

**Citation:**

Palacios C, Wigertz K, Martin BR, Jackman L, Pratt JH, Peacock M, McCabe G, Weaver CM. Sodium retention in black and white female adolescents in response to salt intake. *J Clin Endocrinol Metab.* 2004; 89: 1,858-1,863.

**PubMed ID:** [15070956](#)

**Study Design:**

Randomized crossover trial

**Class:**

A - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To compare sodium retention in response to controlled dietary sodium in different race groups.

**Inclusion Criteria:**

- Race was determined with a screening questionnaire asking the race of parents and grandparents
- Both parents and grandparents had to be white or black to be eligible in the study.

**Exclusion Criteria:**

- Less than 11 or older than 15 years
- Body mass index (BMI) of less than 15th or more than 85th percentile for age
- History of amenorrhea, pregnancy or abortion, eating disorders, oral contraceptive use or tobacco use.

**Description of Study Protocol:****Recruitment**

- Subjects were residents in a Purdue University fraternity house that was transformed during the summer into a metabolic unit
- Recruitment methods were not described.

**Design**

Randomized crossover trial.

**Dietary Intake/Dietary Assessment Methodology**

Subjects completed six 24-hour dietary recalls before the study began, which were analyzed using Nutritionist IV Diet Analysis, as well as 24-hour urine collections.

### **Intervention**

- One-week equilibration period
- Three weeks on low-sodium diet (1.3g, 57mmol)
- Two-week washout period, subjects free to consume self-selected diets
- One-week equilibration period
- Three weeks on high-sodium diet (4g, 172mmol)
- Fixed amounts of dietary potassium (2,186mg per day, 56mmol per day), calcium (816mg per day, 20mmol per day), magnesium (229mg per day, 9.4mmol per day), phosphorus (1,100mg per day, 36mmol per day), protein (70g per day), fat (73.6g per day), and fiber (10g per day)
- Four-day cycle menu with three meals and two snacks was designed for the study.

### **Statistical Analysis**

- Student T-test was used to assess baseline differences between the black and white girls
- Mixed-model ANOVA was used to assess the effects of treatment and race using race, session, sodium treatment, subject, order and response in the model
- Paired T-tests were used to assess whether the slope of urinary sodium excretion over time was different from zero, which reflects adaptation to the dietary treatments
- Changes in weight and blood pressure during the study were also analyzed by repeated measures ANOVA
- Pearson correlation coefficients were obtained to describe the relationships of sodium retention and general characteristics.

### **Data Collection Summary:**

#### **Timing of Measurements**

- Usual sodium intake collected at baseline
- Fecal and urine samples collected daily
- Body weight recorded daily and blood pressure measured every other day
- Blood collected at the end of each three-week diet period
- Whole-body sweat was collected after two weeks of acclimation and adaptation to the diet for 24 hours.

#### **Dependent Variables**

- Body weight measured with electronic scale
- Blood pressure measured with sphygmomanometer
- Blood samples analyzed for plasma renin activity, aldosterone and serum sodium
- Fecal and urine samples analyzed for sodium excretion and urinary creatinine
- Whole-body sweat measured using atomic absorption spectrophotometry.

#### **Independent Variables**

- Subjects studied twice in randomized crossover separated by two-week washout period: After one week of equilibration, subjects consumed low sodium intake (1.3g, 57mmol) for three weeks and high sodium intake (4g, 172mmol) for three weeks

- Food and beverages were prepared with deionized water and weighed on digital scales
- Subjects were strictly supervised to ensure compliance and to avoid consumption of other foods
- Usual sodium intake estimated through six-day dietary records and 24-hour urine collections.

### Description of Actual Data Sample:

- *Initial N*: 25 black and 15 white girls recruited
- *Attrition (final N)*: 22 black, 14 white girls
  - Eight white and 15 blacks completed both sessions of the study, and an additional six whites and seven blacks completed one of the two sessions
  - Three girls chose to withdraw during the study period
  - One girl was withdrawn due to iron deficiency anemia
  - Data from six black girls were not used in fecal or balance analysis due to poor polyethylene glycol recovery
- *Age*: 11 to 15 years (mean age 12.4±0.3 years for black girls; 13.2±0.3 years for white girls)
- *Ethnicity*: 22 black, 14 white
- *Anthropometrics*: Subjects were matched by post-menarcheal age and weight, they had similar baseline characteristics and were normotensive. The white girls were significantly older (P<0.05)
- *Location*: Purdue University, Indiana.

### Summary of Results:

Variables	Low Sodium Diet Blacks (N=19)	Low Sodium Diet Whites (N=12)	High Sodium Diet Blacks (N=19)	High Sodium Diet (N=10)
Urinary sodium excretion (g per day)	0.8±0.05, P<0.001	0.9±0.04, P<0.001	2.5±0.13, P<0.001	3.3±0.14
Urinary creatinine	1.0±0.07	1.0±0.05	1.0±0.07	1.0±0.05
Urinary volume (liter per day)	1.26±0.15	1.16±0.09	1.23±0.01	1.35±0.11
Sodium retention adjusted for sweat (g per day)	0.4±0.07, P<0.01	0.2±0.04	1.0 0.14, P<0.001	0.3±0.09
Apparent sodium absorption (%)	96.5±0.6, P<0.01	97.6±0.3, P<0.01	98.1±0.3	99.0±0.2

### Other Findings

Sodium content of the controlled diets by analysis was 1,310±43mg per day (57±1.9mmol per day) for the low sodium diet and 3,945±47mg per day (172±2mmol per day) for the high sodium diet.

There was a significant race by dietary treatment interaction, in which urinary sodium excretion

was similar at low sodium intake between blacks and whites, but significantly lower in blacks compared with whites at high sodium intake.

Mean daily sodium retention was  $357 \pm 69$ mg ( $15.5 \pm 3.0$ mmol) in blacks and  $239 \pm 37$ mg ( $10.4 \pm 1.6$ mmol) in whites on the low-sodium diet and  $991 \pm 138$ mg ( $43.1 \pm 6.0$ mmol) in blacks and  $334 \pm 90$ mg ( $14.5 \pm 3.9$ mmol) in whites ( $P < 0.001$ ) on the high sodium diet.

The greater sodium retention in blacks was not accompanied by an increase in fecal or sweat sodium excretion.

Blood pressure and weight did not increase despite the sodium retention, and thus, the retained sodium appeared to reside in a non-extracellular compartment speculated to be bone.

### Author Conclusion:

- In summary, we found greater sodium retention in black girls, compared with white girls, under conditions where sodium intake was high
- The findings provide direct evidence for what appears to be more active mechanisms for sodium retention in blacks.

### Reviewer Comments:

- *Small numbers of subjects in groups*
- *All subjects did not complete both sessions of study*
- *Significant differences between groups at baseline in terms of age.*

### Research Design and Implementation Criteria Checklist: Primary Research

#### Relevance Questions

- |    |   |     |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?   | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?  | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies)  | Yes |

#### Validity Questions

- |      |   |     |
|------|---|-----|
| 1.   | <b>Was the research question clearly stated?</b>  | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
<b>2.</b>	<b>Was the selection of study subjects/patients free from bias?</b>	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
<b>3.</b>	<b>Were study groups comparable?</b>	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	???
4.1.	Were follow-up methods described and the same for all groups?	No
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	<b>Yes</b>
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	<b>Yes</b>
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	???
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	???
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes