Original Article

Validation of Simplified Tools for Assessment of Sodium Intake in Iranian Population: Rationale, Design and Initial Findings

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Abstract

Background: The 24-hour urine sodium excretion is considered the gold standard method to estimate salt intake. However, since this method is not easy to perform, this study developed two instruments, including a semi-quantitative food frequency questionnaire (FFQ) and one spot urine sodium excretion, to assess sodium intake. These two methods were then compared with 24-h urine sodium excretion and twelve 24-h recalls during a year.

Methods: This study was performed on 219 healthy subjects aged ≥ 6 years in 2014 – 2015. The FFQ was completed twice, at baseline and one year thereafter, to examine the reproducibility of the FFQ. The validity of three spot urine sodium excretions in the morning, afternoon, and evening and FFQ for the assessment of sodium intake were compared against the 24-h urine sodium excretion method. Moreover, the validity of FFQ was examined against 24-h dietary recalls for the assessment of total sodium consumption and contribution of food groups to sodium intake. The content validity of the FFQ was estimated by an expert panel including 10 nutritionists.

Results: Based on their nutrients, the final food items were categorized into 11 groups including: 1) dairy products, 2) fruits, 3) vegetables, 4) meat and egg, 5) grains and legumes, 6) mixed dishes, prepared foods, and restaurant foods, 8) nuts and seeds, 8) oils and fats, 9) sauces and desserts, 10) drinks, and 11) others.

Conclusions: Spot urine and a specific FFQ comprising 136 items were used to develop a method for the assessment of sodium intake and contribution of foods to its intake among the Iranian population. This method can be used in large-scale population studies at the national level.

Keywords: Food frequency questionnaire, reproducibility, spot urine, urine sodium excretion, validity, 24-hour urine

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Introduction

ypertension, linked with high salt intake, is identified as the main risk factor for death from cardiovascular diseases (CVDs) in Iran.¹ Reducing salt intake is the most costeffective strategy to decrease the burden of this disorder.^{2,3} According to the World Health Organization (WHO), priorities for a national Iranian salt reduction program will be to determine the current levels and major sources of salt intake among the population.³ Therefore, in order to monitor the effects of salt

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reduction programs, an accurate tool is required to evaluate the current status of salt intake and foods contributing to its levels.⁴

A 24-hour (24-h) urinary sodium excretion measurement is the reference method for estimating daily salt intake in populations.⁵ However, this method is inconvenient, especially when repeated measurements and large-scale epidemiological studies at the national level are involved.^{6,7} Therefore, alternative simple and valid methods have been proposed, including spot urine sodium excretion and different dietary assessment methods.8 While some population studies have confirmed the accuracy of the spot urine sodium excretion technique, 9,10 others have claimed that its accuracy depends on the time of the day when urine samples are collected. 11 However, it may not apply to all populations and cannot estimate the contribution of major sources and food groups in salt intake. Therefore, spot urine collection needs to be coupled with a reliable non-laboratory method of dietary assessment. Compared to other dietary assessment methods, semi-quantitative food frequency questionnaire (FFQ) is a simple and inexpensive tool with low recall bias that can estimate usual dietary intake in large-scale studies. 12 The present study aimed to develop simple and accurate tools for salt consumption assessment. We compared two instruments, i.e. a FFQ for the assessment of sodium intake and spot urine sodium excretion at different times of the day (as a biomarker of sodium intake), with 24-h urine collection (as the reference method for sodium excretion measurement). We also validated the FFQ for evaluation of total consumption and major sources of sodium and contribution of food groups to sodium intake compared to monthly 24-h recalls during a year as a reference method.

