ORIGINAL RESEARCH

Inflationary noninvasive blood pressure monitoring reduces lower-limb pain during measurement

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ABSTRACT

Objective: This study aimed to investigate whether inflationary noninvasive blood-pressure measurement reduces pain during blood-pressure monitoring with the lower limbs compared to the conventional noninvasive measurement method.
Methods: Healthy volunteers aged $\geq$ 18 years were recruited for the study. After seating the participants, a manchette was fitted onto each limb (upper limbs: YP-713T YAWARA CUFF2 13 cm; lower limbs: YP-715T YAWARA CUFF2 for thigh 19 cm, Nihon Kohden Tokyo, Japan). The inflationary and conventional noninvasive blood-pressure measurement devices (PVM-9901 and PVM-9901, Nihon Kohden, Tokyo, Japan) were connected, and the blood pressure was measured simultaneously at two points in the upper and lower limbs. After the measurement, the participants answered a questionnaire regarding the lower-limb pain, and the intensity of pain was evaluated using the visual analog scale.
Results: The study included 111 healthy volunteers. The visual analog scale scores of the upper and lower limbs were significantly lower with the inflationary noninvasive blood pressure measurement device than with the conventional noninvasive blood pressure device (upper limbs: 25.6 ± 23.2 vs. 38.8 ± 27.5, $p < .001$ and lower limbs: 42.2 ± 25.1 vs. 54.2 ± 26.1, $p < .01$, respectively).
Conclusions: We examined the effect of pain reduction on the lower limbs with inflationary noninvasive blood-pressure measurements in healthy volunteers. We conclude that inflationary noninvasive blood pressure measurement may reduce pain in the lower limbs during blood-pressure monitoring compared to a conventional noninvasive blood pressure measurement.

Key Words: Blood pressure, Pain measurement, Lower limb, Noninvasive

1. INTRODUCTION

Blood pressure (BP) is a vital indicator of health and is monitored instantaneously in the peri- and postoperative periods. Clinical BP monitoring is also necessary for patients under intensive care, critical care, emergency care, and on hemodialysis.

The current noninvasive blood pressure (NIBP) measurement devices have been developed based on the traditional deflation-based techniques, in which the cuff is quickly pressurized to the target pressure level followed by measurement of the BP after the cuff is deflated. A relatively new, linear, inflationary noninvasive blood pressure (i-NIBP) measurement device, introduced commercially in 2014, slowly pressurizes the cuff at a rate of 10 mmHg/s, and just after the systolic blood pressure (sBP) is measured, the cuff is released to end the measurement process. Recent reports demonstrated that

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this i-NIBP method has a shorter measurement time than the conventional NIBP (c-NIBP) method, while both have comparable accuracies.[1,2]

Moreover, the c-NIBP device requires a high measurement time because when the sBP is high, the maximum pressure reached will be higher, which requires more time to reach. Moreover, excessive pain during measurement, subcutaneous hemorrhage at the measurement site, edema, and peripheral neuropathy have been reported for the c-NIBP technique.[3,4] In contrast, the i-NIBP device operates gradually and enables BP measurement during pressurization such that the maximum pressurization time and overall measurement time spans are shorter (see Figure 1). Additionally, it is expected to reduce those unavoidable complications.

