Comparison between Digital Blood Pressure Monitors for Home Use (Wrist) and (Arm) with a Mercury Sphygomanometer

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Received: July 8, 2024   Accepted: August 2, 2024   Online Published: August 5, 2024
doi:10.5539/gjhs.v16n7p64   URL: https://doi.org/10.5539/gjhs.v16n7p64

Abstract

Blood pressure disease (BP) is one of the major public health problems around the world. There are many digital BP devices used at home. Doubts are usually raised about these devices. This study aimed to compare home (wrist) and (arm) digital blood pressure monitors with a mercury sphygmonanometer. This study was conducted at the University of Tabuk, comparing a digital BP meter (arm) and (wrist) with a properly calibrated mercury BP. A total of 100 randomly selected students aged 18 to 39 years were enrolled. Two blood pressure measurements for each person were recorded by all devices, and the values were recorded taking into account the environment of a person. The data were entered into MS Excel and analysis was done by using Social Sciences version 23.0. The normality of data was performed by the Shapiro-Wilk test and it was normally distributed. The mean and standard deviation were calculated for quantitative variables, while frequencies and percentages were provided for qualitative variables. Paired sample t-test was used to compare the mean values of systolic blood pressure (SBP) and diastolic blood pressure (DBP). Digital arm devices had sensitivity and specificity of 62.5% and 63%, respectively, compared to digital wrist devices, which had sensitivity and specificity of 75% and 56%, respectively. The readings of the digital blood pressure monitors were comparable to the readings of the mercury blood pressure monitor. Both devices could be considered indispensable tools for detecting hypertension at home and thus useful for early diagnosis.

Keywords: equipment and supplies, arm, diastolic pressure

1. Introduction

Hypertension can be treated and prevented early with accurate blood pressure measurements. Accurate blood pressure measurement is a critical preventive measure in the control of hypertension and its associated diseases, both of which are major public health issues. Hypertension ranks third in terms of disease burden (Wadhwani, Siddiqui & Sharma, 2018). When blood pressure consistently exceeds a certain threshold, such as 130/80 or 140/90 mmHg, hypertension is usually diagnosed (Rodrigues Filho, Farias, & Dos Anjos, 2018). The most frequent screening test used in modern medicine is blood pressure measurement which has been around since the 1700s (Pickering et al., 2005).

The majority of blood pressure monitors work by using an inflatable cuff to block an artery in an extremity (Haney, 2005). A blood pressure monitor (BPM), a contemporary tool, is used for measuring blood pressure (BP). To discern between systolic blood pressure (SBP) and Diastolic blood pressure (DBP), auscultatory techniques were created in 1828. Systolic blood pressure is measured when the heart muscles contract to pump blood into the blood arteries, which are subsequently dispersed to the rest of the body, and blood pressure is high.

The mercury sphygmonanometer, which has been in use for less than a century and has performed admirably, is currently being challenged. Mercury devices are being phased out of healthcare facilities to safeguard the environment. Secondly, electronic blood pressure monitors are becoming more accessible and have several benefits, one of which is the ability to identify patterns of blood pressure elevation by taking repeated readings. After the advent of automated devices for use in healthcare settings, affordable blood pressure monitors were introduced for home use (Nasrallah et al., 2019). Since there are a large number of devices available, competition among manufacturers in the market is high.
As for the competition in the pricing of the devices, it may be positive for the consumer, but the quality of the measurements must be verified by confirmation according to British, European, or American protocols (Hughes, Thompson & Collins, 2006). There is a requirement for validation of BP devices and health technologies having high quality for the indispensable delivery of health care effectiveness according to WHO (World Health Organization, 2007). There is a stepwise approach presented by the regulatory framework of the WHO Global Model to enforce the proper regulatory controls on health and medical devices. According to the ISO Standard, there is a protocol for the BP devices validation and calibration which is accepted universally. The universal acceptance of the protocol developed the global regulatory monitoring organization, which is responsible for resolving the issues related to the accuracy of the BP issues which is adjustable in the modern framework of devices. Several measures endorse the standardization and validation protocol which have been influenced across the global spectrum which includes government organizations (regulatory agencies of FDA), non-government organizations (societies working on hypertension, and blood pressure), groups of health professionals, manufacturers and consumers of BP devices (Sharman et al., 2020).