Methods

Design and sampling

This cross-sectional study was performed on healthy individuals aged six years or older in Isfahan (Iran) during 2014 – 2015. The FFQ was completed twice, i.e. at the beginning of the study and after one year, to examine its reproducibility. We investigated the validity of three spot urine sodium excretions at different times of the day as an objective method against the reference method (24-h urine sodium excretion). Spot urine collection (including fasting second-void morning, afternoon, and evening urine specimens) and 24-h urine collection were performed on the same day. At baseline and one year after the end of the study, the validity of the FFQ, as a subjective method for sodium intake assessment, was measured against the 24-h urine sodium excretion method

(as the reference method). Twelve 24-h dietary recalls were also completed on a monthly basis during a year as another reference method for validating the FFQ as a tool to assess total sodium consumption and contribution of food groups to sodium intake. Figure 1 illustrates the study design and data collection.

Atotal of 345 participants, including 167 children and adolescents (age: 6-18 years) and 198 adults (age \geq 19 years) were recruited. The initial FFQ was accompanied by a demographic questionnaire and a 24-h dietary recall which were administered by a trained dietitian. The subjects were selected from healthy individuals who visited the clinics of Isfahan Cardiovascular Research Institute (ICRI) for routine check-up. The inclusion criterion was age \geq 6 years, no history of diabetes insipidus, not having a special dietary regimen or fasting at the day and time of sampling, no history of using diuretics, no renal insufficiency, no menstruation, oral contraceptive use, pregnancy or lactation in women, and not having excessive sweating. We excluded the participants who completed less than nine 24-h dietary recalls, not administered

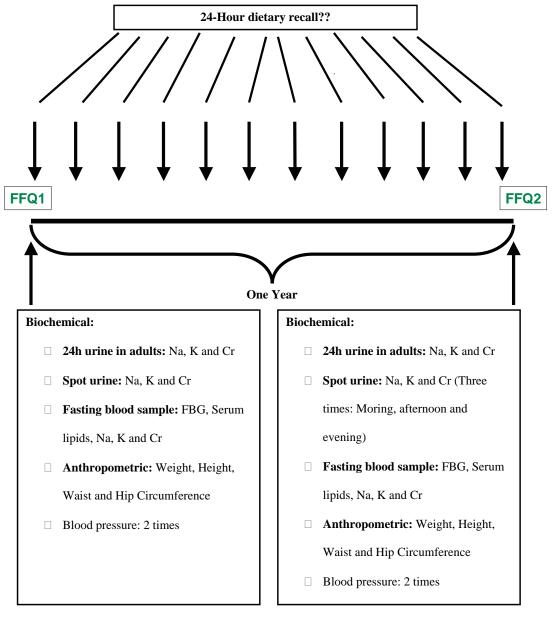


Figure 1. The study design and data collection

second FFO and collected 24-h urine less than 500 mg, miss more than one voiding in a day and had the Cr to body weight ratio less than 20 in men and 15 in women aged < 50 as well as less than 10 in men and 7.5 in women aged \geq 50. The study was approved by the ethics committee of ICRI (a WHO collaborative center). Written informed consent was also obtained from adult participants and the parents of children and adolescents.

Data collection

At baseline, trained health professionals carried out detailed interviews to obtain the required information about the participants' socioeconomic and demographic characteristics. Physical activity was assessed by means of the International Physical Activity Questionnaire.¹³

Anthropometric measurements

At the baseline visit, trained health professionals measured the participants' standing height (while barefoot) and recorded the values to the nearest 0.5 cm. Body weight, measured with the subjects wearing light clothes and no shoes, was also recorded to the nearest 0.5 kg.14

Blood pressure (BP) measurement

BP was measured manually by a trained operator using a mercury sphygmomanometer according to a standard protocol.¹⁵ Before BP measurements, the subjects were asked to sit and relax. Measurements were performed twice on each arm after a five-minute rest. The first Korotkoff sound was recorded as the systolic BP (SBP) and the disappearance of the sounds (V phase) was considered as the diastolic BP. The mean value obtained from the arm with higher BP (DBP). was used in statistical analyses.¹⁵

