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Original Research Article

A comparative study of ProRithm and standard monitoring techniques for non-invasive blood pressure measurement using photoplethysmography and electrocardiography signals through artificial intelligence/machine learning methods

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ABSTRACT

Background: Multi-parameter monitoring devices are essential for providing real-time patient data, which is crucial for effective healthcare interventions. This clinical trial evaluated the accuracy of the ProRithm beat-to-beat cuffless device for arterial blood pressure monitoring, comparing it with a standard sphygmomanometer.
Methods: This observational study included 30 subjects aged 18 and above. Systolic and diastolic blood pressure measurements from both the ProRithm device and the Philips Monitor were compared using statistical analysis.
Results: The analysis revealed no statistically significant differences between the ProRithm device and the manual method. In comparison with manual measurements using a sphygmomanometer, the mean systolic blood pressure was 131.2 mmHg with ProRithm it was 129.3 mmHg. Similarly, with the manual method, while the mean diastolic blood pressure was 76.2 mmHg and with ProRithm it was 75.9 mmHg.
Conclusions: This study indicates that portable, small-sized devices like ProRithm, which facilitate remote monitoring, are effective for real-time blood pressure assessment in clinical settings.

Keywords: Non-invasive blood pressure measurement, ProRithm device, Beat-to-beat cuffless monitoring, Multi-parameter monitoring devices, AI/ML methods, Remote monitoring

INTRODUCTION

Driven by the rise of mobile medicine, advancements in smart sensing technologies, and the growing interest in personalized health, the field of smart wearable devices has seen rapid advancements in recent years.[1] These wearable devices monitor and track various health parameters or deliver medical interventions. By collecting real-time health data, they offer valuable insights to both users and healthcare providers. Common types of wearable medical devices include - fitness trackers: monitor physical activity, heart rate, sleep patterns, and other fitness-related metrics; and smartwatches: equipped with health monitoring features such as heart rate monitoring, electrocardiography (ECG) recording, and activity tracking.

The potential to improve healthcare outcomes, enhance patient engagement, and enable more proactive management of chronic conditions is held by these devices. However, the accuracy, reliability, and security of the data collected by these devices must be ensured.

It is established and well known that hypertension is well established as a leading risk factor for cardiovascular morbidity and mortality. This condition significantly contributes to the incidence of heart attacks, strokes, and other cardiovascular diseases. Managing hypertension effectively is crucial for reducing the overall burden of cardiovascular complications and improving patient outcomes.[2]

Blood pressure telemonitoring (BPT) is a telemedicine strategy involving the use of patient self-measured blood pressure (BP) readings. These readings are transmitted to healthcare providers via the internet. BPT facilitates remote monitoring and management of hypertension, enabling timely clinical interventions and personalized treatment plans.[3]

Traditional cuff-based sphygmomanometers can be uncomfortable and impractical, especially for use during sleep. An alternative approach measures dynamic changes in the pulse waveform over short intervals, eliminating the need for calibration. This method utilizes information from the photoplethysmogram (PPG) morphology, enabling a calibration-free technique with just a single sensor.[4]

PPG is a non-invasive technique measuring blood volume changes in tissue. It estimates blood pressure by analyzing arterial pulsations.[5]

Light absorption

LED light passes through the skin, absorbed by blood vessels.

Blood volume changes

Heartbeats alter light absorption as blood volume fluctuates.

PPG signal

Photodetectors capture changes, generating a pulsatile blood flow signal.

Analysis

Algorithms interpret the PPG waveform to estimate heart rate, SpO_2, and blood pressure.

Estimation

Combining PPG data with calibration factors yields systolic and diastolic pressure.

While convenient, accuracy depends on factors like device calibration and user physiology. Though lot of such devices are available with varied accuracies, we developed probably first of its kind AI/ML driven hybrid model to enhance the sensitivity specificity of the of the blood pressure measurement using combination of ECG and PPG.

METHODS

This investigator-initiated, open-label, observational, non-interventional single-arm study was conducted in the outpatient and emergency wards of a multispecialty hospital in India, involving 30 subjects aged 18 years or older. The study was conducted at health camps conducted by the hospital across Rajahmundry, Hyderabad and Amalapuram in the period of November 2023 to April 2024. Central Ethics committee approval was obtained prior to initiation of the study from St Theresa hospital EC.

