecation. The SUDI-URET of urination is correlated with SUDI-IRRB ($r = -0.394, p < 0.01$) and SUDI-ANMD ($r = -0.411, p < 0.01$) of defecation. The SUDI-FCON of defecation is significantly ($r = 0.363, p < 0.05$) correlated with SUDI-UDIS of urination.

3.5. Correlation between SUDI and Western clinical measures

The correlation coefficient between SUDI and well-validated Western clinical measures were shown in Table 4.

As for the urination, the SUDI-UCHR is significantly ($r = 0.376, p < 0.05$) correlated with BMI, while SUDI-URET and SUDI-UDIS are significantly correlated with UDI-6 ($r = -0.331$ and $r = 0.378$, respectively) and OABSS ($r = -0.510$ and $r = 0.302$, respectively). As for the defecation, the SUDI-IRRB is significantly ($r = 0.444, p < 0.01$) correlated with ROME 3 IBS, and the SUDI-FCON highly ($r = 0.733, p < 0.01$) correlated with ROME 3 FC, which are notable in this study.

The SUDI-UDIS of urination-related discomfort is significantly ($r = 0.295, p < 0.05$) correlated with ROME 3 FC of functional constipation, and the SUDI-FCON of functional constipation is significantly ($r = 0.289, p < 0.05$) correlated with UDI-6 of urogenital distress.

Table 5 showed the differences of SUDI subscale scores in well-validated Western measures, and the SUDI-IRRB is significantly different ($t = -3.963, p < 0.001$) in ROME 3 IBS, which means the similarity of SUDI-IRRB and ROME 3 IBS.

3.6. Urination and defecation characteristics of each Sasang types with SUDI and others

The differences of SUDI, UDI-6, OABSS and ROME 3 FC and IBS among three Sasang type groups were described in Table 6, and there were significant differences between So-Yang and So-Eum Sasang type groups in SUDI-URET, SUDI-UDIS, and SUDI-ANMD, however not is Western clinical measures of UDI-6,

Table 3
Correlation Coefficient Among SUDI Six Subscales

	SUDI-UCHR	SUDI-URET	SUDI-UDIS	SUDI-IRRB	SUDI-FCON	SUDI-ANMD
Urination						
SUDI-UCHR	1					
SUDI-URET		1				
SUDI-UDIS			1			
Defecation						
SUDI-IRRB				1		
SUDI-FCON					1	
SUDI-ANMD						1

Bold represents correlation coefficient over 0.3.

* $p < 0.05$.

** $p < 0.01$.

Table 4
Correlation Coefficient Between Subscales of SUDI and Anthropometrics, UDI, OABSS and ROME3 Criteria.

	BMI	PI	UDI-6	OABSS	ROME-3 IBS	ROME-3 FC
Urination						
SUDI-UCHR	.376*	.283	-.008	-.145	.092	.077
SUDI-URET	-.107	-.132	-.331*	-.510**	-.142	-.074
SUDI-UDIS	.026	.019	.378**	.302*	.198	.295*
Defecation						
SUDI-IRRB	.113	.036	.258	.264	.444**	.052
SUDI-FCON	-.150	-.128	.289*	.111	.218	.733**
SUDI-ANMD	-.113	-.081	.167	.156	.167	-.056

Bold represents correlation coefficient over 0.3.

* $p < 0.05$.

** $p < 0.01$.

*** $p < 0.001$

Table 5
SUDI Subscale Scores Compared to Diagnosis of OABSS and ROME3 Criteria (IBS & FC)

