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SHORT COMMUNICATION

Validation of inflationary non-invasive blood pressure monitoring in adult surgical patients

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Abstract Oscillometric determination of blood pressure may be advantageous, as cuff inflation requires lower cuff pressure and shorter duration than deflation. In this observational study, we compared the blood pressure value, cuff pressure, and duration of cuff inflation between a prototype of inflationary non-invasive blood pressure (NIBP) and conventional deflationary NIBP in adult patients during anesthesia. Three hundred and twenty-three pairs of measurements were obtained from 64 subjects. The bias and precision of systolic pressure and diastolic pressure were 2.9 ± 8.3 and 5.6 ± 6.1 mmHg, respectively. Inflationary NIBP could better determine NIBP with lower cuff pressure than deflationary NIBP (124 ± 22 vs. 160 ± 33 mmHg, $p < 0.05$). Inflationary NIBP could also determine NIBP more quickly (13.0 ± 2.3 vs. 32.7 ± 13.6 s, $p < 0.05$). These data suggest that inflationary NIBP may reduce cuff-related discomfort and complications, and has reasonable accuracy compared to deflationary NIBP in adult surgical patients.

Keywords Blood pressure · Non-invasive · Oscillometric · Inflationary

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Non-invasive blood pressure (NIBP) monitoring is one of the most important indicators of patients' cardiovascular status. Currently, almost all NIBP monitors are based on the oscillometric method and determine the systolic, mean, and diastolic pressure during cuff deflation [1, 2]. In this algorithm, the cuff pressure has to be elevated higher than systolic pressure, and adverse events such as pain, petechiae, ecchymoses, limb edema, venous stasis, thrombophlebitis, peripheral neuropathy, and compartment syndrome have been reported [3, 4].

We hypothesized that these limitations could be circumvented if blood pressure could be measured during cuff inflation. Accordingly, we developed a prototype NIBP monitor that determines diastolic, mean, and systolic pressure during cuff inflation. In this study, we compared the blood pressure value, highest cuff pressure, and the duration of measurement of an NIBP monitor using an inflation measurement algorithm (inflationary NIBP) and a conventional deflationary NIBP monitor during anesthesia.

This prospective, observational study was approved by the institutional review board and written informed consent was obtained from each participant.

Patients scheduled for general anesthesia of more than 3 h from March 2008 through March 2009 were screened for possible participation. Patients who could not have the blood pressure cuff placed on both arms were excluded from the study. Also, enrollment was limited to one case per day, for logistical reasons. The only other exclusion criterion was age <18 years.

Non-invasive blood pressure was monitored at the right upper arm every 5 min during anesthesia with a standard patient monitor (either BSM-9800 or 5150; Nihon Kohden, Tokyo, Japan). Additionally, a blood pressure cuff (Durable Adult Size 11;Welch Allen, Skaneateles, NY, USA) was applied on the left upper arm. NIBP was determined successively with a conventional deflationary NIBP monitor (OPV-1510, Nihon Kohden) and the prototypical inflationary NIBP monitor. The sequence of measurement was randomized and these measurements were repeated every 60 min when hemodynamics was deemed stable.

The data were statistically analyzed and expressed as means ± SD unless otherwise specified. The difference of systolic and diastolic pressure between inflationary NIBP and deflationary NIBP was determined by the Bland–Altman method. Also, the duration of the measurement and the highest cuff pressure was compared between inflationary NIBP and deflationary NIBP.

Three hundred and twenty-three pairs of measurements from 64 patients (38 males and 26 females) were included in the final analysis. The mean ± SD values for age, height, weight, and anesthesia duration were 60 ± 15 years, 160 ± 8 cm, 61 ± 12 kg, and 277 ± 169 min, respectively. The types of surgical interventions were as follows: 38 gastrointestinal, 8 gynecological, 8 orthopedic, and 10 other specialties. The average number of measurements was 5 ± 4 per case.

The bias and precision (1 SD of the difference) of inflationary NIBP against the deflationary NIBP in all the measurement pairs are summarized in Table 1. Also, the bias ± precision of 283 measurement pairs without arrhythmia and 40 measurement pairs with arrhythmia are separately described in Table 1. In either situation, inflationary NIBP tended to slightly overestimate systolic and diastolic pressures. The lengths of each measurement cycle of inflationary NIBP and deflationary NIBP are summarized in Fig. 1. Inflationary NIBP was able to determine blood pressure with a significantly shorter duration of cuff inflation than deflationary NIBP (13.0 ± 2.3 vs. 32.7 ± 13.6 s, $p < 0.05$). The inflationary NIBP monitor was also able to determine blood pressure with a significantly lower cuff pressure (124 ± 22 vs. 160 ± 33 mmHg, $p < 0.05$).

In this preliminary evaluation, inflationary NIBP was able to determine blood pressure more quickly than deflationary NIBP, and with lower cuff pressure.

