The effectiveness of *Ocimum basilicum* (basil) tea as an adjunct to medications in decreasing the blood pressure of hypertensive individuals

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Abstract

Introduction This study aimed to determine the effectiveness of basil tea as an adjunct to anti-hypertensive medications in decreasing the blood pressure of hypertensive subjects.

Methods Hypertensive patients were randomly allocated into either experimental (anti-hypertensive medications + basil tea) or control (antihypertensive medications alone) group. Experimental subjects drank basil tea twice daily for 28 days, with blood pressure readings done at baseline and on a weekly basis for four weeks.

Results A significant difference in systolic blood pressure was elicited for both treatment (p=0.005) and control (p=0.034) groups. There is a significant difference in the mean systolic (p=0.021) and diastolic blood pressure P (p=0.023) between the two groups at the fourth week in the basil tea group. There was a significant difference (p=0.046) in the mean difference in diastolic blood pressure from baseline to Week 4 in the basil tea group. There was a statistically significant decrease in systolic blood pressure between baseline and Week 4 (p=0.05).

Conclusion Basil tea, used as an adjunct to anti-hypertensive medications, elicited a statistically significant reduction in systolic blood pressure and a statistically significant difference in change of diastolic blood pressure after four weeks of treatment.

Key words: Basil, hypertension

Worldwide, hypertension is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths. This accounts for 57 million disability adjusted life years (DALYS) or 3.7% of total DALYS.[1] However, it is alarming that hypertension exists globally in 22% of adults aged 18 and over as of 2014 and it is known that 28% of Filipino adults had high blood pressure as of 2013.[2] The economic burden of hypertension is greater once it is left uncontrolled, which then leads to further complications.[1] Thus, alternative measures have to be explored to help aid in decreasing the financial burden for the patient.

In developing countries like the Philippines, traditional medicine is popular because it is accessible

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and affordable. *Ocimum basilicum* (basil tea) is a common plant found in the country that is known as a treatment for numerous ailments in addition to its popular use as a culinary herb. In Algeria and China, *O. basilicum* is a common herbal remedy for hypertension.[3] Studies on rats, but not on humans, have been done to explore the effect of *O. basilicum* on hypertension.[4] In recent years, studies on *O. basilicum* have found promising effects on the cardiovascular system. Preclinical trials on rats report its cardioprotective property against isoproterenol-induced myocardial infarction.[5] Another study noted that it has vasorelaxant and ADP-induced antiplatelet aggregation activity.[6] It can lower blood pressure in hypertensive-induced rats using the aqueous extract along with a reduction in endothelin, a potent vasoconstrictor.[4]

This study aimed to determine the effectiveness of *O. basilicum* tea infusion as an adjunctive treatment for hypertension in producing a statistically significant decrease in the systolic and diastolic blood pressure of hypertensive individuals. This study also aimed to determine the proportion of subjects who developed side effects while taking *O. basilicum* tea as adjunctive treatment.

Methods

This was a randomized, single-blind, negative-control clinical trial to determine the effect of *O. basilicum* leaf and stalk tea in decreasing the systolic blood pressure (SBP) and diastolic blood pressure (DBP) of hypertensive individuals in five barangays in San Juan City. Eligible subjects who consented were randomly assigned to either the experimental group (basil tea + antihypertensive medication/s) or the control group (antihypertensive medication/s alone), with the assigned intervention taken for 28 days. The investigators measured the blood pressure weekly for four weeks. The study was approved by the Ethics Review Committee of UERMMMCI and coordinated with the City Chief Medical Officer.

Whole plants of *O. basilicum* were authenticated at the National Museum, and its leaves and stalks were then air-dried until brown by a botanist in a clean room with a net surrounding it to prevent contamination. The dried leaves and stalks were ground and placed into tea bags, with each tea bag containing 1.5 grams of dried *O. basilicum*. The dosage of 1.5 grams was arbitrarily set based on the quantity per teabag of commercially-available teas.

The barangays chosen had the highest cases of hypertension in San Juan City as determined by the City Chief Medical Officer. Medical records from the barangay health centers were then reviewed in five barangays: Corazon de Jesus, Salapan, Batis, Kabayanan, and San Perfecto to identify potential adult male and female subjects. The researchers then went house-to-house, identified, oriented and screened the potential subjects. Those who agreed to participate were asked to sign an informed consent form and were thereafter interviewed to gather data for subject profiling.

The inclusion criteria were as follows: 1) stage I/II hypertensive, 2) currently taking anti-hypertensive maintenance medications, 3) 35 to 70 years old and 4) understood the compliance form mechanics. Those with any of the following were excluded: 1) renal conditions such as glomerulonephritis, chronic kidney disease, and end-stage kidney disease; 2) hepatic conditions such as hepatitis and cirrhosis; 3) hematologic conditions such as anemia, bleeding disorders, and platelet disorders; 4) congestive heart failure; 5) terminal illness; 6) hypersensitivity to *O. basilicum*; 7) anticoagulant/antiplatelet medications and 8) pregnancy or lactation.

A sample size of at least nine subjects per group was computed using the formula for the difference between population means and the following parameters: $Z_\alpha = 1.96$, $Z_\beta = 0.84$; $S_1 = 10.4$, $S_2 = 13.9$ and $\mu_1 = 100$, $\mu_2 = 84.4$ The researchers aimed to recruit at least 15 subjects per group, with 30 subjects total, as allowance for attrition.

The researchers obtained the subjects' height, weight, baseline BP, and usual daily physical activities. The researchers carried each weekly visit-from week 0 to week 4, in pairs. One person interviewed the subjects about side effects, compliance, and for all other concerns related to the study. The other person measured the blood pressure. The interviewer first talked to the subject alone. After obtaining the necessary information, the blinded researcher was then called to measure the BP using an aneroid sphygmomanometer (Baxtel®), and following the JNC 8 guidelines for taking the BP.[7] The blood pressure was measured with the respondent relaxed and in sitting position, with both feet flat on the ground. The arm was supported to be at the level of the heart. The subjects were instructed not to drink any caffeinated beverages such as coffee, not to do strenuous activity, not to smoke 30 minutes prior to

their BP measurement and not talk to the BP assessor. If they were unable to comply with these provisions, a 30-minute resting period was observed before their BP was measured. An average of two BP recordings with an interval of 5 minutes on the same extremity was done throughout the study. A third BP recording on the contralateral arm was added if the BP increased on the second reading. The weight was measured using a bathroom weighing scale. The daily physical activities were measured using the metabolic equivalent task (MET) presented in the 2011 Compendium of Physical Activities.[8] To take into account each subject's sex, age, body mass and height, the corrected METs formula was used.

After obtaining the baseline data, the subjects of the experimental group were given their supply of tea bags and distilled water for 28 days. They were instructed to steep the tea bag in hot water (1 regular cup) for 10 minutes and to take it twice a day - after breakfast and after dinner.[9] They were allowed to drink it cold by adding ice after the tea bag was steeped in hot water for the said duration. They were also allowed to add a teaspoon of brown sugar that was provided to them for better taste. They were also given hard copies of the instructions in Filipino.

Each subject was given a compliance sheet and was asked to fill it out every time he/she drank the infusion. They were also asked to keep their used tea bags for the week in a plastic bag, and this was checked weekly by the researchers to ensure compliance. They were also asked to take note of any side effects associated with drinking the infusion.

The researchers visited every subject once weekly to check the BP, compliance sheets and used tea bags. The researchers also asked at every visit if the subjects felt any side effects brought about by drinking the tea. This was repeated until the treatment period was over. The weight and daily physical activities were again recorded on the last week of visit. Over the course of the study period, both the experimental and control group subjects were asked to follow their doctors' recommendations regarding diet and physical activity.

