

Comparison of Continuous Non-Invasive Blood Pressure Monitors Finapres Nova and Caretaker 4 During Rest and Laboratory Interventions

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Abstract

Aim: *There is a significant demand for a reliable continuous non-invasive blood pressure monitor which could be used to detect fatal changes in blood pressure for example during and after surgical operations. Thus, this study aimed to find out if two continuous non-invasive blood pressure monitors, Finapres Nova and Caretaker 4, react similarly to fast changes in blood pressure.*

Methods: *21 healthy young adult subjects were recruited for measurements which included four rest phases and three laboratory intervention tests intended to induce fast changes in blood pressure. The tests were hand grip test, cold pressor test, and Valsalva maneuver.*

Results: *Mean discrepancies and standard deviations for systolic and diastolic blood pressures measured with Finapres and Caretaker were -1.6 ± 8.4 mmHg and -2.3 ± 5.3 mmHg during rest. Caretaker reacted to the blood pressure changes caused by the interventions significantly less than Finapres ($p=0.004$ for systolic and $p=0.006$ for diastolic blood pressure during cold test and $p<0.001$ for systolic and diastolic pressures during hand grip test).*

1. Introduction

Blood pressure is one of the important vital signs to be measured in the basic health checks, intensive care units, and during and after surgical operations. During most of the major surgical operations, it is important to monitor the changes in blood pressure and react fast to the alarming alterations. To detect these fast changes in blood pressure, continuous blood pressure monitoring is the only option. Intra-arterial cannula is the gold standard and currently almost exclusively used method in critical continuous blood pressure monitoring. Considering the risks of invasive blood pressure monitoring (for example tissue damages and infections) the demand for a reliable continuous non-invasive blood pressure monitor is high.

Several non-invasive solutions have been developed over the years but the ability of these continuous non-invasive blood pressure monitors to react to the fast

changes in blood pressure has not been studied widely enough. Earlier versions of Finapres have been compared to intra-arterial blood pressure monitoring or oscillometric device during rest and laboratory interventions in a few previous studies [1-6]. Studies made using Caretaker device and including dedicated blood pressure altering interventions have not been published in scientific literature.

In this study, two continuous non-invasive blood pressure monitors, Finapres Nova and Caretaker 4, were compared with each other during rest and three laboratory tests aiming to cause fast changes in blood pressure. These tests were hand grip test, cold pressor test, and Valsalva maneuver.

2. Methods

2.1. Measurement devices and protocol

The continuous blood pressure monitors used in the study were Finapres® NOVA (Finapres Medical Systems, Enschede, the Netherlands) and Caretaker 4 (Caretaker Medical LLC, Charlottesville, Virginia, USA). The operating principles of the devices are described in detail in [7] and [8]. In brief, both devices have an inflatable finger cuff. Finapres is based on Penaz's volume clamp method [9] and Caretaker utilizes an algorithm called Pulse Decomposition Analysis to calculate blood pressure values based on the measured pulse waves [8].

During the measurements, Finapres was attached to the middle finger and Caretaker to the index finger of the subject's right hand. During the measurements, the subjects were sitting still with their arms resting on a table. Before the measurements, Finapres and Caretaker were calibrated according to the manufacturers' instructions. Finapres inflates its own calibration arm cuff two times to calibrate itself. An average of these two measurements was used to manually calibrate Caretaker.

The measurement protocol is presented in Table 1. The hand grip was performed during 1.5 minutes with the non-instrumented hand. During the cold test a cold pack was held on the subject's left forearm for one minute. The

Valsalva maneuver was performed by holding the breath and trying to push the air out by contracting the chest and stomach muscles without letting the air out for 10 seconds. The subjects were allowed to use their left hand to block their nose during the Valsalva maneuver.

Table 1. Study protocol

Episode	Time (min:sec)
Rest	0:00-3:00
Hand grip test	3:00-4:30
Rest	4:30-7:30
Cold test	7:30-8:30
Rest	8:30-11:30
Valsalva maneuver	11:30-11:40
Rest	11:40-14:30

2.2. Analysis of the data

To analyze the performance of the devices during rest, an average of the measurement points during the last 20 seconds of each resting phase was calculated. The averages were compared between Finapres and Caretaker with Bland-Altman analysis.

Even though neither of the devices was considered as a reference, agreement between the devices during the rest phases was evaluated according to the ANSI/AAMI/ISO 81060-2:2019 standard. The standard requires that the mean difference between the devices should be less than 5 mmHg and the standard deviation less than 8 mmHg. [10]

In the case of hand grip and cold pressor tests, the reactions of the devices to the interventions were studied by comparing the changes in the measured blood pressures between the monitors. The changes were calculated by taking an average of the measurement points during the last 10 seconds of the test. The average was compared to the baseline which was calculated as an average of the measurement points during 20 seconds before the start of the test.

