

Comparing the accuracy of wearable devices readings with cuff sphygmomanometers for blood pressure measurement: Systematic Review and Meta-analysis

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Abstract

Wearable devices for BP measurement as an emerging technology for closer monitoring BP and achieving better BP control monitoring. However, the accuracy of wearable devices needs to be systematically validated and analyzed. This study aims to compare wearable device readings for BP measurement with those from cuff sphygmomanometers in prospective clinical studies, therefore, to determine whether wearable devices provide reliable and portable BP monitoring. The Web of Science, MEDLINE, Embase, Cochrane Library, and PubMed databases were searched from January 1, 1952 to October 8, 2021. Data were compiled from 21 articles comprising 897 participants. There was no significant difference between systolic and diastolic readings for wearable devices and cuff sphygmomanometers, with a combined mean difference of 0.58 mmHg (95% CI, -0.35 to 1.51; $n = 21$; $I^2=0\%$, $P = 0.22$) for SBP and -0.33 mmHg (95% CI, -1.50 to 0.85; $n = 19$; $I^2=56\%$, $P = 0.58$) for DBP. The subgroup analysis showed that BP readings of wearable devices lower than cuff sphygmomanometers at the wrist site (-1.85 mmHg, 95% CI, -2.75 to -0.95; $n = 11$; $I^2 = 10\%$, $P = 0.05$). Wearable device measurement for BP is comparable to the readings of cuff sphygmomanometers. Although the accuracy still should be improved, wearable device measurement may be a reliable and convenient approach for daily BP monitoring to improve BP control.

Introduction

Hypertension remains the most prevalent chronic disease condition threatening human health⁽¹⁾. Globally, the number of population with hypertension was over one billion in 2019, contributing to a major cause of cardiovascular diseases (CVDs)⁽²⁾. A number of studies showed that blood pressure (BP) control is essential for lowering the incidence of cardiovascular events and mortality^(3–5). Even if actions have been taken to strengthen BP control at the goal of systolic blood pressure (SBP)/diastolic blood pressure (DBP) $< 130/80$ mmHg^(6, 7), the rates of antihypertensive treatment and BP control are still inadequate worldwide, approximately 54.7% and 31.7%, respectively⁽⁸⁾.

Technological advances have driven cuffless BP measurement in wearable devices, making BP measurement convenient and frequent, which can help improve BP control^(9–12). However, previous studies comparing the accuracy of standard blood pressure measurement devices and wearable devices only recruited a limited number of patients (85 subjects in ANSI/AAMI/ISO(13), 33 subjects in ESH IP2(14))^(15–30), or only performed in healthy people and young people^(19, 30). The comparisons between wearable devices and cuff sphygmomanometers for BP measurement in different populations, wearable technologies, and measurement sites were insufficient. Therefore, this meta-analysis aims to compare the accuracy of wearable device readings with cuff sphygmomanometers for BP measurement, highlighting the reliability of wearable devices in the abovementioned subgroup populations.

Methods

All supporting data are available within the article and in the Data Supplement.

Search Strategy and Selection Criteria

We systematically searched the Web of Science, MEDLINE, Embase, Cochrane Library, and PubMed databases using keywords associated with wearable electronic devices and BP measurement. A total of 3849 articles were discovered. After removing duplicates, there were 2683 unique articles. Of these, 118 had their full texts analyzed, 97 reports were removed, and we then used the information from 21 of these articles (**Table S1**).

Studies contrasting the measurement of BP by wearable devices and cuff sphygmomanometers (including electronic cuff sphygmomanometers and traditional stethoscope sphygmomanometers) qualified articles for analysis. Studies that met the following requirements were taken into consideration for inclusion: (1) An article evaluating the accuracy of BP readings obtained from wearable devices; (2) The wearable device was an explicit uncuffed BP measurement; (3) The mean and standard deviation (SD) of BP measured by the wearable device and/or gold standard (cuff sphygmomanometer) were reported (or sufficient data were available to calculate); (4) The sample size was 10 cases or more; (5) Both two types of devices were used to measure subjects' BP in a sitting or resting position. Article screening is shown in Fig. 1.

Data Extraction

Data extracted included publication year, country, the type of study, age, body mass index (BMI), sex (percentage of men and women), the number of participants, and specific BP assessment device (name of the measurement device, measurement technique, and site), and readings for BP measurements (mean and SD of BP of the two device groups).

