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Pilot study for non-invasive diabetes detection through classification of photoplethysmography signals using convolutional neural networks

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Abstract

Diabetes is a chronic disorder affecting vascular health, often altering pulse wave characteristics. Traditional pulse wave analysis (PWA) methods face challenges such as variability and complexity of signals. This study aims to overcome these limitations by leveraging deep learning models for more accurate and efficient classification. The methodology used in this study involves four key steps: data collection, data preprocessing, Convolutional Neural Network (CNN) model development, and model evaluation. Primary data were collected using a multipara patient monitor, including finger photoplethysmography (PPG) signals, blood pressure, mean arterial pressure, oxygen saturation, and pulse rate. Single pulse wave cycles from 60 healthy individuals and 60 patients with type 2 diabetes underwent preprocessing. The CNN model was trained using 50 PPG images from each group and achieved a training accuracy of 92%. The prediction capability of the model was evaluated using 20 unseen images, comprising 10 healthy and 10 diabetes PPG images. It attained a 90% overall test accuracy in distinguishing between PPG images of individuals with diabetes and those who are healthy. These findings suggest that CNN-based analysis of PPG signals provides a precise, non-invasive tool for diabetes screening. To further enhance accuracy, future studies should focus on increasing the dataset size and performing hyperparameter tuning to optimize the CNN model.

Keywords: Pulse wave analysis, Diabetes screening, Non-invasive, Signal processing

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Introduction

Diabetes is a chronic metabolic disorder that affects millions of people worldwide (Nirala et al., 2019). It leads to numerous serious health complications, including cardiovascular diseases, renal disorders, nervous system damage, and vision impairment. If blood glucose levels are not adequately monitored and managed, these conditions can worsen, potentially causing organ failures and eventually resulting in death. Diabetes can impair the function and structure of the arteries, leading to changes in pulse wave characteristics (Fan et al., 2011).

There is a demand for an accurate and reliable non-invasive blood glucose (NIBG) measurement technique, which has been extensively researched (Darwich et al., 2023) (Di Filippo et al., 2023). In contrast, finger-prick blood glucose (BG) measurement, being invasive, causes pain and discomfort and carries a risk of infection (Ahmed et al., 2022). NIBG technology has the potential to significantly enhance the quality of life for diabetic patients by eliminating the pain associated with frequent invasive measurements (Tang et al., 2020). Among the various NIBG methods studied, photoplethysmography (PPG) stands out due to its simplicity, low cost, and potential for widespread integration into wearable devices (Chu et al., 2021). PPG has already proven successful in measuring oxygen saturation (SpO_2) and pulse rate, making it a promising option for non-invasive blood glucose monitoring (Susana et al., 2022).

A PPG device measures changes in the transmittance or reflectance of near-infrared light as blood flows through peripheral capillaries (Reiss et al., 2019). Light absorption and reflectance at specific wavelengths are sensitive to the hemodynamic properties of the body, which are closely linked to cardiovascular health (Shin et al., 2022). Since long-term blood glucose levels impact the cardiovascular system and can be observed through pulse morphology profiles, identifying a correlation between PPG pulse morphology and blood glucose levels could be a promising approach for NIBG prediction (Susana et al., 2022).

Prior research on analyzing NIBG measurements has explored a range of machine learning models including support vector machine (SVM) (Bunescu et al., 2013), random forest (Georga et al., 2012), K-nearest Neighbor (KNN) (Altman, 1992), Gaussian process regression (GPR) (Tomczak, 2017), and artificial neural network (ANN) (Yadav et al., 2017). These studies have investigated numerous morphological profiles and heart-rate-variance features extracted from PPG signals, which are linked to vascular function and autonomic neuropathy. Various signal-processing techniques like Fast Fourier transform (FFT), (Kaiser-Teager energy) KTE, and spectral entropy have also been utilized to extract features across different domains (Chu et al., 2021). The studies on non-invasive blood glucose prediction using deep learning and photoplethysmography demonstrated high accuracy (Chu et al., 2021) (Lu et al., 2022). These advancements promise improved, non-invasive diabetes detection.

