

# The effects of foot reflexology on blood pressure and heart rate: A randomized clinical trial in stage-2 hypertensive patients

Praew Kotruchin MD, PhD<sup>1</sup>  | Supap Imoun MSN<sup>2</sup> | Thapanawong Mitsungnern MD<sup>1</sup> | Patcharin Aountraï MSN<sup>2</sup> | Maneenuch Domthaisong MSN<sup>2</sup> | Kazuomi Kario MD, PhD<sup>3</sup> 

<sup>1</sup>Department of Emergency Medicine, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

<sup>2</sup>Accident and Emergency Nursing Unit, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

<sup>3</sup>Division of Cardiovascular Medicine, Jichi Medical University School of Medicine, Shimotsuke, Japan

## Correspondence

Praew Kotruchin, MD, PhD, 123/2000 Department of Emergency Medicine, Faculty of Medicine, Khon Kaen University, Muang, Khon Kaen 40002, Thailand.  
Email: kpraew@kku.ac.th

## Abstract

Hypertension (HT) is a prominent cardiovascular risk factor. Although there are various pharmacological treatment choices for this condition, many patients fail to adhere to them, making non-pharmacological options attractive alternatives. Foot reflexology has been proven to decrease blood pressure (BP), but data are limited in patients with stage-2 HT. We conducted a randomized clinical trial to examine the effectiveness of foot reflexology in reducing BP and heart rate (HR). Stage-2 HT patients were enrolled and randomized into the intervention and the control groups ( $n = 47$ , each), the former of which underwent foot reflexology during a follow-up visit. Office BP and HR were measured before and at 15 and 30 min after the procedure in the intervention group and after resting in the control group. In the intervention group, systolic BP (SBP), diastolic BP (DBP), and HR at 15 min were significantly lower than at baseline:  $-3.29$  mm Hg (95%CI;  $-5.64$  to  $-0.93$ ),  $-1.71$  mm Hg (95%CI;  $-3.11$  to  $-0.32$ ), and  $-1.71$  beats per min (bpm; 95%CI;  $-2.88$  to  $-0.54$ ), respectively. Similar trends were also observed at 30 min. However, when compared with the control group, only the reduction in HR was significant ( $-4.96$  bpm; 95%CI,  $-9.63$  to  $-0.28$ ). We conclude that foot reflexology was effective in reducing HR in stage-2 HT patients and partially effective in reducing BP.

## 1 | INTRODUCTION

Uncontrolled hypertension (HT) is an important risk factor for major cardiovascular events.<sup>1</sup> Moreover, one study in the United States found that only half of patients achieve target blood pressure (BP).<sup>2</sup> Based on national health survey data, the rate of uncontrolled HT (BP  $>140/90$  mm Hg) in Thailand is approximately 80% in patients undergoing conventional treatment.<sup>3</sup> Recent HT guidelines recommend a lower BP target ( $\leq 130/80$  mm Hg) for the prevention of cardiovascular events in adults,<sup>4,5</sup> which further increases the rate of uncontrolled HT. In addition to elevated BP, increased heart rate (HR) is also common in HT patients. Epidemiological studies found that around 40% of HT patients had HR  $>80$  beats per minute (bpm)<sup>6</sup>

and that HR was associated with increased risk of cardiovascular events and all-cause mortality.<sup>7</sup> There have been various studies examining the effectiveness pharmacological treatments for BP and HR,<sup>8,9</sup> but there are limited data available on the impact of non-pharmacological treatment options.