Quality Assessment

We conducted a quality assessment for 21 studies, including evaluating the characteristics and number of participants in each study; whether the measurement conditions were comparable between the two groups of devices; the quality of the two devices in terms of the type, model, and technology of the wearable devices and cuff sphygmomanometers reported in the studies; and the overall quality of the studies (**Supplemental Figure S1**).

Statistical Analysis

Differences between the two blood pressure measurement types were calculated using the reported mean difference (MD) with 95% confidence intervals (95% CI). When the MD and 95% CI are not available, the MD and 95% CI will be calculated based on the reported mean, and the 95% CI will be calculated based on the reported standard error (SE) or SD and the correlation coefficient of the MD of the paired data. When studies did not report mean BP and SD for wearable devices, the mean wearable blood pressure (MWBP) was calculated as the sum of the mean cuff sphygmomanometers blood pressure (MCBP) and the BP difference between the two measurement types, and SD was calculated according to the formula $[\sigma(\text{MCBP-MWBP}) = \sqrt{\sigma(\text{MCBP})^2 + \sigma(\text{MWBP})^2}]^{(31)}$. All P values are from two-tailed tests, and results were

considered statistically significant when $P < 0.05$. Mean differences were combined with inverse variance weighting using a random effects model to account for heterogeneity between studies. Changes in effect size due to inter-study heterogeneity were quantified using the I^2 statistic. Publication bias was assessed by examining funnel plots followed by a trim and fill procedure. All meta-analyses were performed using Revman software 5.4.

Results

Literature Search and Study Characteristics

In total, we used data from 21 articles (**Table 1**), including 897 participants with sample sizes ranging from 10 to 100 participants. The study that provided information on participants stated that there were 375 men (51.72%), with an average age of 55.07 years. Most studies ($n = 13$) were conducted in Asia, 6 studies were conducted in China^(17, 24–26, 30, 32), 4 in Japan^(21, 33–35), 3 in Korea^(16, 23, 27); 1 in Egypt⁽¹⁵⁾, Israel⁽²⁰⁾, ITALY⁽³⁶⁾, Australia⁽¹⁹⁾, Thailand⁽²⁸⁾, Indonesia⁽¹⁸⁾, and UK⁽²²⁾ and Netherlands⁽²⁹⁾ respectively. All studies reported SBP and DBP, except for 2 studies^(15, 29) that reported only SBP. In 21 studies, wearable devices and cuff sphygmomanometers were measured at the same time.

Meta-analyses

Comparison of the results of the blood pressure measurements

Twenty-one studies compared the differences in SBP measurement between wearable devices and cuff sphygmomanometers, three of which compared two types of wearable devices^(17, 20, 34). And 19 studies^(16–28, 30, 32–36) compared the difference in DBP measurement between two group devices. There was no difference in SBP and DBP between wearable devices and cuff sphygmomanometers (pooled MD, 0.58 mmHg; 95% CI, -0.35 to 1.51; $n = 21$; $I^2 = 0\%$, $P = 0.22$ for SBP; pooled MD, -0.33 mmHg; 95% CI, -1.50 to 0.85; $I^2 = 56\%$, $P = 0.58$ for DBP) (Fig. 2). We compared the statistical heterogeneity observed between the two types of devices. There was moderate heterogeneity in 19 studies reporting DBP readings (**Supplemental Figure S2**). We also conducted several subgroup analyses according to the age of populations, measurement site, and measurement technology of wearable devices.

Comparison of BP readings from wearable devices and cuff sphygmomanometers in different populations

Thirteen studies^(15, 16, 19–21, 25, 27, 29, 30, 32–35) reported the mean age of participants. We divided these studies into two groups based on reported mean age: group 1, subjects less than 60 years old, and group 2, subjects older than or equal to 60 years old. The results showed that there was no difference in SBP and DBP readings between wearable devices and cuff sphygmomanometers in both age groups (pooled MD, 0.39 mmHg; 95% CI, -1.41 to 2.18; $n = 13$; $I^2 = 0\%$, $P = 0.67$ for SBP; pooled MD, 0.15 mmHg; 95% CI,

-1.09 to 1.39; $n = 11$; $I^2 = 0\%$, $P = 0.81$ for DBP) (**Supplemental Figure S3**). The funnel plot for comparing the accuracy of measuring systolic BP and diastolic BP in the two age groups (**Supplemental Figure S4**).

