Validation of a Fully Automatic Photoplethysmographic Device for Toe Blood Pressure Measurement

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Abstract *Objectives:* This study was designed to assess the accuracy and reliability of a new, portable, fully automated photoplethysmography (PPG) device for toe blood pressure (TBP) measurement.
Design: Within-subject comparison with conventional laser Doppler (LD) measurement.
Materials and methods: Four TBP measurements were performed on both lower limbs, alternatively with LD and PPG in 200 patients recruited at the Nîmes University Hospital. Reproducibility was assessed by the intraclass correlation coefficient (ICC). The concordance between the two methods was evaluated by Lin's concordance correlation coefficient (CCC), in the whole population as well as in comorbidity subgroups. A potential bias was investigated with the Bland and Altman method.
Results: The ICC was 0.887 (95% confidence interval (CI) 0.852—0.913) and 0.893 (0.860—0.918) on the right side ($n = 193$), 0.905 (0.875—0.928) and 0.898 (0.866—0.922) on the left side ($n = 188$) for PPG and LD measurements, respectively. The CCC was 0.913 (0.885—0.934) on the right side and 0.915 (0.888—0.937) on the left side, and remained >0.8 regardless of co-morbidities.
Conclusions: This new, fully automatic, photoplethysmographic device yielded reliable TBP measurements and showed good agreement with the reference LD system over a wide range of values.
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Peripheral arterial disease (PAD) is a common consequence of systemic atherosclerosis, but may remain clinically silent, especially in sedentary subjects or in diabetic patients with peripheral neuropathy. Asymptomatic forms are thus believed to be more common than symptomatic forms, but both are associated with an increased risk of cardiovascular mortality and morbidity, in addition to local trophic complications.[1–3] Therefore, screening for PAD appears to be of importance and requires an accurate, quick and cost-effective diagnostic approach.

The ankle brachial pressure index (ABI) is a sensitive and specific method[4] not only for diagnosing but also for assessing the severity of PAD,[5] and is largely recommended.[6]

However, ABI measurement requires specific tools (blood pressure cuffs and handheld 5–10-MHz continuous-wave Doppler probe), is operator dependent, time consuming[7] and remains underused, especially in outpatients. Moreover, its reliability is limited or compromised when medial calcinosis reduces peripheral artery compressibility, especially in patients with diabetes, chronic renal failure or advanced age, in whom the risk of PAD is greater.[8,9]

Measuring systolic blood pressure at the toe (TBP) and calculating the toe-brachial index (TBI) has been proposed to overcome this limitation because small distal arteries are less prone to medial calcinosis.[10–13] Although some authors consider the TBI useful only in patients with elevated ABI (i.e., >1.3),[10] others emphasise the risk of falsely normal ABI in patients with moderate incompressibility of ankle arteries.[11]

However, TBP measurement also requires specific equipment, including small pneumatic cuffs and plethysmography or laser Doppler (LD) devices, and its validity depends on its use by skilled and meticulous operators. Several specialised systems have been developed, the more recently validated using laser Doppler.[14] So far, the use of such devices on a large-scale has been hampered by their complexity and/or cost, so that TBP is often regarded as unsuitable for the outpatient clinic.

This is why we developed a new miniaturised and fully automated TBP measurement device using photoplethysmography (PPG) flow detection, with automatic pulp blood draining as well as occlusion cuff inflation and deflation. We assessed the usability, accuracy and reliability of this device in a large sample of patients with and without cardiovascular risk factors or expected PAD, using a within-subject comparative design with conventional, LD laboratory equipment.

Materials and Methods

Subjects

A 200-subject study population sample was recruited at the Nîmes University Hospital over a 4-month period from in- and outpatients aged 18 years or over: a total of 50 consecutive diabetic patients admitted to the Department of Diabetes and Metabolic Medicine, 50 patients from the Department of Internal Medicine and 100 patients referred to the Department of Vascular Medicine. Exclusion criteria were marked limb tremor or skin ulceration on toe

measurement sites. All participants gave written informed consent. The study protocol was approved by the local Ethics Committee and conducted in accordance with the Declaration of Helsinki.

Experimental procedure

Room temperature was maintained at 24–25 °C. Individuals were rested in a supine position and acclimatised for at least 10 min. Information on patient demographics and co-morbidities was collected with a questionnaire and medical record analysis, especially as regards diabetes, hypertension, PAD, distal ulcer and smoking habits.

