

Citation:

Myers JB. Reduced sodium chloride intake normalises blood pressure distribution. *J Hum Hypertens*. 1989 Apr; 3(2): 97-104.

PubMed ID: [2760911](#)

Study Design:

Randomized 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 determine the effect of high and low sodium diet on the normalization of the blood pressure (BP) curve in a group of individuals.

Inclusion Criteria:

- Hospital employees and local residents with their families in Newcastle, NSW, Australia
- Healthy, normotensive individuals.

Exclusion Criteria:

- Non-hospital employees and non-local residents of Newcastle, NSW, Australia
- Individuals who were not healthy or who had high blood pressure.

Description of Study Protocol:**Recruitment**

Individuals who were hospital employees and some local residents and their families from New Castle, NSW, Australia volunteered for the study.

Design

- Three study periods of two weeks each were conducted, as follows:
 - First study period: Subjects were on usual diet
 - Second and third study periods: Crossover diet phase involving a reduced- and a high-sodium diet (the order of those diets was randomized)
- Protocol followed for taking measurements during those periods included:

- Baseline measurements for BP, 24-hour urine for sodium (Na) and potassium (K)
- After wash-out periods, measurements for BP, 24-hour urine for Na and K were taken
- Subjects were randomly assigned to high- or low-sodium diet for two weeks, then BP and 24-hour urine measurements taken
- Subjects were switched to the alternate diet (either high or low sodium), after which BP and 24-hour urine measurements taken.

Dietary Intake/Dietary Assessment Methodology

- Article did not provide information on the nature and sodium levels of assigned sodium-restricted and high-sodium diets
- Assessment of intake was assumed using urinary sodium measurement.

Blinding Used

Technicians measuring BP were blinded as to type of diet subjects were receiving.

Intervention

The intervention involved an assigning subjects reduced- and high-sodium diets (the order of those diets was randomized) during the second and third study period crossover diet phase of the study.

Statistical Analysis

- ANOVA, ANOVAR, paired and unpaired T-test
- Tests for shrewdness, regression analysis and linear modeling.

Data Collection Summary:

Timing of Measurements

- Baseline measurements for BP, 24-hour urine for Na and K
- After washout periods, measurements for BP, 24-hour urine for Na and K were taken
- Subjects were randomly assigned to high- or low-sodium diet for two weeks, then BP and 24-hour urine measurements taken
- Subjects were switched to the alternate diet (either high or low sodium), after which BP and 24-hour urine measurements taken
- Supine and erect BP measurements on consecutive days at the end of each diet period.

Dependent Variables

- Variable 1: High-sodium diet
- Variable 2: Low-sodium diet.

Independent Variables

- BP: Systolic BP (SBP), diastolic BP (DBP), supine and erect (BP cuffs standardized to arm circumference)
- BP measurements taken by same one of two trained observers who were not aware of diet subjects were on; mercury sphygmomanometer was used
- Protocol used for measuring BP throughout study included taking a supine BP after 10 minutes and an erect BP after five minutes
- Times were validated in other normotensive subjects.)

Control Variables

- Age, weight, sex, height
- Urine Na, K.

Description of Actual Data Sample:

- *Initial N*: 200 volunteers
- *Attrition*: N=172; 99 females, 73 males
- *Age*: 36.9±1.3 years (mean ±SEM); range, three to 77 years
- *Other relevant demographics*: Hospital employees and their families, with some volunteers from the same community
- *Anthropometrics*:
 - Weight 66.5±1.3kg (range, 15 to 112kg)
 - Height 165.5±1.0cm (range 95 to 194cm)
- *Location*: New Castle, Australia.

Summary of Results:

Skewness Coefficients for Systolic and Diastolic Blood Pressure Distribution in 172 Healthy Volunteers at the Start of the Study on their Usual Diet and After Two Weeks on a Reduced- and High-sodium Diet

Diet Period	Skewness	
	Reduced Sodium	High Sodium
Blood pressure		
Supine: systolic	0.08	0.56
diastolic	0.03	0.49
Erect: systolic	0.20	0.46
diastolic	-0.10	0.18

Values higher than 0.43, P<0.02 (two-tailed).

Clinical Findings of Sodium Sensitive and Insensitive Subjects Reduced- and High- Sodium Diet. Means ± SEM.

Subjects	Sodium Sensitive	Sodium Insensitive
N	38	134
Age (year)	40.1±3.5	35.8±1.3
Supine BP (mmHg)		
Reduced sodium		

Systolic	115.6±3.2	117.6±1.2
Diastolic	73.3±2.2	75.8±1.1
High sodium		
Systolic	129.3±3.5***	118.7±1.3
Diastolic	84.7±2.2***	75.2±1.0
Erect BP (mmHg)		
Reduced sodium		
Systolic	111.5±2.9	115.4±1.2
Diastolic	77.5±2.2	80.8±0.9
High sodium		
Systolic	125.2±3.2 *	116.8±1.3
Diastolic	87.2±2.4**	79.8±1.0

*P<0.025, **P<0.01, ***P<0.005 between subjects grouped by increment in DBP on the reduced, high and usual sodium intakes.

Subjects were considered sodium-sensitive if supine BP at end of run-in period was higher than on low-Na diet but less than on the high-Na diet.

Other Key Findings:

- Older adults had higher BP with DBP increasing linearly to the sixth decade, P<0.05
- There was an incremental increase in SBP in those older than 45 years, P<0.05
- Urinary K was similar for all patients during run-in period
- Urinary Na was highest on high-sodium diet, P<0.05
- 22% of subjects were salt-sensitive
- Increased DBP on high-sodium diet in sodium-sensitive subjects occurred in all age groups
- Skewness of BP distribution was normalized by low sodium intake and was lower on low-sodium diet in both sodium-sensitive and sodium-insensitive subjects
- In the 20- to 49-year group with a two-fold increase in sodium intake, there was a greater change in BP in females with a family history of hypertension but not in males
- Females with a negative family history of hypertension had lower BP at initial visit compared to males with a negative family history and to females with a positive family history
- "Sodium sensitive" subjects less than 18 years of age were exclusively female, so this is not a comparable group.

Author Conclusion:

The data support the conclusion that at all ages the majority of subjects do not change their BP with change in dietary sodium, but a significant proportion do, the latter accounting for the DBP shift to lower levels on the reduced sodium diet and contributing significantly to the normalization of the skewness of the distribution of BP on changing from a high to reduced sodium diet.

Reviewer Comments:

Limitations identified by author:

- *The subjects in the study, being volunteers, may not be representative of the population*
- *Suggestion of possible sampling error, given that sodium-sensitive subjects in less than 18 years of age group were mostly females.*

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.	Was the research question clearly stated?	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
2.	Was the selection of study subjects/patients free from bias?	???
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?	???
2.2.	Were criteria applied equally to all study groups?	Yes

2.3.	Were health, demographics, and other characteristics of subjects described?	???
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study groups comparable?	???
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
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")?	Yes
4.	Was method of handling withdrawals described?	No
4.1.	Were follow-up methods described and the same for all groups?	???
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%.)	No
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	No
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
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
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?	Yes
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	???
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?	N/A
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	???
6.8.	In diagnostic study, were details of test administration and replication sufficient?	Yes
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
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?	???
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
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes

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)?	Yes
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?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes