### **Original Article**

# Validation of a self-monitoring device for estimating 24-hour urinary salt excretion

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Background: The purpose of this study was to investigate the relationship between salt intake and urinary salt excretion and to examine the validity of a self-monitoring device for estimating 24-h urinary salt excretion from overnight urine samples. Methods: Twelve young, healthy female volunteers consumed test meals from days 1 to 14 and estimated urinary salt excretion on days 2–15 by using a self-monitoring device. The salt content of the test meals was as follows: 10 g (days 1–5), 6 g (days 6–8), 13 g (days 9–11), 6 g (day 12), 13 g (day 13), and 6 g (day 14). Results: The average 24-h urinary salt excretion (the ratio of urinary salt excretion to salt intake of the previous day) estimated from the overnight urine samples was as follows:  $8.01\pm1.15$  g ( $0.73\pm0.11$ ) on days 2–6,  $5.86\pm0.85$  g ( $1.01\pm0.15$ ) on days 7–9,  $9.69\pm1.64$  g ( $0.74\pm0.13$ ) on days 10–12,  $6.51\pm1.56$  g ( $1.03\pm0.25$ ) on day 13,  $8.60\pm3.25$  g ( $0.71\pm0.14$ ) on day 14, and  $6.28\pm1.31$  ( $1.05\pm0.22$ ) on day 15. Thus, the salt excretion/salt intake ratio was approximately 0.8 during the high-salt phase and 1.0 during the low-salt phase. Conclusion: The estimation of 24-h urinary salt excretion from overnight urine samples by using a self-monitoring device is a reasonably valid method in this young and healthy female population for detecting daily changes in salt intake.

Key Words: salt intake, urinary salt excretion, self-monitoring device, overnight urine, blood pressure

#### INTRODUCTION

Hypertension accounts for 6% of deaths per year, and its prevention and treatment are a global concern.<sup>1</sup> Based on the National Health and Nutrition Examination Survey in Japan, the prevalence of hypertension is reported to be higher than 30%.<sup>2</sup> The prevalence of hypertension increases with age, and, because the number of elderly individuals in Japan is rising, the determination of adequate strategies for the management of hypertension on a national level is important.<sup>3</sup> Excess dietary salt intake is known to play a major role in the onset and development of hypertension.<sup>4-8</sup> Salt consumption in Japan is higher than that in Western countries, and this tendency of consuming salt-rich diets has not changed in recent years.<sup>9,10</sup> Thus, salt restriction is the most important lifestyle modification for controlling the incidence of hypertension in the Japanese population. However, encouragement or education to reduce salt intake seems insufficient in comparison to that present in Western countries.<sup>2,10</sup>

One of the most important ways to educate people about salt restriction is to accurately evaluate their daily salt intake. Usually, salt intake is assessed using nutrition surveys. However, this method relies on both the honesty and memory of the subject as well as the skill of the investigator; therefore, the accuracy of the results is generally low. Some medical institutions estimate salt intake by using a 24-h urine sample,<sup>11,12</sup> but repeated measurements to evaluate daily salt intake are quite difficult. Further, salt intake estimation using spot urine<sup>13</sup> or the second morning urine<sup>14</sup>, although easy, also require the measurement of sodium and creatinine concentrations, and thus, cannot be performed on a daily basis.

Conversely, a self-monitoring device can estimate 24-h urinary salt excretion from overnight urine samples; moreover, subjects can use this device at home and thus obtain daily measurements.<sup>15</sup> The Working Group for Dietary Salt Reduction of the Japanese Society of Hypertension also recommends the use of this device for evaluating salt intake.<sup>16</sup> Previously, we have reported that the use of this self-monitoring device leads to a decrease in the estimated 24-h urinary salt excretion and seems to be an effective tool for salt-restriction education.<sup>17,18</sup> However, how 24-h urinary salt excretion estimated from over night urine samples reflects the salt intake of the previous day is still unclear. To address this issue, we investigated

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Manuscript received 18 April 2012. Initial review completed 30 May 2012. Revision accepted 18 August 2012. doi: 10.6133/apjcn.2013.22.1.03

#### MATERIALS AND METHODS

#### Subjects

We prospectively enrolled 12 young, healthy female volunteers from the Faculty of Health and Social Welfare Sciences, Nishikyushu University, Japan. Taking the menstrual cycle of each participant into consideration, this study was conducted over 15 consecutive days between the first week of April and the second week of May 2011. The exclusion criteria included subjects with physical, psychological, and social difficulties; those undergoing medical treatment; or those with diseases such as chronic kidney disease. The subjects were given oral and written explanations of the purpose and outline of this study, and written informed consent was obtained from each subject. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki, and it was approved by the Ethics Committee of Nishikyushu University.