The data were analyzed using a paired-samples t-test, independent samples t-test, and repeated measures analysis of variance (rANOVA) to compare the change in SBP and DBP for each treatment arm throughout the course of the study. Intention-to-treat (ITT) rather than a per-protocol analysis was done. For each dropout in the basil leaves tea and control arms, the last observation was carried forward and used for each subsequent time point, mimicking a non-effective medication scenario. An alpha of 0.05 was used in a 2-tailed normal distribution for all statistical tests. Microsoft Excel 2016 was used to encode the data, while IBM SPSS 24 was used to perform the specific statistical tests.

The demographic variables considered for initial comparison between treatment and control groups included sex, age, baseline SBP, baseline DBP, body mass index (BMI), MET scores, alcohol consumption, smoking, and therapy regimen (monotherapy or dual therapy, and drug type). Homogeneity of these variables at the beginning of the study was then established using the following: Levene's test was used for homogeneity of variance of blood pressure; independent t-test was used to check the homogeneity of age, BMI, and MET; and chi-square test was done for homogeneity of sex, those smoking and drinking alcohol, drug type, and if the subjects were on mono- or dual-therapy. Change in SBP and DBP between week 0 (baseline) and week 4 (end of study) was analyzed with a paired-samples t-test. Independent samples t-test was then done to determine whether the decrease in blood pressure was due to either the basil or the antihypertensive maintenance medications the subjects were taking. Lastly, repeated measures ANOVA (rANOVA) was used to analyze the significance of the changes in SBP and DBP weekly, and Mauchly's Sphericity test was used to validate the results of the rANOVA.

Treatment success was defined by a subject's ability to meet his/her target blood pressure as prescribed by the JNC 8 guidelines: <140/90 for subjects aged younger than 60 years and <150/90 for subjects aged 60 years or older.[7] Relative risk for treatment success was then calculated to determine which group - basil leaves tea or control was more likely to experience treatment success.

Results

The researchers were able to recruit 12 subjects per group with 4 dropouts (basil tea 3, control 1). The reasons for dropping out were unavailability of the subject, dislike of the taste of tea, and surgery within the duration of the study. The control group was older than the basil tea group and had a higher baseline systolic blood pressure but the differences were not significant. There were more women in the

study. The basil tea and control groups were comparable and this was confirmed by Levene's test for homogeneity, allowing the researchers to proceed with the analysis of change in blood pressure. The demographic characteristics of the two groups are seen in Table 1.

Change in blood pressure was determined as the difference between the baseline and Week 4 systolic and diastolic blood pressures. There was a significant decrease in the SBP in both groups but not in the DBP, as seen in Table 2. The mean difference in the SBP between the basil tea and control groups was significant, as seen in Table 3. The individual difference in SBP and DBP from baseline to week 4 were also calculated for each participant and revealed that the difference was significant for DBP, as seen in Table 4.

Although the paired-samples t-test produced statistically significant results, it was limited to an examination of the difference in SBP and DBP only between the baseline and Week 4 measurements. A rANOVA of the weekly changes in SBP and DBP for each group showed a statistically significant difference in SBP for the basil tea group only between the baseline and Week 4, as seen in Table 5. In contrast, there was no statistically significant reduction in SBP in the control group (overall rANOVA $p = 0.265$) at any point. Likewise, no statistically significant reduction in DBP was seen for both basil tea (overall rANOVA $p = 0.225$) and control (overall rANOVA $p = 0.665$) groups. Figure 1 shows the trend in blood pressure changes over the four-week period with their corresponding p-values generated by rANOVA.