Convolutional neural networks (CNNs) are a class of deep learning models with the capability to discern intricate patterns and features within complex datasets like images, speech, or text (Alzubaidi et al., 2021). CNNs have achieved remarkable results in various fields of machine learning and artificial intelligence, especially in computer vision and image processing. CNNs can automatically learn relevant features from raw data without human intervention or prior knowledge, making them suitable for analyzing complex and noisy signals such as pulse waves (Li et al., 2019).

This study proposed to use CNNs to classify PPG wave images obtained from the PPG device of multipara patient monitor into diabetic or non-diabetic subjects. The hypothesis was that CNNs could achieve high accuracy in discriminating between diabetic and non-diabetic pulse waves. The significance of this study lies in its potential to introduce an innovative approach to utilizing PPG signals for diabetes screening. Unlike other methods, PPG images were directly input into the CNN without prior time-domain or frequency-domain analysis. Among various deep learning models previously reported for PPG analysis, CNNs were chosen for their effectiveness in automatically extracting features from complex data, surpassing manual feature extraction, and they are particularly well-suited for image processing tasks (Chu et al., 2021).

Materials and Methods

Ethical clearance was obtained from the Ethics Review Committee of the University of Kelaniya prior to the initiation of the study. The methodology of this study consists of four main steps: data collection, data preprocessing, CNN model development, and model evaluation.

Study settings

The study was conducted at the medical clinics of the Base Hospital, Kiribathgoda, the Family Medicine Clinic at the Faculty of Medicine, University of Kelaniya, and Gampaha Wickramarachchi Ayurveda Teaching Hospital. Healthy individuals were recruited from those accompanying the patients.

Inclusion criteria

For individuals with diabetes, the selection criteria included the confirmed diagnosis of type 2 diabetes (based on fasting glucose levels of ≥126 mg/dL), age 18 or older, and absence of cardiovascular disease history, with diagnoses confirmed by the consultant physician at the study setting. Age and gender-matched individuals were selected for the control group based on health criteria, ensuring the absence of significant medical conditions or major surgical history. Eligibility mandated a BMI within the healthy range of 18.5-24.9 kg/m^2, oxygen saturation levels above 95%, stable pulse rate between 60 to 100 beats per minute, and blood pressure within the normal range, specifically below 120/80 mmHg but not less than 90/60 mmHg.

Exclusion criteria

The study excluded participants based on the following criteria: individuals younger than 18 years, those with severe psychiatric disorders or cognitive impairments that could interfere with the interview process, individuals with acute or chronic infections, pregnant or lactating women, cancer patients, and individuals with undiagnosed medical conditions.

Sample size

Deep learning (DL) requires substantial data for well-behaved models (Wang et al., 2019). For this study, 120 participants were chosen for the diabetic and healthy groups, primarily for ease of data management during the initial stages. Out of 60 images from each group, 50 images were used as training data, while the remaining 10 from each group were not introduced to the model during training, and the predictions of the model were later checked using these 20 unassessed images. Future studies will aim to expand the sample size. While 60 samples per group may suffice for preliminary analysis, rigorous validation of results is imperative, alongside the implementation of methodologies to address the inherent limitations of a small sample size. Furthermore, collecting additional data is strongly recommended, as it typically enhances the performance of CNN models. It is crucial that the dataset represents a wide range of variations seen in finger pulse images.

Data collection

The primary objective of this study is to differentiate between the PPG signals of healthy individuals and those of patients with diabetes. Data was collected from 60 individuals in each group with informed consent. This study employed the multiparameter patient monitor depicted in Figure 1 (Model: Datalys 760, Lutech Medical, USA) to collect non-invasive PPG, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO2), and pulse rate.

Figure 1 Lutech Datalys 760 Multipara Patient Monitor along with its components: the blood pressure cuff and the SpO_2 probe used for collecting PPG signals, oxygen saturation, pulse rate, and blood pressure for the study.

The Datalys 760 delivers both waveform and numerical data, along with trend analysis, making it ideal for continuous monitoring. Accurate collection of PPG images is critical in this study, as high-precision data is essential for inputting into the CNN. PPG signals were exported by connecting the device to a printer, a crucial step for signal analysis. These specifications were fundamental for the methodology, ensuring the precise data required for effective PPG signal analysis.