#### Intervention schedule

The intervention schedule is shown in Figure 1. From day 1 to 14, all subjects consumed test meals containing varying amounts of salt (sodium chloride) but consistent energy or nutritional content. From day 2 to 15, a self-monitoring device was used to measure the urinary salt excretion from overnight urine samples. The nutrient value of test meals was calculated using the standard Food Composition Table of Japan (Table 1). Nutrient analysis was performed by SRL Corporation (Fukuoka, Japan) to

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determine the actual content of potassium, sodium, and other salts in the test meals. The sodium and potassium content in the test meals were analyzed using the atomic absorption luminous-intensity method and inductively coupled plasma emission spectrometry, respectively. The salt content (g) was calculated using the following formula: "sodium (mg)  $\times 2.54/1000$ ."

The self-monitoring device can estimate 24-h urinary salt excretion from 8-h overnight urine samples.<sup>15</sup> Thus, each subject was asked to urinate and empty their bladder before retiring; and to collect all the overnight urine for 8-h before waking up to estimate the volume and urinary sodium chloride concentration.

Blood pressure was measured twice from the upper arm by an oscillometric device (HEM-7080IT) every morning after urination and by asking the participants to sit still for a few minutes.

During the study period, the subjects were allowed to consume only test meals, tap water, and barley tea. Travelling and physical exercise was prohibited.

#### Test meal

The salt content of the test meals was adjusted to 10 g (days 1–5), 6 g (days 6–8), 13 g (days 9–11), 6 g (day 12), 13 g (day 13), and 6 g (day 14) (Figure 1). Subjects ate breakfast between 0600 and 0900 hours, lunch between 1100 and 1400 hours, and supper between 1800 to 2200 hours. Food items for preparing the test meals was purchased, weighed, and distributed by the study investigator.

#### Self-monitoring device

The self-monitoring device (KME-03) used in this study was developed by the Kawano ME laboratory, Kanagawa, Japan. This device consists of a 1-L urine cup and an



Figure 1. Intervention schedule. Subjects consumed test meals from days 1 to 14. Urinary salt excretion was measured from overnight urine samples from days 2 to 15 using a self-monitoring device. Blood pressure was measured daily throughout the study period.

Calculated value					Analytical value		
Day	Energy (kcal)	Protein (g)	Fat (g)	Carbohydrate (g)	Potassium (mg)	Sodium (mg)	Salt (g)
1	1765	64.2	38.3	275	2260	4213	10.7
2	1765	70.1	36.7	277	2063	4395	11.2
3	1765	65.5	35.7	275	2034	4360	11.1
4	1765	67.8	37.6	274	1956	4296	10.9
5	1765	63.7	41.1	272	2090	4179	10.6
6	1717	65.7	36.4	267	2137	2358	6.0
7	1717	60.5	39.0	273	2353	2264	5.8
8	1717	61.6	37.7	267	2083	2170	5.5
9	1767	70.8	37.1	276	2165	5304	13.5
10	1767	66.2	36.1	274	2060	5132	13.0
11	1767	68.5	38.0	273	2051	5174	13.1
12	1717	61.1	40.5	265	2139	2464	6.3
13	1767	69.0	37.4	274	2332	5214	13.2
14	1717	60.5	39.0	273	2361	2361	6.0

Table 1. Nutrient content of the test meals

Table 2. Characteristics of participants

Characteristics	
Number	12
Age, years	21.3±0.6
Height, cm	158±3.7
Weight, kg	55.0±5.0
BMI, kg/m <sup>2</sup>	22.1±1.8

Values are the means  $\pm$  standard deviation

electrical device with volume and conductivity sensors. The volume sensor, which consists of 50 small resistant chips, measures overnight urine volume in the cup. The sodium chloride concentration was adjusted by a correlation formula such that it was between the value obtained with the ion electrode method and the value for the conductivity method because measurement of concentration by conductivity is affected by other electrolytes such as potassium. The overnight urine volume was measured by the resistance sensor, while the overnight urinary sodium chloride concentration was measured by conductivity sensor; these values were then integrated. The selfmonitoring device estimates 24-h salt excretion from overnight urine samples by using the following formula: Y = 1.95X + 4.5 g/day, where Y is the estimated 24-h urinary salt excretion and X is the sodium content of the overnight urine sample.15

#### **Outcome markers**

The outcome was the measurement of the relationship between salt intake and estimated 24-h urinary salt excretion.

#### Statistical analysis

All values are presented as mean±SD. Differences in the variables were compared using ANOVA and the Tukey–Kramer's HSD test. All data were statistically analyzed using the JMP software program (v 8; SAS Institute, Cary, NC, USA). *P*-values <0.05 were considered statistically significant.