Previous studies have shown complementary therapies (eg, music therapy, acupuncture, and reflexology) to be effective adjunctive treatments for lowering BP.<sup>10-13</sup> Foot reflexology, a traditional therapy that is well-known in many Asian countries (such as China, India, and Thailand), is one such promising treatment.<sup>14,15</sup> However, there is yet no consensus regarding the effect of foot reflexology on systolic and diastolic BP (SBP and DBP).<sup>16-18</sup> Although one trial found foot reflexology to be beneficial in terms of stress response

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and biofeedback,<sup>19</sup> there have yet been no randomized trials showing its effect on both BP and HR. In addition, while many trials have explored the benefits foot reflexology in chronic disease and cancer patients,<sup>20,21</sup> few have enrolled only HT patients.<sup>16-18</sup>

Foot reflexology is a noninvasive treatment and has long been practiced in Thailand. It is recommended by the Department of Thai Traditional and Alternative Medicine under the Ministry of Public Health in order to promote health in older adults,<sup>22</sup> suggesting that it may be useful as an adjunctive treatment for HT patients. This was a well-controlled, randomized trial to examine the effects of foot reflexology on office SBP, DBP, and HR in individuals with stage-2 HT.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design and setting

This study was a parallel-group, randomized clinical trial (RCT) conducted from November 1, 2018 to May 31, 2019 at the Hypertensive Crisis Clinic at Srinagarind Hospital, a tertiary-care university hospital located in northeast Thailand. The Khon Kaen University ethics committee approved the study protocol, and informed consent was obtained from all participants before enrollment. This trial was registered retrospectively on ClinicalTrials.gov (registration number: NCT04516005).

### 2.2 | Participants

Eligible participants were adults between 40 and 80 years of age diagnosed with stage-2 HT (defined as office SBP  $\geq 140$  mm Hg and/or DBP  $\geq 90$  mm Hg at the first hospital visit) and who had been on a stable anti-HT drug regimen for at least 3 months before enrollment. Exclusion criteria were (a) pregnancy, (b) history of foot surgery or bone fracture, (c) skin disease of the foot, and (d) diabetic neuropathy.

### 2.3 | Sample size calculation

The sample size for comparing mean SBP and DBP with repeated measures was calculated using the following parameters: two tails, alpha error probability of 0.05, and power of test of 0.8. The expected differences in SBP and DBP between the intervention and control group were 10 and 6 mm Hg, respectively.<sup>16</sup> Based on this, we determined that a total 80 participants (40 in each group) would be required.

### 2.4 | Study protocol

#### 2.4.1 | Randomization

After giving informed consent, participants were randomized into either the intervention group (foot reflexology group) or the control

group using computer-generated block randomization (block of four [1:1]; Figure 1). Non-team members performed the randomization, and investigators involved in enrolling participants had no access to the randomization lists. Randomization numbers were kept in opaque, sealed envelopes, which were selected and opened by the treatment investigators after history taking and physical examination of the patients. Treatment investigators and participants knew the results of the randomization, but the investigator responsible for statistical analysis was blinded.

#### 2.4.2 | Foot reflexology

Foot reflexology was performed in all participants in the intervention group after they had rested for 5 min in a sitting position. In all cases, the procedure was performed by the same researcher, who was trained and certified by the Ministry of Public Health's Department of Thai Traditional and Alternative Medicine. Acupressure was applied at the plantar side of the right foot at the first metatarsal bone, around 1-1.5 cm proximal to the first metatarsophalangeal joint (Figure 2). Approximately 3 kg of pressure was applied using a knuckle of the right index finger (dorsal part of the proximal interphalangeal joint in a flexing position) in a perpendicular manner and held for 15 s then released for 5 s. This hold-release cycle was performed five times over the total course of 2 min. The Department of Thai Traditional and Alternative Medicine recommends this method in accordance with zone and meridian theories.<sup>14</sup>

#### 2.4.3 | Conventional treatment

Participants in the intervention and the control group received the same conventional treatment, including anti-HT drugs, according to standard HT guidelines.<sup>4</sup> At the end of the follow-up visit, all participants were instructed to adhere to their drugs and encouraged to lead healthy lifestyles including salt restriction, regular exercise, and healthy diets.

