Emphasized warning reduces salt intake: a randomized controlled trial

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Abstract

Excessive salt intake is a major cardiovascular risk factor. At variance to the developed countries, the main source of sodium in transitional and developing countries is salt added while cooking and/or at the table. The objective of this trial was to examine the impact of warning labels placed on home salt containers on daily salt intake. A sample of treated hypertensives (n = 150) was randomized in two subgroups, one receiving just a leaflet about the harmful effects of excessive salt intake (control; n = 74), and the other one receiving in addition warning stickers for household salt containers (intervention; n = 76). Arterial blood pressure (BP) and 24-hour urinary sodium excretion (Na24) were measured in all the subjects at the start of the trial, and 1 month and 2 months later. The average starting Na24 was 207 ± 71 mmol in the control group and 211 ± 85 mmol in the intervention group (P = .745). One month and 2 months later, a significant decrease was observed in the intervention group (to 183 ± 63 mmol and 176 ± 55 mmol; P < .0001), as opposed to the control group (203 ± 60 mmol and 200 ± 58 mmol; P = .1466). Initial BP was 143.7/84.1 mm Hg in the control, and 142.9/84.7 mm Hg in the intervention group (P = .667). One month and 2 months later, a significant drop in BP, by 5.3/2.9 mm Hg, was observed in the intervention group as opposed to the control group (0.4/0.9 mm Hg). Decrease in Na24 positively correlated to BP lowering (r² = 0.5989; P < .0001). A significant reduction in 24Na and BP is achieved with warning labels on harmful effects of excessive salt intake. Decreasing daily salt input by 35 mmol may result in an extra BP lowering by some 5–6/2–3 mm Hg.

Keywords: Arterial hypertension; blood pressure; salt consumption; sodium.

Introduction

The worldwide prevalence of arterial hypertension in adult populations is about 30%, representing a major public health problem. Excessive salt (NaCl) intake is a leading cardiovascular risk factor, enhancing, in particular, blood pressure (BP) elevation. Moreover, immoderate NaCl intake is also related to osteoporosis, obesity, albuminuria, and gastric cancer. Reduction in salt consumption does not only improve the prevention and management of arterial hypertension, but offers a number of additional health benefits. The World Health Organization recommends daily salt intake below 5 g, while the daily consumption in the world averages 10–13 g. Therefore, many campaigns have been launched aimed at moderating salt ingestion. It is estimated that reduction in daily NaCl intake by mere 3 g would reduce the worldwide number of strokes by 32,000–66,000, and heart attacks by 54,000–99,000, with a decrease in total mortality by 44,000–92,000, and consequent annual savings of 10–24 billion US $.

The first step in salt intake reduction is identification of its sources. In developed countries, salt intake is mainly derived from industrial, processed food, which is responsible for about 75% of the daily intake. Therefore, current interventions aim at salt reduction in manufactured foods. In other, less developed countries, the main NaCl source is in adding salt during home cooking procedures, amounting to 72% in China, 76% in Brazil, and 80% in Korea. Available data for southern Europe are similar: in Croatia, most salt, 56.4%, is introduced...
during cooking and by additional seasoning, followed by grocery bread, 29.8%, and other bakery products, 12.8%, with an average daily intake of 11–13 g. Consequently, in transitional and developing countries, salt intake must be primarily curtailed at the level of cooking and adding at the table.

Our hypothesis was that placing particularly designed warning stickers about harmful effects of excessive salt on household containers (salt shaker, household salt containers, spicy dietary supplements with high NaCl content) might considerably reduce its daily intake. When adding salt during cooking procedures or in spicing a meal, the consumer is exposed to continuous and repeated warning about the risk. Potential advantages of this strategy are: (1) a clear message about the harmful effects, given at the right moment (reaching for salt while cooking or adding at the table); (2) long–term, self–reinforcing message (over several months); (3) all family members exposed to the warning; and (4) low cost of the intervention.

After many consultations with health professionals, designers, psychologists, and social workers, we have developed a simple, self–adhesive warning label (Figure 1). In the available literature, we have found no study on the impact of such labeling, and the effectiveness of this approach is unknown.