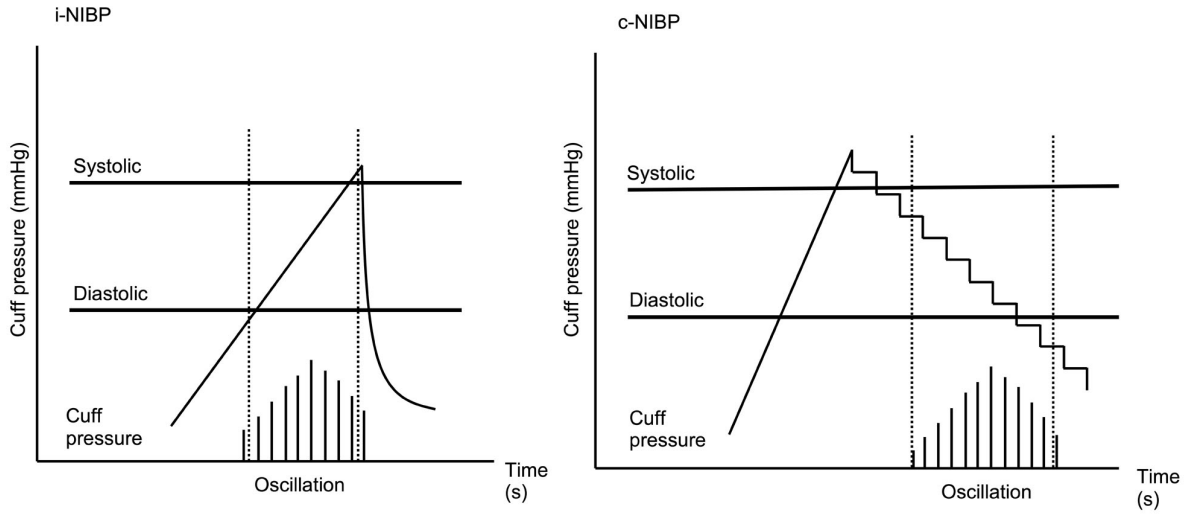

Figure 1. Difference between i-NIBP and c-NIBP measurement techniques

We translated and arranged the original figure from the manufacturer's homepage.[9] For c-NIBP measurement, the cuff pressure is quickly pressurized above the systolic pressure and gradually deflated while measuring the blood pressure. For i-NIBP measurement, the cuff is pressurized more slowly than for c-NIBP measurement, and BP is measured during the pressurization process, followed by cuff deflation as soon as the systolic pressure has been measured.

In some patients, BP measurement of the forearm is challenged by their morbidities (e.g., dialysis patients with shunt extensions in the upper limbs, patients with upper-limb trauma and burn, or those with lymph-node dissection after breast cancer surgery). For such cases, BP must be measured on the lower limbs. When BP is measured on the lower limbs, more discomfort is experienced than with the upper limbs.[5] Physiologically, a BP reading measured on the thigh is higher than that on the forearm and requires more time.[5] Moreover, the maximum pressure in the lower limbs is higher, which inevitably leads to higher pressurization of the manchette. Therefore, c-NIBP measurement on the thigh requires higher pressurization and longer measuring periods, which complicate this process for the patients. In contrast, no report has yet described the occurrence of pain experienced during i-NIBP measurement with the lower limbs.

Therefore, we hypothesized that if the i-NIBP measurement could reduce the measurement time and associated complications, especially with the lower limbs as opposed to the upper limbs, then it would be regarded as safer and relatively more useful. The objective of this study was to investigate and compare the extent of pain reduction during i-NIBP and c-NIBP measurements on the lower and upper limbs.

2. METHODS

2.1 Design

This was an experimental study to compare the differences in pain caused by different blood pressure measurement methods in healthy volunteers. The participants were recruited from December 2017 to July 2019 using publicly shared posters. The criterion used for inclusion was age $\geq$ 18 years. Additionally, those who could not undergo i-NIBP measurement because of unsuitable manchette size, presence of arrhythmia, unstable hypertension, or risk of limb ischemia were excluded. During the experiment, if uncontrollable pain, significant hypertension, or limb ischemia symptoms appeared, the experiment was interrupted. The study was approved by the Clinical Research Ethics Review Committee of the University of Tsukuba Hospital (H29-147).