Brachial blood pressure
Systolic and diastolic blood pressures were measured at rest in supine position, using an automated system (Dinamap DPC-320N, GE Medical Systems, Milwaukee, WI, USA).

Toe pressure measurement
All measurements were performed on the first toe of both lower limbs, if available, or on the second toe, if not. Prior to blood pressure measurement, one sequence of inflation–deflation of the pneumatic cuffs was completed but not recorded to avoid or limit post-ischaemic effects. Toe systolic pressure assessments were repeated for a total of four measurements, twice with the new PPG device — SysToe® (Atys Medical, Soucieu-en-Jarrest, France, Patent # 08 58291, 5 December 2009), and twice with the reference LD system (PF 5010 Doppler Laser monitor, Perimed, Stockholm, Sweden), the techniques being used alternatively in a randomised order, one technique followed by the other one (e.g., LD, PPG, LD, PPG or PPG, LD, PPG, LD).

TBP measurement with LD was conducted according to the manufacturer's instructions. After wrapping the appropriately sized pneumatic cuff around the first phalanx of the toe, the laser probe was placed distal to the cuff on the toe pulp. Pulp blood draining was performed manually by gentle compression immediately before inflating the occlusion cuff to 250 mmHg. The cuff was then automatically and linearly deflated. Systolic blood pressure was read automatically by software when the LD probe detected the return of blood perfusion (Fig. 1).

For blood pressure measurement with the PPG device, an appropriately sized pneumatic cuff (occlusion cuff) was wrapped around the first phalanx of the toe. The PPG sensor was placed on the toe pulp and maintained with a second pneumatic cuff (blood draining cuff) delicately wrapped so that it fitted the toe without applying any pressure when deflated. Turning on the device launched an automatic sequence starting with inflation of the blood draining cuff, then inflation of the occlusion cuff followed by deflation of the blood draining cuff, after which the occlusion cuff was slowly and linearly deflated. The infrared PPG system, working in reflection mode at 880 nm wavelength, with a fixed power of 75 mW, provided penetration depth of about 3 mm in the skin. During deflation, the return of blood perfusion was detected when the direct current (DC) curve showed a continuous upslope indicating a steady increase in toe blood volume (Fig. 1). The pressure measured within the occlusion cuff at the beginning of this upslope was assumed to correspond to local systolic blood pressure.
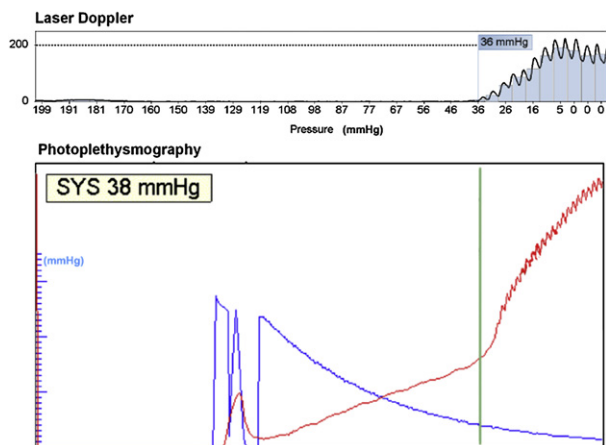
Figure 1 Print of a typical automatic toe blood pressure measurement with laser Doppler (LD) and photoplethysmography (PPG) in a patient with peripheral arterial disease. Time is shown on the horizontal axis. On the LD curve (upper part of the graph), the figures along the horizontal axis correspond to the instantaneous pressure in the occlusion cuff, whereas the curve shows the LD signal. On PPG curve (lower part of the graph), the blue curve shows the pressure in the occlusion cuff, read in mm Hg on the left scale, whereas the red curve shows the PPG signal in % of its maximum amplitude change during the measurement sequence.