Comparison of BP readings from wearable devices of different techniques and cuff sphygmomanometers.

Sixteen studies^(15–18, 20–22, 25–27, 30, 32–36) reported on techniques used for BP measurements in wearable devices. We divided these studies into four groups: subgroup 1, photoplethysmography (PPG); subgroup 2, oscillometry; subgroup 3, electrocardiograph (ECG); and subgroup 4, PPG-ECG combination. Overall, there was no significant difference in BP readings between wearable devices and cuff sphygmomanometers, with the pooled MD in SBP was 0.87 mmHg (95% CI, -0.39 to 2.14; $n = 16$; $I^2 = 0\%$, $P = 0.18$) and the pooled MD in DBP of 15 studies^(15–18, 20–22, 25–27, 30, 33–36) was -0.02 mmHg (95% CI, -1.45 to 1.50; $n = 15$; $I^2 = 56\%$, $P = 0.97$). Except that ECG-based BP measurements have higher readings for systolic and diastolic BP compared to cuff sphygmomanometers, BP readings from PPG, oscillometry, and PPG-ECG combination-based measurements are similar to the readings from cuff sphygmomanometers (**Supplemental Figure S5**). The funnel plot for comparing the accuracy of measuring SBP and DBP with different techniques (**Supplemental Figure S6**).

Comparison of BP readings from wearable devices at different measurement sites and cuff sphygmomanometers.

In addition, we conducted a subgroup analysis of 17 studies^(15–18, 20, 21, 23–25, 27–30, 32–35) that reported measurement sites, including subgroup 1, wrist and subgroup 2, fingers. The pooled MD in SBP between wearable devices and cuff sphygmomanometers was 0.33 mmHg (95% CI, -0.68 to 1.34; $n = 16$; $I^2 = 0\%$, $P = 0.53$). There was no significant difference in SBP readings between wearable devices and cuff sphygmomanometers in each subgroup and overall level (Fig. 3A). However, the pooled MD in DBP between wearable devices and cuff sphygmomanometers was -1.42 mmHg (95% CI, -2.33 to 0.51; $n = 14$; $I^2 = 18\%$, $P = 0.05$), and the wrist MD in DBP of 11 studies^(16–18, 20, 21, 23, 24, 27, 28, 34, 35) was -1.85 mmHg (95% CI, -2.75 to -0.95; $n = 11$; $I^2 = 10\%$, $P = 0.05$). The results showed that DBP readings of wearable devices at the wrist was lower than cuff sphygmomanometers, the difference was statistically significant (Fig. 3B). The funnel plot for comparing the accuracy of measuring SBP and DBP at different measurement sites (**Supplemental Figure S7**).

Based on differences in wrist DBP readings, we performed a further subgroup analysis of the wrist wearables devices with different techniques. Ten studies of wrist wearable devices that reported measurement techniques, subgroup 1, oscillometry^(18, 21, 34, 35); subgroup 2, PPG^(16, 20); and subgroup 3, other techniques, including PPG and ECG^(17, 27), PTT⁽²⁴⁾, Hall device⁽²³⁾, LCPS and ECG⁽¹⁷⁾. The analysis results show that there was no significant difference in DBP readings between cuff sphygmomanometers and the wrist wearable devices of oscillometry and PPG technology (Oscillometry MD, -0.75 mmHg (95% CI, -2.68 to 1.19; $n = 4$; $I^2 = 0\%$, $P = 0.45$; PPG MD, 0.70 mmHg; 95% CI, -4.09 to 5.50; $n = 2$; $I^2 = 0\%$, $P = 0.77$).

(**Supplemental Figure S8**). The funnel plot for comparing the accuracy of diastolic BP at the wrist with different techniques (**Supplemental Figure S9**).

Discussion

Principal Findings

Our work is the first systematic review and meta-analysis of wearable blood pressure measuring devices, even though there have been numerous reviews on the state of the field^(9, 10, 37–39). The average SBP and DBP measurements between wearables and cuff sphygmomanometers did not show a significant difference in the meta-analysis of 21 studies (pooled MD was 0.58 mmHg and – 0.33 mmHg, respectively; $P > 0.05$). This indicates that, in these studies, wearable devices are comparable to cuff sphygmomanometers regarding to BP measurement (Fig. 2).

