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Development and Validation of a Health Status Scale for Korean Hypothyroid Patients

SoonGyo Yeoum^{1*} and KiSook Kim²

¹Department of Nursing, Seoil University, 28, Yongmasan-ro 90 gill, Jungnang-gu, Seoul - 02192, Korea; yeoumsg @ seoil.ac.kr

²Department of Nursing, Changwon National University; kskim2011@changwon.ac.kr

Abstract

Objectives: The signs and symptoms of hypothyroidism are nonspecific. The present study was aimed to develop a health status scale for Korean hypothyroid patients and evaluate its validity and reliability. **Methods/Statistical Analysis:** It was designed as a methodological study with a sample of 171 hypothyroid patients at a university hospital in Seoul, Korea. Data analysis was conducted using item analysis, Cronbach's α , correspondence analysis, test-retest reliability, and confirmatory factor analysis. **Findings:** To ensure construct validity, only those items with corrected item-total correlations higher than .30 in item analysis were selected. Cronbach's α ranged from .74 to .85, and intra-class correlation coefficients, from .40 to .85. Correspondence analysis revealed no significant differences (t = .43, p = .67) between the average values of the first (2.46 ± 0.49, δ ± SD) and the second (2.42 ± 0.63) measurement. To ensure convergent validity, only those items with factor loadings .4 or higher were selected in confirmatory factor analysis; construct reliability was .93, and average variance extracted, .54. Finally, 30 items in 6 categories were selected. **Application/Improvements:** This scale is very useful for individual assessment of thyroid failure and treatment monitoring. It was categorized according to body are. Thus, it can simultaneously assess health status of hypothyroid patients and identify specific challenges that need to be addressed by nursing staff.

Keywords: Health Status, Hypothyroidism, Reliability, Scale, Validity

1. Introduction

Thyroid hormones have a broad impact on human organs. Thus, when thyroid function decreases, patients experience a wide range of physical signs and symptoms, affecting the thyroid gland itself and the cardiovascular, musculoskeletal, nervous and gastrointestinal systems, as well as the metabolism, skin, and periocular area; reduced thyroid function also has psycho-emotional effects¹⁻⁴.

Hypothyroidism may be difficult to discern, because its symptoms can vary among patients with the same type of hypothyroidism, may not be severe, and are frequently observed in all age groups^{5, 6}. Most people tend to overlook hypothyroidism as symptoms may be similar to menopausal and aging symptoms⁷. In Korea, an estimated 69% of women are considered menopausal symptoms as a natural aging process⁸. Moreover, the elderly are

prejudiced regarding the presence of aging symptoms. For example, the elderly most commonly think that 1) having a variety of symptoms in old age is natural, 2) the symptoms of old age are difficult to treat, and 3) they should adapt their lives around their symptoms rather than treat them⁹. Therefore, symptoms of hypothyroidism can easily go undetected.

The number of patients with hypothyroidism has increased by 6.8% in a year in Korea within the last 5 years¹⁰. The cause of primary hypothyroidism is unknown in more than 50% of cases. However, thyroid autoimmune antibodies found in 70% of hypothyroid patients are considered the common cause¹¹. It is also found in about 10% of eu-thyroid subjects, and subclinical hypothyroidism advances to overt hypothyroidism in nearly 5% of all cases each year¹²⁻¹⁶. These findings highlight the continuously increasing prevalence of hypothyroidism.

Thyrotropin (TSH), a sensitive indicator of thyroid status, causes a change in lipid levels even when only slightly increased. Thus, if hypothyroidism is neglected, it can seriously affect the cardiovascular system, thereby increasing the risk of hypercholesterolemia, hypertension, and atherosclerosis, or worsen current cardiovascular risk^{2,17,18}.

To date, no Korean scale has been developed to identify hypothyroidism. The Chronic Thyroid Questionnaire (CTQ)¹⁹, which contains 104 questions comprising problem lists and symptoms related to hypothyroidism, has been used abroad. Some items of this scale were deliberately overlapping, for example 'feeling generally worn out, 'feeling less energetic,' and 'feeling slower physically were all included. The validity of the CTQ has not been assessed because this list has been expanded through interviews between endocrinologists and patients, and hence, findings obtained using the CTQ cannot be generalized.