The performance of the devices during Valsalva maneuver was analyzed by calculating the baseline average similarly than with the other tests and finding the maximum values of the phases 1 and 4 of the Valsalva maneuver and the minimum value during the phase 3 for all subjects. The mean of the minimum value and the means of the maximum values of the Valsalva maneuver phases were calculated and compared between the devices. The meanings of Valsalva maneuver phases are described in detail in [11].

2.3. Statistical methods

The statistical significance of the changes in the measured blood pressures during hand grip and cold pressure tests was tested with Wilcoxon signed rank test.

The statistical significance of the differences in the measured changes in blood pressures between Finapres and Caretaker were tested with Mann-Whitney U-test. Non-parametric tests were used because of the relatively small sample size. The minimal level considered for statistical significance was $p < 0.05$.

3. Results

21 young adult subjects (12 men, 9 women) aged between 21 and 37 years (median 23 years) attended the measurements. Subjects were in good general health. Anthropometric information of the subjects is presented in Table 2.

Table 2. Anthropometric information

Characteristic	Total amount (n=21)
Female sex (n)	9
Age (years)	23 (22-27)
Height (cm)	175 (167-183)
Weight (kg)	75 (65-83)

Characteristics are shown as a number and a median (25th percentile - 75th percentile).

Bland-Altman plots of the rest phases of all subjects for systolic and diastolic blood pressures measured with Finapres and Caretaker are shown in Figure 1. Mean discrepancies during the rest phases for systolic and diastolic pressures were -1.6 mmHg and -2.3 mmHg. Correspondingly, standard deviations were 8.4 mmHg and 5.3 mmHg.

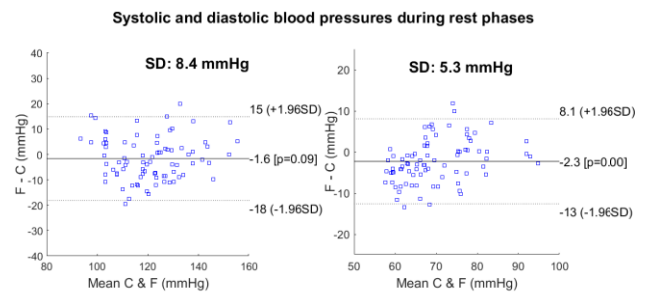


Figure 1. Bland-Altman plots for the comparison of the systolic (left) and diastolic (right) blood pressures measured with Finapres (F) and Caretaker (C) during rest.

Figures 2 and 3 present box plots for the changes in systolic and diastolic blood pressures between the baseline and the hand grip test and the baseline and the cold pressor test. Also, p-values of the Wilcoxon signed rank test for each change are shown in the figures.

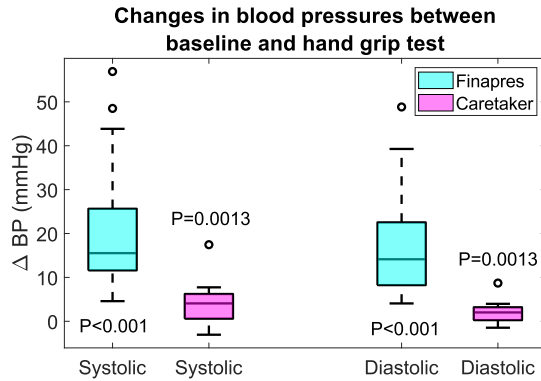


Figure 2. Changes in systolic and diastolic blood pressures between baseline and the end of the hand grip test with Finapres and Caretaker. P-values are from the Wilcoxon signed rank tests for the changes in blood pressure.

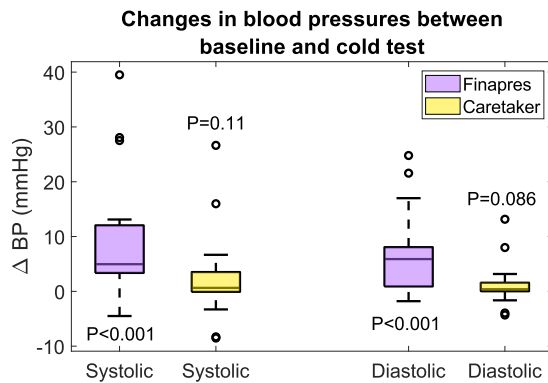


Figure 3. Changes in systolic and diastolic blood pressures between baseline and the end of the cold pressor test with Finapres and Caretaker. P-values are from the Wilcoxon signed rank tests for the changes in blood pressure.