Methods

The participants in this study were all consecutive adult, treated hypertensives of either gender, registered in a family medicine practice in Mostar, Bosnia and Herzegovina. The sample size was determined using the Sample Size and Power Calculation program, version 1.02, based on a pilot study resulting in a mean urinary sodium excretion in 24 hours (Na24) of 200 ± 60 mmol, and on the presumed Na24 reduction by ≥25 mmol; for the power of 0.8 and a \( P \) value of <0.05, each of the two groups had to have at least 60 subjects.
After signing the informed consent form, approved by the Split University School of Medicine Ethics Committee, the participants were randomized in two groups (from September 2012 to July 2013), according to instructions in sealed envelopes: the control group received individual information leaflets about the untoward effects of excessive salt consumption, and the intervention group, in addition to the informational leaflets, received warning stickers to be mounted on all salt containers.

In individual case report forms recorded were general demographic and anthropometric data, BP (standard mercury sphygmomanometry), and Na24; the collection of urine was performed following the standard procedure, and the sodium measurement was done in the University Hospital Mostar Central Laboratory using ionic electrodes. One month and 2 months later, BP and Na24 were retested in all the subjects in the same way, allowing for a deviation from predetermined date by ≤10 days.

The results were expressed as means and standard deviations (SD). The significance of the observed differences was tested by analysis of variance, χ², Student t-test, and Mann–Whitney U test, as appropriate. The correlation between Na24 and BP was assessed with linear regression analysis. P < .05 was considered significant.

Results

Of the 171 participants, 150 (87.7%) entered and completed the formal study: 74 in the control and 76 in the intervention group. Excluded were 10 subjects due to lack of cooperation, five because of change in antihypertensive therapy, and six as a result of missing data (Figure 2). The baseline characteristics of the subjects are shown in Table 1; there were no significant between–group differences. The same is true regarding the starting Na24 values (P = .745). However, after 1 and 2 months, the control measurements showed markedly lower Na24 in the intervention than in the control group (Table 2); a significant decrease in sodium excretion over time (F = 25.48; P < .001) and group interaction (F = 12.71; P < .001) was revealed (Figure 3).

At the beginning of the trial, there were no significant BP differences between the groups (in systolic [P = .796], diastolic [P = .667], and mean BP [P = .899]). In the control group, the BP values did not fluctuate considerably during the study, while in the intervention group, a significant, progressive reduction in systolic, diastolic, and mean BP was observed (Table 3). Mixed–model analysis of variance revealed a statistically significant decrease in systolic BP over time (F = 4.69; P = .014) with no significant group interaction (F = 2.33; P = .109). The same was true for diastolic BP over time (F = 8.017; P = .001). The observed differences in terms of mean BP are graphically presented in Figure 4. Despite a perceptible dichotomy between the study groups, this divergence did not reach the conventional level of statistical significance (F = 1.58; P = .165).

Linear regression analysis revealed a significant reci-

Table 1
Baseline characteristics of the participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control Group (N = 74)</th>
<th>Intervention Group (N = 76)</th>
<th>Significance Test</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>59.3 ± 12</td>
<td>59.4 ± 13</td>
<td>t = 0.0373</td>
<td>.405</td>
</tr>
<tr>
<td>Gender, F/M</td>
<td>37/37</td>
<td>40/36</td>
<td>χ² = 0.104</td>
<td>.747</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>82.99 ± 11.9</td>
<td>81.6 ± 12.3</td>
<td>t = 0.868</td>
<td>.959</td>
</tr>
<tr>
<td>Body height, cm</td>
<td>177.6 ± 9.5</td>
<td>175.2 ± 11.1</td>
<td>t = 0.344</td>
<td>.879</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26.4 ± 2.5</td>
<td>26.1 ± 3.0</td>
<td>t = 0.493</td>
<td>.898</td>
</tr>
<tr>
<td>Level of education, PSE/BME</td>
<td>61/13</td>
<td>60/16</td>
<td>χ² = 0.292</td>
<td>.589</td>
</tr>
<tr>
<td>Number of antihypertensives (range 1–4)</td>
<td>2.1 ± 0.9</td>
<td>2.2 ± 1.0</td>
<td>Z = 0.712</td>
<td>.478</td>
</tr>
</tbody>
</table>

BME, bachelor or master degree; PSE, primary or secondary education; Z, Z score in Mann–Whitney U test.