2.2 Measurement procedure

The study protocol is shown in Figure 2. Before starting the study protocol, sufficient consideration was given to the participant's understanding of the outline, voluntary participation, anonymity, and confidentiality of personal information. After explaining the above information to the participants in writing, each participant provided informed consent and answered the questionnaire that retrieved personal information, medical history, and other health-related information to confirm their good health status of the participant. Each participant was made to sit on a chair, and the manchette was attached to the forearm and thigh (YP-713T YAWARA CUFF2 13 cm and YP-715T YAWARA CUFF2 19 cm, Nihon Kohden Tokyo, Japan, respectively). After a 5-min rest period, the i-NIBP and c-NIBP monitoring devices (PVM-9901, Nihon Kohden, Tokyo, Japan) were connected to each cuff, and BP was measured (see Figure 1). Thereafter, the participants answered a questionnaire regarding pain using the visual analog scale (VAS) score. After a 1-min rest period for each measurement, BP was measured on each of the four limbs using each method. In total, eight BP readings were recorded.

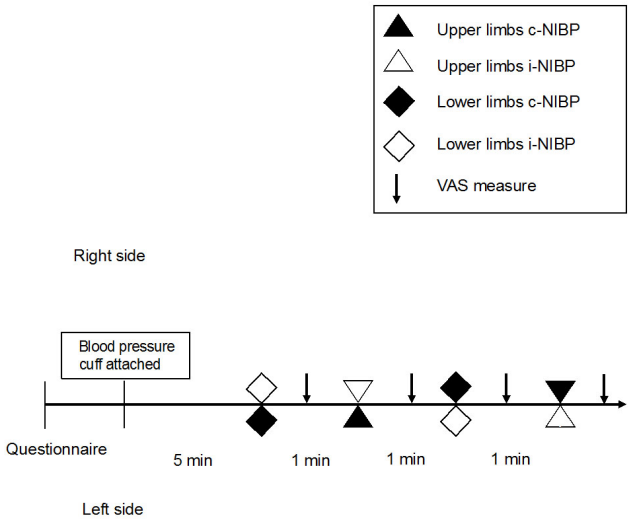

Figure 2. Study protocol

After answering the questionnaire, the participants were fitted with cuffs on their upper and lower limbs. Simultaneous i-NIBP and c-NIBP measurements were performed and repeated four times (eight NIBP readings obtained).

2.3 Data collection

The age and sex of all participants were recorded. After BP measurement, the degree of pain was evaluated based on the VAS score range (0–100). For systolic, diastolic, and mean BP measurements, differences in the maximum pressure and press time were assessed. The difference in maximum pressure was determined by subtracting the actual sBP from the maximum pressure reached during measurement.

2.4 Data analysis

The values were expressed as means ± standard deviations for parametric data and medians (interquartile ranges [IQRs]) for nonparametric data. One-way analysis of variance was performed for evaluating sBP, VAS, the difference in maximum pressure, and press time for i-NIBP and c-NIBP values for each limb. Multiple comparisons were performed using Bonferroni's correction method. For multivariate analysis, linear regression analysis was performed with VAS as the independent variable, and age, gender, and measurement method as dependent variables to investigate pain-inducing factors.

Subsequently, another linear regression analysis was performed with the difference in the maximum pressure and press time for each measurement method as the variables for evaluation. All data analyses were performed using the SPSS Version. 26.0 software (IBM Japan, Tokyo, Japan). The level of statistical significance was set as $p < .05$.

3. Results

Of the 117 healthy volunteers, six were excluded whose BP measurements were not possible because of unsuitable manchette size (see Figure 3). None of the collected data withdrew their consent. Background data of the participants revealed a median age of 41 years (IQR 29–49), and 60 participants were male (54.1%). Results of four deflationary and linear inflation measurement methods on both the upper limbs and legs for each of the 111 participants are shown in Figure 4.