Urination				
OABSS	Negative (n = 30)	OAB (n = 18)	Statistical analysis	
SUDI-UCHR	10.50 ± 2.50	9.89 ± 2.47	$t = 0.823, p = 0.415$	
SUDI-URET	9.33 ± 2.06	8.06 ± 2.69	$t = -1.855, p = 0.070$	
SUDI-UDIS	12.57 ± 2.73	13.67 ± 3.01	$t = -1.302, p = 0.199$	
OABSS	Negative (n = 30)	Grade 1 (n = 5)	Grade 2 (n = 13)	
SUDI-UCHR	10.50 ± 2.50	10.40 ± 2.30	9.69 ± 2.59	$F = 0.477, p = 0.624$
SUDI-URET	9.33 ± 2.06	9.20 ± 2.77	7.62 ± 2.63	$F = 2.610, p = 0.085$
SUDI-UDIS	12.57 ± 2.73	13.80 ± 2.28	13.62 ± 3.33	$F = 0.837, p = 0.440$
Defecation				
ROME-3 IBS	Negative (n = 33)	IBS (n = 15)		
SUDI-IRRB*	17.24 ± 3.10	21.60 ± 4.36	$t = -3.963, p < 0.001$	
SUDI-FCON	15.91 ± 3.17	17.73 ± 4.27	$t = -1.656, p = 0.105$	
SUDI-ANMD	11.55 ± 2.85	12.47 ± 3.68	$t = -0.946, p = 0.349$	
ROME-3 FC	Negative (n = 45)	FC (n = 3)		
SUDI-IRRB	18.76 ± 4.09	16.33 ± 2.89	$t = 1.004, p = 0.321$	
SUDI-FCON	16.38 ± 3.62	18.00 ± 3.61	$t = 1.004, p = 0.321$	
SUDI-ANMD	11.80 ± 3.20	12.33 ± 2.08	$t = -0.284, p = 0.778$	

* $p < 0.05$ **Table 6**
SUDI, UDI-6, OABSS and ROME-3 (FC & IBS) Measures of Each Sasang Type Groups

	So-Yang (n = 21)	Tae-Eum (n = 10)	So-Eum (n = 17)	Statistical analysis
Urination				
SUDI-UCHR	9.71 ± 2.61	10.40 ± 2.72	10.88 ± 2.15	$F = 1.060, p = 0.355$
SUDI-URET*	7.95 ± 2.16	8.90 ± 1.85	9.94 ± 2.54	$F = 3.689, p = 0.033, SY < SE$
SUDI-UDIS*	14.33 ± 2.01	11.50 ± 3.17	12.18 ± 2.96	$F = 5.151, p = 0.010, SY > TE \& SE$
UDI-6	9.70 ± 2.99	8.30 ± 1.83	9.29 ± 3.12	$F = 0.810, p = 0.451$
OABSS (-/OAB)	21 (12/9)	10 (6/4)	17 (12/5)	$\chi^2 = 0.758, p = 0.684$
OABSS (-/gr1/gr2)	21 (12/2/7)	10 (6/1/3)	17 (12/2/3)	$\chi^2 = 1.225, p = 0.874$
Defecation				
SUDI-IRRB	19.29 ± 3.82	18.00 ± 2.94	18.12 ± 4.88	$F = 0.521, p = 0.597$
SUDI-FCON	16.57 ± 3.28	16.00 ± 4.00	16.65 ± 3.94	$F = 0.109, p = 0.897$
SUDI-ANMD*	13.10 ± 2.57	11.30 ± 2.83	10.59 ± 3.47	$F = 3.559, p = 0.037, SY > SE$
ROME 3 FC (-/FC)	21 (19/2)	10 (10/0)	17 (16/1)	$\chi^2 = 1.055, p = 0.590$
ROME 3 IBS (-/IBS)	21 (12/9)	10 (8/2)	17 (13/4)	$\chi^2 = 2.378, p = 0.305$

* $p < 0.05$

OABSS, and ROME 3. The ability of retaining urine (SUDI-URET), urinary discomfort (SUDI-UDIS), and defecation anomaly discomfort (SUDI-ANMD) of So-Yang type (7.95 ± 2.16, 14.33 ± 2.01, and 13.10 ± 2.57) is significantly different from those of So-Eum type (9.94 ± 2.54, 12.18 ± 2.96, and 10.59 ± 3.47, respectively).

