# Validation of inflationary noninvasive blood pressure monitoring in the emergency room

Junichi Sasaki[a], Yoshiharu Kikuchi[b], Takashi Usuda[b] and Shingo Hori[a]

**_Objective_** **The aim of this study was to compare the values of a noninvasive blood pressure (NIBP) measurement during cuff inflation (inflationary NIBP) and deflationary NIBP measurements and to verify whether inflationary NIBP is equivalent to conventional deflationary NIBP and is acceptable for clinical use in the emergency room (ER).**

**_Materials and methods_** **A total of 2981 NIBP data points were collected from 175 patients (age, 56.5 ± 22.2 years; range, 7–92 years) who had been treated in the resuscitation area of the ER at Keio University Hospital. The data points were obtained using two alternate algorithms with a standard monitor (BSM-6000). One algorithm consisted of continuous inflationary and deflationary measurements in a single cycle (dual algorithm, 1502 data points); this algorithm was used to verify the success rate and the precision of the data. The second algorithm (1479 data points) consisted of only conventional deflationary measurements and was used to verify the duration of the measurement cycle.**

**_Results_** **The success rate of the inflationary NIBP (completed using only the inflationary method) was 69.0%. Failures in the inflationary measurements were caused by arrhythmia and/or body motions. The mean difference and SD of the systolic pressure and the diastolic pressure between inflationary NIBP and deflationary NIBP were − 0.6 ± 8.8 and 3.5 ± 7.5 mmHg, respectively. The confidence intervals were − 0.6 (95% confidence interval = − 1.1 to − 0.1) and 3.5 (95% confidence interval = 3.0 to 4.0) mmHg. The coefficients of correlation were 0.96 and 0.93. Inflationary NIBP was capable of determining the NIBP more quickly compared with deflationary NIBP (average of 15.9 vs. 34.2 s; _P_ < 0.05).**

**_Conclusion_** **Inflationary NIBP measurements have a reasonable accuracy and a sufficient rapidity, compared with deflationary NIBP measurements, in ER patients. _Blood Press Monit_ 20:325–329 Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.**

**Blood Pressure Monitoring** 2015, **20**:325–329

**Keywords: emergency department, inflationary, noninvasive blood pressure monitoring, oscillometric method**

[a]Department of Emergency and Critical Care Medicine, Keio University School of Medicine and [b]Nihon Kohden Corporation, Tokyo, Japan

Correspondence to Junichi Sasaki, MD, Department of Emergency and Critical Care Medicine, School of Medicine, Keio University, 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan
Tel: + 81 3 3225 1323; fax: + 81 3 3353 2232;
e-mail: sasakij@1989.jukuin.keio.ac.jp

**Received** 10 June 2015 **Revised** 28 June 2015 **Accepted** 1 July 2015

## Introduction

Noninvasive blood pressure (NIBP) monitoring using an automated sphygmomanometer is used to obtain blood pressure values, which are required in various clinical situations including operating rooms, ICUs, and emergency rooms. Historically, the measurement principle of an automated sphygmomanometer can be based on two methods: the auscultation method and the oscillometric method. Currently, most NIBP monitoring devices are based on the oscillometric method and determine the blood pressure during cuff deflation (deflationary NIBP) [1,2]. However, a NIBP measurement during cuff inflation (inflationary NIBP) can be advantageous as inflationary NIBP can complete the measurement with a lower cuff pressure and a shorter measurement duration compared with conventional deflationary NIBP.

In patients who receive anesthesia during surgery, the inflationary NIBP has been shown to show a reasonable accuracy compared with conventional deflationary NIBP [3]. However, the use of NIBP monitoring using inflationary NIBP in emergency room patients with various unstable conditions has not been reported previously. In addition, the values obtained using inflationary and deflationary NIBP reportedly differ [4]. The aim of this study was to compare the values of inflationary NIBP and deflationary NIBP measurements and to verify whether inflationary NIBP is equivalent to conventional deflationary NIBP and is acceptable for clinical use in the emergency room. Also, we examined the usefulness of the inflationary NIBP by (a) comparing the durations of the measurement cycles for inflationary NIBP and deflationary NIBP and (b) determining the success rate of the inflationary NIBP measurements.

## Materials and methods

### Study design

This was an observational study to verify the values and the usefulness of the inflationary NIBP. The study was approved by the institutional review board.