This study was conducted based on the evidence from previous studies (Netea, Lenders, Smits, & Thien, 2003) and tests of the accuracy of devices used for personal use. The aim was to compare home (wrist) and (arm) digital blood pressure monitors with manual apparatus by using a mercury sphygmomanometer.

2. Methods

2.1 Study Design

The study design was quasi-experimental. The study was conducted at Tabuk University and a total of 100 participants over 18 years of age were enrolled. Monitoring of blood pressure with all three devices was performed in each participant over two weeks. According to global regulatory control, the universally accepted protocol (ISO 81060-2:2018) is independent of the BP devices’ validation and mandatory for all health and medical devices (Sharman et al., 2020).

2.2 Study Tool

Readings from a digital arm sphygmomanometer and a digital wrist sphygmomanometer were compared with those from a mercury sphygmomanometer. In addition, the standard mercury device served as a control. Readings taken with the mercury device, the digital arm device, and the digital wrist device were compared for differences. There was a total of six readings for each subject and two readings for each method. All devices were reviewed, standardized, and calibrated by experts. The International standards of validation endorse especially that no new BP devices or technologies can be used if not approved by ISO Standard (ISO 81060-2:2019) (Stergiou et al., 2018). This legislation is implemented in all types of organizations either government or non-government, for health care and professional and research communities.

2.3 Data Collection

Participants were given comprehensive instructions and training on the proper use of digital blood pressure monitors before the measurements. They were demonstrated how to correctly position the cuff, maintain the appropriate arm posture, and follow the device's operating procedures to ensure that the participants used the devices correctly and to minimize deviations in measurement results due to user error.

The environment setting was controlled to ensure the accuracy of blood pressure readings. Each measurement was conducted in a quiet, temperature-controlled room to minimize external influences. The room temperature was maintained between 20°C and 22°C (68°F to 72°F) to avoid the impact of temperature extremes on blood pressure measurements. Participants were seated comfortably with their legs and back uncrossed, and their arms were positioned at heart level during the measurements. Ambient noise levels were kept to a minimum to avoid any potential distractions that could affect the accuracy of the readings. The use of a consistent and well-calibrated sphygmomanometer and appropriate-sized cuffs was ensured to provide reliable measurements (Netea et al., 2003). Each device measured each participant’s blood pressure twice, and the average of these readings was recorded. Measurements were repeated at 30-second intervals for accuracy.

2.4 Data Analysis

The data were entered into MS Excel and analysis was done by using the statistical package for Social Sciences version 23.0. Shapiro-Wilk test was applied to test the normality of data, which showed that the data was normally distributed. The mean and standard deviation were calculated for quantitative variables, while frequencies and percentages were reported for qualitative variables. A paired sample t-test was used to compare the mean values of SBP and DBP measurements taken by the same subjects with the standard mercury meter and two other digital
devices on the arm and wrist in men, women, and all subjects, and P-value of <0.05 was considered to be statistically significant.

2.5 Ethical Consideration

Informed consent was obtained from all participants before including them in the study. Participants were provided with detailed information about the study’s purpose, procedures, and any potential risks. They were informed that participation was voluntary and that they could withdraw at any time without any negative consequences. The study was approved by the institutional ethics committee and informed consent was taken by the participants before enrollment. Standard procedures for blood pressure measurement were followed (Nasrallah et al., 2018).