Table 2
Sodium excretion during the trial in the two study groups

<table>
<thead>
<tr>
<th>Time</th>
<th>Na24 (mmol ± SD)</th>
<th>Control (N = 74)</th>
<th>Intervention (N = 76)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 months</td>
<td>207.1 ± 70.97</td>
<td>211.2 ± 85.18</td>
<td>.745</td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>203.4 ± 59.87</td>
<td>182.6 ± 62.62</td>
<td>.040</td>
<td></td>
</tr>
<tr>
<td>2 months</td>
<td>200.4 ± 58.49</td>
<td>176.4 ± 54.53</td>
<td>.011</td>
<td></td>
</tr>
<tr>
<td>ANOVA*</td>
<td>F = 1.95</td>
<td>F = 27.22</td>
<td>P = .147</td>
<td>P &lt; .0001</td>
</tr>
</tbody>
</table>

ANOVA, analysis of variance.

* One–way analysis of variance refers to the columns; t–test with the Bonferroni adjustment refers to the rows.
Discussion

Because of its high prevalence, arterial hypertension is the leading cardiovascular risk factor. Actual salt intake reduction can significantly lower BP and the prevalence of hypertension. Since NaCl is an important component of most everyday food, a preservative, and a flavor enhancer, its intake is tough to limit. The main nutritional origin of salt in developed countries is processed food, and most current initiatives focus on the control of NaCl content in such products. The Consensus Action on Salt and Health (CASH) program in the UK, with the help of media and agreements with the food industry, reduced the average daily salt intake from 9.5 g to 8.1 g. In a similar way, Finland managed to reduce the share of salt in the main food products by 20%–25%.

In less developed countries, the main source of nutritive salt is its addition at cooking or serving. The role of food industry in these regions is therefore less important, and an individualized approach, with particular reference to the main source of salt, is suggested. Raising awareness of untoward effects of excessive salt intake in public campaigns is certainly a useful measure, but insufficient.

In similar circumstances, amid the efforts to reduce the prevalence of smoking, one of the measures was to put warnings on cigarette boxes. Nowadays, most countries require labels on these boxes indicating the dangers of smoking. Smokers are forced to see a clear warning about smoking hazards whenever they reach for a cigarette. Such strategy raises awareness of the hazards and encourages quitting reflections. Since this strategy has shown some effects on smoking (this hazardous addiction is extremely difficult to suppress), we assumed that a similar approach could have an impact on daily salt intake.

In this trial, we included adult hypertensive volunteers, registered in a family medicine practice, taking, on average, two antihypertensive drugs. The baseline daily sodium elimination, reflecting faithfully its intake, expressed as Na24, was high, about 209 mmol (12.3 g NaCl). The handing of an informational leaflet to the control group did not result in a significant reduction either in Na24 or in BP. The failure of the leaflet probably lies in the fact that our subjects were treated hypertensives, repeatedly warned about the problem. Reiterating the same information in a similar way did not lead to the desired effect.

In addition to the leaflets, the intervention group was given specially designed stickers with a clear and brief message about the risk, to be attached on their household salt containers. Each time upon taking the container or salt-shaker, the participants were exposed to the same, reinforcing message. Indeed, these subjects markedly reduced their sodium excretion by some 35 mmol (2.1 g NaCl), or about