#### 2.4.4 | BP and HR measurements

Each patient's BP level at first HT diagnosis was retrieved from electronic medical records (Health Object, Srinagarind Hospital) in order to assess their eligibility. After enrollment, office BP and HR were measured by a nurse at baseline (0 min) and again at 15 and 30 min after foot reflexology in the intervention group and after resting in a quiet room in the control group. A validated, FDA-approved automatic BP device (DINAMAP Pro 300, GE healthcare) with the appropriate cuff size for the patient's arm circumference was used for all measurements. Two BP measurements were taken at 2-min intervals, and the average BP and HR were recorded for analysis.

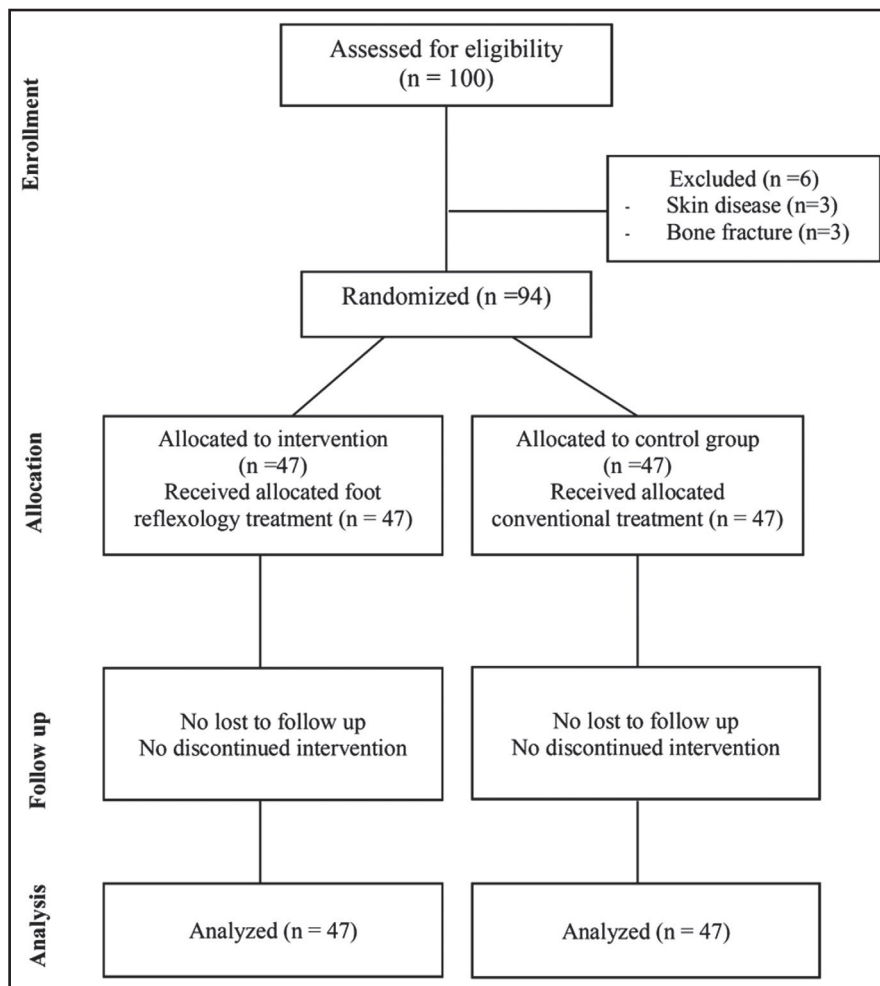


FIGURE 1 CONSORT flow diagram. Flow diagram of the progress through the phases of the parallel-randomized trial