Presented at the 34th International Symposium on Intensive Care and Emergency Medicine (ISICEM) in March 2014, Brussels, Belgium.



DOI: 10.1097/MBP.0000000000000145

### Study setting and population

NIBP data were collected from patients admitted to the resuscitation area of the emergency room at Keio University Hospital during an 8-week period from September to November 2013.

### Study protocol

The measurements were performed using two alternate algorithms for NIBP measurements that were included in the test device (patient monitor BSM-6000; Nihon Kohden Corporation, Tokyo, Japan): a dual mode and a deflationary mode. With the dual mode, the blood pressure values were measured using both inflationary NIBP and deflationary NIBP; the inflationary NIBP and the deflationary NIBP measurements were obtained at almost the same time because a single measurement cycle consists of an inflationary NIBP measurement, followed immediately by a deflationary NIBP measurement. The deflationary mode is a conventional deflationary NIBP measurement. Both the inflationary NIBP and the deflationary NIBP measurement algorithms used in this study were developed by Nihon Kohden Corporation. Under stability conditions, the accuracies of the inflationary NIBP and the deflationary NIBP used in this study developed by Nihon Kohden Corporation conform to ISO81060-2.

### Measures

The systolic (SYS) and diastolic (DIA) blood pressures were measured from both the inflationary and the deflationary measurements using the dual mode. The duration of the measurement cycles was measured from the inflationary measurement part in the dual mode and the deflationary NIBP measurement in the deflationary mode.

### Data analysis

All the NIBP data stored in the test device were retrieved by Nihon Kohden Corporation and the statistical analysis was carried out at the Keio University School of Medicine. The data were statistically analyzed and expressed as the mean difference ± SD, unless otherwise specified.

The mean difference and SD of the SYS and DIA blood pressures between the inflationary NIBP and the deflationary NIBP measurements was determined. In addition, the analysis was carried out on subgroups of hypotensive/hypertensive patients. Bland–Altman plots were constructed to compare the values of the inflationary and the deflationary NIBP. As ISO81060-2 specifies that the error and the SD of a noninvasive sphygmomanometer should be within ± 5 and 8 mmHg; the deflationary NIBP measurements, which were used as references for the inflationary NIBP measurements that complied with the ISO81060-2, had the same error and SD. Consequently, the clinically acceptable mean difference and SD were determined to be within ± 10 and 11.3 mmHg in this study. These criteria were calculated from the composition of the error and the SD of the deflationary NIBP and the value of ISO81060-2. The mean difference was derived by addition and the SD was derived by the root sum square [5].

The average measuring time (duration) of the inflationary NIBP was calculated from the time required for a successful inflationary measurement performed in dual mode and the average measuring time of deflationary NIBP was calculated from the time of the deflationary measurement in the deflationary mode. An independent *t*-test was used to compare the duration of the inflationary NIBP measurements and that of the deflationary NIBP measurements. Excel 2010 (Microsoft Corp., Redmond, Washington, USA) was used to carry out the statistical analysis.

The success rate of the inflationary NIBP measurements was calculated by dividing the number of successful inflationary measurements performed in dual mode by the total number of dual mode measurements. The success rate for the deflationary measurements was calculated by dividing the number of successful deflationary mode measurements by the total number of deflationary mode measurements.

## Results

### Enrolled patients' distribution

A total of 175 patients participated in this study (101 men and 74 women). The mean ± SD values for age were 56.5 ± 22.2 years (7–92 years). The breakdown of patient diseases was as follows: cardiovascular, 23%; cerebral, 20%; trauma, 20%; gastrointestinal, 12%; kidney, 5%; respiratory, 4%; toxicosis, 4%; allergy, 3%; endocrine, 2%; and others, 7%. In this study, no patients required resuscitation.

### Success rate

Among the 1502 measurements that were performed in dual mode, 1036 (69%) of the inflationary NIBP measurements were successful for determining the SYS and DIA values (Table 1). Failures in the inflationary measurements were caused by arrhythmia and/or body motions. Arrhythmia and body motions were detected by verifying the waveform data of the measurement. Among the 1479 measurements that were performed in deflationary mode, 1459 (99%) of the deflationary NIBP measurements were successful for determining the SYS and DIA values.