Table 1. Baseline demographic characteristics of basil tea and control groups

Variable	Basil tea (n = 12)	Control (n = 12)	p-value
Age (yr)	53.7 ± 9.90	59.9 ± 6.73	0.084**
Sex			1.000***
Male	3	3	
Female	9	9	
SBP (baseline)	149.7 ± 13.80	159.6 ± 19.28	0.191*
DBP (baseline)	88.2 ± 8.09	88.2 ± 9.57	0.965*
Smoker	3	3	1.000***
Alcohol	4	3	0.653***
BMI	26.5 ± 4.00	26.3 ± 5.07	0.930**
MET	79.8 ± 21.48	87.2 ± 20.07	0.397**
Therapy			0.682***
Monotherapy	7	6	
Dual Therapy	5	6	
Drug Type			0.223***
ARB[a]	7	9	
ACEi[b]	1	2	
CCB[c]	8	4	
BB[d]	1	3	

*Levene's Test for homogeneity of variance;
**Independent t-test
***Chi-square test;
[a] ARB: Angiotensin II receptor blocker;
[b] ACEi: Angiotensin converting enzyme inhibitor;
[c] CCB: Calcium channel blocker;
[d] BB: Beta blocker

Table 2. Blood pressure changes in basil tea and control groups from baseline to week 4

		Baseline	Week 4	Mean difference (95% CI)	p-value*
SBP	Basil tea	149.7 ± 13.80	137.1 ± 7.97	12.6 (4.66, 20.52)	0.005
	Control	159.6 ± 19.28	151.6 ± 17.84	8.0 (0.71, 15.29)	0.034
DBP	Basil tea	88.2 ± 8.09	83.2 ± 7.58	5.0 (-0.89, 10.89)	0.089
	Control	88.2 ± 9.57	90.9 ± 7.94	-2.7 (-7.86, 2.53)	0.282

* Paired-samples t-test

Table 3. Comparison of change in mean blood pressure between basil tea and control groups

	Basel tea	Control	Mean difference (95% CI)	p-value*
SBP				
Baseline	149.7 ± 13.8	159.6 ± 19.28	9.9 (-4.28, 24.11)	0.161
Week 4	137.1 ± 7.97	151.6 ± 17.83	14.5 (2.49, 26.51)	0.021
DBP				
Baseline	88.2 ± 8.09	88.2 ± 9.57	0.1 (-7.42, 7.59)	0.982
Week 4	83.2 ± 7.58	90.9 ± 7.94	7.8 (1.18, 14.32)	0.023

* Independent samples t-test

Table 4. Comparison of mean difference in blood pressure between basil tea and control groups

	Basel tea	Control	Difference of means (95% CI)	p-value*
SBP (week 0 - week 4)	12.4 ± 12.33	7.9 ± 11.77	4.5 (-14.71, 5.69)	0.369
DBP (week 0 - week 4)	4.9 ± 9.26	2.6 ± 8.04	7.5 (-14.85, -0.15)	0.046

* Independent samples t-test

Table 5. Systolic blood pressure changes in basil tea group per week from baseline

	Mean SBP	Mean difference (95% CI)	P-value*
Baseline	149.7 ± 13.79	--	--
Week 1	141.7 ± 12.59	8 (-5.57, 21.57)	0.637
Week 2	138.2 ± 11.61	11.5 (-1.89, 24.89)	0.120
Week 3	137.2 ± 10.19	12.5 (-0.33, 25.25)	0.059
Week 4	137.1 ± 7.97	12.6 (0.002, 25.16)	0.050

* rANOVA

Treatment success for both groups with the last observation carried forward is tabulated in Table 6 and shows that the basil tea group is more likely to reach their blood pressure goals as prescribed by the JNC-8 guidelines (definition of treatment success for this study). However, the frequency of treatment successes and failures shows no statistically significant difference (p=0.414) between the