The 12-item Thyroid Symptom Questionnaire (TSQ)²⁰ measures residual symptoms and complaints after thyroxine replacement therapy. This tool includes only residual symptoms after treatment, and it has not been validated. Thus, the use of this tool in the general population to detect hypothyroidism is not appropriate.

The Thyroid-dependent Quality of Life Questionnaire (ThyDQoL)²¹ measures hypothyroidism's broad influence on human organs. No information regarding the time since diagnosis or the present thyroid status of the interviewees is provided; only information about functional aspects of daily life was collected. Therefore, this instrument is not sensitive enough to detect the thyroid status of patients with a wide range of variation.

The existing tools focused on the functional aspects of daily life or the partial aspects related to the impact of the hormone; further, the measurements overlapped. Thus, they could not cover the broad impacts of hormones, and type and frequency of hypothyroidism symptoms in each study are diverse .22 It is therefore necessary to develop comprehensive tools whose validity and reliability are tested more completely, based on extensive patient reports. It is also necessary to determine whether Korean patients have symptoms and problems similar to those reported elsewhere, since textbooks use data from populations that are largely Caucasian. Hence, this study aims to develop a tool for measuring the health status of Korean hypothyroid patients and to verify its reliability and validity.

This tool in the present paper included the general symptoms related to hypo-metabolism and the changes caused by an accumulation of polysaccharides. It also measured the overall hypo-metabolic statuses of patients based on the broad impact on peripheral tissues, and was categorized according to the body area. Thus, it can be used to assess care-related issues and also ensure the quick identification of a change from the eu-thyroid state to hypothyroidism or from hyperthyroidism to hypothyroidism because of natural causes or as a result of the treatment.

Methods

This work was designed as a methodological study to develop a health status scale for Korean hypothyroid patients (HSS-KH). The measurement scale was constructed utilizing health-status-related questions, and the questionnaire's validity and reliability were verified.

2.1 Development

researchers reviewed records and existing questionnaires, then asked the experts, to identify signs, symptoms, and health problems caused by hypothyroidism^{1,3,4,12-14,18-25}. After reconfirming issues frequently observed in questionnaire content as reported in the literature, the questions were categorized according to each body system and simplified. Literature review was based on journals of endocrinology related to the thyroid gland as well as other relevant journals and books.

Content validity was investigated through inter-subjective decisions by experts to determine whether the questions in the scale properly represented the attribute or concept they were designed to measure. The Content Validity Index (CVI) was then estimated after asking experts to grade the relationship of the contents to hypothyroidism. Only questions with a Content Validity Index (CVI) score .60 or higher were selected for inclusion in the questionnaire.

The questions were then more precisely revised and corrected in a review of all the open-ended questions, based on empirical opinions from experts on questions with similar definitions, and unrelated and unusual questions. The experts were two medical doctors specializing in thyroid disease for 25-30 years and one nurse who had cared for patients with thyroid diseases for over 5 years at a university hospital in Seoul. A self-report scale was then developed that employed a 5-point Likert scale, where a high score signifies poor health status.

Considering the previous studies²⁶⁻³⁰ related to the health status and thyroid gland to identify the health status issues, it is essential that physical and mental problems accounted for a large portion of the health concepts identified by the patients and that patient can evaluate a significant portion of their own health status through identification of these problems. Accordingly, we operationalized health status as a hypothyroid patient's perception of abnormal physical and mental problems.

2.2 Validation

As in existing studies, the subjects were asked to consider symptoms they experienced and any change in health status at the time of their initial diagnosis or prior to treatment, using the scale. They also had continuously controlled serum thyroid hormone concentrations, as measured using a radioimmunoassay, after being diagnosed with hypothyroidism, using TSH at higher than 4.05 mlU/ L and free thyroxine (T4) at less than 0.85 ng/ dL

The 171 study subjects were selected from patients with hypothyroidism who were given medical care at the endocrine outpatient clinic of university hospitals in Seoul from October 2009 to January 2010. Our analysis was not limited to a particular gender or age group. In all age and sex groups, the autoimmune antibody was observed, which is the main cause of hypothyroidism.