## 2.5 | Adverse event monitoring

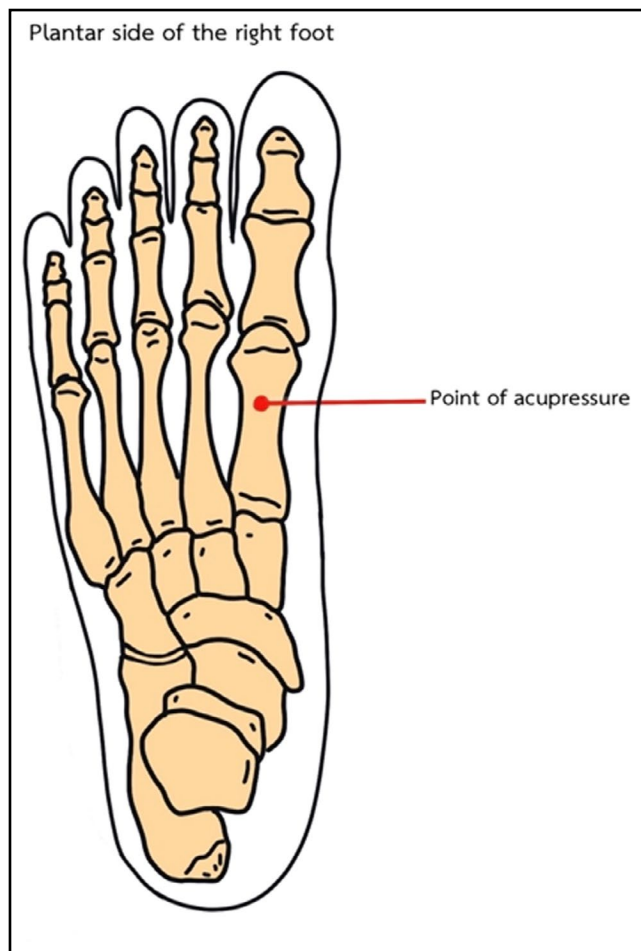
All participants were instructed to immediately report any adverse events occurring after enrollment and during the study period. Participants with life-threatening adverse events (as determined by the treatment investigators) were withdrawn prematurely from the study for safety reasons.

## 2.6 | Statistical analysis

All analyses were based on the intention-to-treat principle. Baseline characteristics were shown as mean  $\pm$  standard deviation (SD) or percentage (%). A paired *t* test was used to compare SBP, DBP, and HR at baseline and at 15 and 30 min after acupressure in the intervention group and after resting in the control group. A general estimating equation (GEE) was used to compare SBP, DBP, and HR between the two randomized groups. A probability value of  $<.05$  was considered statistically significant. All statistical analyses were performed using STATA version 10.1 (registered to Khon Kaen University).

## 3 | RESULTS

A total of 100 participants were enrolled, 94 of whom were included in the final analysis (47 participants in each group). Of the six who were excluded, three had skin diseases of the feet and three had a history of metatarsal bone fractures (Figure 1). The mean age was  $57.5 \pm 8.5$  years in the intervention group and  $56.0 \pm 8.5$  years in the control group. In both groups, the majority of participants were women: 70.2% and 72.3% in the intervention and control group, respectively. Participants in the two groups had similar marital status, smoking and drinking habits, underlying diseases, and family history of HT (Table 1). Regarding the type of anti-HT drugs, participants in both groups received comparable calcium channel blockers (CCB) and angiotensin-converting enzyme inhibitors (ACEI)/angiotensin receptor blockers (ARB), but participants in the control group received more beta-adrenergic blockers (12.8% vs 4.3%) and diuretics (8.5% vs 2.1%) compared with the intervention group (Table 1). Baseline office SBP and DBP in the reflexology and the control groups were comparable (SBP: 139.0 and 136.3 mm Hg, respectively, and DBP: 81.2 and 80.8 mm Hg, respectively; all  $p > .05$ ). However, baseline HR in the foot reflexology group was moderately lower than in the control group (76.5 bpm vs 81.4 bpm;  $p = .113$ ; Table 2).