Urine Samples

At baseline, 24-h urine samples and one fasting second-void urine specimen were collected from the adult participants. At the end of study, 24-h urine samples and three urine spots, i.e. fasting spot in the morning and two non-fasting spots in the afternoon and evening, were collected from the participants. The afternoon and evening spots and 24-h urine samples were collected on the same day and second morning voiding was collected tomorrow morning after finishing 24-h urine collection. Each participant was provided with four containers labeled with their name and a special code. A big sterile plastic container was used for the collection of 24-h urine samples (including all urine from the second void of a particular day to the first void of the next day). Furthermore, three small containers were provided for collecting three spot urine samples in the morning (second voiding urine), afternoon (3-5 P.M.) and evening (7-10 P.M.). The children and adolescents who agreed to collect urine samples were also provided with similar containers at the end of study.

We asked participants to deliver their urine samples to the ICRI laboratory, which meets the criteria of the National Reference Laboratory, in the morning when their 24-h urine collection was completed. In order to obtain fasting second-void morning urine and perform biochemical measurements, the participants were asked to be fasting when they visited the laboratory. Urinary chemical parameters, including urinary sodium, potassium, chloride, and creatinine, were measured in both 24-h urine and spot samples. The accuracy of urinary samples as 24-h specimens was evaluated by measuring the concentration of creatinine with Jaffe method (Technical SMA 12 – 60).¹⁶

Development of the FFQ

Three main components, including a food list, categories of frequency consumption, and a proper portion size for each food item, were first required. The initial food list contained 136 food items which were extracted from the 24-h dietary recalls completed in previous studies in this population.^{17,18} In this study, we evaluated the content and criterion validity of the FFQ.

Face and content validity of the questionnaire were assessed by an expert panel consisting of 10 nutrition experts. After obtaining responses from the experts on the contents of the questionnaire, the most important and correct contents in the FFO were selected by calculating content validity ratio (CVR). The CVR is an item statistic that is useful in rejection or retention of specific items. In CVR, the experts were requested to specify whether an item was necessary for operating a construct in a set of items or not. To this end, we scored each item from 1 to 3 (not necessary, useful but not necessary, and necessary). CVR varies between 1 and -1. Greater levels of content validity exist when larger numbers of panelists agree that a particular item was essential. Using these assumptions, Lawshe developed the following equation:

CVR = (Ne - N/2)/(N/2)

where Ne is the number of panelists indicating "essential" and N is the total number of panelists. 19 In validating the FFQ, a CVR value was computed for each food item. Then, the computed CVR was compared with Lawshe's table.¹⁹ Questions with a higher value in the table were considered valid and other questions were omitted. The content validity index (CVI) for each question was also calculated as the number of experts who gave a score of 3 or 4 (from a range of 1 - 4) to a given question divided by the total number of experts. Questions with CVI values greater than 0.79 were considered valid.19

A pilot study was performed on 25 volunteers to verify the FFQ, evaluate the comprehensiveness of the food list and portion size, and omit any unnecessary questions. We asked our study participants to report any extra foods or portion sizes that had not been included.

To evaluate the criterion validity of the FFQ for assessment of total daily sodium intake, we utilized two reference methods including 24-h urine sodium excretion and twelve 24-h recalls. The twelve 24-h recalls were also used to validate the FFO for determining food item contributions to sodium intake.

The dietary reference method

All participants completed twelve 24-h recalls monthly over a period of one year. The first 24-h recall was completed by a trained nutritionist during the subjects' baseline visit to the ICRI. A trained nutritionist completed the other monthly recalls through phone calls. The 24-h dietary recall interviews obtained information about foods and drinks consumed during the preceding 24-h period. The participants were asked to report the portion size using familiar local utensils.

In the case of mixed dishes, to estimate the serving size of each person, the total amount of cooked food and the number of persons who consumed it were collected and the amount of food intake for each person was calculated. For every food item, the amount of added salt, sugar, and various oils and fats, along with the use of chicken skin and method of cooking were recorded. Additional questions were asked after reporting food consumption to assess easily forgotten foods such as sweets, beverages, and snacks.