The sample size calculation indicated that a minimum sample size of 134 was required at a significance of 0.05, effect size of 0.3, and 95% power using the G*Power 3.1.2 program. However, to account for dropout, more subjects were recruited.

Given that the signs and symptoms of hypothyroidism are nonspecific²², to establish the construct validity of the scale, the items were tested using item analysis, which is used to evaluate whether each item meets the original purposes of measuring or diagnosing possible issues. Item analysis using classical test theory aims to identify the items with internal consistency and exclude the items which do not satisfy this criterion³¹. The correlation coefficient between individual items and total one was evaluated. Items with an item-total correlation .30 or less were excluded (item discrimination)³².

Cronbach's α was chosen to test internal consistency, using a cut-off of .60³³. Correspondence analysis was evaluated by comparing total mean values measured twice. The intra-class correlation coefficient (ICC) reflects the degree of reliability as follows: excellent, > .75; fair to

good, .40–.75; and poor, < .40³⁴. Considering that having a large number of cases is not necessary for calculating ICCs³⁵ and the possible return rate, the researchers sent the questionnaire to 80 subjects. While 51 questionnaires were returned (response rate: 64%), 49 complete questionnaires were used for test-retest reliability.

Convergent validity was examined confirmatory factor analysis (CFA). Only questions whose factor loading was .4 or higher and significance level was less than .05 were selected³³. The health status scale for Korean hypothyroid patients (HSS-KH) was developed on the basis of the results of the above validity and reliability tests.

2.3 Data collection and Analysis

The data were collected anonymously in an outpatient waiting room over a 15-minute period by experienced research staff after they explained the purposes and intentions of the research and obtained informed consent from the subjects. Prior consent to participate was received from subjects, who were informed that they would be required to complete a questionnaire after a medical examination in the outpatient clinic, fill out the same questionnaire again when delivered to them 2 weeks later, and then return it to the researcher by using the enclosed postage stamp and envelope.

Examination of blood test results at the time of diagnosis determined whether individuals were appropriate subjects for the present study. The subjects were informed that the data would be used for research purposes only, and that personal information would be kept confidential. They were offered the right to refuse participation.

The collected data were analysed using SPSS-WIN (18.0) and AMOS (19.0). Corrected item total correlation coefficients and *Cronbach's* α values were calculated, and t-test, ICC, CFA were used for analysis.

3. Results

3.1 Scale Development

The initial questions were constructed for the complete scale based on the results of the literature review and experts' opinions. Forty questions in 7 categories were developed after revising the content to eliminate jargon and ambiguity.

Table 1. Item Analysis of the Health Status Scale for Hypothyroid Patients

	Corrected	
Items	Item-Total	
Items	Correlation	
29. I have difficulty in concentrating.	.71	
21. I feel some muscle weakness.	.66	
28. I feel blue.		
	.63	
33. I am losing interest.	.61	
27. My reaction time is getting longer.	.60	
8. My hair has lost its shine and is rough.	.58	
14. I experience puffiness in my face (puffy	.58	
hands or legs).	F0	
23. I feel stiffness in my muscles.	.58	
26. I am moving more slowly.	.58	
30. I feel that my memory function is	.57	
declining.	5.0	
11. My skin is dry.	.56	
24. I have pins and needles in my arms and	.56	
legs.		
31. My speech has decreased in speed.	.56	
13. My face is pale.	.55	
20. I feel tired.	.55	
15. I have been getting more and more	.52	
wrinkles (palm, sole, nose, lips).	50	
16. I find puffiness around my eyes.	.50	
7. My skin is thick and hardened.	.48	
9. My hair (eyebrows) is/are falling out.	.48	
32. I suffer from insomnia.	.48	
1. I have dizziness.	.47	
2. I have experienced weight gain.	.46	
10. My nails grow slowly.	.46	
3. I have a headache.	.44	
38. My tongue feels thick.	.43	
39. My tongue is enlarged.	.40	
40. My pronunciation is unclear.	.40	
6. My skin is cold.	.37	
17. My appetite is decreasing.	.37	
35. I have a hearing problem.	.36	
37. My voice is hoarse.	.35	
19. I often suffer from constipation.	.34	
5. I am sweating less.	.33	
4. I can't tolerate the cold.	.31	
36. I suffer from ringing in the ear.	.31	
34. My sense of smell has diminished.	.21†	
Cronbach's α	.92	

N = 171 †The italicized item was eliminated because its r value was below .30.