3. Results

A representative sample of 100 healthy subjects (47 males and 53 females) was analyzed. The mean age of participants was 23.98 ± 5.15 years. The mean ± SD SBP of the reference device (mercury) was 124.38 ± 7.467 mmHg, 119.55±6.008, and 121.82±7.124 for male, female, and all subjects, respectively, whereas with the digital arm device, it was 126.43 ± 10.523, 117.53±8.67, and 121.71±10.436. For the digital wrist device, they were 130.21±8.516, 122.85±10.461, and 126.31±10.238. The mean ± SD DBP of the reference device was 71.23±7.387, 64.43±5.059, and 67.63±7.102 for male, female, and all subjects, whereas it was 75.28±6.402, 73.11±6.527, and 74.13±6.527 for the digital arm device and 78.70±7.877, 76.66±6.297, and 77.62±7.121 for the digital wrist device.

The mean difference in SBP measurements of the reference and the two automatic devices was observed and presented in Table 1. It was found that there were statistically significant differences between the SBP measurements with the reference mercury and the digital wrist meter in the three groups of males, females, and all subjects.

Table 1. Results from the Pair samples t-test for SBP measurements of the reference and the two automatic devices

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>t statistic</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP Mercury - SBP digital arm Male</td>
<td>-2.043</td>
<td>9.860</td>
<td>1.438</td>
<td>-1.420</td>
<td>46</td>
<td>.162</td>
</tr>
<tr>
<td>SBP Mercury - SBP digital wrist Male</td>
<td>-5.830</td>
<td>8.074</td>
<td>1.178</td>
<td>-4.950**</td>
<td>46</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SBP Mercury - SBP digital arm Female</td>
<td>2.019</td>
<td>10.248</td>
<td>1.408</td>
<td>1.434</td>
<td>52</td>
<td>.157</td>
</tr>
<tr>
<td>SBP Mercury - SBP digital wrist Female</td>
<td>-3.302</td>
<td>11.522</td>
<td>1.583</td>
<td>-2.086*</td>
<td>52</td>
<td>.042</td>
</tr>
<tr>
<td>SBP Mercury - SBP digital arm All subjects</td>
<td>.110</td>
<td>10.222</td>
<td>1.022</td>
<td>.108</td>
<td>99</td>
<td>.915</td>
</tr>
<tr>
<td>SBP Mercury - SBP digital wrist All subjects</td>
<td>-4.940</td>
<td>10.081</td>
<td>1.008</td>
<td>-4.454**</td>
<td>99</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

From the results of the t-test in Table 2, it was evaluated that the differences in DBP measurements obtained with the mercury reference device and each of the other two devices are statistically significant for all groups, males, females, and all subjects.

Table 2. Results from the Pair samples t-test for DBP measurements of the reference and the two automatic devices

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>t statistic</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DBP Mercury - DBP digital arm Male</td>
<td>-4.043</td>
<td>9.334</td>
<td>1.362</td>
<td>-2.969**</td>
<td>46</td>
<td>.005</td>
</tr>
<tr>
<td>DBP Mercury - DBP digital wrist Male</td>
<td>-7.468</td>
<td>10.673</td>
<td>1.557</td>
<td>-4.797**</td>
<td>46</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DBP Mercury - DBP digital arm Female</td>
<td>-8.679</td>
<td>8.622</td>
<td>1.184</td>
<td>-7.329**</td>
<td>52</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DBP Mercury - DBP digital wrist Female</td>
<td>-12.23</td>
<td>7.350</td>
<td>1.010</td>
<td>-12.110**</td>
<td>52</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DBP Mercury - DBP digital arm All subjects</td>
<td>-6.500</td>
<td>9.216</td>
<td>.922</td>
<td>-7.053**</td>
<td>99</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DBP Mercury - DBP digital wrist All subjects</td>
<td>-9.990</td>
<td>9.327</td>
<td>.933</td>
<td>-10.710**</td>
<td>99</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