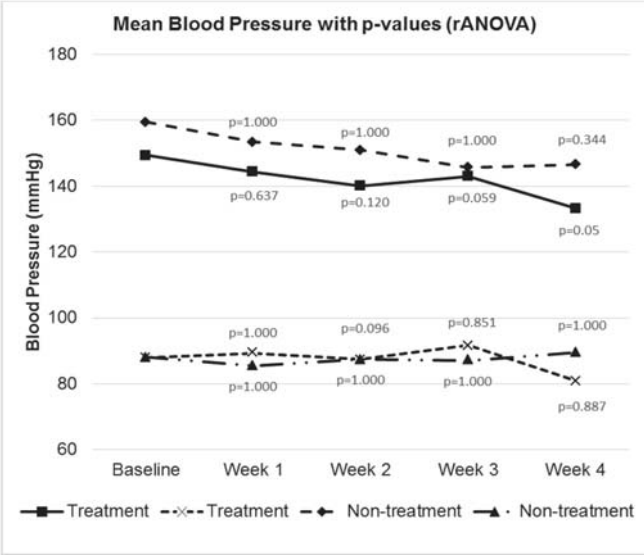

Figure 1. Trend in blood pressure change from baseline to Week 4

treatment and control groups. Treatment success in the worst-case scenario is also tabulated in Table 7, showing results that yield the same implications as those in Table 6.

The side effects listed by the subjects are flatulence and increased appetite. In the basil tea group, one participant experienced flatulence, while three participants experienced increased appetite. No participant in the control group experienced any such side effect. Using Fisher's Exact Test, both flatulence ($p = 1.000$) and increased appetite ($p = 0.217$) did not demonstrate statistical significance. The number needed to harm was calculated to be 12 for flatulence and four for increased appetite.

Discussion

The general objective of this study was to determine the effectiveness of *O. basilicum* (basil) tea as an adjunctive treatment with antihypertensive medications in decreasing the blood pressure of hypertensive individuals. *O. Basilicum* has been used to lower hypertension throughout history, and has been a part of traditional medicine practices in Algeria and China.[3,4]

The results show a statistically significant decrease in systolic but not in the diastolic blood pressure from baseline to Week 4. The results of the paired samples t-test showed statistically significant decreases in systolic blood pressure for both treatment and control groups after the four-week study period. However, since this test only measured change in blood pressure within each group, it did not reveal whether this effect was due to basil tea consumption or the antihypertensive medications that the participants were taking. Using an independent samples t-test comparing the baseline and Week 4 SBP measurements for the two groups,

Table 6. Treatment success: Last observation carried forward

	Treatment Success	Treatment Fail	RR for Treatment Success	p-value*
Basil tea	7	5	1.40	0.414
Control	5	7		

*Chi-square test with Yate's correction

Table 7. Treatment success: Worst case scenario

	Treatment Success	Treatment Fail	RR for Treatment Success	p-value*
Basil tea	7	5	1.17	0.683
Control	6	6		

*Chi-square test with Yate's correction

the authors could confirm that a statistically significant difference in the mean change of blood pressure between the two groups - indicating that the significant reduction in systolic blood pressure seen in the paired samples t-test was, in fact, due to the basil tea treatment.

An interesting finding, however, with the independent t-test, is the statistically significant difference that was also seen in the DBP in week 4 (p=0.023). At first glance, this may seem inconsistent with the results of the paired samples t-test, which indicated no significant reduction in DBP for either group in the four-week study period. The difference is that the paired sample t-test looked at the differences in blood pressure within each group from baseline to week 4, while the independent samples t-test compared the measurements between the basil tea and control groups at baseline and week 4 rather than within each group.

The differences in SBP and DBP from baseline to week 4 were also calculated for each participant. The differences were then compared using an independent t-test. There was no statistical difference in the change in SBP between the two groups, but a statistically significant difference was seen in the change in DBP. This shows that the difference in the change in DBP between the treatment and control groups from baseline to week 4 was statistically significant. The result showing this comparison was not statistically significant for SBP means that the change in SBP was not different between the two groups.

