Comparison of Four Smartphone Compatible Blood Pressure Monitors

Roderick Treskes, Enno van der Velde, Daniëlle Eindhoven, Martin-Jan Schalij

Leiden University Medical Center, Leiden, The Netherlands

Abstract

Out-of-office blood pressure (BP) monitoring is advocated by the guidelines for various reasons. Recently developed smartphone compatible BP monitors are potentially very useful for out-of-office BP monitoring. This study is ought to compare performances of these BP monitors.

Patients with recent myocardial infarction and no documented history of atrial fibrillation or atrial flutter were eligible for our study. After inclusion, six BP monitors from different manufacturers were applied to the patient. Three consecutive measurements were done with each BP monitor. Means were statistically analysed using a linear mixed model with Bonferonni to correct for multiple comparisons.

A total of 33 patients were included. Compared to the reference device, one BP monitor yielded a significant higher mean systolic BP and three monitors yielded a significant higher diastolic BP.

One validated smartphone compatible device yielded no systematic difference in means of systolic and diastolic BP. One device yielded systematic difference in means of systolic and diastolic BP. Further research will be done to corroborate these findings.

1. Introduction

Out-of-office blood pressure (BP) monitoring is advocated by recent guidelines in patients with arterial hypertension.[1] Advantages of out-of-office BP monitoring are the possibility of multiple BP measurements and the ability to prevent the "white coat hypertension", the well-known and demonstrated[2] phenomenon that BP is elevated in presence of a physician.[1]

For out-of-office BP monitoring, results of BP measurements ideally would be generated and send to the physician automatically. This diminishes the effect of human error. Although the gold standard for systolic and diastolic BP measurement is the auscultation of Korotkoff sounds with a stethoscope while deflating an handheld mercury sphygmomanometer,[3] this method often requires a trained health care professional and is therefore unsuitable for out-of-office BP measurement. On the contrary, smartphone BP monitors are mostly automated oscillometric devices which send results via Bluetooth to the smartphone, making these monitors suitable for out-of-office BP measurement.

Over the past few years, several smartphone compatible BP monitors have been approved by the FDA and European Union for over-the-counter purchasing.[4]

To our knowledge, no study has been done to compare these smartphone compatible BP monitors in a clinical setting in a clinical population.

It is therefore the purpose of this study to compare the results of the measurements and the user friendliness of four smartphone compatible blood pressure monitors in a clinical setting in a clinical population.

2. Methods

2.1. Patient population

Patients with recent (<1 year) ST elevation myocardial infarction and no documented history of atrial fibrillation or atrial flutter, visiting the outpatient clinic of our hospital, were eligible for the study.

2.2. Blood pressure monitors

Six BP monitors, each from a different manufacturer, were applied during the study: the Welch Allyn 767 (Welch Allyn, Skaneateles Falls, NY), the Omron M7 (Omron, Kyoto, Japan), the Withings Wireless Blood Pressure Monitor (Withings, Issy-les-Moulineaux, France), iHealth BP5 (iHealth Lab, Inc., Mountain View, CA), QardioArm (Qardio Inc., San Francisco, CA) and the iHealth BP7 (iHealth Lab, Inc., Mountain View, CA). All BP monitors were purchased for the study. None of the manufacturers was involved in the design or execution of the study, had access to the study data or was involved in the decision to publish the study results in the proceedings.

The Welch Allyn 767 is a handheld aneroid mobile sphygmomanometer. It is placed around the bare upper arm of the patient, according to the user manual of the manufacturer. The monitor is CE-marked for use in the European Union. For this study, it was applied by a

trained physician who was blinded to the results of measurements of other BP monitors applied to the same patient. The Korotkoff sounds, auscultated at the elbow joint, were used to determine systolic and diastolic blood pressure. Phase I was used to determine systolic blood pressure. Phase V was used to determine diastolic blood pressure.

The Omron M7 is an automated oscillometric blood pressure monitor. It is placed around the bare upper arm of the patient, according to the user manual of the manufacturer. The monitor has been CE-marked for use in the European Union. Inflation and deflation are automated and started by pushing a button on the device. It is every two years calibrated by the hospitals' Instrumentation Department. The Omron M7 is not smartphone compatible.