Questions 12, 18, 22, and 25 yielded CVI scores less than .60 and were hence eliminated Table 1. Accordingly, the scale, containing 36 items, was developed.

3.2 Construct Validity

The subjects comprised 154 women (90.1%) and 17 men (9.9%). The majority were in their 50s (n=59, 34.5%), In terms of BMI, most were classified as normal weight (48.2%). Duration since the onset of hypothyroidism was 2 to 5 years for the majority (78.9%). Most of the subjects had normal thyrotropin levels (44.3%), normal free-T4 levels (84.7%), and normal free T3 levels (98.5%).

Construct validity was evaluated based on the corrected item-total correlation(r), which ranged between .21 and .71. Question 34 had an r value below .30 and was hence eliminated. These data confirm the scale's validity in terms of its overall construction .

3.3 Internal Consistency

An adequate level of reliability was thus confirmed, with *Cronbach's* α values between .74 and .85 by category.

Table 2. Characteristics of Hypothyroid Subjects

Classification	n(%)	Classification	n(%)
Gender Male Female	17(9.9) 154(90.1)	Latest TSH (mIU/mL) <0.17 0.17- <4.05(normal) ≥4.05	42(34.4) 54(44.3) 26(21.3)
Age(y) <30 30-<40 40-<50 50-<60 ≥60	4(2.3) 24(14.0) 34(19.9) 59(34.5) 50(29.2)	Latest free T4(ng/dL) <0.85 0.85- <1.86(normal) ≥1.86	6(3.7) 138(84.7) 19(11.7)
BMI †(Kg/m²) <18.5(Underweight) 18.5-<23(Normal) 23-<25 (Overweight) ≥25 (Obese)	6(3.7) 79(48.2) 39(23.8) 40(24.4)	Latest free T3(ng/dL) < 0.78 0.78- <1.82(normal) ≥1.82	64(98.5) 1(1.5)
Onset of disease(y) <1 1-<2 2-<5 ≥5	12(7.0) 21(12.3) 135(78.9) 3(1.8)		

N = 171

[‡] The following questions were excluded by the content validity verification.

^{12.} My face gets flushed.

^{18.} I suffer from nausea and vomiting.

^{22.} I have myalgia.

^{25.} I have muscle cramps.

[†]BMI (kg/m²): body mass index

[‡] Reference range: TSH, 0.17–4.05 mlU/ L: T4, 0.85–1.86 ng/dL (TSH kit, free T4 RIA kit, Immunotech)

Table 3. Internal Consistency and Test-retest Reliability of Health Status Scale in Hypothyroid Patients