### Comparison of SYS and DIA blood pressures

Overall, 2981 NIBP data points were collected. The SYS and DIA blood pressure values were compared for 1029 data points that were obtained using both the inflationary and the deflationary measurement values in dual mode. The mean difference and the SD between the

**Table 1 Number of measurements performed using dual mode and deflationary mode**

| | Dual mode (include inflationary and deflationary measurement) | Deflationary mode |
|---|---|---|
| Number of patients | 175 | 175 |
| Total measurements | 1502 | 1479 |
| Artifacts [*n* (%)] | | |
| Body motion | 379 (25) | 307 (21) |
| Arrhythmia | 176 (12) | 185 (13) |
| Body motion and arrhythmia | 49 (3) | 53 (3) |
| No artifacts | 898 (60) | 934 (63) |
| Successful measurements | 1036 (69)[a] | 1459 (99) |

For the dual mode, successful measurements indicate the number of successful inflationary measurements performed using the dual mode.
[a]The measurement algorithm developed by Nihon Kohden Corporation and used in their commercial monitors automatically switches from an inflationary to a deflationary measurement whenever the situation makes inflationary measurements difficult to complete (i.e. presence of body motion, arrhythmia).

inflationary NIBP and the deflationary NIBP measurements were $-0.6 \pm 8.8$ and $3.5 \pm 7.5$ mmHg for the SYS and DIA blood pressures, respectively (Table 2). The confidence intervals were $-0.6$ (95% confidence interval $= -1.1$ to $-0.1$) and 3.5 (95% confidence interval = 3.0 to 4.0) mmHg. The coefficients of the correlation were 0.96 and 0.93. Bland–Altman plots are shown in Fig. 1.

### Duration of measurement cycle

The average durations of the inflationary and deflationary NIBP measurements were 15.9 and 34.2 s, respectively (Fig. 2). Inflationary NIBP could determine the blood pressure values more quickly than deflationary NIBP ($P < 0.05$).

## Discussion

The oscillometric method calculates blood pressure values on the basis of changes in the cuff pressure and changes in the oscillation amplitude that are observed as a vibration of the cuff pressure by the arterial pulse under the cuff. This method is used by most automated sphygmomanometers as it is generally well correlated with blood pressure values determined by auscultation with a stethoscope [6].

Currently, most NIBP monitoring devices are based on the oscillometric method and determine the blood pressure during cuff deflation [1,2]. In the algorithm for conventional deflationary NIBP, the cuff pressure has to be elevated higher than the SYS blood pressure, and adverse events such as pain, petechiae, ecchymoses, limb edema, venous stasis, thrombophlebitis, peripheral neuropathy, and compartment syndrome have been reported [7,8]. Unlike deflationary NIBP, inflationary NIBP can release the cuff pressure immediately after the SYS blood pressure is obtained. Therefore, when inflationary NIBP is used in patients with fragile skin, patient discomfort caused by subcutaneous bleeding in the cuff region can be reduced; furthermore, the measurement can be completed more quickly and the previously mentioned problems associated with deflationary NIBP can be overcome.

Evaluations of inflationary NIBP have been carried out previously for anesthetized patients in operating rooms [3]. However, inflationary NIBP has not been examined in a variety of patients with significant changes in the measurement conditions. Although this study was carried out for 8 weeks in the emergency room of a single institution, we believe that the utility of inflationary NIBP in the emergency room can be evaluated on the basis of the results of this study as we were able to perform ~3000 NIBP measurements in 175 patients with varying ages and disease backgrounds. The success rate using inflationary NIBP in the emergency room was 69%, whereas the success rate of deflationary NIBP in the emergency room was 99%. When the measurement algorithm has both inflationary and deflationary measurement, it can be designed to operate with two options: to complete the measurement only with the inflationary measurement when it is successful, which yields a faster NIBP measurement, or to switch the measurement automatically from inflationary to deflationary measurement when the measurement condition is found to be difficult for successful inflationary measurement (i.e. presence of body motion, arrhythmia). This countermeasure enables the use of inflationary NIBP without increasing the failure rate of the overall NIBP measurements; inflationary NIBP is considered to be sufficiently effective for use in the emergency room.