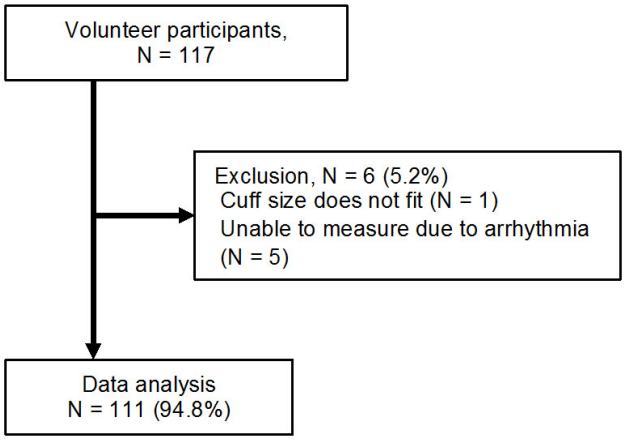

Figure 3. Study flowchart showing the sample size calculation

The VAS scores of the upper and lower limbs were significantly lower with the i-NIBP device than with c-NIBP mea-

surements (see Figure 4b. upper limbs: 25.6 ± 23.2 vs. 38.8 ± 27.5, $p < .001$ and lower limbs: 42.2 ± 25.1 vs. 54.2 ± 26.1, $p < .003$, respectively). The c-NIBP measurement of the thigh had the highest VAS value; however, the VAS values for the leg i-NIBP and forearm c-NIBP measurements were not significantly different (see Figure 4b. 38.8 ± 27.5 vs. 42.2 ± 25.1, $p = 1.000$). In addition, the difference in the maximum pressure was significantly lower during i-NIBP than in c-NIBP measurements (see Figure 4c. upper limbs: 15.7 ± 8.2 mmHg vs. 68.3 ± 16.0 mmHg, $p < .001$ and lower limbs: 10.8 ± 5.9 mmHg vs. 42.6 ± 13.1 mmHg, $p < .001$, respectively). The press time for BP measurement was also significantly shorter in i-NIBP than in c-NIBP measurements (see Figure 4d. upper limbs: 16.3 ± 4.4 s vs. 30.9 ± 8.2 s, $p < .001$ and lower limbs: 34.8 ± 8.1 s vs. 63.6 ± 16.7 s, $p < .001$, respectively).