Domains	Items	Mean ± SD	Corrected Item Total Correlation	Cron bach's α	ICC	95% CI
	1. I have dizziness.	2.28 ± .93	.45		.82	.7089
GA†	2. I have experienced weight gain.	2.28 ± 1.22	.44	.75	.85	.7591
GAI	3. I have a headache.	2.28 ± 1.02	.43	./5	.84	.7390
	4. I can't tolerate the cold.	.43		.63	.4277	
	5. I am sweating less.	2.08 ± 1.12	.33		.40	.0254
	6. My skin is cold.	2.46 ± 1.17	.42		.56	.3373
	7. My skin is thick and hardened.	1.96 ± 1.08	.57		.54	.3171
	8. My hair has lost its shine and is rough.	2.40 ± 1.33	.57		.69	.5182
	9. My hair (eyebrows) is/are falling out.	2.32 ± 1.28	.52		.70	.5282
SA‡	10. My nails grow slowly.	1.74 ± 0.97	.53	.83	.50	.2669
511.	11. My skin is dry.	2.98 ± 1.33	.60		.76	.6186
	13. My face is pale.	2.40 ± 1.28	.53		.82	.7090
	14. I experience puffiness in my face (puffy hands or 2.35 ± 1.16 legs).				.65	.5079
	15. I have been getting more and more wrinkles (palm, sole, nose, lips).	2.25 ± 1.10	.58		.80	.6789
OP§	16. I find puffiness around my eyes	2.24 ± 1.05			.76	.6186
GI¶	17. My appetite is decreasing. 2.18 ± 1.01				.83	.7190
Gig	19. I often suffer from constipation.	2.34 ± 1.12			.69	.5081
	20. I feel tired.	3.86 ± 1.05	.57		.73	.5784
	21. I feel some muscle weakness.	3.20 ± 1.08	.67		.62	.4177
NM‡‡	23. I feel stiffness in my muscles.	2.66 ± 1.24	.61	.81	.70	.5282
	24. I have pins and needles in my arms and legs.	2.76 ± 1.18	.65		.72	.5584
	26. I am moving more slowly.	2.38 ± 1.20	.51		.75	.5985
	27. My reaction time is getting longer.	2.46 ± 1.11	.63		.55	.3272
	28. I feel blue.	2.55 ± 1.19	.67		.67	.4880
	29. I have difficulty in concentrating.	3.27 ± 0.92	.77		.73	.5784
PP§§	30. I feel my memory function is declining.	3.28 ± 1.03	.65	.85	.64	.4378
	31. My speech has decreased in speed.	2.31 ± 1.04	.52		.76	.6186
	32. I suffer from insomnia.	2.66 ± 1.32	.44		.82	.7088
	33. I am losing interest.	2.94 ± 1.26	.66		.63	.4378
	35. I have a hearing problem.	1.92 ± 1.11	.49		.74	5884
	36. I suffer from ringing in the ear.	1.72 ± 0.98	.36		.63	.5277
OT	37. My voice is hoarse.	2.41 ± 1.31	.39	.74	.65	.4579
	38. My tongue feels thick.	1.38 ± 0.53	.60	./4	.83	.7089
	39. My tongue is enlarged.	1.27 ± 0.45	.66		.50	.2669
	40. My pronunciation is unclear.	.59		.85	.7591	

†GA: General Aspects; ‡SA: Skin and Appendages; §OP: Ophthalmopathy; ¶GI: Gastro-Intestinal System; ‡‡NM: Neuromuscular System; §§PP: Psycho-emotional Problems; !!!|OT: Other Problems

ICC: Intra Class Correlation Coefficient; CI: Confidence Interval

N = 171(In case of ICC, N=49)

One and two questions were developed for OP and the GI, respectively, therefore their Cronbach's a values could not be calculated or were not significant, so they are not described in Table 3

Correspondence analysis: (before: Mean δ (distance mean) \pm SD (2.46 \pm .49), after: Mean δ \pm SD (2.42 \pm .63), t = .43, p = .67.

3.4 Correspondence Analysis

This analysis revealed no significant differences (t = .43, p = .67) between the first (2.46 \pm 0.49, δ \pm SD) and the second (2.42 \pm 0.63) average values of the measurement. It was confirmed that the subjects responded similarly to the both measurements.

3.5 Test-Retest Reliability

ICC Values of 13 out 35 questions were .75 or higher (excellent). Those of 22 questions were .40 to .75 (fair to good). ICCs were found to be between .40 and .85. Accordingly, the test-retest reliability of this scale was verified

3.6 Convergent Validity

It was assumed that the variables in confirmatory factor analysis were not intercorrelated. Four questions (5, 35, 36, and 38) whose factor loading was below .4 were excluded. The total CR (critical ration) was significant (\geq 1.965. p<.05), average variance extracted (AVE) was .54, and construct reliability was .93. Convergent validity of the scale was thus confirmed at the reference level or higher ($x^2=771.761$, p<.001, GFI= .97, AGFI= .93, CFI=.92, RMSEA=.08) Figure 1, Table 4>. In this way, the HSS-KH was validated.

4. Discussion

This study developed a scale assessing the health status of hypothyroid patients, verified its reliability and validity, and found it to contain 30 items in 6 categories.