Table 3

<table>
<thead>
<tr>
<th>Blood Pressure*</th>
<th>0 Month</th>
<th>1 Month</th>
<th>2 Months</th>
<th>Difference (mm Hg)</th>
<th>ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>F</td>
</tr>
<tr>
<td>Control group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>143.7 ± 18.1</td>
<td>142.2 ± 18.4</td>
<td>143.3 ± 18.5</td>
<td>−0.4</td>
<td>0.55</td>
</tr>
<tr>
<td>Diastolic</td>
<td>84.1 ± 8.9</td>
<td>84.3 ± 9.8</td>
<td>83.2 ± 8.9</td>
<td>−0.9</td>
<td>0.99</td>
</tr>
<tr>
<td>Mean†</td>
<td>103.9 ± 11.3</td>
<td>103.6 ± 11.8</td>
<td>103.2 ± 11.5</td>
<td>−0.7</td>
<td>0.22</td>
</tr>
<tr>
<td>Intervention group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>F</td>
</tr>
<tr>
<td>Systolic</td>
<td>142.9 ± 20.6</td>
<td>138.5 ± 17.2</td>
<td>137.6 ± 16.1</td>
<td>−5.3</td>
<td>F = 21.02</td>
</tr>
<tr>
<td>Diastolic</td>
<td>84.7 ± 10.3</td>
<td>81.4 ± 8.5</td>
<td>81.8 ± 8.5</td>
<td>−2.9</td>
<td>F = 15.1</td>
</tr>
<tr>
<td>Mean†</td>
<td>104.1 ± 13.2</td>
<td>100.4 ± 10.5</td>
<td>100.5 ± 10.3</td>
<td>−3.6</td>
<td>F = 17.14</td>
</tr>
</tbody>
</table>

ANOVA, analysis of variance.

* mm Hg ± standard deviation.
† Difference between the first and the last measurement.
‡ Diastolic + 1/3 pulse pressure.
16%, that is five times more than the controls without the self-adhesive labels! Such differences may be only marginally attributable to the regression toward the mean phenomenon. Moreover, a moderate BP reduction, by some 5.3/2.9 mm Hg was noted in the intervention group, with virtually no change in the control group. Since our subjects were relatively well-controlled hypertensives (initial BP around 143/84 mm Hg), a greater lowering was not expected.

Reduction in Na24 was linked to BP fall in the intervention group: the larger the drop in sodium intake/excretion, the bigger the drop in BP. At the same time, compliant persons consuming more salt initially showed later a larger decrease in Na24 and in BP. However, the marked decrease in Na24 was not paralleled by a similar decrease in BP (by less than 4%). These discrepancies may be due to the already fair hypertension control, and/or to a slower BP response to sodium restriction. It is important to stress that all these changes were following a progressive time trend.

It seems that the main advantage of this intervention is its timing. The exposed person, similarly to a smoker, sees the warning at any reach for a salt shaker or other salt container. Another advantage of this type of message is its clarity; it points out the need to reduce salt; it is not about sophisticated chemistry, pathophysiology, measurement units, molar values, daily needs, or similar data that are esoteric and puzzling for the average consumer. Further, the cost of the intervention is low. Our stickers cost €0.05 apiece. If each household in Bosnia and Herzegovina received two labels (the country has 3.8 million inhabitants in about one million households), the purchase price of the stickers would be below €100,000, which is acceptable.

Beside that, the favorable effects are not limited to hypertensive persons only: if the message is involved in meal preparation and consumption, other family members are exposed to the intervention as well.

This trial has several limitations. First, the effects of warning labels were followed for a short period of time (2 months), and it is unknown whether the observed trend would last any longer. Indeed, only long-term reduction in salt intake offers significant health benefits. Second, we have not examined the impact of the labels on family members, which may be very important and stimulating for further research. Third, the warning labels achieved a noticeable but still insufficient reduction in daily salt intake (by 16.5%; from 211 to 176 mmol vs. 3.5%; from 207 to 200 mmol/l in the controls): the intake was still markedly above the recommended one.

A short-term intervention cannot completely correct dietary habits, but in the long run, combined with other measures, it may significantly contribute to a reduction in salt intake and BP lowering, particularly in countries where industrial, processed food is not the main source of sodium.

Figure 4. Scatterplot of daily sodium excretion (Na24) decline after 2 months in the intervention group (N = 76), fitting a regression line. Each point presents the intersection of two individual measurements, at the start and at the end of the intervention period; the higher the starting value the greater the decrease.

Figure 5. Mean blood pressure fluctuation during the study (N = 150). Ordinate: mean BP (diastolic + \( \frac{1}{3} \) pulse pressure) in mm Hg; symbols represent arithmetic means, error bars represent standard errors of the means.

Figure 6. Linear regression between changes in urinary sodium excretion (Na24) and blood pressure (BP) in the intervention group (start vs. end of the trial; N = 76).

References


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