Dietary intake analysis

The 24-h dietary recalls were coded by giving a gram weight to every portion reported. Using the Iranian Food Consumption Program (IFCP) designed by the ICRI,²⁰ all dietary data were entered and analyzed. The IFCP calculated nutrient intakes and food group servings for all foods reported in the recalls. It has a research quality nutrient database analyzing nutrients and calories for a variety of food items using the Iranian Food Composition Table,²¹ which was modified based on the USDA National Nutrient Database and translated to Persian. Trained nutritionists assisted in completing and rechecking as well as data entry of the assembled dietary questionnaire.

The reliability of the questionnaire was obtained through a test-retest process which involved completing the FFQ twice (at baseline and one year after the study).

Results

A total of 345 eligible individuals, including 167 children and adolescents (81 boys and 86 girls) and 198 adults (96 men and 102 women) agreed to participate in the study. We included participants who had at least one FFQ and one 24-h urine collection for validation against 24-h urine sample. In addition,

for validating FFQ against the 24-h dietary recall method, the subjects who had less than nine 24-h dietary recalls in a year were excluded. Finally, 146 subjects refused to complete the study (they did not participate in the dietary assessment interview or did not provide 24-h urine and/or spot urine samples). Figure 2 shows the study flowchart.

Development of the FFQ

After the expert panel decisions and the pilot study, we added more kitchen scales to make it easier for the respondents to state their usual portion sizes. In the case of ready food, we used the mean amounts of ingredients estimated by the 24-h dietary recalls in previous studies.^{17,18}

In addition, we categorized the foods with similar nutritional composition including citrus, berries, melons, and leafy vegetables. No other major changes were made to the questionnaire. The respondents were asked how often they consumed the foods in the past year and the frequencies were categorized as seldom/never, once a month, two-three times a month, once a week, two-three times a week, four-six times a week, once a day, two-three times a day, four-five times a day, and six or more times a day.

For calculating gram consumption of each food item, all choices were converted to frequency consumption per day. Portion sizes

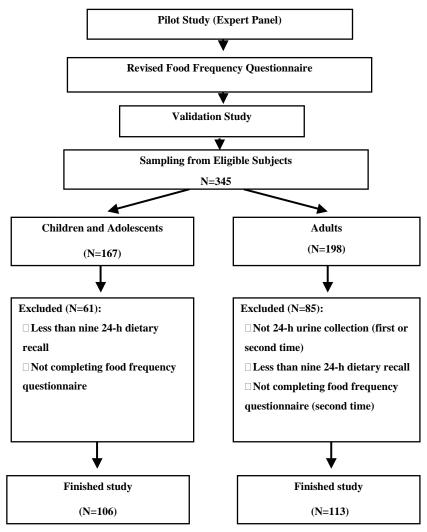


Figure 2. The flowchart of study participants

of consumed foods were converted to grams using household measures. The frequency consumption per day was then multiplied by the defined portion size in grams.¹⁷ Seldom and never were calculated as"zero".

The FFQ included some questions about dietary supplements and five questions about discretionary salt intake (including added salt at the table and salt used for food preparation at home). More precisely, in order to estimate each participant's salt consumption, questions related to salt intake asked about use of a salt shaker, the weight of the salt bags usually bought by the family and the length of time during which it was consumed, and the total number and age of family members. The frequency of consumption of seasonal fruits (during the time they were available) was also asked. Their mean consumption during the year was then calculated based on the length of time each item is generally available in Iran. Food items that did not appear in the 24-h recalls of previous studies but contained nutrients related to BP, especially sodium and seasonal foods, were also added to the FFQ.