There was no significant difference between the readings of wearable and conventional BP measuring devices in the subgroup analysis. However, we observed the MDs for SBP and DBP in people under 60 were lower than those in people aged 60 and above (MD 0.30 mmHg vs 0.72 mmHg in SBP; MD 0.65 mmHg vs -1.31 mmHg in DBP) (**Supplemental Figure S3**). Wearable devices estimate blood pressure readings based on oscillometry, PPG, ECG, or PTT signals, which are influenced by physiological factors such as haemoconcentration, vascular resistance, and vascular elasticity^(37, 40). Blood vessel elasticity decreases in the elderly, and arterial stiffness is increasing with the aging process^(41–44). These factors may interfere with the wearable devices to receive the signal, so we speculate that wearable devices may be more suited for the younger population.

Subgroup analysis of different measurement techniques mainly compared oscillometric, PPG and ECG techniques. Among them, oscillometric BP measurement has been developed for more than a century. It is widely used in offices, homes, and ambulatory BP measurement devices⁽⁴⁵⁾. Even though wrist measurements increase BP readings error compared to upper arm measurements⁽⁴⁶⁾, oscillometric BP measurement technology has been widely proven^(47, 48), so we can still be sure of its accuracy if the BP measurement method is correct. PPG and ECG are widely used in clinical monitoring such as heart rate and blood oxygen saturation⁽¹⁰⁾. But ECG usually needs to obtain electrical signals from multiple parts of the body, so wearable devices that monitor ECG signals alone can produce erroneous BP readings, that are extrapolated from single-lead ECG data. In this study, there were no significant differences in subgroup analyses using different measurement techniques. The results of two studies that used ECG technology alone to monitor BP revealed that the MD between the two groups SBP was 4.48 mmHg (95% CI, -0.21 to 9.17) and DBP was 2.37 mmHg (95% CI, -3.45 to 8.2). Both SBP and DBP measurements were greater than those of the cuff sphygmomanometer, even though the results were not statistically significant (**Supplemental Figure S5**).

The subgroup analysis of the measuring site of the wearable device showed that at the overall level and wrist site wearable devices and cuff sphygmomanometers both show significant differences (-1.42

mmHg; 95% CI -2.33 to -0.51; -1.85mm Hg, 95% CI -2.75 to -0.95 for overall DBP and wrist DBP, respectively) (Fig. 3). In AAMI protocol, these variances in BP measurement are acceptable⁽¹³⁾. Further subgroup analysis of wrist wearable devices demonstrates that there is no statistically significant difference between the DBP readings measured by oscillometry, PPG technique, and cuff sphygmomanometers (-0.75 mmHg; 95% CI -2.68 to 1.19 for oscillometry, and 0.70 mmHg; 95% CI -4.09 to 5.50 for PPG) (**Supplemental Figure S8**). It is further shown that the accuracy of blood pressure measurement in wearable devices depends on the measurement method used.

Although, an increasing number of studies provide data on the accuracy of new cuffless BP measurement devices, there are problems such as insufficient research methods and inappropriate evaluation criteria for cuffless BP measurement devices^(39, 49). In addition, most of the published studies are small-scale confirmatory data from wearable device technology development teams, and a large number of devices have not been verified, so existing studies may have misleading conclusions^(39, 50). Recently, ISO has formulated a new standard (ISO81060-3) specifically for the verification of continuous cuffless blood pressure devices⁽⁵¹⁾. In the future, more large-scale, long-term, and long-term evaluations of the blood pressure measurement accuracy of cuffless devices and standard cuff devices will be required. RCT studies with clinical endpoints as outcomes are verified under new standards to ensure the reliability of research data. New algorithms and machine learning are constantly being developed and improved⁽⁵²⁻⁶²⁾, and we have high hopes for the potential of wearable technology for blood pressure measurement, but more research and practice is needed before it can be used in real clinical settings.

Limitations

First, high-quality RCT studies comparing the accuracy of BP measurement between wearable devices and cuff sphygmomanometers are limited. Our meta-analysis is based on prospective non-RCT studies with small-scale patients that cause potential biases^(63, 64). Large-scale RCT studies still warrant confirming the accuracy of wearable devices. Second, BP measurement by wearable devices overcomes the limitations of office BP and increases out-of-hospital BP monitoring^(9, 65-67). However, the standard for blood pressure measurement by wearable devices and the criteria for hypertension diagnoses remain to be discussed. Third, according to the list of PRISMA2020 statement⁽⁶⁸⁾, the data collection process should be reported in the method section, including the reviewer who collected the data, any process of obtaining or confirming the data. This meta-analysis excluded a number of studies with missing data, did not contact the original authors for supplementation, and may have some selection bias.