**FIGURE 2** Location of foot reflexology used in the present study. Acupressure was applied at the plantar side of right foot at the first metatarsal bone, around 1–1.5 cm proximal to the first metatarsophalangeal joint

In the reflexology group, SBP, DBP, and HR decreased significantly from baseline after intervention, with mean differences of  $-3.29$  mm Hg (95% CI:  $-5.64$  to  $-0.93$ ),  $-1.71$  mm Hg (95%CI:  $-3.11$  to  $-0.32$ ), and  $-1.71$  bpm (95% CI:  $-2.88$  to  $-0.54$ ), respectively, at 15 min and  $-3.18$  mm Hg (95% CI:  $-5.57$  to  $-0.79$ ),  $-1.55$  mm Hg (95%CI:  $-2.97$  to  $-0.14$ ), and  $-2.94$  bpm (95% CI:  $-3.98$  to  $-1.90$ ), respectively, at 30 min (Figure 3). In the control group, there were no significant differences from baseline at 15 min after resting, but SBP and HR had decreased significantly after 30 min, with mean differences of  $-2.04$  mm Hg (95%CI:  $-4.07$  to  $-0.18$ ), and  $-1.83$  bpm (95% CI:  $-3.25$  to  $-0.41$ ), respectively. The mean difference in DBP at 30 min was not statistically significant ( $-0.23$  mm Hg; 95%CI:  $-0.88$  to  $2.00$ ; Figure 3).

Comparison between the two groups using the GEE showed that overall SBP and DBP at the end of the study in the foot reflexology group were lower than in the control group:  $-2.68$  mm Hg (95%CI:  $-2.60$  to  $7.96$ ) and  $-0.49$  mm Hg (95%CI:  $-3.27$  to  $4.25$ ), respectively. However, these differences were not statistically significant.

**TABLE 1** Baseline characteristics

Measures	Foot reflexology group (n = 47)	Control group (n = 47)
Age, y (mean $\pm$ SD)	57.5 $\pm$ 8.5	56.0 $\pm$ 8.5
Female, %	72.3	70.2
Body mass index, kg/m <sup>2</sup> (mean $\pm$ SD)	24.7 $\pm$ 3.5	24.3 $\pm$ 3.6
Occupation, n (%)		
Farmer	3 (6.4)	0
Merchant	6 (12.7)	10 (21.3)
Homemaker	9 (19.2)	6 (12.7)
Self-employed	4 (8.5)	7 (14.9)
Government officer	16 (34.0)	15 (31.9)
No occupation	9 (19.2)	9 (19.2)
Marital status, n (%)		
Single	6 (12.7)	6 (12.7)
Married	34 (72.3)	34 (72.3)
Divorced	7 (14.9)	7 (14.9)
Current smoker, n (%)	9 (19.1)	8 (17.0)
Alcohol consumption, n (%)	7 (14.9)	6 (12.7)
Family history of hypertension, n (%)	30 (63.8)	27 (57.4)
Diabetes, n (%)	12 (25.5)	11 (23.4)
Hyperlipidemia, n (%)	25 (53.2)	23 (48.9)
Type of anti-hypertensive drugs, n (%)		
Calcium channel blockers	30 (63.8)	32 (68.1)
ACEI/ARB	32 (68.1)	31 (66.0)
Beta-adrenergic blockers	2 (4.3)	6 (12.8)
Diuretics	1 (2.1)	4 (8.5)
No. of anti-hypertensive drugs, n (%)		
1	18 (38.3)	23 (48.9)
2	28 (59.6)	23 (48.9)
$\geq 3$	1 (2.1)	1 (2.1)

Abbreviations: ACEI, angiotensin-converting enzyme inhibitors; ARB, angiotensin receptor blockers; No, number.

Interestingly, HR in the foot reflexology group was significantly lower than in the control group, with a difference of  $-4.96$  bpm (95%CI:  $-9.63$  to  $-0.28$ ; Table 2, Figure 3).

