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Photoplethysmography technology use in smart devices for early diagnosis of arterial hypertension: a systematic review

Running title: PPG use for early AH diagnosis

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Abstract

Background: According to the World Health Organisation (WHO), 1 in 4 men and 1 in 5 women have arterial hypertension (AH). It is important to diagnose AH early and constantly monitor blood pressure (BP). We assess the diagnostic accuracy of AH detection using smart devices with photoplethysmography (PPG) and seek to provide guidance from current evidence to clinicians about the value and limitations of their potential use to early diagnose this chronic disease.

Material and methods: This systematic review of Medline, Google Scholar, and PubMed databases was conducted according to the PRISMA guidelines. All publications examining any type of AH detection using PPG in smart devices were evaluated. Study quality was assessed using the QUADAS-2 risk of bias tool.

Results: The search strategy identified a total of 705 publications, of which 9 studies were included in the systematic review. Of the 9 studies included, 2 used Samsung Galaxy smartphones, and 7 used wearable watch-like devices. A sphygmomanometer was used as a reference standard in all studies.

Conclusion: The current evidence base consists of small, biased, and low-quality studies which are insufficient to advise clinicians on the true value of PPG devices for AH detection. Further research is required with reference standards, standardized

validation, and transparent algorithms for PPG technology to be used as a valid tool for early AH diagnosis.

Key words: arterial hypertension; photoplethysmography; smart devices; wearable devices

Introduction

Arterial hypertension (AH) is a widespread chronic disease, which can damage the heart, brain, kidneys, and other organs. Its symptoms are often imperceptible, making it difficult to diagnose the disease early. For this reason, hypertension is called a “silent killer” [1]. According to the World Health Organisation (WHO), 1 in 4 men and 1 in 5 women have AH [2]. That’s about 1.3 billion people, and only 21% of them control their disease, 42% are diagnosed and treated, and 46 % do not know they are sick [3]. As a result of bad diagnosis and difficult treatment [3], raised blood pressure (BP) is responsible for 13.5% of deaths worldwide [4]. That is why, it is important to diagnose AH early and constantly monitor BP. Nowadays many people are using various portable smart devices every day, which play a huge role in their lives. Most of them have integrated photoplethysmography (PPG) technology, which is able to measure BP [5]. We developed a discussion about whether these smart devices could be used to track our BP and improve the capability of early AH diagnosis.

We collected and summed up articles from databases that included reports about early AH detection using smart devices with PPG technology, which could help solve the early diagnosis problems. In addition to that, we analysed the accuracy of this technology to improve the prevention of AH.

In this systematic review, we assess the diagnostic accuracy of AH detection using smart devices with PPG to answer the question, is early diagnosis of AH possible for people who use smart devices with integrated PPG technology.

Material and methods

Eligibility and search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. MeSH was used to generate keywords: “hypertension detection”, “hypertension monitoring”, “hypertension screening”, and “photoplethysmography”. A systematic review of Medline, Google Scholar, and PubMed

databases was performed with language restrictions (only English articles included). MeSH was used to generate keywords.

Inclusion and exclusion criteria

Publications examining AH detection using PPG in smart devices in previously mentioned databases were evaluated. We included (a) any original study which shows the use of smart devices and PPG technology in various clinical settings; (b) studies that compared the measurement of BP by smart devices to other established modalities in terms of accuracy, agreement, validity, and other parameters; (c) studies that compared the measurement of vital signs (blood pressure and/or heart rate) by smart/wearable devices to other established modalities in terms of usability/suspicion in hypertension disease; (d) studies that evaluated the advantages and disadvantages of wearable devices in terms of efficacy, cost, safety, outcomes, availability, and others. We excluded studies with no reliable extracted data, overlapped data sets as well as theses, book chapters, editorials, author responses, conference papers, reviews, posters, letters, and patents, and duplicated data.

Outcomes

The outcomes considered were the evaluation of the accuracy, precision, and reliability of smart devices using PPG technology as a tool for early AH assessment.

Data extraction

Three independent reviewers initially screened all publications' titles that were identified from literature searches. After the first screening, Mendeley was used to remove duplicates. Secondly, abstracts of the relevant articles were further screened. Then eligibility criteria were applied to the full articles and the articles included were selected after full reading. Disagreements or any discrepancies were debated for consensus and a fourth team member was consulted, who checked a random sample to ensure the reliability of the selection. Data were stored in a standardized tabular format to summarize the eligible studies included in the review.