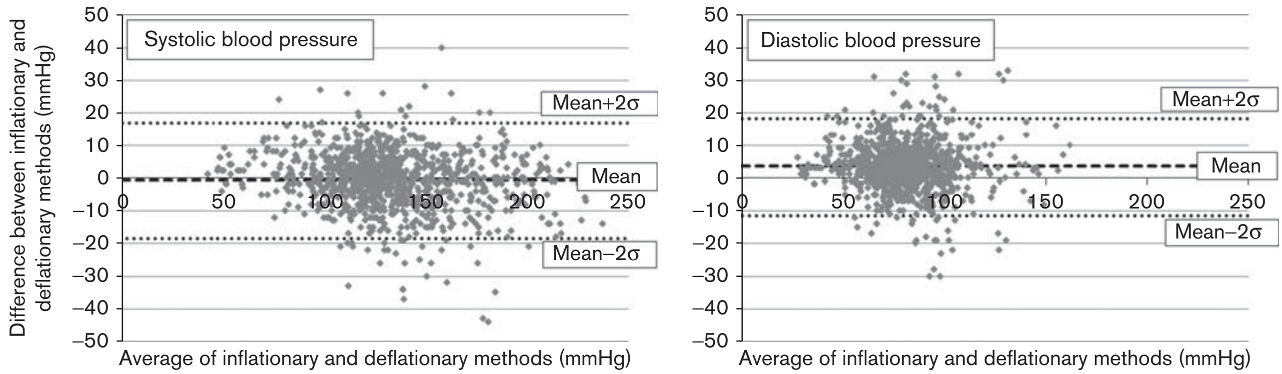
Because inflationary NIBP is theoretically based on the oscillometric method, DIA errors of measurement can

**Table 2 Measurement values for inflationary NIBP and deflationary NIBP**

| SYS blood pressure (mmHg) | Number of measurements | Inflationary NIBP (mmHg) | Deflationary NIBP (mmHg) | Difference between inflationary BP and deflationary NIBP (mmHg) | Coefficient of correlation |
|---|---|---|---|---|---|
| ≥200 | 46 | 204.4 ± 15/117.9 ± 24 | 212.1 ± 11/111.5 ± 24 | −7.7 ± 11.8/6.4 ± 8.8 | 0.65/0.93 |
| 90–200 | 908 | 134.1 ± 24/83.4 ± 15 | 134.7 ± 25/80.1 ± 15 | −0.6 ± 8.6/3.3 ± 7.5 | 0.94/0.88 |
| <90 | 75 | 75.8 ± 15/49.7 ± 11 | 71.7 ± 14/45.6 ± 11 | 4.1 ± 6.9/4.1 ± 5.7 | 0.89/0.88 |
| All | 1029 | 133.0 ± 32/82.5 ± 19 | 133.6 ± 33/79.0 ± 20 | −0.6 ± 8.8/3.5 ± 7.5 | 0.96/0.93 |

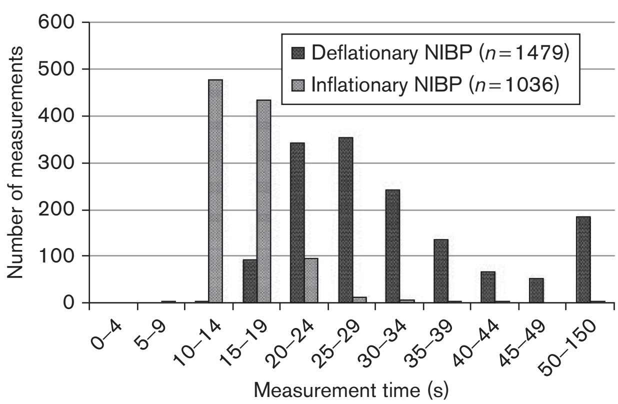
The results were classified according to the SYS blood pressure obtained using deflationary NIBP. The values of the inflationary NIBP and deflationary NIBP measurements are expressed as the average ± SD and SYS/DIA. The differences in blood pressure between the inflationary NIBP measurement and the deflationary NIBP measurement are expressed as the mean difference ± SD and SYS/DIA.
DIA, diastolic; NIBP, noninvasive blood pressure; SYS, systolic.

**Fig. 1**




Bland–Altman plots of the systolic and diastolic blood pressures of the inflationary and deflationary methods.