Therefore, the food items were finally divided into 11 groups including: 1) dairy products; 2) fruits; 3) vegetables; 4) meat, poultry, fish, and eggs; 5) grains and legumes; 6) mixed dishes, prepared foods, restaurant foods, and fast foods; 7) nuts and seeds; 8) oils and fats; 9) sauces and desserts; 10) drinks; and 11) others. Food items with similar nutrient contents including carbohydrates, fat, protein, fiber, sodium, and energy as well as similar patterns of consumption were categorized into the same group. The list of food groups and some example food items are presented in Table 1.

A method described by Block, et al.²² was used to estimate the

energy and nutrient contents including carbohydrate, protein, total fat, saturated, monounsaturated, and polyunsaturated fatty acids, cholesterol, fiber, sodium, potassium and other minerals as well as vitamins. Contents of each food item and food group based on the FFQ and mean of 24-h recalls. This method calculated the ratio between the amount of a nutrient in each food item and all food items, multiplied by 100.

Discussion

The development of an FFQ for a specific population needs some key aspects including an appropriate food list, 23,24 identifiable portion size,24 and categories of consumption frequency.23 Our FFQ considered the frequently of foods consumed by a substantial segment of the population. These foods contained significant amounts of sodium, food constituents, and other nutrients related to BP and cardiovascular diseases (e.g. glucose and lipid).²⁴⁻²⁶ Similar to other studies, the present FFQ was developed according to the current dietary habits of the population while aggregating the food list based on the foods reported in the 24-h dietary recalls of provided by a previous study.^{27,28} Then, the food list was categorized based on the participants' conceptual framework.^{29,30} Since food consumption and portion sizes may vary in different seasons, a validation study was performed and the 24-h recalls were administrated throughout a year.³¹ The current study recruited different age groups and both genders because age and gender may affect food intake and thus, the validity and reproducibility of the FFO.24

The current study classified several nutritionally similar foods in

Table 1. Food items of food frequency questionnaire

1	Dairy products	Whole milk, 2% fat milk, Low fat milk; High fat cheese (TABRIZ, LIGHVAN, BOLGHARI), Feta cheese; Cream cheese;
		Dough; Kashk; Ice cream; Cream
2	Fruits	Apple; Banana; Date; Orange (in season); Tangerine (in season); Lemon (in season); Kiwi (in season); Grapefruit (in season); Lime (in season); Pomegranate (in season); Persimmon (in season); Plum (in season); Berries (in season); Cherry and Sour cherry (in season); Apricot (in season); Peach, Nectarine and Pear (in season); Fig (in season); Grape (in season); Melons (in season); Fruit juices; Dried fruits (any type)
3	Vegetables	Eggplant and Zucchini (cooked); Carrot (fresh and cooked); Onion (fresh and cooked); Mushroom (fresh and cooked); Green beans, French beans, Okra and Fava-bean (cooked); Mixed vegetables (cooked); Cucumber (fresh); Fresh vegetables; Tomato (fresh, cooked, paste and juice); Lettuce and cabbage (fresh and cooked); Garlic (fresh); Pepper (fresh and cooked); Beetroot (cooked); Turnip (cooked); Spinach (cooked); Corn and Maize (cooked); Pickles; Salty; Canned vegetables; Olive; Carrot juice; Other vegetable juices
4	Meat, Poultry, Fish and Egg	Egg; Chicken (with and without skin); Other poultry; Lamb (with and without fat); Beef (with and without fat); Fish; Canned fish; Other meet
5	Grains and Legumes	Rice (cooked); Whole bread; Refined bread; Baggett; Dried bread; Pasta and Spaghetti (cooked); Lentil and Mung (cooked); Splitpea (cooked); Beans (cooked); Canned beans; Boiled potato; Fried potato
6	Mixed Dishes, Prepared Foods and Fast Foods	Pizza; Hamburger; Cheeseburger; Falafel; Sambusa; Kentaki; Minisandwich; Chelo kebab; Chickek kebab; Stews (Ghameh, Ghormesabzi, and Fesenjan); Salad olivieh; Tahchin with chicken; Khorake mahicheh; Kebab; Koko; Kotlate; Soup; Halim (any types); Broth (any type); Prepared foods (any type)
7	Nuts and Seeds	Walnut; Amond, Hazelnut and Pistachio (raw, salty and roasted); Peanut (raw, salty and roasted); Seeds (raw, salty and roasted)
8	Oils and Fats	Non- hydrogenated vegetable oils; Hydrogenated vegetable oils; Frying oils; Ghee; Olive oil; Tallow
9	Sauces and Desserts	Mayonnaise (low and high fat); Khardal sauce; Soy sauce; Salad sauce; Ketchup; Jelly; Caramel; Chocolate dessert; Other dessert
10	Drinks	Tea; Coffee; Coke, Pepsi (regular); Low calorie soft drink; Industrial fruit juice; Sandis; Beverages (any type); Delester;
11	Others	Biscuit; Keraker; Potato chips; Puff; Popcorn; Sugar; Cube sugar; Nabat and Poolaki; Jam; Cake; Sweets; Cookie; Sohan; Gaz; Chocolate; Candy