The PPG signal is sensitive to the subject's movements and breathing activity, which can cause shifts and offsets in the baseline of the signal (Al Fahoum et al., 2023). To mitigate these artifacts, participants were instructed to sit comfortably without moving and to breathe normally during the measurement. The SpO_2 probe was securely attached to their left index finger to ensure stable data collection, and the PPG signal was recorded for at least 1 minute.

Participant information was gathered using an interviewer-administered questionnaire that covered a range of variables, including age, gender, medical history, presence of other illnesses, medication history, surgical history, Body Mass Index (BMI), recorded investigation results, and diagnosis. This thorough approach ensured a comprehensive understanding of each participant's health status and background.

Data preprocessing

The PPG signals obtained from the patient monitor were processed to prepare them for analysis. Initially, each pulse wave recording was examined, and one single pulse wave cycle was isolated for each subject. This step was crucial to ensure that the analysis focused on the characteristic shape and features of a typical pulse wave, eliminating any extraneous data that could introduce noise or variability. Once the single pulse wave cycles were isolated, these cropped images underwent a series of preprocessing steps designed to standardize the data for the machine learning model. Image preprocessing began with resizing each pulse wave image to a uniform size of 75x100 pixels. This resizing was essential to ensure that all images fed into the model had the same dimensions, facilitating consistent processing and comparison across the dataset.

In addition to resizing, the pixel values of the images were rescaled to a specific range, typically [0, 1]. This rescaling process normalized the pixel values, making the data more suitable for the model by ensuring that the input values were within a standardized range. Normalization is a common practice in image processing and machine learning, as it helps improve the convergence rate of the training process and enhances the model's performance (Koo & Cha, 2017). Through these preprocessing steps, the images were transformed into a consistent and standardized format, ready for input into the CNN model. The goal was to optimize the model's ability to accurately analyze and classify the pulse wave images, distinguishing between different health conditions based on their unique characteristics. Figure 2 displays a selection of these preprocessed PPG waves from the diabetes group, illustrating the uniform appearance and standardized format of the data after preprocessing. This careful preparation of the images was a critical step in ensuring the reliability and accuracy of the subsequent analysis.

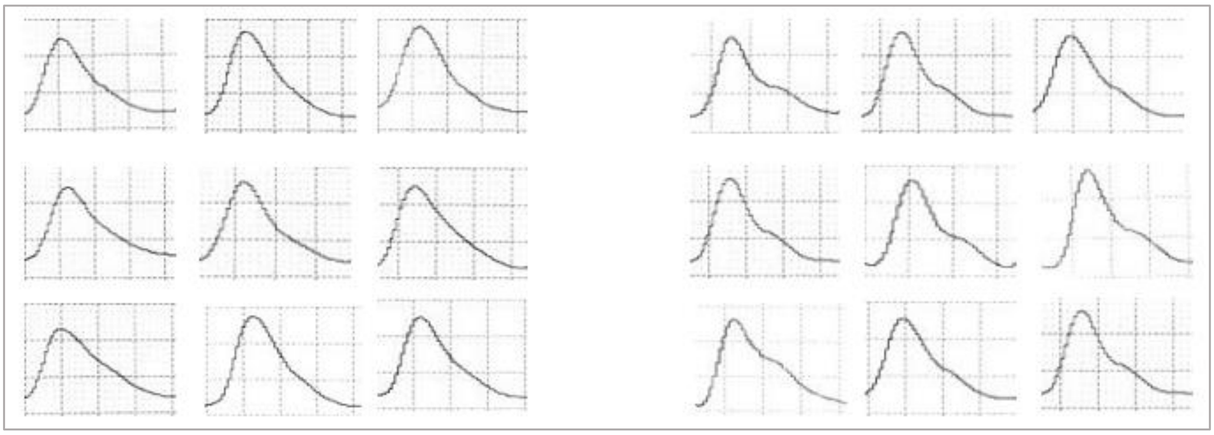

Figure 2 Representative preprocessed finger PPG signals from type 2 diabetes patients (left) and healthy individuals (right) highlighting characteristic differences in pulse waveforms.