All the differences in the measured changes between Finapres and Caretaker during hand grip and cold tests were statistically significant according to Mann-Whitney U-test. This indicates that Caretaker and Finapres showed statistically different changes in blood pressure values during the interventions. The p-values are shown in Table 3.

Table 3. P-values for the differences in the measured changes in systolic and diastolic blood pressures during interventions between Finapres and Caretaker.

Intervention	Systolic	Diastolic
Hand grip	P < 0.001	P < 0.001
Cold pressure	P = 0.004	P = 0.006

Figure 4 shows the means of the extreme values of systolic and diastolic blood pressures during Valsalva

maneuver compared to the baseline measured with Finapres and Caretaker.

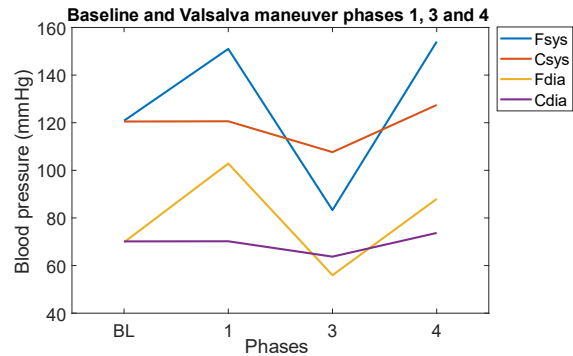


Figure 4. Mean systolic (sys) and diastolic (dia) blood pressures measured with Finapres (F) and Caretaker (C) during the baseline (BL) and the extreme values of Valsalva maneuver phases 1, 3 and 4.

4. Discussion

Bland-Altman plots in Figure 1 indicate only small mean discrepancies for both systolic and diastolic pressures (-1.6 and -2.3 mmHg) and quite small standard deviations (8.4 and 5.3 mmHg) during the rest phases. Both mean discrepancies and the standard deviation of the diastolic pressure would fulfill the requirements of the ANSI/AAMI/ISO 81060-2:2019 standard and the standard deviation of the systolic pressure would only slightly exceed the limit. However, variations in the blood pressure values during resting state were small and therefore the study cannot be used to evaluate the performance of the devices to follow changes in resting blood pressure values.

It can be clearly seen in Figures 2–4 that Caretaker is not able to react to the fast changes in blood pressure as effectively as Finapres. The changes in blood pressure were systematically greater according to Finapres than Caretaker ($p=0.004$ for systolic and $p=0.006$ for diastolic pressure during cold test and $p<0.001$ for systolic and diastolic pressures during hand grip test). Caretaker is not able to measure the brief local maximum and minimum blood pressure values as the phases 1, 3, and 4 of Valsalva maneuver clearly reveal in Figure 4. For some subjects Caretaker device did not react to the changes in blood pressure at all and the changes in blood pressures during the cold pressor test were not statistically significant according to Caretaker ($p=0.11$ for systolic and $p=0.086$ for diastolic pressure). On the contrary, the changes were clearly statistically significant according to Finapres ($p<0.001$ for systolic and diastolic pressure). Hand grip and cold pressor tests showed that even though the changes in the blood pressures lasted a bit longer than during Valsalva maneuver, Caretaker reacted to them only mildly (Figures 2 and 3). Kwon et al. have earlier suggested that

Caretaker underestimates the changes in intra-arterial blood pressure because the blood pressure in the finger arteries is lower than in brachial artery which can also be seen as an attenuation in blood pressure trends [12].

It is impossible to know whether Caretaker or Finapres is closer to the real values of blood pressure because reference values from gold standard intra-arterial catheter were not available in the study. It is probable that Finapres reacts to the changes in blood pressure fast enough, but it cannot be ruled out that it has overreacted to them. Earlier studies have suggested that Finapres overreacts to the fast increases in blood pressures [2, 13, 14, 5]. Idema et al. suggested that the reason would be the increased number of distortions in the pulse waves with the increased blood pressure [13]. Imholz et al. suggested that overreactions during Valsalva maneuver would result from the phasic vasoconstrictions and following vasodilations [2].

5. Conclusion

In our study, Finapres and Caretaker showed similar blood pressure readings during rest but their reactions to fast changes in blood pressure differed significantly. Probably Caretaker is not able to react fast enough, and it likely underestimates the magnitudes of the changes. On the contrary, Finapres might overestimate the changes sometimes. However, because the devices were not compared with an intra-arterial catheter in this study, it is impossible to say which device is the closest to the real values of blood pressure.

Acknowledgments

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