Statistical analysis

For each measurement device and each lower limb, reproducibility was assessed by the intraclass correlation coefficient (ICC) between the two repeated pressure measurements. This reliability index was computed as described by Carrasco et al.,[15] the individual effect in the model being considered as a random effect. The measurement model was thus $y_{ij} = \mu + u_i + \varepsilon_{ij}$ in which $\varepsilon_{ij} \sim N(0,\sigma^2)$ and $u_{ij} \sim N(0,\tau^2)$ are independent and y_{ij} denotes the measurement for individual i at occasion j. This model decomposes the total variance between error variance (σ^2) and inter-individual variance (τ^2). Then, ICC $= \tau^2/(\tau^2 + \sigma^2)$ is the proportion of the total variance that is due to subjects. The reproducibility of a method of measurement is judged acceptable when the ICC is higher than 0.8.

The concordance between the two methods of measurement was assessed by the concordance correlation coefficient (CCC) of Lin.[16] The concordance computation was based on the average of the two measurements done by each device on each lower limb if the devices were separately judged reproducible, and on the first and second measurement separately, otherwise.

The Bland and Altman method was used to search for a potential bias between the devices.

Reproducibility of measurements and concordance of devices were assessed on the whole sample, by department, and on subsamples defined by co-morbidities. Reproducibility and concordance were also assessed for TBI.

Each of the two lower limbs was treated separately to avoid an additional source of variability.

All coefficient estimates are given with their 95% confidence interval (CI). Data management and statistical analysis were performed under R software version 2.9.2 (R Development Core Team (2009), R Foundation for Statistical Computing, Vienna, Austria.)

Results

LD measurement could not be obtained in two subjects because of tremor artefacts. PPG measurements were possible in all 200 subjects. TBP measurement could not be performed by either method in five right lower limbs and in 10 left lower limbs where toes or legs had been amputated. Therefore, 193 right lower limbs and 188 left lower limbs, in 114 males and 84 females, were available for comparison. There were 109 (55%) diabetic patients, 51 (25.6%) patients with identified PAD, 82 (41.4%) patients with arterial hypertension, 23 (11.6%) patients with distal ulcers and 58 (29.3%) smokers (Table 1).

Although the average time for measurements was similar between the two systems, the software procedure was longer with the LD device (software initialisation and patients' identification) than with PPG system. Typically; a series of measurements lasts about 5 min with the PPG versus about 10 min with the LD system. For the present study, the entire procedure (i.e., two measurements with each device) took about 15 min to complete.

The ICC was 0.887 (95% CI 0.852–0.913) and 0.893 (0.860–0.918) on the right side, 0.905 (0.875–0.928) and 0.898 (0.866–0.922) on the left side, respectively, for PPG and LD measurements.

The CCC of systolic pressure and TBI for all subjects and for each subgroup are reported in Table 2. Concordance was fair (CCC >0.8), or good (>0.9) in most subgroups. The analysis was not done for patients with ulcers, because the number of subjects in this subgroup was too small. The concordance was not altered by systolic pressure level and remained above 0.8, regardless of brachial pressure values.

Fig. 2 shows LD versus PPG measurements for each lower limb. The 45° line through the origin represents the perfect situation of concordance. The best linear regression model explaining LD measurement values as a function of PPG values was the model without a constant. The estimated coefficients (0.922 for the right side and 0.939 for the left side) were significantly different from 0 ($p < 0.001$) and close to 1. The coefficient of determination (R^2) for the right and left models were 0.984 and 0.983, respectively.

PPG measurements yielded mean pressure values 7 mmHg higher than LD. However, the Bland and Altman analysis showed that the difference between the two methods did not depend on toe pressure values (Fig. 3).

Discussion

This study demonstrated that the fully automatic portable PPG device that we developed yielded reliable TBP measurements in patients, regardless of their co-morbidities, and showed good agreement with the reference LD system over a wide range of values.

PPG measurement yielded, on average, slightly higher TBP values than LD, although previous studies have reported the opposite.[17] LD is regarded as highly sensitive and may be able to detect flow in patients with very low TBP in

Table 1   Subjects characteristics.

