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Diet quality, body weight, and postmenopausal hot flashes: a secondary analysis of a randomized clinical trial

Haley Brennan[1]

Abstract

Background A low-fat vegan diet, supplemented with soybeans, has been shown effective in reducing postmenopausal hot flashes. This secondary analysis assessed the association of a plant-based index (PDI), healthful (hPDI), and unhealthful (uPDI), with changes in hot flashes in postmenopausal women.

Methods Participants ($n = 84$) were randomly assigned to a low-fat vegan diet supplemented with soybeans ($n = 42$) or a control group ($n = 42$) for 12 weeks. Three-day dietary records were analyzed and PDI indices were calculated. A repeated measures analysis of variance (ANOVA) was used for statistical analysis.

Results All three scores increased in the vegan group, compared with no change in the control group; the effect sizes were: PDI + 9.8 (95% CI + 5.8 to + 13.8; $p < 0.001$); hPDI + 10.9 (95% CI + 6.4 to + 15.3; $p < 0.001$); and uPDI + 3.6 (95% CI + 0.5 to + 6.6; $p = 0.02$). The change in all three scores negatively correlated with change in body weight (PDI: r=-0.48; $p < 0.001$; hPDI: r=-0.38; $p = 0.002$; and uPDI: r=-0.31; $p = 0.01$). The changes in PDI and uPDI were negatively associated with changes in severe hot flashes (r=-0.34; $p = 0.009$; and r=-0.43; $p < 0.001$, respectively), and associations remained significant after adjustment for changes in body mass index (r=-0.31; $p = 0.02$; and r=-0.41; $p = 0.001$, respectively).

Conclusions These findings suggest that minimizing the consumption of animal products and oil may be an effective strategy to reduce hot flashes in postmenopausal women, and that categorization of plant foods as "healthful" or "unhealthful" may be unwarranted.

Trial registration ClinicalTrials.gov, NCT04587154, registered on Oct 14, 2020.

Keywords Diet quality, Hot flashes, Nutrition, Plant-based, Vegan

*Correspondence:
Hana Kahleova
hkahleova@pcrm.org
[1]Physicians Committee for Responsible Medicine, 5100 Wisconsin Ave, NW, Suite 400, Washington, DC 20016, USA
[2]School of Medicine, University of Utah, Salt Lake City, UT, USA
[3]Adjunct faculty, George Washington University School of Medicine and Health Sciences, Washington, DC, USA

Introduction

A low-fat vegan diet, supplemented with soybeans, has been shown to be e ective in reducing body weight and postmenopausal hot flashes [1]. In another randomized clinical trial, the Women's Health Initiative, a dietary intervention increasing whole grains, fruits, and vegetables and decreasing dietary fat reduced hot flashes, particularly in those participants who lost at least 10% of body weight [9]. e positive e ects of a plant-based diet on body weight and hot flashes may be partly explained

for each participant. Physical activity was assessed by the International Physical Activity Questionnaire (IPAQ) [11].

Statistical analysis

Sample size and power calculation

Because no prior study had examined the e ects of a vegan diet with cooked soybeans on vasomotor symptoms, there was no sound basis for a power analysis.

e investigators therefore aimed to enroll up to 40 participants evenly divided between study groups as an initial cohort, with one more cohort to compensate for seasonality.

Statistical methods

A repeated measures analysis of variance (ANOVA) was used by a statistician blinded to dietary interventions.

is has been shown to be a suitable method for studies where each group has multiple dependent variable observations collected at several time points [12]. Results are presented as means with 95% confidence intervals. Pearson correlation was used to evaluate the magnitude and significance of the association between the changes in hot flashes and body weight and changes in all three indices and their individual food components, first unadjusted and then and then Pearson partial correlations controlling for the changes in body mass index.

Results

Of 1,662 women inquiring about the study, 361 were screened by telephone, and 84 participants were randomly assigned to the 2 study groups, with 71 participants completing the whole study (Supplemental Fig. 1).

e detailed baseline demographics are given in Supplemental Table 1. ere were no significant between-group di erences, except for the vegan group being slightly younger.