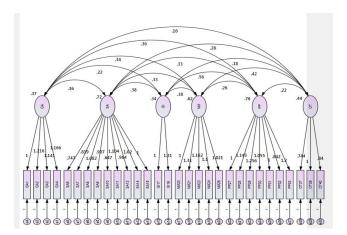


Figure 1 Confirmatory factor Analysis for convergent validity.

This tool included extensive measures of patient-perceived hypothyroid status and categorized according to body area. Patients were asked questions about general aspects and skin & appendages both which were caused by a low metabolism, ophthalmopathy caused by the accumulation of glycosaminoglycan, their gastrointestinal problems due to fluid stagnation, neuromuscular problems caused by muscle weakness or peripheral neuropathy, psycho-emotional problems due to changes awareness or various emotions, and any other problems thought to be caused by a change to the sensory organs. After the process of item development, including the content and type of each item, its content validity was evaluated by experts' clinical opinions.

Item analysis is a useful method for testing construct validity when the number of questions does not exceed 80. The histogram of the items with an item-total correlation of .30 or higher showed a normal distribution, thereby showing that the overall construction of the instrument was valid. The adequate level of inter-item correlation coefficients in the subcategories indicated that this scale has internal consistency and high ICC on all items, and is therefore stable.

Convergent validity of the tool was verified and considered acceptable when construct reliability was .7 or higher and AVE was .5 or higher³⁶. The standardized estimates, CR, AVE, and construct reliability with a higher reference level showed this instrument has convergent validity. Therefore, it can be concluded that this scale is appropriate for measuring the health status of hypothyroid patients.

Four following questions were excluded from this scale in the examination of content validity. Malar flush was observed in only about half of the subjects in a previous study. Nausea and vomiting was also seen in only 13% of the patients in a previous sample Schick musculoskeletal problems, including myalgia, varied by 8–82% in hypothyroidism and 18–84% in hyperthyroidism in the previous study 22. We concluded that this category did not have adequate discriminant power to identify hypothyroidism alone. Also, the sensitivity of muscle cramps was low in previous research (17.6%) 5.

Problem with sense of smell had a low corrected itemtotal correlation and was eliminated by item analysis. If any, this symptom was observed in a very small number of subjects (0.25%) in previous research²².

Of four questions excluded by CFA, sweating issues were frequently observed even in euthyroid subjects as well as in persons with hypothyroidism⁵, but in only half

Table 4. Convergent Validity of Health Status Scale in Hypothyroid Patients

Domains	No. of Items	Unstandardized Estimates	Standard Error	Critical Ration	p	Standardized Estimates	AVE	Construct Reliability
GA	1	1.00				.60		
	2	1.22	.22	5.47	<.001	.57		
	3	1.14	.20	5.65	<.001	.60		
	4	1.17	.24	4.9	<.001	.49		
SA	6	0.75	.15	5.16	<.001	.45		
	7	0.82	.12	6.71	<.001	.6		
	8	1.08	.15	7.16	<.001	.65		
	9	0.91	.14	6.29	<.001	.56		
	10	0.65	.11	6.13	<.001	.54		
	11	1.10	.15	7.19	<.001	.65		
	13	0.96	.14	6.84	<.001	.61		
	14	1.02	.15	6.79	<.001	.61		
	15	1.00				.64		
GI	17	1.00				.51	.54 .93	
	19	1.04	.24	4.28	<.001	.48		02
NM	20	1.00				.65		.93
	21	1.31	.16	8.48	<.001	.78		
	23	1.16	.15	7.74	<.001	.69		
	24	1.1	.15	7.49	<.001	.67		
	26	1.02	.14	7.10	<.001	.63		
PP	27	1.00				.68		
	28	1.14	.12	9.42	<.001	.70		
	29	1.26	.11	11.56	<.001	.84		
	30	1.06	.11	9.98	<.001	.74		
	31	1.00				.63		
	32	0.84	.13	6.35	<.001	.50		
	33	1.2	.12	9.93	<.001	.74		
OT	37	0.74	.13	5.73	<.001	.45		
	39	1.00				.81		
	40	0.84	.09	8.89	<.001	.91		

†Total CR \geq 1.965, p < .05.