4. Discussion

The Sasang type-specific pathophysiological symptoms are pivotal for differentiating Sasang types and Cold-Heat pattern, however development of reliable clinical index for these were not satisfactory till now.^{4,14,15} This study developed SUDI as objective clinical measures for pathophysiological symptoms of urination and defecation based on previously reported systematic review.^{4,15} And we also examined the internal consistency of six subscales of SUDI, attested clinical validity with well-validated Western measures of UDI-6, OABSS, and ROME 3 criteria, and demonstrated its clinical usefulness for differentiating So-Yang and So-Eum Sasang types.

The SUDI and its six subscales were structured based on previous review¹⁵ which has three subscales of SUDI-UCHR, SUDI-URET, and SUDI-UDIS for problematic physical characteristics, ability to retain or hold urination and discomfort micturition of urination, and three

subscales of SUDI-IRRB, SUDI-FCON, and SUDI-ANMD for irritable bowel, functional constipation and defecation anomaly or irregularity discomfort (Table 2). And their internal consistency examined with Cronbach alpha were from 0.554 to 0.803 which are acceptable for clinics.

The urination and the defecation are interrelated each other, and make up excretory function of a person as a whole (Table 3). The retention of urine (SUDI-URET) is negatively correlated ($r = -0.334, p < 0.05$) with discomfort micturition (SUDI-UDIS), and the irritable bowel (SUDI-IRRB) is positively correlated ($r = 0.306, p < 0.05$) with defecation anomaly discomfort (SUDI-ANMD). The ability to hold urine (SUDI-URET) is negatively correlated with irritable bowel movement (SUDI-IRRB) ($r = -0.394, p < 0.01$) and defecation anomaly discomfort (SUDI-ANMD) ($r = -0.411, p < 0.01$), and the functional constipation (SUDI-FCON) is positively correlated ($r = 0.363, p < 0.05$) with urinary discomfort (SUDI-UDIS).

The subscales of SUDI are significantly correlated with western clinical measures (Tables 4 and 5). As for the urination, SUDI-URET and SUDI-UDIS scores were significantly correlated with UDI-6 ($r = -0.331$ and 0.378 , respectively) and OABSS ($r = -0.510$ and 0.302 , respectively). And as for the defecation, there were significant correlation between SUDI-IRRB and ROME 3 IBS ($r = 0.444, p < 0.01$) and SUDI-FCON and ROME 3 FC ($r = 0.733, p < 0.01$). These

might mean that the subscales of SUDI might be used for integrative intervention of traditional Eastern and Western orthodox medicine. However problematic physical characteristics of urine (SUDI-UCHR) and anomaly discomfort in defecation (SUDI-ANMD) were found to encompass unique ideas of traditional Korean medicine (Tables 4 and 5).

The problematic characteristics of urine (SUDI-UCHR) showing high turbidity, strong odor, and foam (Table 2) is positively correlated with BMI ($r = 0.376, p < 0.05$) which might denote obesity and metabolic syndrome of Tae-Eum Sasang type,^{15,34} Heat pathogen-related clinical symptoms of traditional East-Asian medicine, and Hot subgroup of Sasang typology.¹⁴ The SUDI-UCHR and SUDI-FCON might be used for the differentiation of the Cold-Heat subgroup of Sasang typology in combination with SDFI and Body Mass Index¹⁴ when further clinical studies were provided on it.¹⁵

There also were correlation between discomfort micturition and functional constipation, and this might be an interesting findings need further studies in integrative Eastern–Western medicine (Table 4). The discomfort micturition (SUDI-UDIS) which might related with Heat syndrome (or pathogen) has correlation with Functional Constipation of ROME 3 FC ($r = 0.295, p < 0.05$), and the functional constipation (SUDI-FCON) also has correlation with urogenital distress of UDI-6 ($r = 0.289, p < 0.05$).¹⁵

The clinical usefulness of SUDI subscales for Sasang type differentiation was scrutinized, and there were significant differences between So-Yang and So-Eum Sasang types in SUDI-URET, SUDI-UDIS, and SUDI-ANMD (Table 6). Nevertheless, interestingly, the UDI-6, OABSS, and ROME 3 criteria of Western medicine could not show the differences among Sasang types (Table 6).