Hot ashes and body weight

Severe hot flashes were reduced by 92% (from 1.3/day to 0.1/day) in the vegan group ($p<0.001$) and did not change significantly in the control group (from 0.7/day to 0.4/day; $p=0.13$; between-group $p=0.02$). Mean body weight decreased by 3.6 kg in the vegan group and 0.2 kg in the control group (e ect size: -3.4 kg [-4.5 to -2.3]; $p<0.001$).

PDI, hPDI, uPDI

All three scores increased in the vegan group, compared with no change in the control group; the e ect sizes were: PDI+9.8 (95% CI+5.8 to +13.8; $p<0.001$); hPDI+10.9 (95% CI+6.4 to +15.3; $p<0.001$); and uPDI+3.6 (95% CI+0.5 to +6.6; $p=0.02$). e scores for the individual food components are listed in Table 1. e changes in all three scores negatively correlated with changes in body weight, with PDI (r=-0.48; $p<0.001$), hPDI (r=-0.38; $p=0.002$), and uPDI (r=-0.31; $p=0.01$). e changes in PDI and uPDI were negatively associated with changes in severe hot flashes (r=-0.34; $p=0.009$; and r=-0.43; $p<0.001$, respectively), and remained significant after adjustment for changes in body mass index (BMI; r=-0.31; $p=0.02$; and r=-0.41; $p=0.001$, respectively).

Discussion

In contrast with a 2023 review that suggested that higher PDI and hPDI levels were associated with favorable health outcomes, while higher uPDI scores were mostly found unfavorable [13], the present analysis demonstrated that both "healthy" and "unhealthy" plant-based indices—hPDI and uPDI—were inversely associated with weight changes and with changes in vasomotor symptoms in the context of a low-fat vegan diet with daily soybean consumption. is finding resonates with findings of a previous report on weight loss in overweight adults [14].

e PDI and its subscales were developed solely on epidemiological associations with type 2 diabetes, cardiovascular disease, and certain cancers, along with mediating conditions, such as obesity, and not on clinical trial data or other evidence of true health e ects. e foods used to create the "unhealthy" index include fruit juices, sweetened beverages, refined grains, potatoes, and sweets/desserts. e current results suggest that at least some of these foods may, in fact, lend themselves to healthful weight loss when they replace animal-derived products. e first four in this list are higher in carbohydrate (which has 4 kcal/g) and lower in fat (which has 9 kcal/g), compared with meat, dairy products, and eggs, and so are naturally lower in energy density. For example, potatoes are included among the "unhealthy" plant foods, yet evidence of an association between potato intake and type 2 diabetes risk is weak and inconsistent, and is a subject to potential confounders, such as the use of fat during the preparation, and the combination with meat and other animal foods with which potatoes are usually consumed. In a previous study in overweight adults with insulin resistance, potatoes were comparable to beans in weight loss and improvements in insulin resistance [15]. An explanation for the beneficial e ects on vasomotor symptoms is more challenging because the mechanism by which a plant-based diet ameliorates these symptoms remains unclear. e PDI itself may have fundamental issues, given that it rates oils as "healthy," despite their high energy density.

In the Women's Health Initiative, a randomized clinical trial that included more than 17,000 women, increasing whole grains, fruits, and vegetables and reducing dietary fat increased the chances of becoming free of hot flashes at 1 year by 14% in women who followed the

Table 1 Plant-based dietary index (PDI), healthful (hPDI), and unhealthful plant-based dietary index (uPDI), and the individual PDI food components at baseline and 12 weeks. The listed food component scores reflect points for the PDI, where plant-based food groups were awarded positive scores, while animal-based food groups were assigned reverse scores. Data are presented as means with 95% confidence intervals. *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$