Conclusions

This meta-analysis revealed that readings for blood pressure from wearable device measurements are comparable to the readings of cuff sphygmomanometers. Although the accuracy of wearable devices still needs to be improved in several situations, such as the measurement at the wrist, wearable device measurement may be a reliable approach for daily BP monitoring to improve BP control and reduce CVD risks.

Summary

What is known about the topic?

- Continuous blood pressure monitoring can accurately identify different clinical phenotypes of hypertension and significantly change the quality of blood pressure detection and management.
- The development of technology has promoted the development of wearable devices that can measure blood pressure frequently, but monitoring blood pressure by wearable devices has not yet been widely accepted.

What this study adds?

- We reviewed the existing studies and verified the accuracy of the wearable blood pressure monitoring equipment by comparing with the current cuff sphygmomanometer.
- The accuracy of blood pressure measurement readings from wearable devices across different age groups, different technologies, and different measurement sites was compared.
- The limitations and development prospects of current research on wearable blood pressure monitoring devices are proposed.

Declarations

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Conflict of interest

No conflicts of interest, financial or otherwise, are declared by the authors.

Author Contributions:

J.J.C conceived the study. Z.X.L and Q.W did the literature search and analysed the data. J.J.C, Z.X.L, X.J.S and J.R.W contributed to key data interpretation. Z.X.L wrote the article; J.J.C performed critical reviews of the manuscript, supervised the study and approved to publish, and provided funding for the study. Y.L, T.H, W.Z, and H.Y checked the manuscript. All authors read and approved the manuscript.

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Tables

Table 1 is available in the Supplementary Files section.

