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SHORT REPORT

Systolic Pressure and Pulse Rate Range Performance Comparison of Seven Non-Invasive Blood Pressure Monitors

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Purpose: To evaluate blood pressure (BP) and pulse rate (PR) measurement range and determination time of selected non-invasive blood pressure (NIBP) monitors.

Patients and Methods: Seven oscillometric NIBP monitors underwent laboratory-based simulations of high and low BP and PR values to determine the outer bounds that each monitor could measure. Reliability was determined by devices' ability to detect simulation signals of chosen BP/PR values. Determination times were analyzed using One-Way ANOVA followed by post-hoc Tukey honestly significant difference.

Results: All monitors reliably reported 50–180 mmHg and 80–140 bpm simulations, except Connex which provided the narrowest ranges (only reliable at 140 and 230 bpm; 50–180 mmHg). B125 and Efficia CM120 had the widest ranges for PR (30–240 bpm and 30–220 bpm, respectively) and systolic BP (30–250 mmHg for both). Connex presented the quickest mean determination time (19.23s), followed by B125 (24.14s).

Conclusion: NIBP monitor performances varied considerably outside mid-range BP/PR and there were significant differences across determination times. NIBP devices that strike a balance between range and speed may provide the greatest clinical utility.

Keywords: reliability, blood pressure, heart rate

Introduction

Accurate and consistent blood pressure (BP) measurement is necessary to assess the risk of cardiovascular events, the leading cause of morbidity and mortality worldwide.[1,2] Acute hypertensive/hypotensive or tachycardic/bradycardic crises often indicate underlying, time-sensitive conditions requiring immediate intervention.[3–6] Monitoring BP through a reliable method is important for the early detection of these episodes.

Non-invasive blood pressure (NIBP) monitoring systems are commonly used in hospital, clinic, and at-home settings.[7] These monitors are widely accepted by clinicians due to ease-of-use, cost, portability, and patient comfort, and do not require expert interpretation.[7] Additionally, there are minimal risks of adverse events such as infection, bleeding, or thrombotic complications.[8] However, recent studies have contributed to concern for inaccuracies, especially among diverse patient populations and at extreme BP and pulse rate (PR) values.[1,2]

Many NIBP monitoring devices are available for medical use with proprietary technologies, which may lead to variations in real-world performance. Previous research reviewed the opportunities and challenges of existing and emerging NIBP technologies;[1] however, comparative assessments of performance among NIBP devices are limited. This study aims to assess BP/PR measurement range reliability and determination time of seven commercially available, oscillometric NIBP monitors under simulations of high and low BPs and PRs, especially at extreme values.

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Materials and Methods

In this simulation-based laboratory study, the performance of seven NIBP monitoring devices was subjected to wide ranges of BP and PR values to identify conditions of measurement success or failure (Table 1). These monitors were selected to include a range of technologies, major global manufacturers and industry leaders, and devices that are widely used in patient care. These seven monitors have met the performance requirements of governing regulatory authorities and applicable international standards, including performance measurement accuracy.

Steps and Outcomes

Three BP simulators (CuffLink, BP Pump 2, and ProSim 8 [Fluke Medical, Everett, WA, USA]) were utilized to minimize the potential bias for any simulator–monitor combination. Each NIBP monitor underwent controlled simulations to evaluate its BP/PR range performance and establish the outer bounds that each of the seven NIBP monitors could measure. Test scenarios simulated high and low extremes of systolic pressures (30–260 mmHg) and PRs (30–240 bpm). Determinations were "successful" if the monitor generated a reading at the specific simulated value; output accuracy was not evaluated. The device was considered "Reliable" if it successfully generated a reading in all trials at that setting, "Unreliable" if a device failed to detect ≥1 trial at any given BP/PR level and "Failed" if it failed at all trials at a BP/PR level. BP/PR levels were excluded from testing scenarios when meeting at least one of the following criteria: (1) the device repeatedly failed at less extreme levels, anticipating a failure at the next increase/decrease, or (2) PRs were already accounted for during previous pressure tests and could thus jump to more extreme levels for testing. Determination times were measured at 120 mmHg systolic BP and 80 bpm for three tests per device and were defined as the total time between test start and measurement display to the user.

Analysis

To illustrate the BP/PR ranges each monitor could reliably measure, device performances at the simulated BP/PR levels were tabulated as the number of successful determinations versus failures. Determination times were analyzed through pairwise comparisons, using One-Way ANOVA followed by post-hoc Tukey honestly significant difference in SAS 9.4. The monitor most recently cleared by the FDA (B125) was chosen as the referent for statistical comparisons.