Model development and evaluation

The CNN model architecture was defined using the Keras Sequential API. This architecture typically comprises convolutional layers for feature extraction, max-pooling layers for down sampling, flattening layers to transform feature maps into vectors, and fully connected (dense) layers for classification. The architecture was configured with specific parameters, including the number of layers, filter sizes, and activation functions. The model was compiled with an optimizer (Adam), a loss function (categorical cross-entropy), and accuracy as the evaluation metric. Model compilation configures the learning process for training (Talaat et al., 2023). The CNN model was trained using 100 prepared and preprocessed images. Training involves iteratively adjusting the internal parameters of the model (weights and biases) to minimize the loss function while making accurate predictions (Alzubaidi et al., 2021). This process was carried out over a specified number of epochs.

For evaluation, the prediction capability of the model was tested on individual images using 20 unassessed images, comprising 10 PPG images from healthy subjects and 10 PPG images from subjects presented with diabetes. Each image was loaded, resized, converted to an array, rescaled, and expanded to include a batch dimension. The model then predicted the class of each image based on output probabilities, with the final class label printed to indicate performance.

Statistical analysis

The clinical relevance and applicability of the CNN-based algorithm for PWA were evaluated by analyzing its correlations with various parameters, including age, gender, BMI, SBP, DBP, pulse pressure (PP), MAP, pulse rate, and oxygen saturation, using Pearson's correlation analysis, with significance levels set at $p < 0.05$.

Results

The CNN model achieved the best performance with a training accuracy of 92% in classifying the pulse images into diabetic or non-diabetic subjects. The training accuracy and loss curves of this model are shown in Figure 3. It provides insights into the learning process of the model. The steady increase in accuracy and decrease in loss during training signifies the successful convergence of the CNN model. The convergence pattern indicates that the model effectively learned the intricate patterns in the pulse wave images, enhancing its predictive capabilities.