Risk of bias

All studies were assessed by three independent reviewers using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool. This assesses four key domains: (1)

patient selection; (2) index test used (smart devices with PPG signal); (3) reference standard used (cuff-based sphygmomanometer); and (4) flow and timing. Each domain is given a score of high, low, or unclear for risk of bias and applicability.

Ethics

In this case, separate ethical approval was not required as the study is a systematic review of previously published information from relevant studies.

Results

The search strategy identified a total of 705 publications (Fig. 1), of which 9 studies were included in the systematic review.

Devices

Of the 9 studies included, 2 used Samsung Galaxy smartphones, and 7 used wearable watch-like devices. A sphygmomanometer was used as a reference standard in all studies. 4 studies pointed out the reference device type: 2 as a BP monitor — Omron HBP1300, while 2 other studies chose a mercury sphygmomanometer.

Risk of bias

The included studies were found to be of low quality overall. None were graded as meeting all QUADAS-2 criteria. Mostly the major concerns related to the high risk of bias were patient selection (selection of non-random patients, insignificant number of participants), and flow and timing (time intervals between index test and the reference standard were not described).

Detection of AH

The 9 studies compared methods for BP monitoring using PPG sensor technology applications against conventional cuff-based sphygmomanometers. A comparative summary of studies is presented in Table 1.

Discussion

Our systematic review included nine studies. We found that the results of these studies are heterogeneous, while the evaluation of BP is based on the same PPG technology, but different devices/programs were used. However, despite the difference in results, there were several commonalities.

This systematic review has identified the potential for AH detection using smart devices and apps with PPG technology, but with insufficient evidence to demonstrate clinical applicability at this time. We identified a high risk of bias, especially for the patient selection to participate in the study, and insufficient information regarding study flow and timing. Findings suggest the need for larger independent studies to assess the role of smart devices using PPG technology for AH, detection because most studies lacked research quality.

Raised BP is responsible for 13.5% of deaths worldwide as well as 46% of people with AH do not know that they are sick, whereas AH causes huge damage to all target organs. That is why it is important to diagnose AH early and constantly monitor BP [4].

Traditionally, BP is measured using a sphygmomanometer. Over the years automated methods become common to measure BP. It has eased use and applicability to ambulatory or home BP measurements [15]. This method has recently been used to measure BP with a smartphone. Cuffless measurement methods open the door to more comfortable and acceptable BP monitors [16]. PPG is a simple non-invasive technique based on the optical measurement method. The main principle of PPG is infrared light, which has the deepest penetration ability and can reflect the blood pulse from the deep tissue. The light that travels through living tissue is better absorbed by blood than other surrounding biological structures. That is why changes in blood volume correspond to changes in the intensity of light [17, 18]. This technology was used to develop low-cost, simple, portable devices to improve primary care and to help monitor oxygen saturation, BP, cardiac output, assess autonomic function and detect peripheral vascular disease [19]. Smartphone technology has had a huge breakthrough over the past few decades. Also, PPG-based smartphone algorithm paired with smartwatches become more popular and continues to develop [20]. Over the last few years, wearable devices with integrated PPG sensors have been suggested to improve the early detection and management of hypertension [5]. Remote monitoring of BP with wearable devices could be a great way to exchange medical data between patients and healthcare professionals and could become a big part of telemedicine [21]. In this systematic review, we aimed to assess the value and accuracy of smart devices with PPG technology and the possibility of improving these technologies by using noise-reducing

apps. For example, cuff-less BP estimation using the Kalman filter on the Android platform. Kalman filter is an optimal recursive data processing algorithm, that gives more accurate and robust results for the cuffless BP estimation. It is suitable for wearable devices. During this research, we discovered that programs that were used in smart devices to absorb and process information have equal importance for detecting and monitoring BP for accurate interpretation as the devices themselves. The average absolute error of not using the Kalman filter is 7.0 ± 7.3 mm Hg for DBP and 8.2 ± 7.1 mm Hg for SBP, and that of our method is 3.9 ± 3.3 mm Hg for DBP and 4.7 ± 3.8 mm Hg for SBP, which can meet the needs of daily monitoring [13].

This review highlights the need for real-world studies, with minimization of selection bias to establish the true diagnostic accuracy of smart devices (smartphones, smartwatches, and wristbands) using PPG technology. With regard to smart device applications, greater transparency from commercial providers regarding AH detection algorithms is required, and further work is needed to evaluate their role in early AH detection and diagnosis. Large-scale randomized clinical trials are needed to compare these devices and establish their values.

After further studies and trials, PPG technology could be integrated into primary care practices as a more convenient approach to continuous monitoring of BP.