The rANOVA showed that there was no statistically significant reduction in SBP from baseline to week 4 for the control group, though the paired samples t-test did show that there was significant difference from baseline to week 4. Both the paired samples t-test and rANOVA assumed that the conditions at each time point were dependent and the means were compared within each group, but the paired samples t-test only compared two time points and may therefore be more prone to a type 1 error than the rANOVA that compared data from five time points in the study, and thus may explain this apparent discrepancy.

Two side effects were mentioned for the basil tea regimen - flatulence and increased appetite. The odds ratio for each is undefined, as the control group did not experience such side effects. Using Fisher's Exact Test, both side effects were not shown to be statistically significant, though they were both included in the analysis precisely because no previous studies have shown any side effect profile for human consumption of basil tea.

The calculation of relative risk for treatment success showed that the basil treatment was effective (RR = 1.40), though the difference in successes between the treatment and control groups were not significant (p = 0.414). This may be explained by the fact that there were three dropouts in the treatment group after the baseline subject data were obtained. Per intent to treat analysis procedures, the subjects' initial data were analyzed as part of treatment group and since they did not agree to further visits, their last observed BP was used for each subsequent time point (last observation carried forward). Thus, these subjects were noted as 'treatment failures' from the start of the study, and may have contributed to the lack of significance when treatment successes were calculated. Computations for the worst case scenario were also performed, which likewise indicated that the treatment was effective (RR=1.167), though the difference in successes between the two groups was not significant (p=0.683).

There have been no human trials and very few animal studies that have explored the exact mechanism of action of *O. basilicum's* effects on hypertension. These studies have shown that several pathways may be involved in the mechanisms of action for *O. basilicum*.

A study by Aftab demonstrated that crude extract of basil and pure eugenol extract, which was determined to be a major phytochemical compound of *O. basilicum*, caused a fall in systolic, diastolic and mean blood pressure in anesthetized rats. Comparing multiple drug effects, the study deduced that eugenol acting as a calcium channel blocker was the most likely pathway through which *O. basilicum* effected the fall in BP.10

Another study by Umar explored the effect of the O. basilicum aqueous extract on hypertensive-induced Wistar rats and showed that this caused a decrease in their SBP and DBP, and a decrease in hypertension-induced hypertrophy of the heart of rats. There was also a variable decrease in angiotensin-II and a considerable decrease in serum endothelin concentrations. Endothelin is a potent vasoconstrictor and is involved in cardiac remodeling. This study suggests that the decrease in

blood pressure and cardiac hypertrophy caused by *O. basilicum* extract may be partly due to similar actions to endothelin converting enzyme inhibitors leading to decreased serum endothelin levels.[4]

Another study by Fathiazad on Wistar rats demonstrated a suppression in isoproterenol-induced ST-segment elevation.[5] The sharp reduction in left ventricular contractility and a marked increase in left ventricular end-diastolic pressure were also significantly improved with the aqueous extract of *O. basilicum*. The results were related to the potent antioxidant activities of its phenolic compounds, with rosmarinic acid as the principal phenolic compound, and presence of flavonoids that were found during phytochemical screening. The study suggested that *O. basililicum* has cardioprotective effects related to its antioxidant properties.

These animal studies support the findings of the present study, which shows a statistically significant drop in systolic BP in the basil treatment group. The multiple mechanisms of action described by the animal studies may all contribute to the decrease in SBP seen in this study. However, more studies are needed to determine the different effects of the multitude of phytochemicals found in *O. basilicum*.

Basil tea, when used as an adjunct to antihypertensive medications, elicits a statistically significant reduction in systolic blood pressure and a statistically significant difference in the change of diastolic blood pressure after four weeks of treatment for this specific population of respondents. Its long-term effects were not assessed and not part of the scope of the study. The limited results of this study showing that *O. basilicum* has antihypertensive effects as an adjunct should encourage researchers to explore and determine its antihypertensive properties. Further studies employing a larger sample size and assessing its long-term effects may be carried out.

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