Figures

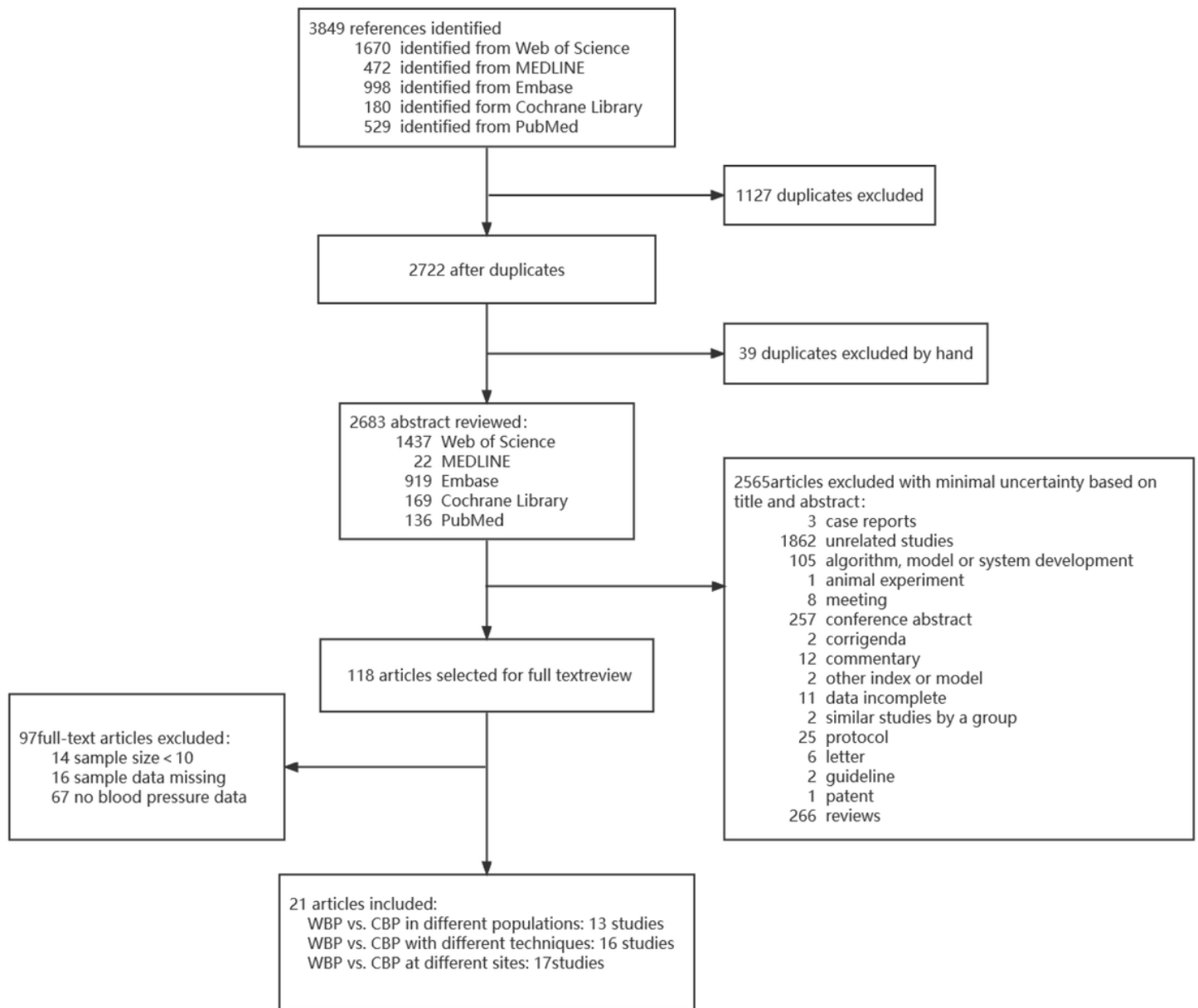
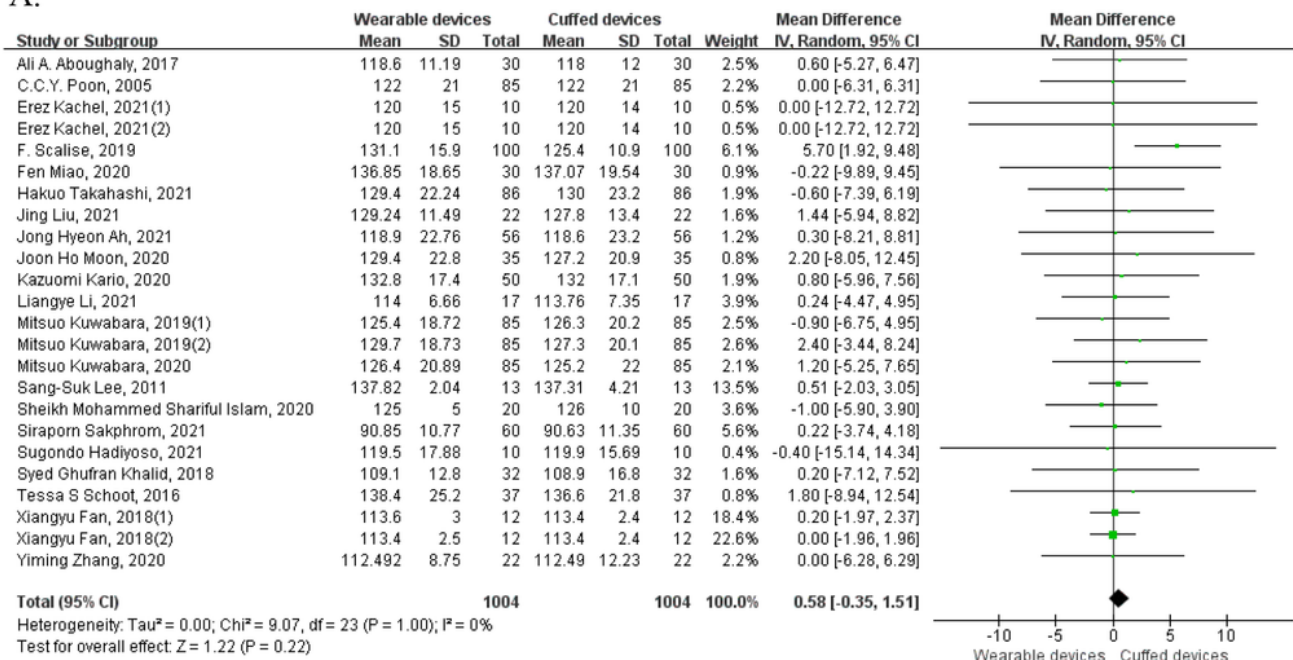


Figure 1

Flowchart of literature search and selection.