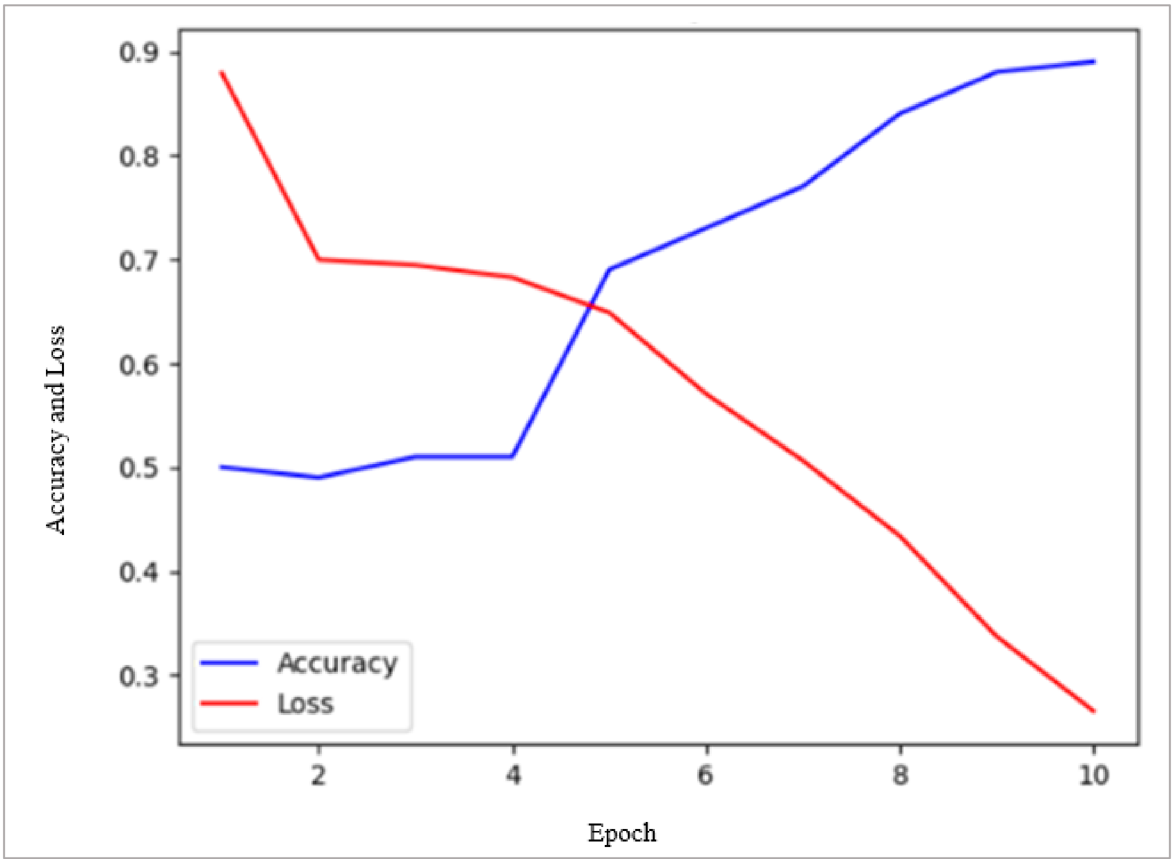

Figure 3 Accuracy and loss curves of the CNN model

As depicted in Table 1, the model correctly predicted 8 out of 10 healthy PPG images, demonstrating its ability to accurately identify healthy cases. Additionally, it accurately predicted all 10 diabetes PPG images, indicating a high level of precision in detecting diabetic cases. Overall, the model correctly predicted 18 out of 20 unassessed images, resulting in an overall test accuracy of 90%. This reported accuracy reflects the performance of the model under the test conditions, with efforts made to minimize the influence of potential confounding factors.

Table 1 Model prediction performance on unassessed healthy and diabetes PPG images

Image Type	Total Images	Correct Predictions	Accuracy Rate
Healthy PPG Images	10	8	80%
Diabetes PPG Images	10	10	100%
Overall	20	18	90%

The descriptive statistics of the demographic and clinical data of the subjects are shown in Table 2, where *n* represents the number of subjects in each group. According to the descriptive statistics, it is evident that individuals in the control group were carefully matched with the diabetic group in terms of age and gender. This matching ensures that any observed differences between the two groups can be more confidently attributed to diabetes-related factors rather than age or gender variations. In diabetes research, it is crucial to match control groups with diabetic groups to ensure the validity of the study results (Hina & Saadeh, 2022).

Table 2 Descriptive statistics of the demographic and clinical data of the subjects

Variable	Diabetic group (n = 60)	Control group (n = 60)	p-value
Age (years)	52.4 ± 9.8	49.6 ± 8.7	0.12
Gender (Male/Female)	30/30	30/30	1.00
BMI (kg/m2)	25.3 ± 3.9	24.4 ± 3.6	0.15
SBP (mmHg)	132.8 ± 22.9	111.1 ± 9.9	<0.001
DBP (mmHg)	72.8 ± 11.4	67.7 ± 8.5	<0.001
PP (mmHg)	60.0 ± 15.0	43.4 ± 6.7	<0.001
MAP (mmHg)	93.0 ± 13.1	82.2 ± 7.6	<0.001
Pulse rate (bpm)	76.7 ± 10.3	76.6 ± 10.1	0.993
Oxygen saturation (%)	98.4 ± 0.9	99.1 ± 0.4	<0.001

Discussion

The findings of this study highlight the significant potential of using Convolutional Neural Networks (CNNs) for the classification of diabetic and healthy individuals based on finger pulse wave analysis. Compared to previous studies (Susana et al., 2022) (Chu et al., 2021) (Lu et al., 2022) which primarily focused on predicting diabetes using photoplethysmography (PPG) signals, this study offers a novel approach by employing CNN for image processing without the need for feature extraction. The CNN model achieved a training accuracy of 92%, indicating strong performance on the training dataset. More importantly, the model attained an overall test accuracy of 90%, highlighting the effectiveness of CNN in extracting and learning from complex patterns within the PPG wave data. While both training and test accuracies are important, test accuracy is the most critical measure of a performance of a model. It provides valuable insight into how well the model generalizes beyond the training dataset, indicating its potential effectiveness in real-world applications (Talaat et al., 2023).