The study also observed the sensitivity and specificity of digital arm and digital wrist devices and they are presented in Tables 3 and 4. It was observed that the digital arm device has a sensitivity and specificity of 62.5% and 63%, respectively. In comparison, the digital wrist device has a 75% sensitivity and 56% specificity.
Table 3. Sensitivity and specificity for digital arm device

<table>
<thead>
<tr>
<th>Test result from Digital arm device</th>
<th>True status</th>
<th>Classical mercury</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High blood pressure</td>
<td>normal</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>count</td>
<td>10</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>62.5%</td>
</tr>
<tr>
<td>normal</td>
<td>count</td>
<td>6</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>37.5%</td>
</tr>
<tr>
<td>Total</td>
<td>count</td>
<td>16</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 4. Sensitivity and specificity for digital wrist device

<table>
<thead>
<tr>
<th>Test result from Digital wrist device</th>
<th>True status</th>
<th>Classical mercury</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High blood pressure</td>
<td>normal</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>count</td>
<td>12</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>75%</td>
</tr>
<tr>
<td>normal</td>
<td>count</td>
<td>4</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>25%</td>
</tr>
<tr>
<td>Total</td>
<td>count</td>
<td>16</td>
</tr>
<tr>
<td>% Within mercury</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

4. Discussion

According to the findings of the current study in which the digital arm and wrist BP machines were compared with the mercury sphygmomanometer, among the three devices, the digital wrist device had the highest means and standard deviations for both SBP and DBP in all groups of subjects. The study also observed that the digital arm device provided a similar SBP value to the mercury device, while the wrist device had a different SBP value.

The arm device could detect nearly 63% (two-thirds) of individuals with hypertension, while the wrist device was able to detect 75% (three-quarters). On the other hand, the arm device was able to detect 63% (two-thirds) of people with normal blood pressure, while the wrist device could detect 56% of participants. It was noted that the digital wrist device had higher sensitivity than the arm device, while the arm device had higher specificity than the wrist device.

The digital wrist device could be used for people with high blood pressure, while the arm device is suitable for normal blood pressure. The present study was conducted in a controlled clinical setting, and the mean age of the participants was 23.9 ± 5.1 years. This contrasts with the results of the study by Watson et al. (1998) in which the mean age was 63 ± 10.1 years. Previous studies reporting on the accuracy of digital instruments revealed almost as precise as mercury instruments (Wan et al., 2010; Stevens et al., 2011).

A study by Rotch et al. (2001) highlighted differences in blood pressure readings when using arm, wrist, and finger models compared to a standard mercury sphygmomanometer. Among these, the arm model was the most accurate, despite its tendency to slightly underestimate SBP and overestimate DBP. However, the mean SBP and DBP readings from the arm model did not show a statistically significant difference from those of the conventional mercury sphygmomanometer. This was contrary to the findings of the present study.

To assess the degree of fluctuation in blood pressure measurements, study Yarows and Brook (2000) analyzed readings from twelve electronic blood pressure monitors. A mercury sphygmomanometer was compared to each monitor. Two people with normal blood pressure underwent 85 readings for each of the evaluated models. All monitors indicated decreased values of DBP as compared to measurements acquired by the mercury, and the study
only found minor variations in the results from each monitor. The outcomes also showed that the wrist and finger monitors examined gave readings that were comparable to readings taken from the upper arm unit. In a study conducted on ambulatory patients, an electronic arm monitor recorded a mean DBP of 80 15 mm Hg and a mean SBP of 127 21 mm Hg. The average SBP measurement obtained differed significantly from the mercury sphygmomanometer (Johnson et al., 1999).

A meta-analysis examined the research on how accurately digital blood pressure monitors diagnose hypertension compared to the gold standard mercury sphygmomanometer. According to their investigation, digital blood pressure monitoring was nearly as accurate as a mercury sphygmomanometer. This is consistent with our investigation, which found that a digital wrist device with mercury as the gold standard had a sensitivity of 75%. Our results support research that suggests using digital blood pressure monitoring for more effective and appropriate management of hypertension (Muniyandi et al., 2022; Karnjanapiboonwong et al., 2020). Due to variations in device models and study methods, results from individual studies cannot be compared to those of other studies with the same broad purpose (Rotch et al., 2001).