Results

Reliability

All monitors reliably reported systolic levels of 50–180 mmHg (Figure 1). The B125 and Efficia CM120 (zero failures from 30 to 120 mmHg), and IntelliVue MX430 (one failure at 30 mmHg) exhibited the highest performance at low-range systolic pressures. Most failures in the remaining monitors were observed for values ≤40 mmHg or ≥250 mmHg. All devices except Connex were reliable at values from 150 to 250 mmHg, and all monitors were unreliable at 260 mmHg. Connex had the narrowest range overall, with reliable performance limited to 50–180 mmHg.

Table 1 Non-Invasive Blood Pressure Monitors

Manufacturer (Location)	Device
GE Healthcare (Chicago, IL, USA)	B125
Mindray (Shenzhen, China)	Ipm12
	VS-900
Nihon Kohden (Tokyo, Japan)	Life Scope 3000 Series
Philips (Amsterdam, Netherlands)	Efficia CM120
	IntelliVue MX430
Welch Allyn (Auburn, NY, USA)	Connex

	B125		iPM12		VS-900		Life Scope		Efficia CM120		IntelliVue MX430		Connex	
	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability
Low Systolic Pressure (mmHg)														
30	4/4	●	2/5	●	2/5	●	2/5	●	5/5	●	5/6	●	0/0	●
40	3/3	●	3/3	●	2/3	●	3/3	●	3/3	●	3/3	●	0/3	●
50	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●
60	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●
80	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●
High Systolic Pressure (mmHg)														
150	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●	3/3	●
170	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●
180	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●
190	2/2	●	2/2	●	2/2	●	2/2	●	1/1	●	1/1	●	1/2	●
200	3/3	●	2/2	●	2/2	●	2/2	●	2/2	●	2/2	●	3/3	●
220	2/2	●	1/1	●	1/1	●	1/1	●	2/2	●	2/2	●	2/3	●
250	2/2	●	2/2	●	2/2	●	2/2	●	3/3	●	3/3	●	0/1	●
260	2/9	●	7/10	●	5/10	●	4/10	●	6/9	●	9/10	●	0/0	●

● Reliable (no failed tests) ● Unreliable (≥1 failed test) ● Failed (no successful tests) ● Skipped (test not completed)

Figure 1 Evaluation of systolic blood pressure range.

For pulse rates, all monitors provided reliable measurements between 50 and 140 bpm, except Connex, which was unreliable at 50–60 bpm. B125, Life Scope, and Efficia CM120 exhibited no failures from 30 to 80 bpm (Figure 2). B125 (zero failures from 140 to 240 bpm) and IntelliVue MX430 (zero failures from 140 to 230 bpm and one failure at 240 bpm) provided the widest reliability at high-range PRs.

	B125		iPM12		VS-900		Life Scope		Efficia CM120		IntelliVue MX430		Connex	
	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability	Success	Reliability
Low Pulse Rate (bpm)														
30	9/9	●	9/9	●	8/9	●	9/9	●	9/9	●	8/9	●	7/9	●
35	7/7	●	6/7	●	6/7	●	7/7	●	7/7	●	7/7	●	5/9	●
40	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	8/9	●	6/9	●
High Pulse Rate (bpm)														
140	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●
160	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	7/9	●
180	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	9/9	●	8/9	●
190	0/0	●	0/0	●	0/0	●	0/0	●	0/0	●	0/0	●	1/2	●
200	9/9	●	8/9	●	9/9	●	9/9	●	9/9	●	9/9	●	7/9	●
210	0/0	●	0/0	●	0/0	●	2/5	●	0/0	●	0/0	●	0/1	●
220	9/9	●	8/9	●	8/9	●	3/6	●	9/9	●	9/9	●	7/9	●
230	9/9	●	8/9	●	8/9	●	7/7	●	8/9	●	9/9	●	9/9	●
240	9/9	●	8/9	●	8/9	●	6/9	●	8/9	●	8/9	●	6/9	●

● Reliable (no failed tests) ● Unreliable (≥1 failed test) ● Failed (no successful tests) ● Skipped (test not completed)

Figure 2 Evaluation of pulse rate range.

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Table 2 Analysis of Determination Times

Device	Mean ± SD (s)	Median [min, max] (s)	P-value
B125	24.14±3.48	22.29 [21.98–28.15]	–
iPM12	39.12±14.32	31.92 [29.82–55.61]	0.0184
VS-900	29.97±3.35	29.36 [26.96–33.58]	0.6746
Life Scope 3000 Series	29.80±2.55	30.40 [27.00–32.00]	0.7005
Efficia CM120	51.06±2.57	50.39 [48.89–53.89]	<0.0001
IntelliVue MX430	48.88±3.03	50.56 [45.38–50.70]	0.0002
Connex	19.23±0.71	19.17 [18.56–19.97]	0.8112

Abbreviation: SD, standard deviation.