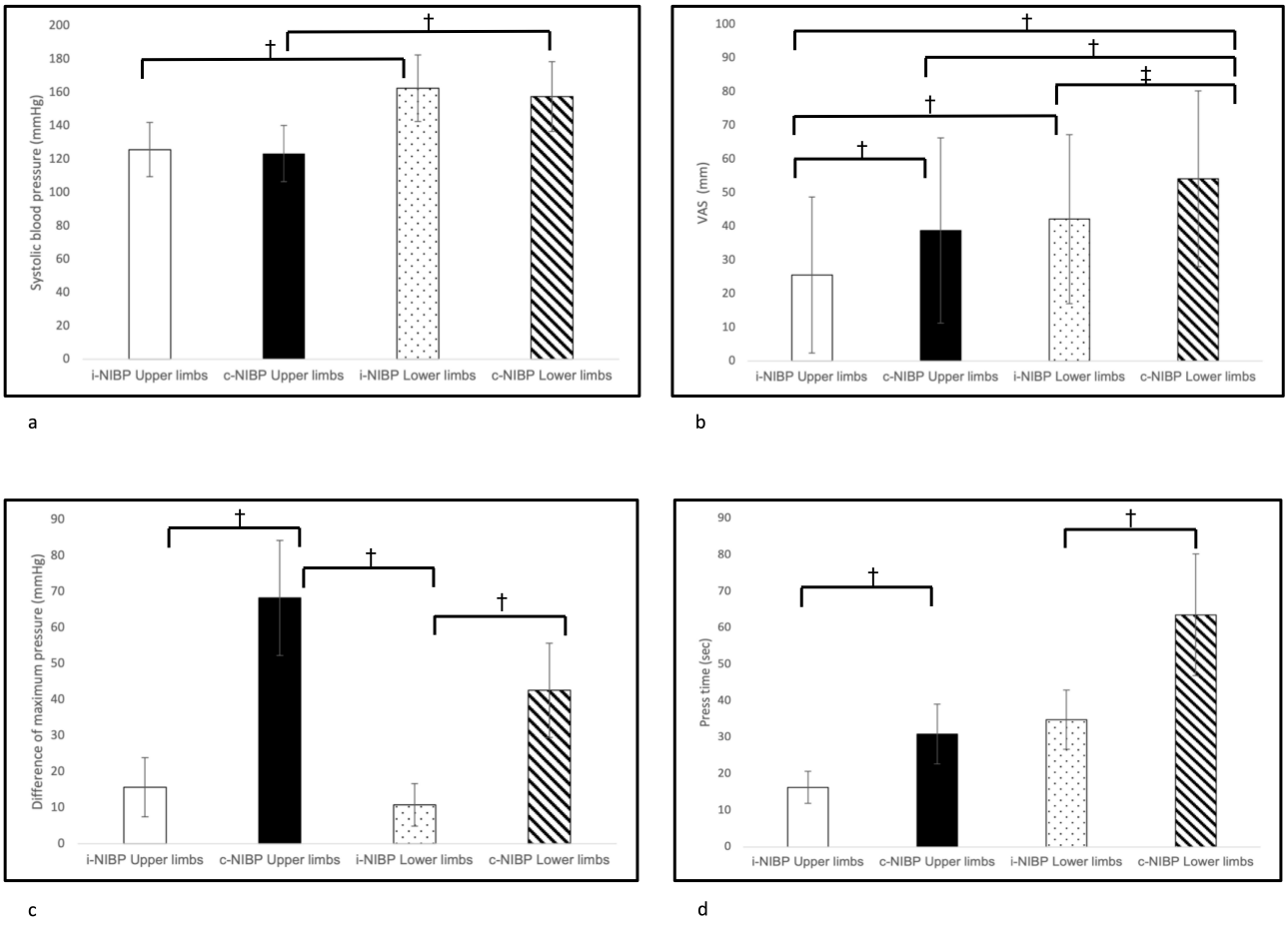

Figure 4. Comparison of BP measurement data

*All variables are presented as means ± SD. a. Systolic blood pressure (mmHg), b. VAS, c. *Difference in maximum pressure (mmHg), d. Press Time (s). †$p < .001$ ‡ $p < .05$. (c-NIBP, conventional noninvasive blood pressure; i-NIBP, inflationary noninvasive blood pressure; VAS, visual analog scale).*

The results of the multivariate analysis demonstrated that the difference in measurement methods contributed to the increase in the VAS score of the upper and lower limbs (upper limb: b = 1.321, 95% confidence interval [CI] [0.68–1.95], $p < .001$; lower limbs: b = 1.210, 95% CI [0.57–1.84], $p < .001$) (see Table 1). Sensitivity analysis of linear regression was performed by adding the difference in maximum pressure and pressing time as explanatory variables, and the results revealed that the factors that increased the VAS score of the upper and lower limbs were particularly related to the press time (upper limb: b = 0.820, 95% CI [0.294–0.374], $p < .002$; lower limbs: b = 0.269, 95% CI [0.028–0.512], $p < .029$) (see Table 2).

4. Discussion

In this study, we investigated whether i-NIBP versus c-NIBP measurement with the lower limbs could reduce pain in healthy volunteers. We demonstrated that i-NIBP measurement could significantly reduce pain during BP monitoring with the thigh and forearms. Although cases of upper-limb

pain during i-NIBP measurement have been reported,[1] data on i-NIBP measurements of the lower limbs were limited, and previous reports were not specifically focused on pain. Therefore, our study is the first to evaluate lower-limb pain during BP measurement with the i-NIBP device.