And, the results in current study are consistent with previous clinical studies on Sasang type-specific pathophysiological symptoms. Previous studies showing infrequent nocturia of So-Eum type,³⁵ frequent residual urine sense of So-Yang type,¹⁷ and high life satisfaction from regular bowel movement of So-Yang type³⁶ might be related with retention capacity of urine (SUDI-URET), discomfort micturition (SUDI-UDIS), and anomaly discomfort (SUDI-ANMD), respectively.

The So-Eum Sasang type was proposed to have good excretory function of urination and defecation when compared to So-Yang type in Jema Lee's book, Longevity and Life Preservation in Eastern Medicine.^{7,15} This might explain the findings that So-Eum type has high capacity of holding urine (high SUDI-URET), infrequent discomfort with micturition (low SUDI-UDIS), and fewer uneasiness from defecation irregularity (low SUDI-ANMD) in current study (Tables 2 and 6). And, the comments of Jema Lee⁷ that the uneasiness from irregular rhythm of defecation is the typical clinical symptom for identifying health problems of So-Yang type person might be recognized as that the high score of SUDI-ANMD is an representative clinical index for health problems of So-Yang Sasang type.¹⁵

The SUDI as for the pathophysiological clinical symptoms⁴ exposed significant differences between So-Yang and So-Eum Sasang types in this study and might be used for the Sasang type differentiation in clinics.^{6,15} In previous studies, the psychological temperaments of Extraversion, Novelty-Seeking and Harm-Avoidance of Cloninger, Behavior Activation and Inhibition of Gray, and Sasang Personality Questionnaire (SPQ) showed difference between So-Yang and So-Eum Sasang types.^{8,9} The physical features of Body Mass Index and Ponderal Index exhibited differences between Tae-Eum and So-Eum Sasang types, and pathophysiological characteristics of Sasang Digestive Function Inventory (SDFI)¹² and autoimmune reactivity^{4,6} revealed differences between Tae-Eum and So-Eum Sasang types.⁶

The pathophysiological symptoms of urination and defecation are pivotal for Sasang type differentiation and subgroup identification of Sasang typology, however these are hard to be standardized

for the lack of objective comparison with other persons'. This study has made objective measures for excretory function of Sasang typology, yet still has limitations for general use in clinics.

First, large numbers of patients or clinically diagnosed patients of excretory functional problems would be needed to confirm the findings in this study. Although previous clinical reports supported results of current study,^{17,35,36} SUDI subscale score differences between Sasang types along with age and gender validity is required for general use in clinics.

Second, the clinical usefulness of SUDI for identifying pathologic pattern should be examined, since notable correlations among SUDI-UCHR, SUDI-FCON, Cold-Hot subgroup of Sasang typology¹⁴ and metabolic syndrome³⁴ were suggested.¹⁵ SPQ, SDFI, and BMI were shown to be clinically useful for differentiating Col-Hot subgroup of Sasang typology,^{14,37} and the SUDI might increase the sensitivity and specificity when combined.

Last but not the least, clinical study from East-West integrative medicine perspective is guaranteed to examine the clinical usefulness of Sasang typology on digestive system diseases and treatments. The SDFI of digestive function was found useful for the diagnosis and treatment of function dyspepsia in clinics.¹² As for the function gastrointestinal disease of irritable bowel movement and functional constipation, SUDI-IRRB and SUDI-FCON in combination with ROME 3 criteria might be clinically useful for applying personalized treatment of medical herbs and acupuncture.^{15,34}

This study developed and validated clinical measure of SUDI for excretory function of Sasang typology. The SUDI would be useful for diagnosing Sasang types of a person and analyzing Sasang type-specific treatment effects with further studies using increased number of participants and clinical patients of related diseases.

Conflict of interest

The authors declare no conflicts of interest.

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Data availability

Data will be made available on request.

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