Determination Time

Connex presented the shortest mean determination time (19.23s), followed by B125 (24.14s; Table 2). Efficia CM120 took the longest time (51.06s), which was significantly longer than the referent group ($p < 0.0001$). IntelliVue MX430 (48.88s, $p = 0.0002$) and iPM12 (31.92s, $p = 0.0184$) also had significantly longer determination times.

Discussion

The findings in this study provide insights into the performance of selected NIBP monitors under simulations of high/low systolic BP and PR values. Seven NIBP monitors were chosen to assess various models/manufacturers across a global perspective, aiming to support clinical decision-making. This assessment is needed to provide an objective, comparative assessment of these technologies and to address recent concerns regarding NIBP-related inaccuracies among diverse patient populations and extreme BP/PR values.[1,2]

All devices but one were reliable in the mid-systolic BP range of 90–120 mmHg[4,9] and mid-PR 60–100 bpm[10] values, with varying performance outside of these ranges. At systolic BP simulations of 30 mmHg, reliable performance was observed only with the B125 and Efficia CM120 monitors. The majority of monitors displayed reliable performance at BP simulations up to 250 mmHg, except for Connex, which had the narrowest range of reliability (50–180 mmHg). Connex results were also not reliable for high/low PR values. Overall, simulated tests for PRs presented greater variability compared to BP readings. While Life Scope and Efficia CM120 were reliable at all low PRs, B125 was the only monitor to output reliable readings at all high and low PRs.

Capturing BP/PR values outside of mid-ranges is important to detect potentially emergent conditions. While all monitors have met the accuracy and international standards requirements for regulatory clearances, assessment of measurement performance at extreme conditions adds to the knowledge in the field. Exposure to abnormal BP/PR values is harmful and may indicate serious health conditions, leading to mortality and morbidity.[5,6,11,12] Sustained/profound elevations in BP present imminent risks of complications, including pulmonary edema, ischemic heart disease, myocardial infarction, and stroke.[3,13–15] Similarly, acute crises of hypotension may suggest potentially life-threatening shock/sepsis,[4] and abnormally high/low PRs may present worsening severe symptoms.[5,6] Therefore, reliable/timely detection is vital. In this study, the NIBP monitor with the quickest determination time was the Connex device (19.23s), followed by B125 (24.14s) and Life Scope (29.80s).

BP and PR measurements often involve tradeoffs between device measurement speed, range, and reliability to ensure timely identification of values requiring urgent attention. A monitor's utility will be limited to certain types of patients if it does not measure extreme BP/PR values or the determination time exceeds clinical requirements. While Connex presented the quickest determination time, it exhibited limited performance in high-low BP/PR values. Notably, B125 had the second-shortest determination time and performed reliably in both high and low ranges of BP/PR. While Efficia CM120 was relatively reliable at reporting high and low BP/PR, this device took over twice as long as Connex and B125 to generate a reading.

This evaluation has important limitations. First, the results from a simulated study can only be interpreted under specific conditions/environments. Second, monitors performed differently at each simulation level, resulting in a unique number of tests at each BP/PR level. Third, although manufacturing practices release only devices that pass rigorous validation testing, this analysis included measurements from one NIBP device for each model rather than an average from multiple devices. Finally, this preliminary study explored device utility in urgent clinical scenarios (ie, extreme values of BP/PR, determination time of readings) and did not assess/validate accuracy as an outcome, which should be explored in future clinical studies.

Conclusion

The results from this study highlight the complexities and tradeoffs that must be considered when working with BP monitoring devices. Device reliability varied considerably outside mid-range BP/PR and significant differences were observed in determination times. Timely detection of BP/PR is crucial for identifying potentially emergent conditions. Devices that strike a balance between range and speed may provide the greatest clinical utility. An additional clinical study measuring the performance of NIBP monitors is warranted.

Data Sharing Statement

The data that support the findings of this study are proprietary and cannot be shared publicly due to commercial confidentiality and legal restrictions. Access to the data may be available upon reasonable request.

Ethics Approval and Informed Consent

For this type of study, study ethics approval was not required.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the study conception, design, execution, acquisition of data, analysis and interpretation, or in all of these areas; took part in drafting, revising, or critically reviewing the manuscript; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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