The Withings Wireless Blood Pressure Monitor is an automated oscillometric blood pressure monitor. It is placed around the bare upper arm of the patient, according to the user manual of the manufacturer. The Withings Wireless Blood Pressure Monitor is CE-marked for use in the European Union. The monitor communicates with the smartphone via Bluetooth. Inflation and deflation is automated and started by a command from the smartphone. Results of measurements are transferred to the Withings application on the smartphone.

The iHealth BP5 is an automated oscillometric blood pressure monitor. It is placed around the bare upper arm of the patient, according to the user manual of the manufacturer. The iHealth BP5 has been CE-marked for use in the European Union. The device communicates with the smartphone via Bluetooth. Inflation and deflation is automated and started by a command from the smartphone. Results of measurements are transferred to the iHealth MyVitals application on the smartphone.

The QardioArm is an automated oscillometric blood pressure monitor. It is placed around the bare upper arm of the patient, according to the user manual of the manufacturer. The BP monitor has been CE-marked for use in the European Union. The device communicates with the smartphone via Bluetooth. Inflation and deflation is automated and started by a command from the smartphone. Results of measurements are transferred to the Qardio application on the smartphone.

The iHealth BP7 is an automated oscillometric blood pressure monitor. It is placed around the bare wrist of the patient, according to the user manual of the manufacturer. The patient needed to bring his or her elbow joint in flexion to bring to monitor at the same height of the heart. This required approximately 30 degrees of flexion, depending on the height of the patient. The device has been CE-marked for use in the European Union. The device communicates with the smartphone via Bluetooth. Inflation and deflation is automated and started by a command from the smartphone. Results of measurements are transferred to the iHealth MyVitals application on the smartphone.

2.3. Study procedures

Patients were taken to a separate room at the outpatient clinic visit. Patients were in a sitting position when the BP monitors were applied. Five minutes of rest were applied before measurements began. During these five minutes, the order of all six BP monitors was randomized. After this, BP monitors were applied to the patient, according to the instruction manual, one by one and in randomized order. Each BP monitor was inflated three times without rest. After three measurements, the monitor was detached and the next monitor was applied. One minute of rest was taken during the switch of two BP monitors. After all measurements were finished, the results of these were told to the patient. Patient could not see or deduce their BP before all six BP monitors were applied. Patients were asked not to talk, drink coffee or walk during and in between measurements.

As a parameter of user friendliness, the amount of failed measurements was counted per device. We defined a failed measurement as no blood pressure on the smartphone (Withings Wireless Blood Pressure Monitor, iHealth BP5, QardioArm or iHealth BP7) or Omron screen after automated inflation and deflation of the BP monitor applied to a patients arm according to the manual of the BP monitor corresponding manual. No extra measurement was done to replace a failed measurement.

This study was conducted according to the principles of the Declaration of Helsinki (version 10, October 2013) and according to the Medical Research Involving Human Subjects Act. All patients could leave the study at any time they want without providing a reason. The study was approved by our hospital Medical Ethics Committee. All patients provided written informed consent before participating.

2.4 Statistical analysis

Statistical analysis was done using SPSS (IBM, Armonk, NY) to perform a linear mixed model. Bonferonni was used to adjust for multiple comparisons.

2.5 Ethical conduct

This study was conducted according to the principles of the Declaration of Helsinki (version 10, October 2013) and according to the Medical Research Involving Human Subjects Act. All patients could leave the study at any time they want without providing a reason. The study was approved by our hospital Medical Ethics Committee. All patients provided written informed consent before participating.

3. Results

3.1. Patient population characteristics

So far, 33 patients were included. Mean age was 63.8 years. Of all 33 patients, 27 were male. Mean BMI was 26.8 kg/m^2. Mean systolic BP, measured by the Welch Allyn, was 119.0 mmHg. Mean diastolic BP was 71.4 mmHg. Mean heart rate was 63.5 beats per minute (bpm). Patient population characteristics are provided in Table 1.

Table 1. Patient population characteristics

Included patients [n]	33
Sex (male/female)	27/6
Age (years)	63.8±11.4[39.4-81.6]
BMI (kg/m2)	26.8±3.3[22.2-33.3]
Mean systolic blood pressure (mmHg)	119.0±14.4[101.7-160.0]
Mean diastolic blood pressure (mmHg)	71.4±8.7[50.0-90.0]
Mean heart rate (bpm)	63.5±11.6[40-92]

3.2. Comparison of monitors

Systolic BP

The mean systolic BP of the iHealth BP7 was 8.0 mmHg higher than the mean systolic BP of the Welch Allyn 767. This difference was statistically significant (*P*=0.008; 95% CI 1.480 – 14.520). All other mean differences in mean systolic BP were not statistically significant.