## 4 | DISCUSSION

Hypertension is a leading cause of major cardiovascular events and disability-adjusted life years in many populations,<sup>1</sup> and early administration of anti-HT drugs is recommended for BP control in stage-2 HT patients.<sup>4</sup> However, previous trials have reported low adherence to medication in more than half of treated HT patients, partly due to the presence of intolerable side effects.<sup>23,24</sup> This

**TABLE 2** Comparison of systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) between the foot reflexology and control groups

	Foot reflexology	Control	<i>p</i>
<b>SBP</b>			
Difference in change (95% CI)	-2.68 (-2.60 to 7.96)		.320 <sup>a</sup>
Baseline, mean (95% CI)	139.0 (135.5 to 142.6)	136.3 (132.2 to 140.5)	.959 <sup>b</sup>
After 15 min, mean (95% CI)	132.3 (128.3 to 136.3)	136.5 (132.1 to 140.8)	.466 <sup>b</sup>
After 30 min, mean (95% CI)	130.6 (126.7 to 134.5)	138.4 (134.3 to 142.5)	.017 <sup>b</sup>
<b>DBP</b>			
Difference in change (95% CI)	-0.49 (-3.27 to 4.25)		.798 <sup>a</sup>
Baseline, mean (95% CI)	81.3 (78.5 to 84.0)	80.8 (78.0 to 83.5)	>.999 <sup>b</sup>
After 15 min, (95% CI)	78.6 (75.9 to 81.4)	80.0 (77.4 to 82.5)	>.999 <sup>b</sup>
After 30 min, (95% CI)	77.9 (75.0 to 80.8)	81.0 (78.6 to 83.4)	.295 <sup>b</sup>
<b>HR</b>			
Difference in change (95% CI)	-4.96 (-9.63 to -0.28)		.038 <sup>a</sup>
Baseline, mean (95% CI)	76.5 (73.3 to 79.6)	81.4 (77.6 to 85.2)	.113 <sup>b</sup>
After 15 min, mean (95% CI)	73.9 (70.8 to 77.0)	80.6 (76.9 to 84.3)	.015 <sup>b</sup>
After 30 min, mean (95% CI)	72.4 (69.6 to 75.3)	79.6 (75.7 to 83.5)	.008 <sup>b</sup>

<sup>a</sup>Using the generalized estimating equations (GEE) model.

<sup>b</sup>Pairwise comparison of between group contrasts (Bonferroni).

suggests that integrative treatment including non-pharmacological therapies may be beneficial. This study found that foot reflexology was effective in lowering HR in stage-2 HT patients, as demonstrated by the significant difference in the degree of HR reduction between the intervention and control group. We also observed decreases in both SBP and DBP, but these differences were not statistically significant.