Compared to the c-NIBP measurement technique, i-NIBP measurement with the upper limbs reduced subjective pain in healthy volunteers, as reported in a randomized controlled trial.[1] Furthermore, VAS during c-NIBP measurement of the lower limbs was the highest of all NIBP measurements of the upper and lower limbs. However, the VAS scores were non-significantly different between the lower-limb i-NIBP and upper-limb c-NIBP measurements. With the i-NIBP measurement method, the lower-limb pain had reduced to the same extent as the upper-limb pain experienced during c-NIBP measurement (see Figure 4b); this could be attributable to the difference between the actual BP and maximum pressurization required during i-NIBP measurement (see Figure 4c). This study also demonstrated a significant reduction in the actual measurement time for pressurizing the limbs because of minimal pressurizing effects on the lower limbs by the manchette (see Figure 4d).

Table 1. Linear regression analysis for pain

Variables	B	95% CI*	*p*-value
Upper limbs			
Age	0.018	-0.009-0.04	.188
Sex (female)	1.605	0.094-1.95	< .001
Measurement methods (c-NIBP)	1.321	0.682-1.95	< .001
Lower limbs			
Age	0.060	0.032-0.087	< .001
Sex (female)	0.984	0.348-1.62	.003
Measurement methods (c-NIBP)	1.210	0.575-1.84	< .001

*95% confidence interval

Table 2. Sensitivity analysis of linear regression analysis for pain

Variables	B	95% CI*	*p*-value
Upper limbs			
Age	0.100	-0.200-0.401	.508
Sex (female)	17.0	10.2-23.9	< .001
Difference of maximum pressure (mmHg)	0.015	-0.164-0.194	.868
Press time (s)	0.820	0.294-0.347	.002
Lower limbs			
Age	0.550	0.238-0.862	< .001
Sex (female)	9.64	2.33-17.0	.009
Difference of maximum pressure (mmHg)	0.087	-0.166-0.342	.498
Press time (s)	0.269	0.028-0.512	.029

*95% confidence interval

The respective BP measurement methods and measuring time were mutually related as contributors of lower-limb pain experienced during BP measurement. It was suggested that shortening the measuring time for lower-limb BP with i-NIBP measurement might reduce the pain. When the BP measurement methods were compared, the pressure applied on the limbs and the measuring time were revealed as important factors affecting BP measurement.

Although BP measurement with the upper limbs is used as the standard in usual clinical settings, patients who have shunts for dialysis, burn wounds, or a history of breast cancer with bilateral lymph-node dissection[6] are unable to undergo this measurement with the upper limbs and require lower-limb BP measurement. Therefore, lower-limb BP measurement is an important indicator for understanding the circulatory dynamics in such patients. However, the sBP in the lower limbs is usually higher than that in the upper limbs[7,8] and sBP measurement in the upper limb requires more time. Hence, higher pressure and longer pressurization time with the manchette may increase the pain. Therefore, we suggest that i-NIBP measurement, which has a lesser pressurization time, would be more useful than c-NIBP measurement in controlling pain and the risk of adverse events during BP monitoring in particular cases when BP measurement is possible only with the lower limbs.

This study has a few limitations. First, the baseline data, such as the body mass index and medical history, were not collected for each healthy volunteer, which might have influenced the results. Second, BP was measured using a manchette named YAWARACUFF2 (Nihon Kohden, Tokyo, Japan), which is known to reduce complications, including subcutaneous hemorrhages; however, since no other manchettes were evaluated in this study, the role of this manchette itself in reducing the limb pain remains unclari-

fied.

5. Conclusions

We examined the effect of pain reduction on the lower limbs with different NIBP measurement methods in healthy volunteers. The results suggest that i-NIBP measurement may reduce pain during BP monitoring in the lower limbs compared with c-NIBP measurement. Inflationary non-invasive blood pressure monitoring should be used for patients who need to have their blood pressure measured at the lower limbs due to their morbidities, or when they need to have their blood pressure measured immediately in the emergency room. Therefore, in daily nursing practice, choosing to measure i-NBP may be a care option to protect patients from discomfort.

Acknowledgements

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Conflicts of Interest Disclosure

The authors declare that there is no conflict of interest.

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