Inclusion criteria

The following criteria of patients were included: individuals aged 18 years or older, both male and female participants, participants with a clean bill of health, with no prior history of peripheral vascular disease, and individuals willing to provide voluntary consent to participate in the study.

Exclusion criteria

The following criteria of patients were excluded: participants under the age of 18 were not eligible for inclusion in the study due to ethical considerations and potential differences in physiological responses, individuals with a history of peripheral vascular, pregnant individuals, and participants with implanted medical devices that could interfere with PPG or ECG measurements, such as pacemakers or defibrillators.

These inclusion and exclusion criteria aim to recruit a homogeneous group of healthy individuals who can provide reliable data for the comparative evaluation of ProRithm and standard monitoring techniques for non-invasive blood pressure measurement using PPG and ECG signals through AI/ML methods.

Prior to any study-specific screening evaluations for subject eligibility, written informed consent was obtained from all participants. Comprehensive medical histories and demographic information were documented for each subject.

Multiple sets of readings were then taken by treating physicians, based on subject availability. Initially, readings were acquired using the manual sphygmomanometer method for a duration of 5 minutes, with the results recorded. Subsequently, readings for the same subjects were obtained using the ProRithm device following the same protocol. The collected readings were analyzed and uploaded for algorithm readability assessment. Final analysis occurred after all subjects completed a minimum of three sets of readings.

We employed a combined approach utilizing ECG and PPG with specific parameters for blood pressure estimation. The PPG signal, generated through the interaction of a light-emitting diode (LED) and a photodetector (PD), captures key points such as the systolic peak, dicrotic notch, and diastolic peak, corresponding to the highest and lowest blood pressure values within a cardiac cycle.[5,6]

The dicrotic notch indicates aortic valve closure caused by blood reflux into the heart. Our approach utilized a hybrid algorithm for PPG-based blood pressure prediction, employing pulse transit time (PTT). PPG sensors, positioned at various locations, measured the pulse wave's travel time from the heart to peripheral arteries. Additionally, we integrated ECG and PPG sensors within a unified system, inspired by prior research conducted by Sagirova et al.[7]

We took steps to tackle inaccuracies in ECG signals, like motion glitches and baseline shifts, which could impact blood pressure monitoring accuracy, by employing AI/ML algorithms. In our method, pulse arrival time (PAT) was computed by adding the pre-ejection period (PEP) and PTT. PAT signifies the duration for the pulse wave to journey from the heart to a specific arterial spot, usually gauged from the R-peak of the ECG to specific points on the PPG waveform.[8] PTT was determined as the delay between two points along the arterial tree using pulse signals from PPG-ECG or dual PPG sensors. The blood pressure estimation formula employed in our method was BP=A/PTT + B, where A and B are individual-specific parameters.[9]

RESULTS

We utilized Medcalc version 8.0 for Windows to perform statistical analysis. In our study, we employed the two-tailed Student’s t test to compare systolic and diastolic blood pressure measurements obtained from the ProRithm device against those from the manual method, with a significance level (alpha value) set at 0.05. The analysis showed no statistically significant differences between the two methods. Specifically, for systolic blood pressure, the mean measurement was 131.2 mmHg with the manual method and 129.3 mmHg with the ProRithm device. Similarly, for diastolic blood pressure, the mean was 76.2 mmHg with the manual method and 75.9 mmHg with the ProRithm device.

The p value calculated for the two-tailed test was 0.209 for systolic blood pressure and 0.625 for diastolic blood pressure. Since both p-values were greater than the significance level of 0.05, we concluded that no statistically significant difference existed between the blood pressure measurements obtained using the ProRithm device and those obtained manually. This implies that the ProRithm device yielded comparable results to the manual method, affirming its reliability for blood pressure measurement.

Table 1: Demographics of the subjects.