#### RESULTS

Subject characteristics are presented in Table 2. Each subject strictly adhered to the experimental schedule and

consumed all the test meals during the study. The salt content of the test meals per day was as follows:  $10.90 \pm$ 0.25 g (days 1–5),  $5.92 \pm 0.29 \text{ g}$  (days 6–8, day 12, and day 14), and  $13.20 \pm 0.22$  g (days 9–11 and day 13) (Table 1). The mean potassium content was  $2149 \pm 129$  mg, and there was no obvious variation in the potassium content during the 14 days (Table 1). The relationship between the analyzed salt intake and estimated urinary salt excretion from the overnight urine samples is shown in figure 2. The ratio of urinary salt excretion to the salt intake of the previous day (U/S Ratio: urinary salt excretion/salt intake) is shown in figure 3. The mean urinary salt excretion (U/S ratio) was as follows:  $8.01 \pm 1.15$  g  $(0.73 \pm 0.11)$  on days 2–6; 5.86 ± 0.85 g  $(1.01 \pm 0.15)$  on days 7–9;  $9.69 \pm 1.64$  g (0.74 ± 0.13) on days 10–12; 6.51  $\pm$  1.56 g (1.03  $\pm$  0.25) on day 13; 8.60  $\pm$  3.25 g (0.71  $\pm$ 0.14) on day 14; and  $6.28 \pm 1.31$  (1.05  $\pm$  0.22) on day 15. Thus, the salt excretion/salt intake ratio was approximately 0.8 during the high salt phase and 1.0 during the low salt phase.

The blood pressure decreased by  $-2.1 \pm 2.7/-2.5 \pm 3.7$  mm Hg when salt intake decreased from 10 g to 6 g. However, blood pressure did not change significantly when salt intake increased from 6 g to 13 g (mean change:  $0.0 \pm 3.7$  mm Hg in systolic blood pressure and  $-1.2 \pm 2.5$  mm Hg in diastolic blood pressure.

#### DISCUSSION

This study had 2 main findings. Firstly, urinary salt excretion estimated from the overnight urine reflected the salt intake from the previous day. Secondly, the ratio of salt intake to urinary salt excretion estimated from the overnight urine (U/S ratio) was approximately 1.0 when a low concentration of salt was consumed; however, the ratio was approximately 0.8 when a high concentration of salt was consumed. Overall, we observed that the estimated 24-h urinary salt excretion from the overnight urine samples reflected salt intake from the previous day. These results highlight the usefulness of the self-monitoring device as a tool for hypertensive patients to monitor their daily salt intake at home, thus allowing them to manage their daily salt intake.

Approximately 90% of orally ingested salt is excreted in the urine.<sup>19</sup> In the present study, the estimated salt ex



Figure 2. Relationship between salt intake and the estimated 24-h urinary salt excretion from the overnight urine samples



Figure 3. The ratio of salt intake to the estimated 24-h urinary salt excretion (U/S ratio)

cretion was almost 100% of the actual intake in the samples taken during the low-salt concentration phase. On the other hand, the estimated salt excretion was approximately 80% of the actual intake during the high-salt concentration phase. Thus, the high-salt concentration phase seems to provide a reasonable estimation, while the low-salt concentration phase may have overestimated actual salt intake. Conversely, the high-salt concentration phase may underestimate salt intake, whereas the low-salt concentration phase may provide a good estimate of salt intake. Yamasue *et al* estimated 24-h urinary salt excretion from overnight urine samples using a self-monitoring device and reported that the self-monitoring device overestimated salt intake at low-salt concentrations.<sup>15</sup> Therefore, salt intake may be overestimated by the overnight urine collection method when salt intake of the subjects is low. Estimating methods are often associated with a risk of under- or over-estimation, which is a limitation of these methods.

It is believed that sodium homeostasis takes several days when salt intake is altered. However, the estimated 24-h urinary salt excretion during the final 3 days of this study clearly indicated that either high- or low-salt intake during a single day can be detected using this device. Thus, this device can detect daily changes in salt intake and therefore can serve as a useful tool for encouraging salt restriction.

Yamasue *et al* reported the use of a self-monitoring device, with data obtained for 224 subjects whose salt intake ranged between 3 and 20 g/day.<sup>15</sup> Here, we reported

**Table 3.** Relationship between urinary salt excretion and blood pressure

Dev	Salt intake	SBP	DBP	
Day	(g/day)	(mm Hg)	(mm Hg)	
2-6	10.9±0.25	106±7.9	65.2±7.3	
7-9	5.92±0.29	104±6.6	62.8±6.1	
10-12	13.2±0.22	$104 \pm 9.0$	62.9±7.0	
13	6.3	103±9.4	61.4±7.3	
14	13.2	$102 \pm 8.4$	61.3±7.2	
15	6.0	$103\pm9.9$	61 8±9 1	

Values are the means±SD

SBP: systolic blood pressure; DBP: diastolic blood pressure

that the mean urinary salt excretion determined by a selfmonitoring device using overnight urine samples was positively associated with that determined by 24-h home urine sampling (5 samples) in hypertensive subjects whose salt intake ranged between 5 and 14 g/day (r = 0.63, p < 0.01).<sup>17</sup> Thus, we believe that a self-monitoring device can be applied for the estimation of 24-h urinary salt excretion in the Japanese population.