In the present study, the readings of the digital blood pressure monitors (arm) and (wrist) were comparable to the readings of the mercury sphygmomanometers. The arm and wrist devices were able to detect almost 63% and 75% of subjects with hypertension. A similar study by Araujo-Moura et al. (2022) reported that automatic blood pressure monitors demonstrate high measurement validity as compared to the mercury sphygmomanometer. Another study by However, a previous study by Osonuga et al. (2021) reported the reliability of digital sphygmomanometers for measuring SBP, however, caution is needed when using them to measure DBP. In contrast to this, Khosravi et al. (2022) reported significant discrepancies between the measurements from digital devices and mercury sphygmomanometers, indicating that digital devices cannot be considered the gold standard for measuring BP. However, a systematic review and meta-analysis study evaluating the diagnostic accuracy of a digital blood pressure measurement device and mercury sphygmomanometer suggested moderate accuracy of a digital blood pressure monitor as compared to a mercury sphygmomanometer (Muniyandi et al., 2022).

The findings from this study highlight several key considerations for the effective implementation of digital blood pressure monitors in home settings. Firstly, selecting the appropriate equipment is crucial. The digital wrist device, which demonstrated higher sensitivity, may be particularly useful for individuals who need to monitor for hypertension, as it is better at detecting elevated blood pressure levels. In contrast, the digital arm device, noted for its higher specificity, might be better suited for individuals who have normal blood pressure but require accurate monitoring to confirm stable conditions. Ensuring that the selected devices meet international validation standards (e.g., ISO 81060-2:2018) is essential for reliable measurements. Secondly, the frequency of measurements should be tailored to the individual's health needs. For those diagnosed with hypertension, more frequent monitoring, such as daily or weekly, can help track fluctuations and assess the effectiveness of treatment. Conversely, individuals with stable, normal blood pressure may only need to measure their blood pressure every month to ensure continued stability. Regular measurement schedules help in maintaining accurate records and detecting any changes early. The users should receive detailed instructions on how to correctly operate the devices, including proper cuff placement and measurement techniques. Misuse or incorrect operation can lead to erroneous results, highlighting the need for clear and comprehensive user training. Moreover, the environmental conditions during measurement should be controlled to minimize external factors that could affect results. Measurements should be conducted in a quiet, temperature-regulated environment, with the participant seated comfortably and their arm supported at heart level. Consistent measurement conditions help in obtaining reliable and accurate blood pressure readings.

However, a few limitations should also be acknowledged in this study. The sample size was relatively small and consisted mainly of young adults with a mean age of 23.98 years, which does not represent the broader population, particularly older adults who are more likely to have hypertension. The study was conducted in a controlled clinical setting, which may not fully replicate home monitoring conditions where factors such as user technique and environmental conditions could vary more widely. Additionally, the study did not account for potential variations in device performance due to different manufacturers and models, which could influence the generalizability of the findings. Future research needs to conduct research on a larger, more diverse sample and consider real-world home monitoring conditions to validate these findings further.

5. Conclusions

Thus, the study concludes that the digital wrist device had higher sensitivity than the arm device, while the arm device had higher specificity than the wrist device. Both devices could be considered indispensable tools for detecting hypertension at home and are therefore useful for early diagnosis.
Acknowledgments

The author is thankful to all the associated personnel who contributed to this study by any means.

Reporting Checklist

The authors have completed the STROBE reporting checklist.

Ethical Statement

The study was approved by the institutional ethics committee and informed consent was taken by the participants before enrollment.

Funding

None.

Informed Consent

Obtained.

Provenance and Peer Review

Not commissioned; externally double-blind peer reviewed.

Data Availability Statement

The data that support the findings of this study are available on request.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

References


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