the same group. For instance, items such as green beans, French beans, okra and fava-beans were categorized in one group and peach, nectarine, and pear in another. Two groups of meat, i.e. low fat meat and high fat meat, and two groups of fruit juice, i.e. natural (homemade) juices and industrialized ready-to-drink juices, were also considered. Similar to a study by Anjos, et al.³² the present study considered seasonality in the consumption of some foods including seasonal fruits and vegetables. Efforts were made to develop a food list which could also be used in other parts of the country. However, because of some regional patterns of food intake in other areas, this FFQ can be used as a core list and revised to include regional foods in each area.³²

After the pilot study, a category of mixed dishes, readymade, and restaurant food was added to the list. For example, sandwiches and pizzas which were bought from fast food shops were asked about separately. Therefore, the interviewers were trained to clearly check out for processed meats or pizza cheese that were consumed alone or as part of sandwiches or pizza to avoid duplication of ingredients.^{29,30}

Another biomarker of sodium dietary intake is spot. Using an equation proposed by Tanaka, et al.8 some population-based studies indicated high correlations between first or second-void spot urine and the 24-h urinary sodium excretion. 11,33-36 Moreover, Mann, et al. demonstrated that sodium excretion predicted from a random urine sample in the evening significantly correlated with the actual 24-h sodium. Meanwhile, the estimated 24-h random urine sample in the morning had no significant association with the measured value.¹¹ However, a previous unpublished study on the adult population of Isfahan concluded that first-void spot urine sodium excretion was not really acceptable in predicting 24-h urine sodium excretion because of the weak association and high difference between the mean measured and estimated values of 24-h urine sodium and potassium excretion. The current study, hence, validated three spot urine samples, including second-void morning, afternoon, and evening spot urine samples, as another biomarker of dietary sodium intake.

Strengths and limitations

The food list in this study had some advantages over other validated FFQs in Iran. First, it was developed for both genders and different age groups. Moreover, it was arranged based on sodium content of foods. Other advantages of the present study were collecting data during a one-year period and monthly assessment of 24-h recalls as the reference method. This approach considered seasonal variation of food intake. In addition, 24-h urine data collection was used as a reference method to examine the accuracy of both spot urine and FFQ. A limitation of the current study was not collecting 24-h urine samples from some children and adolescents (due to the difficulty of the task for this age group). Another limitation was non-cooperation of participants in completing all twelve 24-h dietary recalls.

In conclusions, a specific quantitative FFQ was developed in the present research. This FFQ can be administered to assess nutrient, particularly sodium, and food groups intake among Iranian adults, children, and adolescents in large-scale population studies, especially national surveys. Furthermore, various urine spot samples collected at different times of the day were used to validate a simple library tool of spot urine for the assessment of sodium intake.

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Disclosure statements

We declare we have no conflict of interest.

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