The misclassification of two healthy PPG images as diabetic could be attributed to several factors, including insufficient model training, limited sample size, or potential underlying pathologies in the individuals classified as healthy. These individuals were included in the healthy group based on criteria such as having a BMI, oxygen saturation, pulse rate, and blood pressure within the normal range, and no previous history of diabetes. However, it is possible that these individuals had underlying health issues that were not detected during the initial screening, which may have influenced the predictions of the model. One limitation of this study is the absence of blood glucose level measurements in the screening process, which could have enhanced accuracy and provided a more comprehensive assessment of the participants' health status. Future studies should address this by including blood glucose level measurements to improve the robustness of the findings.

In comparison to other studies, such as those employing Deduction Learning or ensemble methods (Lu et al., 2022), the CNN-based approach provides a unique advantage in terms of directly utilizing pulse wave characteristics for classification. This direct classification method simplifies the diagnostic process and offers immediate insights into an individual's health status, making it a valuable tool for early detection and intervention. Incorporating image processing into PPG analysis offers significant advantages in terms of feature extraction, noise reduction, model performance, automation, clinical relevance, and comprehensive analysis.

Proper preprocessing steps, such as cropping, resizing, and normalization of pulse wave images, may have enhanced the model's ability to extract relevant features. Pulse waves carry information about the cardiovascular system, and certain features within these waveforms may be indicative of diabetic or non-diabetic status. CNN may have successfully learned and exploited these features. PPG images fed into the CNN architecture for image processing help to elucidate blood glucose variations among samples. However, numerous factors can also influence PPG waveform variation, including finger temperature, probe contact, blood pressure, heart rate variability, vascular tone, and individual differences in skin thickness or hydration. These confounding factors can significantly impact the cardiovascular system and PPG readings. (Chu et al., 2021). A limitation of this study is the lack of comprehensive assessment and control of these confounding factors, which may have affected the accuracy of the results. Future studies should aim to assess and control for these variables to ensure more reliable and accurate findings.

It is important to note the limitations of this study, including the relatively small sample size and the need for larger and more diverse datasets to further validate the performance of the model. To enhance accuracy and as part of future efforts, increasing the dataset size by including more subjects can strengthen the robustness of the model and its ability to generalize. This expansion may require collecting data from diverse populations to account for variations. Additionally, hyperparameter tuning is essential for optimizing the CNN model. Parameters such as learning rate, batch size, and network architecture should be adjusted to determine the most suitable configuration for this specific task.

Finally, for clinical applications, although our PPG-based diabetes detection method is still in its early stages and needs further refinement across various clinical settings, it shows promise in certain treatment scenarios. For instance, it is well-suited for preventive healthcare, such as regular diabetes monitoring to manage progression in healthy or high-risk individuals who are not yet under medical treatment but may face severe diabetes-related issues. Future studies will focus on predicting NIBG levels. If the prediction accuracy of the method improves, it could rival continuous glucose monitoring (CGM) devices. Many CGM methods are already commercialized and are significantly less invasive than standard finger-prick sampling. However, CGM sensors still require the sampling of body fluids like sweat, interstitial fluids, tears, and saliva (Hina & Saadeh, 2022). CGM sensors typically have a lifespan of 7 to 14 days and need calibration every 12 to 24 hours due to a potential 10-15% discrepancy with finger-prick blood glucose measurements. Conversely, our method seeks to remove invasiveness and extend monitoring longevity by incorporating a wearable device.

Conclusions

The findings of this pilot study demonstrate the potential of convolutional neural networks (CNNs) for precise PPG wave analysis, achieving test accuracy of 90% in classifying PPG images into diabetic or non-diabetic subjects. The differences in cardiovascular parameters between the diabetic and control groups further underscore the importance of non-invasive diagnostic tools for early diabetes detection and risk stratification. The CNN-based approach holds promise for revolutionizing non-invasive diabetes detection and could significantly impact diabetes management and patient care. Future studies should include larger and more diverse cohorts to validate and generalize these results. Additionally, longitudinal follow-up is needed to assess the predictive value of the CNN-based approach for clinical outcomes. Further research into the underlying mechanisms of the CNN model and integration with digital health technologies can optimize its applicability in clinical settings.

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Conflict of interest: The authors declare no conflict of interest. All authors read and approved the manuscript.

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