Conclusion

Due to the rising problem of undetected AH early diagnosis can be challenging using only conventional methods. With the growing use of smart devices with PPG technology, the potential for non-invasive, self-monitoring, blood pressure screening becomes easier and more accessible at home. However, the current evidence base consists of small, biased, and low-quality studies which are insufficient to advise clinicians on the actual value of PPG devices for AH detection. Considering the incline in the global use of such devices, further research is required with reference standards, standardized validation, and transparent algorithms.

Conflict of interest

Authors declare no conflict of interest.

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Table 1 Summary of included reviews

Study	Technology for AH detection	Reference test	Participants	Results	Conclusion
Ganti et al .. 2021 [6]	PTT-based wrist-worn device (SeismoWatch)	ECG and sphygmomanometer	44	Mean absolute difference of DBP, MAP and SBP was 2.90 mm Hg, 3.39 mm Hg and 5.36 mm Hg accordingly	Reliable and convenient device to track BP in a diverse population.

<p>Holyoke et al. [7]</p>	<p>Contec CMS50EW pulse oximeter and a Samsung Galaxy XCover 4 smartphone</p>	<p>Sphygmomanometer</p>	<p>62</p>	<p>The differences between the calculated and the manually measured BP did not meet the ESH-IP2 standards</p>	<p>The device was not sufficiently accurate for use</p>
<p>Atomi et al. [8]</p>	<p>Wristwatch-type PPG sensor</p>	<p>Sphygmomanometer</p>	<p>27</p>	<p>The correlation coefficient between the measured SBP and the estimated SBP was 0.80. The mean error was 1.58 mm Hg. The standard deviation of errors was 8.54 mm Hg</p>	<p>The device has the potential to give appropriate data for medical staff and advice to users</p>

Liu et al. 2021 [9]	A wearable MWPPG prototype	Mercury sphygmomanometer	22	PCA-based operations on MWPPG signals, yielding errors of 1.44 ± 6.89 mmHg for SBP and -1.00 ± 6.71 mmHg for DBP	The proposed PCA-based method can improve the performance of MWPPG in wearable medical devices
Socrates et al. 2021 [10]	Finger photoplethysmography, three ECG leads and a watch-like-device	Sphygmomanometer	71	Mean 24 h BP for the RefBP, and TestBP-V1.5 were systolic $134.0 (\pm 17.3)$, and $139.1 (\pm 20)$ mm Hg, and diastolic $79.3 (\pm 11.7)$ and $83.5 (\pm$	The software update significantly improved AH detection

				13.0) mm Hg, respectively	
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Hsiao et al. [11]	The wristband prototype of wearable sphygmomanometer	Sphygmomanometer	134	The error in SBP is 6.9 mm Hg \pm 8.6 mm Hg. The AAMI standard is not reached	The proposed system was not sufficiently accurate for use
Dey et al 2018 [12]	Samsung Galaxy S6 smartphone	Mercury sphygmomanometer	205	The inclusion of multiple independent partitioning results in 18.0% and 11.5% improvements in accuracies for DBP and SBP respectively	BP measurement using a single PPG sensor can be improved using demographic and physiological partitioning
He et al 2017 [13]	Optimal recursive data processing algorithm suitable for the cuff-less devices	Sphygmomanometer	6	The average absolute error of not using Kalman filter is 7.0 \pm 7.3 mm Hg	Kalman filter has more accurate and robust results for the cuff-less

				for DBP and 8.2 ± 7.1 mm Hg for SBP, and with Kalman filter is 3.9 ± 3.3 mm Hg for DBP and 4.7 ± 3.8 mm Hg for SBP	BP estimation
Jain et al 2016 [14]	Low-cost health monitoring system	Sphygmomanometer	72	The computed error falls under the standard allowable error mentioned by AAMI; MAE < 5 mm Hg and ESD < 8 mm Hg	The method proposes reliable diastolic as well as systolic BP estimation

PTT — pulse transit time; PPG — photoplethysmography; ECG — electrocardiogram; BP — blood pressure; AH — arterial hypertension; DBP — diastolic blood pressure; SBP — systolic blood pressure; MAP — mean arterial pressure; ESH-IP2 — second International Protocol of the European Society of Hypertension; MWPPG — multi-wavelength photoplethysmography; PCA — principal component analysis; RefBP — reference blood pressure; TestBP — test blood pressure; AAMI — Association for the Advancement of Medical Instrumentation; MAE — mean absolute error; ESD — error standard deviation