Diastolic BP

The mean diastolic BP of the iHealth BP5 was 5.455 mmHg higher than the mean diastolic BP of the Welch Allyn 767 (*P*=0.02; 95 CI .566 – 10.343). The mean diastolic BP of the QardioArm was 3.955 mmHg higher than the mean diastolic BP of the Welch Allyn 767 (*P*=0.004; 95 CI .985 – 6.924).

The mean diastolic BP of the iHealth BP7 was 6.886 mmHg higher than the mean diastolic BP of the Welch Allyn 767 (*P*<0.001; 95 CI 3.055 – 10.717). The mean diastolic BP of the iHealth BP7 was 5.364 mmHg higher than the mean diastolic BP of the Withings BP monitor (*P*=0.003; 95 CI 1.360 – 9.367). All other differences in mean diastolic BP were not statistically significant.

3.3. Failed measurements

The Welch Allyn 767 and the iHealth BP5 did not fail. The Omron M7 failed once. The QardioArm failed six times. The iHealth BP7 failed eleven times, of which 8 the third time. The Withings BP monitor failed 14 times, of which 7 the first measurement.

An overview of failed measurements per monitor is given in Table 2.

BP monitor	1st measure-ment failed	2nd measure-ment failed	3rd mearuse-ment failed	Total measure-ment failed
Welch Allyn 767	0	0	0	0
Omron M7	0	0	1	1
Withings	7	3	4	14
iHealth BP5	0	0	0	0
QardioArm	2	2	2	6
iHealth BP7	1	2	8	11

4. Discussion

This study was conducted to compare four smartphone compatible BP monitors in a clinical setting in a clinical population. One BP monitor (iHealth BP7) showed significantly higher systolic and diastolic BP. Two monitors (iHealth BP5 and QardioArm) showed significantly higher diastolic BPs.

These smartphone compatible BP monitors are potentially suitable for out-of-office BP measurement. They do not require a trained physician, are automated and are capable of automatic sending of BP measurement results. This makes the smartphone monitors more suitable than regular automated devices, which cannot send results automatically.

However, the reliability of these BP monitors remains a subject for further research. In this study, one BP monitor yielded significantly higher systolic and diastolic measurements. Two BP monitors yielded significantly higher diastolic measurement. This is considerable, since it might mimic hypertension, which might lead to false positive description of anti-hypertensive drugs.

Secondly, user friendliness is a point of consideration. Failed measurements might lead to frustration which may result in reduced use of smartphone compatible monitors.

The results of this study have to be seen in the light of some limitations. First, this study was not done in accordance to the protocol of the British Hypertension Society. This means that this is not a validation study per se. This study is ought to compare the performance of these monitors in a clinical population. Furthermore, patients with atrial fibrillation or atrial flutter were

excluded from this study. This means that present results cannot be extrapolated to patients with atrial fibrillation or atrial flutter. Further research needs to be done to evaluate the BP monitors in this subpopulation.

Acknowledgements

The authors would like to thank all patients who participated in the study.

References

[1] Mancia G, Fagard R, Narkiewicz K et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Eur Heart J 2013;34(28):2159-2219.

[2] Mancia G, Bertinieri G, Grassi G et al. Effects of blood-pressure measurement by the doctor on patient's blood pressure and heart rate. Lancet 1983;2(8352):695-698.

[3] Pickering TG, Hall JE, Appel LJ et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement 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. Circulation 2005;111(5):697-716.

[4] Bruining N, Caiani E, Chronaki C, Guzik P, van d, V. Acquisition and analysis of cardiovascular signals on smartphones: potential, pitfalls and perspectives: by the Task Force of the e-Cardiology Working Group of European Society of Cardiology. Eur J Prev Cardiol 2014;21(2 Suppl):4-13.

Address for correspondence.

Roderick Treskes
Albinusdreef 2
P.O. Box 9600, 2300 RC
Leiden, The Netherlands
R.W.Treskes@lumc.nl