	Vegan group			Control group			Effect size	*P*-value
	Week 0	Week 12	Change	Week 0	Week 12	Change		
PDI	53.8 (50.3–57.2)	61.2 (59.3–63.2)	+ 7.4 (+ 4.5 to + 10.4)***	56.3 (53.0-59.6)	53.9 (50.8–57.1)	-2.3 (-5.1 to + 0.5)	+ 9.8 (+ 5.8 to + 13.8)	$p < 0.001$
hPDI	57.4 (53.7–61.1)	67.0 (65.0-69.1)	+ 9.6 (+ 5.8 to + 13.4)***	59.0 (55.4–62.6)	57.7 (54.4–61.1)	-1.3 (-3.7 to + 1.2)	+ 10.9 (+ 6.4 to + 15.3)	$p < 0.001$
uPDI	54.7 (52.9–56.5)	58.7 (56.9–60.5)	+ 4.0 (+ 1.9 to + 6.0)***	56.3 (53.8–58.9)	56.7 (54.7–58.8)	+ 0.4 (-2.0 to + 2.8)	+ 3.6 (+ 0.5 to + 6.6)	$P = 0.02$
"Healthy" Plant Foods								
Fruits	2.9 (2.4–3.4)	3.4 (3.0-3.9)	+ 0.6 (+ 0.1 to + 1.1)*	3.1 (2.6–3.6)	2.7 (2.2–3.1)	-0.4 (-0.9 to + 0.1)	+ 1.0 (+ 0.3 to + 1.7)	0.004
Vegetables	2.9 (2.4–3.4)	3.6 (3.2-4.0)	+ 0.7 (+ 0.2 to + 1.3)*	3.0 (2.5–3.6)	2.7 (2.2–3.1)	-0.4 (-0.8 to + 0.1)	+ 1.1 (+ 0.4 to + 1.8)	0.004
Whole Grains	2.8 (2.4–3.3)	3.4 (2.9–3.9)	+ 0.6 (+ 0.0 to + 1.1)*	3.1 (2.6–3.7)	3.2 (2.6–3.7)	+ 0.0 (-0.6 to + 0.7)	+ 0.5 (-0.3 to + 1.3)	0.1899
Nuts	2.8 (2.3–3.3)	1.9 (1.5–2.2)	-1.0 (-1.5 to -0.5)***	3.1 (2.5–3.7)	2.9 (2.3–3.4)	-0.2 (-0.7 to + 0.3)	-0.7 (-1.4 to -0.0)	0.0402
Legumes	3.0 (2.5–3.5)	4.8 (4.7-5.0)	1.8 (1.3 to 2.4)***	2.9 (2.3–3.4)	2.6 (2.0-3.1)	-0.3 (-0.9 to + 0.3)	+ 2.1 (+ 1.3 to + 2.9)	$p < 0.0001$
Vegetable Oils	3.0 (2.5–3.5)	2.2 (1.8–2.6)	-0.8 (-1.4 to -0.2)*	3.0 (2.4–3.5)	2.9 (2.3–3.5)	-0.1 (-0.7 to + 0.5)	-0.7 (-1.5 to + 0.1)	0.0974
Coffee and Tea	3.2 (2.7–3.6)	2.9 (2.4–3.5)	-0.2 (-0.8 to + 0.3)	2.8 (2.2–3.3)	2.8 (2.2–3.3)	+ 0.0 (-0.4 to + 0.4)	-0.2 (-0.9 to + 0.4)	0.5285
"Unhealthy" Plant Foods								
Fruit Juice	2.9 (2.3–3.4)	2.4 (1.9-3.0)	-0.5 (-1.2 to + 0.3)	2.7 (2.1–3.3)	2.7 (2.0-3.3)	+ 0.0 (-0.9 to + 0.9)	-0.5 (-1.6 to + 0.7)	0.4103
Sugar Sweetened Beverages	2.1 (1.5–2.7)	1.6 (1.1-2.0)	-0.5 (-1.1 to + 0.1)	2.1 (1.4–2.7)	1.7 (1.2–2.3)	-0.3 (-0.9 to + 0.2)	-0.2 (-0.9 to + 0.6)	0.6715
Refined Grains	2.7 (2.2–3.3)	2.6 (2.1-3.0)	-0.2 (-0.6 to + 0.3)	3.2 (2.7–3.7)	3.0 (2.5–3.5)	-0.2 (-0.8 to + 0.4)	-0.0 (-0.7 to + 0.8)	0.9492
Potatoes	2.4 (1.8–2.9)	2.8 (2.1–3.4)	+ 0.4 (-0.3 to + 1.1)	2.9 (2.2–3.5)	2.6 (2.0-3.3)	-0.3 (-1.1 to + 0.6)	+ 0.6 (-0.4 to + 1.7)	0.2190
Sweets	3.1 (2.6–3.6)	2.8 (2.2–3.4)	-0.3 (-1.0 to + 0.3)	2.8 (2.3–3.4)	3.1 (2.5–3.7)	+ 0.3 (-0.6 to + 1.1)	-0.6 (-1.6 to + 0.4)	0.2537
Animal Foods								
Animal Fats	3.2 (2.6–3.8)	4.5 (4.1–4.9)	+ 1.3 (+ 0.6 to + 2.1)**	3.8 (3.2–4.4)	3.3 (2.7-4.0)	-0.4 (-1.0 to + 0.2)	+ 1.8 (+ 0.8 to + 2.7)	$p < 0.0005$
Dairy	3.1 (2.6–3.6)	4.7 (4.4-5.0)	+ 1.6 (+ 1.0 to + 2.2)***	3.3 (2.7–3.9)	2.8 (2.2–3.4)	-0.5 (-1.0 to -0.1)*	+ 2.1 (+ 1.3 to + 2.9)	$p < 0.0001$
Eggs	3.5 (2.9–4.1)	4.8 (4.6–5.1)	+ 1.4 (+ 0.8 to + 2.0)***	3.8 (3.2–4.5)	4.0 (3.4–4.5)	+ 0.1 (-0.5 to + 0.8)	+ 1.2 (+ 0.3 to + 2.1)	0.0068
Meat	3.4 (2.8-4.0)	4.9 (4.8–5.1)	+ 1.6 (+ 0.9 to + 2.2)***	3.5 (2.9–4.1)	3.6 (3.0-4.3)	+ 0.1 (-0.4 to + 0.6)	+ 1.5 (+ 0.7 to + 2.2)	$p < 0.0004$
Seafood	3.9 (3.3–4.5)	4.9 (4.7–5.1)	+ 1.0 (+ 0.4 to + 1.6)**	4.2 (3.7–4.8)	4.5 (4.1-5.0)	+ 0.3 (-0.2 to + 0.8)	+ 0.7 (-0.1 to + 1.5)	0.0737