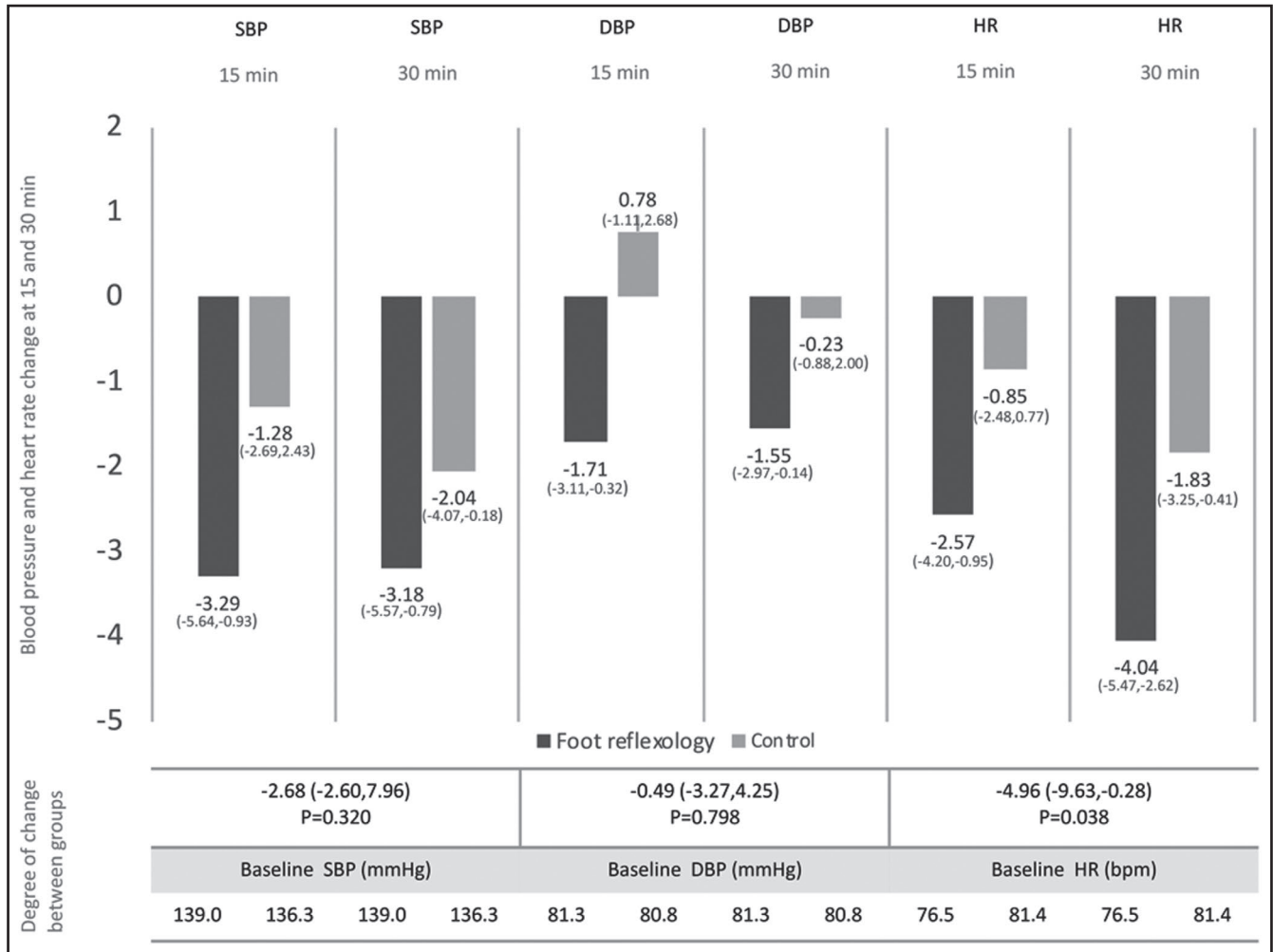
Although this and previous studies have found that foot reflexology can lower BP, results have been inconsistent. An RCT in Taiwan, for example, found that patients who received acupressure at the Taichong point (dorsum of the right foot, at the distal hollow of the junction between the first and second metatarsal bone) exhibited significant reductions in SBP and DBP at 15 and 30 min compared with controls.<sup>16</sup> However, another clinical study in Korean essential-HT patients (nonequivalent control group, pretest-posttest design) showed that foot reflexology lowered SBP but not DBP.<sup>18</sup> These discrepancies might be explained by slight differences in reflexology technique across studies (eg, location of the acupressure point, intensity applied, and duration of the procedure). Further clinical studies should thus

be conducted compare techniques and determine the most beneficial acupressure point, intensity, and duration for BP and HR reduction.