Variable	Frequency	Percent (%)
Age (years)		
20-30	12	40
30-40	6	20
40-50	3	10
50-60	3	10
>60	6	20
Gender		
Male	18	60
Female	12	40
Comorbidities		
None	18	60
1	7	23
>1	5	17
Medication for long term		
Yes	13	43
No	17	57
Surgical history		
Yes	7	23
No	23	77
Education status		
<10 class	6	20
Graduate	7	23
Above graduate	17	57

Table 2: Summary of key algorithms in accordance with the British Hypertension Society (BHS) protocol.

Reference	Source	Model	Feature	Subjects	BP	Absolute difference (%)			Grade
						≤5	≤10	≤15	
Basek et al[11]	PPG, ECG, ABP	1D CNN	Raw	379	SBP	40.6	67.5	80.2	D
					DBP	64.1	87.1	95.0	A
					MAP	62.0	87.1	95.8	A
Ibtehaz et al[12]	PPG	U-Net, MultiResUNet	PPGG	942	SBP	70.8	85.3	90.9	B
					DBP	82.8	92.2	95.7	A
					MAP	87.4	95.2	97.7	A
Baker et al[13]	PPG, ECG,	CNN-LSTM	Raw	6972	SBP	68	90	97	A
					DBP	83	96	99	A
					MAP	84	97	99.6	A

DISCUSSION

Various commercially available non-invasive blood pressure (NIBP) monitoring devices utilize advanced techniques such as PAT, PTT, pulse wave velocity (PWV), and machine learning algorithms to continuously measure blood pressure. These techniques rely on bio-signals acquired from NIBP sensors, enabling real-time monitoring of blood pressure.[10] Numerous studies have assessed the predicted values of systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) generated by different machine learning models against standardized validation protocols used for clinically approved blood pressure monitors.

Multiple studies have validated these algorithms in accordance with the British Hypertension Society (BHS) protocol for non-invasive blood pressure monitoring, aiming to achieve prediction accuracy comparable to that of a cuff sphygmomanometer, the benchmark technique in this field. The detailed descriptions of various inventions are elaborated in Table 2.[11-13]

The present process followed for cuffless blood pressure estimation is outlined in the following flowchart.

Design phase

It utilizes an artificial neural network (ANN) model, implements the leave-one-out (LOO) method for evaluation, evaluates the model on data from one patient at a time, and repeats the evaluation process for all patients.

Testing phase

It employs the same ANN model structure, trains the ANN on the complete dataset, and tests the trained model on a new dataset comprising data from 25 patients not previously seen by the model.

Feature selection

It determines whether to use extracted features from PPG morphology, and cosider the choice between PPG morphology features and interbeat interval (IBI) features for analysis.

The findings of this study suggest that the proposed approach, leveraging PPG/ECG dynamics over short intervals combined with blood pressure estimation derived from PPG/ECG morphology, offers a calibration-free method for estimating blood pressure using a single photoplethysmogram signal. Despite utilizing reference blood pressure values during the neural network training phase, this technique is classified as calibration-free as it requires no calibration during actual application on new subjects. One key benefit of this approach is that PPG dynamics, derived from temporal variations between signal peaks and troughs and integrated into the model, are likely less affected by factors such as improper sensor placement or variations in skin color compared to traditional morphology features alone.

This enhanced robustness may contribute to the observed performance improvement in blood pressure estimation, particularly with the incorporation of interbeat interval features alongside morphology-based estimation. Our data aligns with the findings described by Baker et al suggesting that the present algorithms are ready for clinical application.[13]

Limitations

The primary limitation of this study is the small sample size.

CONCLUSION

Advancements in NIBP technology face several significant challenges in replacing traditional measurement protocols. These challenges include sourcing reliable data, mitigating motion artifacts in PPG signals, ensuring accurate calibration performance, managing dataset sizes, optimizing learning algorithm selection, accommodating variations in sphygmomanometer models, and addressing limitations posed by wires. Intensifying efforts to overcome these obstacles is imperative to enhance the effectiveness of NIBP technology for continuous blood pressure monitoring. An evaluation comparing vital signs measured by the ProRithm device with those obtained using a manual sphygmomanometer revealed no statistically significant disparities. The data gathered from this study suggests that devices like ProRithm, characterized by portability, compact size, and remote monitoring features, will be immensely valuable in clinical environments requiring prompt evaluation of blood pressure fluctuations in real time.

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