 $[\]pm AVE = \sum (Standardized\ estimates^2) \sum (Standardized\ estimates^2) / \{\sum (Standardized\ estimates^2) \sum (Standardized\ estimates^2) + (\sum Standardized\ error)^2 / \{\sum (Standardized\ estimates^2) + (\sum Standardized\ estim$ (∑Standardized error)

 $SCR = (\sum Standardized estimates)^{2}/\{(\sum Standardized estimates)^{2} + (\sum Standardized error)^{2}\}$

⁽ Σ Standardized estimates)²/{(Σ Standardized estimates)² + (Σ Standardized error)² ¶ Goodness of fit: x^2 =771.761, p<.001, GFI=.97, AGFI=.93, CFI=.92, RMSEA=.08.

^{‡‡}Item 5, 35, 36, and 38 were eliminated because their factor loadings are below .40.

^{§§}OP16 is one question in the domain, so it was not included in the model.

of the patients with overt hypothyroidism. Therefore, it is rather considered that, as the disease becomes severe, sweating problems are found less. Hearing problem was not observed frequently in this study nor classified as a classical symptom, and the sensitivity of this problem has also been shown to be low (22%) in existing research⁵. We excluded variables that measured issues with sweating or hearing from the tool. However, Watt et al. classified them as classical symptoms of hypothyroidism. Perhaps these symptoms differ between ethnicities. Tinnitus was excluded in the CFA, but it responded well to treatment¹⁴, and therefore, should be considered actively by nurses when assessing thyroid problems. Thick tongue can be recognized only when pronunciation becomes difficult to follow, and therefore, its factor loading may be low. Consequently, health professionals' perceptions, rather than their patients' perceptions, are considered to result in more accurate measures of this item.

To evaluate existing tools on thyroid disease, Watt et al. examined 75 references from 2,033 studies related to thyroid diseases. The classical symptoms of hypothyroidism based on the classification by the previous systematic search²² are cold intolerance, diminished sweating, oedema (puffiness in face, hands or feet), decreased appetite, nausea/vomiting, constipation, disturbance in peripheral nervous system, hearing problems, change in voice, and enlarged tongue. Widely accepted classical symptoms such as problems with sweating, hearing, and nausea/vomiting were not observed in our subjects. It is thus necessary to consider ruling out these items from the classical symptoms for Korean subjects, on the basis of the current content validity, construct validity, and convergent validity analysis.

In particular, of items included in the present scale our subjects showed a more diverse range of symptoms in the skin & appendage category than Caucasian subjects. This could imply that the results of hormone changes were observed more in the appearance of our subjects than in that of other subjects. ²² Our subjects also had milder gastrointestinal symptoms and similar or more diverse neuromuscular and psycho-emotional symptoms than those in other studies ^{18,22}. In addition, our subjects reported almost no sensory problems such as smelling or hearing.

The HSS-KH is very useful for individual assessment of thyroid failure and treatment monitoring. Furthermore, this instrument, which has been categorized according to body area, can simultaneously assess the health status of hypothyroid patients and identify specific challenges that need to be addressed by nursing staff.

Accordingly, we recommend using this instrument in clinical settings, especially when there are cardiovascular problems, and menopausal and aging symptoms, to classify hypothyroidism symptoms from them. We propose that this tool be used in medical examinations individuals undergo once every second year in accordance with the policy of the National Health Insurance Corporation for the early detection of hypothyroidism. It is expected that this tool can be used to identify age-specific health status through research on youth and the aged.

However, the study is limited by the lack of a control group from a healthy population. Further research also needs to clarify the feasibility of this tool for a larger population because the sample was drawn from only one hospital.

In conclusion, the items in this tool may be used to extensively measure the health status of hypothyroid patients in Korea. This sensitive tool can quickly identify changing hormone statuses and also be used for the early identification of a patient's thyroid status.

Thyroid status should be screened using a tool that covers the impacts on different areas of the body before, after, and during treatment. Healthy life expectancy can be enhanced only when symptoms are continuously monitored using the tool immediately after the symptoms are detected.

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