A.



B.

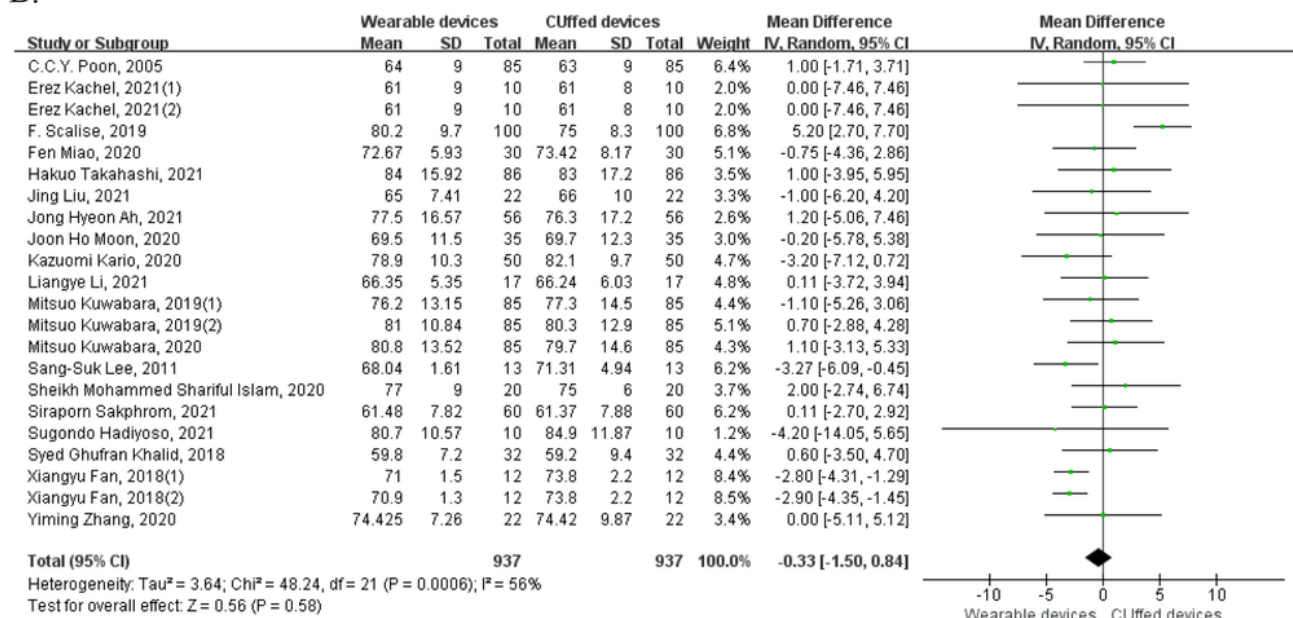
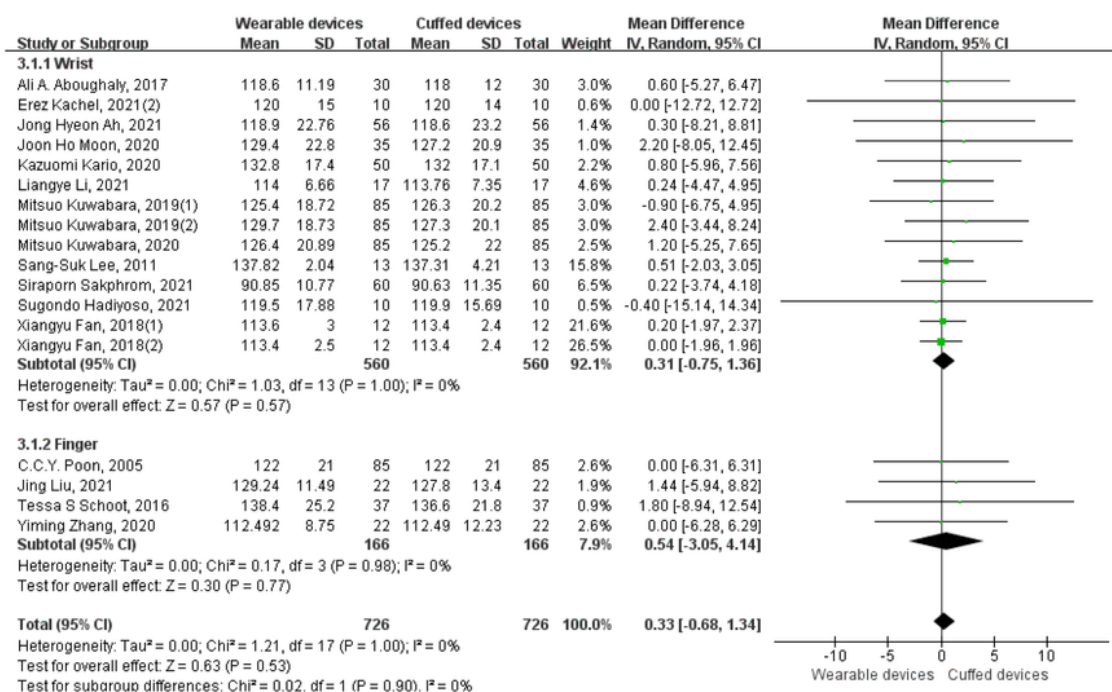