NIBP is an essential parameter to monitor during anesthesia. Currently, oscillometric determination of blood pressure is widely used and the majority of NIBP monitors determine systolic, mean, and diastolic blood pressure during cuff deflation. The cuff pressure is typically raised to 180 mmHg at the first measurement. Then, at the next measurement, the cuff pressure is raised around 30 mmHg higher than the systolic pressure of the previous measurement session. This algorithm inevitably causes the cuff pressure to be significantly higher than the systolic pressure. Inflationary NIBP may circumvent these possible adverse effects. However, to our knowledge, only two manufacturers (Criticare Systems, Waukesha, WI, USA, and Omron Colin, Tokyo, Japan) produce patient and ambulatory blood pressure monitors that incorporate an inflationary NIBP measurement algorithm [5–8]. This situation probably reflects the fact that inflationary NIBP monitors have to distinguish the oscillometric signal from several sources of noise. These sources include the noise produced by the pump that inflates the cuff, the noise caused by the fastener of the cuff, and the noise caused by the friction of the overlapping cuff material. These noises presumably affect the determination of inflationary NIBP more significantly than deflationary NIBP. In the present

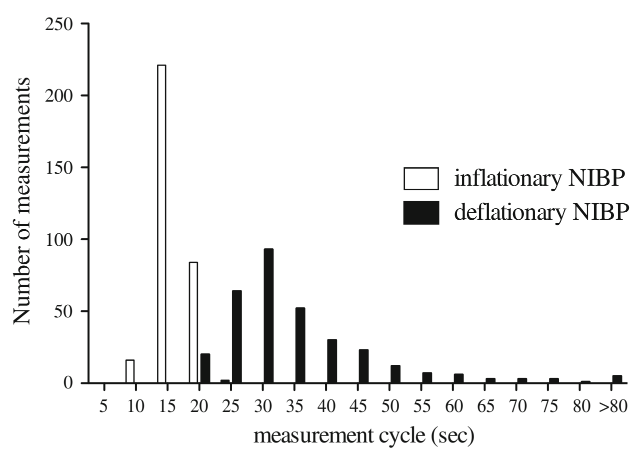

Fig. 1 The duration of the measurement cycle of inflationary non-invasive blood pressure (*NIBP*) and deflationary NIBP. The *X*-axis denotes the upper limit of the measurement cycle of each histogram. *Open bars* and *closed bars* denote data from inflationary NIBP and deflationary NIBP, respectively

Table 1 Difference of systolic and diastolic pressure between inflationary NIBP and deflationary NIBP

	Systolic pressure (mmHg)	Diastolic pressure (mmHg)
All measurements ($n = 323$)	2.9 ± 8.3	5.6 ± 6.1
Measurements without arrhythmia ($n = 283$)	2.5 ± 8.1	5.6 ± 5.7
Measurements with arrhythmia ($n = 40$)	5.8 ± 9.6	5.3 ± 8.6

Data are expressed as bias ± precision (1 SD of difference) against the deflationary non-invasive blood pressure (NIBP) monitor machine, noise from the pump can be successfully removed by placing a low-pass filter. Removal of the noise caused by the friction of the overlapping cuff is more difficult and our preliminary investigation revealed that the material of the cuff is critical. Accordingly, a blood pressure cuff made with nylon was used throughout this study. Another technical issue with inflationary NIBP is the rate of cuff inflation. The American Heart Association states that the optimal rate of decline of cuff pressure is 2–3 mmHg/s during auscultatory measurement [9]. However, more rapid rates of deflation have been successfully used in most deflationary oscillometric NIBP monitors. The present device inflates the cuff at a rate of 10 mmHg/s and this rapid inflation rate enables quick determination of blood pressure.

We found that inflationary NIBP slightly but consistently overestimated both systolic and diastolic pressure compared to measurements with the conventional deflationary NIBP monitor. Furthermore, we found larger bias and smaller precision in diastolic pressure than in systolic pressure. One possible explanation of this finding is that the oscillometric signal near the diastolic pressure may have been more susceptible to external noise than the systolic signal and subsequently the signal failed to be detected or was incorrectly filtered. We also found that the difference of systolic pressure was more affected by the presence of arrhythmia than the difference of diastolic pressure. The underlying mechanisms of these findings remain elusive, and further study is needed to determine whether these findings are related to the difference between the inflationary and deflationary algorithm itself or whether these findings are related to the individual NIBP monitor.

The Association for the Advancement of Medical Instrumentation (AAMI; Arlington, VA, USA) has established that bias <5 mmHg and precision <8 mmHg against reference methods should be achieved by NIBP [10]. Our data suggest that the present inflationary NIBP monitor is reasonably accurate, since it mostly fulfilled these criteria in systolic pressure determination when regular cardiac rhythm was ensured. On the contrary, there was an increased difference in diastolic pressure between the inflationary and deflationary NIBP. We believe that the performance of the reference device significantly affects this finding. Actually, in our preliminary study, the difference of measured value was smaller if the averaged data from several deflationary NIBP monitors were used as a reference (data not shown). However, we compared the blood pressure values between the inflationary NIBP monitor and the particular deflationary NIBP monitor, since it was the only monitor from which the data of cuff pressure and measurement duration could be automatically extracted.

There are several limitations in this study. First, we did not use the auscultation method to derive the reference values. Although the specifications made by AAMI use auscultation, it is not used in the current operative environment [11]. Second, the influence of the type of cuff remains elusive. As stated earlier, the material and the structure of the cuff may more significantly affect the performance of inflationary NIBP than deflationary NIBP. There are many possible types of blood pressure cuffs that may be applied, and whether inflationary NIBP provides acceptable accuracy warrants further investigation. Third, although inflationary NIBP is theoretically advantageous compared with deflationary NIBP, whether the patient's perception or the rates of complications match these theoretical advantages also remains to be seen.

In conclusion, we evaluated a prototypical NIBP monitor that determines blood pressure during cuff inflation. It determined blood pressure more quickly and with lower cuff pressure than the deflationary monitor, with reasonable accuracy.

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