dietary recommendations, regardless of changes in body weight, and by 23% among those who lost at least 10% of body weight [16]. e main mechanisms responsible for the reduction in hot flashes in our study may include a high fiber and a low fat content of the vegan diet, weight loss, a reduction in markers of inflammation [17], and an increased consumption of soy isoflavones [18].

e strengths of the current trial include a randomized, parallel design, which accounted for seasonal variation in diet and other lifestyle factors. e study also has limitations. e PDI scores were based on self-reported diet records. e participants were volunteers and may not represent the general population.

In conclusion, all three scores increased in the vegan group and correlated negatively with changes in body weight. e changes in PDI and uPDI were negatively associated with changes in severe hot flashes and remained significant even after adjustment for changes in BMI. ese findings suggest that minimizing the consumption of animal products and vegetable oil is an e ective strategy for reducing postmenopausal hot flashes and body weight, and that categorization of plant foods as "healthful" or "unhealthful" in this context, as done by the PDI, is unwarranted.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12905-024-03467-4.

Supplementary Material 1

Acknowledgements
Human Ethics and Consent to Participate The study was performed in accordance with the Declaration of Helsinki. The Advarra Institutional Review Board approved the study on September 2, 2020 (Pro00045315). All participants provided written informed consent. This study follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

Author contributions
HK and NDB designed and executed the study; HB, TZ-M, and MS prepared the data for analysis; RH performed the statistical analysis. All authors had full access to the data, contributed to the manuscript, and approved its nal version.

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Data availability
De-identi ed data will be made available upon reasonable request at hkahleova@pcrm.org.

Declarations

Human Ethics and Consent to participate
The study was performed in accordance with the Declaration of Helsinki. The Advarra Institutional Review Board approved the study on September 2, 2020 (Pro00045315). All participants provided written informed consent. This study follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

Consent for publication
Not Applicable.

Competing interests
Dr. Kahleova, Ms. Brennan, Ms. Znayenko-Miller, Ms. Sutton, and Dr. Holubkov received compensation from the Physicians Committee for Responsible Medicine for their work on this study. Dr. Barnard is an Adjunct Professor of Medicine at the George Washington University School of Medicine. He serves without compensation as president of the Physicians Committee for Responsible Medicine and Barnard Medical Center in Washington, DC, nonpro t organizations providing educational, research, and medical services related to nutrition. He writes books and articles and gives lectures related to nutrition and health and has received royalties and honoraria from these sources.

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