Figure 2

Comparison of Blood Pressure (BP) readings between Wearable devices and Cuff sphygmomanometers.

A, Mean Difference (MD) in Systolic Blood Pressure (SBP) readings between Wearable devices and Cuff sphygmomanometers; B, Mean Difference (MD) in Diastolic Blood Pressure (DBP) readings between Wearable devices and Cuff sphygmomanometers.

A.



B.

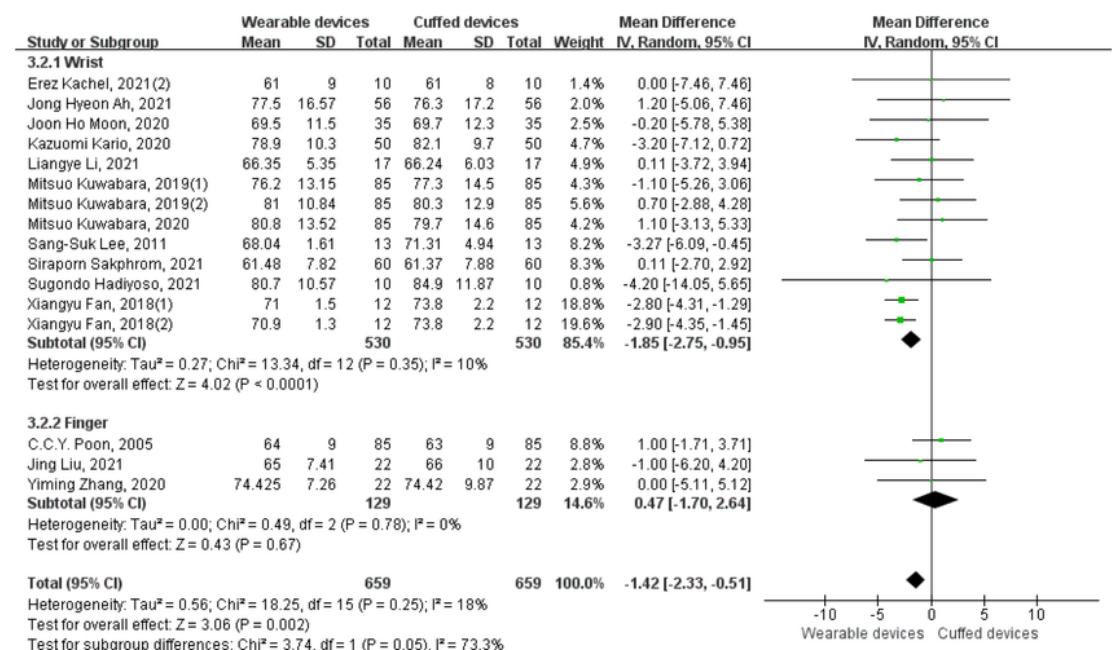


Figure 3

Comparison of Blood Pressure (BP) readings between Wearable devices at different measurement sites and Cuff sphygmomanometers. A, Mean Difference (MD) in Systolic Blood Pressure (SBP) readings between Wearable devices and Cuff sphygmomanometers; B, Mean Difference (MD) in Diastolic Blood Pressure (DBP) readings between Wearable devices and Cuff sphygmomanometers.

Supplementary Files

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