**Fig. 2**




Histogram showing the durations of the measurement cycles of inflationary NIBP and deflationary NIBP. The gray and black bars show the inflationary NIBP data and the deflationary NIBP data, respectively. NIBP, noninvasive blood pressure.

increase minimally, similar to the conventional oscillometric method [4]. When comparing the results between inflationary and deflationary NIBP measurements, which were obtained during the same dual mode cycle and included measurements performed in the presence of body motions and/or arrhythmia, the mean difference and SD between the inflationary NIBP and the deflationary NIBP measurements were 0.6 ± 8.8 and 3.5 ± 7.5 mmHg for the SYS and DIA blood pressure measurements, respectively. Although error problems caused by the use of an inappropriate cuff size during sphygmomanometry have been reported [9], such errors were not considered to have occurred in this study because we performed the inflationary and deflationary NIBP measurements during the same cycle. Inflationary NIBP was acceptable for clinical use as the mean difference and SD were within ± 10 and 11.3 mmHg, respectively. Furthermore, patients whose SYS blood pressure was 90 mmHg or less when measured using deflationary NIBP were analyzed. As a result, the mean SYS blood pressure and the DIA blood pressure measured using inflationary NIBP was 3.5 mmHg lower and 3.7 mmHg higher than the values measured using deflationary NIBP, respectively (Table 2). The measurements in this hypotension group showed a moderately large difference, but as the mean difference of the measurement values obtained using inflationary NIBP in the hypotension group did not increase and fell within the predetermined criteria, this method was considered to be acceptable for clinical use. Similarly, patients with a SYS blood pressure of 200 mmHg or higher as measured using the deflationary mode were also analyzed. The SD of the SYS blood pressure was slightly over 11.3 mmHg (Table 2), but this was acceptable for clinical use.

Compared with the measurements in the deflationary mode, the measurement time was reduced by 54% for the successful inflationary NIBP measurements performed in the dual mode. In emergency rooms where critical treatment is often required, being able to obtain blood pressure measurements quickly is likely to be very valuable.

### Limitations

Because we did not carry out a comparison between auscultation with a stethoscope or invasive blood pressure and inflationary NIBP in this study, more accurate comparisons of blood pressure are not possible.

### Conclusion

These results suggest that inflationary NIBP has a reasonable accuracy and sufficient rapidity compared with deflationary NIBP in emergency room patients.

## Acknowledgements

The authors thank Yuta Tanaka and Iwao Ozawa of Nihon Kohden Corporation for the data retrieval and technical support.

## Conflicts of interest

This study was partially supported financially by Nihon Kohden Corporation. J.S. was supported for travel to meetings for the study. For the remaining authors there are no conflicts of interest.

## References

1 Van Montfrans GA. Oscillometric blood pressure measurement: progress and problems. *Blood Press Monit* 2001; **6**:287–290.
2 Geddes LA, Voelz M, Combs C, Reiner D, Babbs CF. Characterization of the oscillometric method for measuring indirect blood pressure. *Ann Biomed Eng* 1982; **10**:271–280.
3 Onodera J, Kotake Y, Fukuda M, Yasumura R, Oda F, Sato N*, et al*. Validation of inflationary non-invasive blood pressure monitoring in adult surgical patients. *J Anesth* 2011; **25**:127–130.
4 Zheng D, Pan F, Murray A. Effect of mechanical behaviour of the brachial artery on blood pressure measurement during both cuff inflation and cuff deflation. *Blood Press Monit* 2013; **18**:265–271.
5 Evaluation of measurement data – guide to the expression of uncertainty in measurement. Available at: *http://www.iso.org/sites/JCGM/GUM/JCGM100/C045315e-html/C045315e.html?csnumber=50461*. [Accessed 21 October 2014].
6 Pickering TG, Hall JE, Apple LJ, Falkner BE, Graves J, Hill MN*, et al*. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurements in humans: a statement for professionals from the subcommittee of professional and public education of the American Heart Association Council on high blood pressure research. *Hypertension* 2005; **45**:142–161.
7 Bickler PE, Schapera A, Bainton CR. Acute radial nerve injury from use of an automatic blood pressure monitor. *Anesthesiology* 1990; **73**:186–188.
8 Sutin KM, Longaker MT, Wahlander S, Kasabian AK, Capan LM. Acute biceps compartment syndrome associated with the use of a noninvasive blood pressure monitor. *Anesth Analg* 1996; **83**:1345–1346.
9 Bur A, Herkner H, Vlcek M, Woisetschläger C, Derhaschnig U, Delle Karth G*, et al*. Factors influencing the accuracy of oscillometric blood pressure measurement in critically ill patients. *Crit Care Med* 2003; **31**:793–799.