The 24-h urinary salt excretion estimated using overnight urine samples is influenced by the meal composition of the previous night.<sup>20</sup> Therefore, subjects in the present study consumed their meals at a fixed time. Thus, it is assumed that any over- or under-estimation in overnight urine measurements was minimal.

The self-monitoring device cannot measure urinary potassium excretion. Therefore, it is unknown to what degree potassium intake influenced the results of salt excretion. However, the day-to-day variation in potassium intake during the study period was controlled within relatively narrow ranges; further, the potassium content of the test meal was equivalent to the mean Japanese intake. Estimation of urinary salt excretion and urinary potassium excretion using overnight urine measurements could be an important subject for future studies.

Epidemiological studies, such as the INTERSALT study, and other experimental studies have clearly indicated the association between salt intake and blood pressure.<sup>4</sup> Cutler *et al* reported a dose-dependent relationship between salt intake and blood pressure; the reduction of salt intake by 5.8 g (sodium, 2300 mg) was associated with a 5.8/2.5 and 2.3/1.4 mm Hg reduction of blood pressure in hypertensive and non-hypertensive subjects, respectively.<sup>21</sup> In the DASH-sodium study, decreasing salt intake from 8.4 g (sodium, 3300 mg) to 6.4 g (sodium, 2500 mg) in subjects with prehypertension or stage-1 hypertension resulted in a 2.1 mm Hg decrease in the systolic blood pressure.<sup>22</sup> In this study, when the salt intake reduced from 10 g to 6 g, systolic blood pressure decreased by 2.1 mm Hg and diastolic blood pressure decreased by 2.5 mm Hg. However, blood pressure did not change significantly when salt intake increased from 6 g to 13 g. The present study was not an intervention to determine the relationship between salt intake and blood pressure; therefore, we were unable to address this issue.

A limitation of the present study was that we did not conduct a 24-h urine collection. The subjects included young women who agreed to participate because they were sure that the verifications in the study had no gender differences. In a previous study, we did not observe any gender difference in the correlation between the predicted urinary salt excretion using self-monitoring devices and total 24-h urinary salt excretion.<sup>17</sup> Because salt homeostasis may differ according to sex, age, and kidney function, further studies with elderly subjects or hypertensive patients are necessary to address the usefulness of this method as a tool to manage salt intake.

In conclusion, the estimation of 24-h urinary salt excretion from overnight urine samples by using a selfmonitoring device is a reasonably valid method in this young and healthy female population for detecting daily changes in salt intake.

#### ACKNOWLEDGEMENT

Ms Nozomi Sugimachi, Ms Eri Miyazaki and Ms Arisa Yamaguchi for their excellent technical assistance.

#### AUTHOR DISCLOSURES

The authors have no conflicts of interest.

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### Original Article

## Validation of a self-monitoring device for estimating 24-hour urinary salt excretion

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## 自我監測裝置之驗證-測量 24 小時尿鹽排出

背景:本研究之目的是探討鹽攝取量與尿鹽排出量之相關性,並檢查用來測量 24 小時尿鹽排出的自我監測裝置之校度。方法:12 位健康的年輕女性自願者,攝取 14 天的實驗餐並藉由自我監測裝置來測量其第 2 天到第 15 天的尿鹽排出量。實驗餐中所含的鹽量分別如下:10 克(第 1 到 5 天)、6 克(第 6 到 8 天)、13 克(第 9 到 11 天)、6 克(第 12 天)、13 克(第 13 天)、及 6 克(第 14 天)。結果:由隔夜的尿液樣本中,24 小時平均尿鹽排出量分別為:第 2 到 6 天為 8.01 克、第 7 到 9 天為 5.86 克、第 10 到 12 天為 9.69 克、第 13 天為 6.51 克、第 14 天為 8.60 克、第 15 天為 6.28 克。因此,在高鹽攝取期,排出鹽量與(前一日)鹽攝取量之比值約為 0.8;在低鹽攝取期比值為 1.0。結論:在這些健康的年輕女性族群中,藉由使用自我監測裝置來測量 24 小時尿鹽排出量,對於偵測每日鹽攝取的改變是一項合理且有效的方法。

關鍵字:鹽攝取、尿鹽排出、自我監測裝置、隔夜尿液、血壓