Although the mechanism behind foot reflexology's ability to lower HR is unclear, it may be similar to that of acupuncture. Although unlike acupuncture, acupressure does not involve the subdermal insertion, pressure is applied at the same points. Meridian theory in traditional Chinese medicine describes the BP- and HR-lowering mechanisms of acupuncture in terms of "Qi" which is believed to be a vital force forming part of any living entity.<sup>14</sup> Acupuncture targets the points of the human body that are responsible for the regulation of vital energy,<sup>14</sup> and puncturing or applying pressure to the Taichong point of the foot allows Qi to flow smoothly, thereby lowering BP.<sup>14,25,26</sup> Another possible mechanism involves the ability of these techniques to induce relaxation. Some studies conducted in elderly and cardiovascular disease patients, for example, found foot reflexivity to be effective in relieving anxiety,<sup>27,28</sup> which decreased BP and HR as observed in the present study.

Blood pressure levels and variability are important parameters for predicting a poor outcomes in cardiovascular patients,<sup>29</sup> and HR is an essential factor in the assessment and treatment of HT patients, especially those with co-morbidities such as heart failure or myocardial infarction. Elevated BP and HR in these patients are associated with increased risk for cardiovascular complications but are, fortunately, correctable.<sup>30-32</sup> Foot reflexology requires only around 2 min per session and is can be easily performed by anyone who is properly trained. In addition, if performed regularly at home by the patient, it may result in long-term improvements in BP, HR, and cardiovascular outcomes. However, further studies are required to determine the long-term benefits of foot reflexology.

The strength of the present study was that we measured SBP, DBP, and HR, whereas most previous studies focused only on BP. Second, this was an RCT, which limited the possibility of selection bias. Third, we standardized the technique and intensity of the procedure by assigning only one certified nurse to perform the intervention. However, our study also had some limitations. Although HR after acupressure in the intervention group was significantly lower than in the control group, average baseline HR in the intervention group was 5 bpm lower than in controls. This difference was not statistically significant; however, care should be taken when interpreting our results since the different starting points might limit the comparability. Another limitation was that this study measured the short-term effects of foot reflexology based on office BP, which made it difficult to control for the white-coat effect. Home BP monitoring (HBPM) or ambulatory BP monitoring (ABPM) have greater correlation with future CV events than office BP, as they represent BP absent the external stress of the hospital environment.<sup>33,34</sup> We suggest that further studies should measure HBPM or ABPM rather than office BP. Furthermore, our data were obtained from Thai participants and may thus not be generalizable to patients of other ethnicities or cultural backgrounds. Finally, lifestyle-related data, such as salt intake, exercise, anxiety, and stress, were not collected or analyzed.



**FIGURE 3** Blood pressure (BP) and heart rate (HR) change in the foot reflexology and control groups and comparison of the degree of BP and HR change between groups. At 15 and 30 min after the intervention, systolic BP (SBP), diastolic BP (DBP), and HR had significantly decreased from baseline in the foot reflexology group. In the control group, there was no significant difference in SBP, DBP, or HR at 15 min, but at 30 min, SBP and HR had decreased significantly. Overall, SBP and DBP at the end of the study in the foot reflexology group were lower than in the control group, but this difference was not statistically significant. However, HR in the foot reflexology group was significantly lower than in the control group. Abbreviations: 95% CI, 95% confidence interval; bpm, beats per minute; mm Hg, millimeter of mercury

## 5 | CONCLUSION

Foot reflexology was effective in reducing HR in stage-2 HT patients and was partially effective in reducing BP. It is noninvasive and can be performed in a short period of time as a complimentary therapy.

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## CONFLICT OF INTEREST

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## AUTHOR CONTRIBUTIONS

Praew Kotruchin: Conceived and designed the analysis; Performed the analysis; Wrote the paper. Supap Imoun: Collected the data; Contributed data. Thapanawong Mitsungnern: Collected the data. Patcharin Aountrai: Collected the data. Maneenuch Domthaisong: Collected the data. Kazuomi Kario: Helped supervise the project and manuscript.

## ORCID

Praew Kotruchin  <https://orcid.org/0000-0003-3519-3415>Kazuomi Kario  <https://orcid.org/0000-0002-8251-4480>

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