	Total $n = 198$	DMMD $n = 50$	IMD $n = 50$	VMD $n = 98$
Men/women ratio	114/84	60/38	23/27	30/20
Age (years) [mean ± SD]	63.78 ± 14.90	65.15 ± 13.59	57.40 ± 14.96	67.55 ± 15.63
PAD [n (%)]	51 (25.6%)	7 (14%)	7 (14%)	37 (37.8%)
Diabetes [n (%)]	109 (55%)	50 (100%)	11 (22%)	48 (49%)
Insulin treated [n (% of diabetics)]	64 (58.7%)	29 (58%)	7 (63.6%)	14 (21.1%)
Hypertension [n (%)]	82 (41.4%)	27 (54%)	9 (18%)	46 (46.9%)
Distal ulcer [n (%)]	23 (11.6%)	1 (2%)	15 (30%)	7 (7.1%)
Smokers [n (%)]	58 (29.3%)	17 (34%)	8 (16%)	46 (46.9%)

DMMD: Diabetes and Metabolic Medicine Department, IMD: Internal Medicine Department, VMD: Vascular Medicine Department, PAD: Peripheral Arterial Disease.

whom PPG would detect no flow.[17] Nevertheless, there was no case in our series where LD could detect the return of blood perfusion while PPG could not. In addition, all patients with values below the 30 mmHg-threshold defining ischaemia were detected by both devices. Moreover, the Bland and Altman analysis showed that the difference between the two devices was not greater for low than for normal or high TBP values. Finally, in the PAD subgroup, the CCC remained satisfactory: 0.869 (0.783–0.922) and 0.911 (0.844–0.950) on the right and left sides, respectively. Therefore, this small difference may simply reflect the microcirculation level reached by each technique, with LD recording flow in smaller vessels in which blood pressure is lower. From a clinical point of view, this difference seems irrelevant and PPG appears to be discriminating enough to detect high-risk subjects.

On the other hand, previous studies[18] reported large variations between PPG and LD, whereas our results showed a much closer agreement between these two techniques. This is probably because of the improved sensitivity and reliability of both state-of-the-art sensors we used in our study.

PPG signals may be influenced by many physiological inputs, including respiration, thermoregulation and sympathetic nervous system activity,[19] which may affect the pulsatile plethysmography curve recorded in the alternating current (AC) mode, but not the DC curve that was used by our system to detect the steady upslope resulting from blood flow return in the toe pulp.

PAD, even if asymptomatic, is a prognostic marker for total mortality and cardiovascular events.[2,18] Therefore, its early detection could allow improving risk factor control and reducing the rate of cardiovascular events, thus ensuring a healthier outcome. In high-risk patients, especially in diabetics, close follow-up is mandatory. Therefore, improving the screening, diagnosis and follow-up of PAD represents a challenge requiring accurate, reliable, simple, accessible and non-invasive tools. Doppler-measured ABI, although validated and recommended,[6] has significant limitations and drawbacks, including the required training and costs.[20] Some authors have tested automatic procedures using toe-applied oscillometry,[21] oximetry[12,22] or PPG for measuring ankle blood pressure.[23] However, none of these techniques has so far been proven suitable for large-scale use. In addition, the validity of ABI measurement is compromised in patients with medial calcinosis, in whom TBP measurement is more appropriate,[8] especially when ABI is ≥1.3.[10]

TBI assessment requires specific, delicate, more or less cumbersome and costly equipment, which has so far

Table 2   LD and PPG measurements of toe pressure and toe-brachial systolic pressure index: concordance correlation coefficient (CCC) and 95% confidence interval (95%CI) in the whole population sample and in comorbidity subgroups.

	Right lower limb CCC (95%CI)	Left lower limb CCC (95%CI)
Toe blood pressure		
Total (n = 198)	0.913 (0.885–0.934)	0.915 (0.888–0.937)
DMMD (n = 50)	0.913 (0.851–0.950)	0.9165 (0.854–0.953)
IMD (n = 50)	0.948 (0.907–0.971)	0.919 (0.854–0.956)
VMD (n = 98)	0.8969 (0.848–0.931)	0.9091 (0.864–0.940)
PAD (n = 51)	0.869 (0.783–0.922)	0.911 (0.844–0.950)
Diabetes (n = 109)	0.9059 (0.864–0.936)	0.9061 (0.862–0.936)
Hypertension (n = 82)	0.912 (0.865–0.943)	0.913 (0.865–0.945)
Smokers (n = 58)	0.920 (0.864–0.953)	0.918 (0.861–0.953)
Toe-brachial systolic pressure index		
Total (n = 198)	0.889 (0.853–0.916)	0.891 (0.856–0.918)

DMMD: Diabetes and Metabolic Medicine Department, IMD: Internal Medicine Department, VMD: Vascular Medicine Department, PAD: Peripheral Arterial Disease.
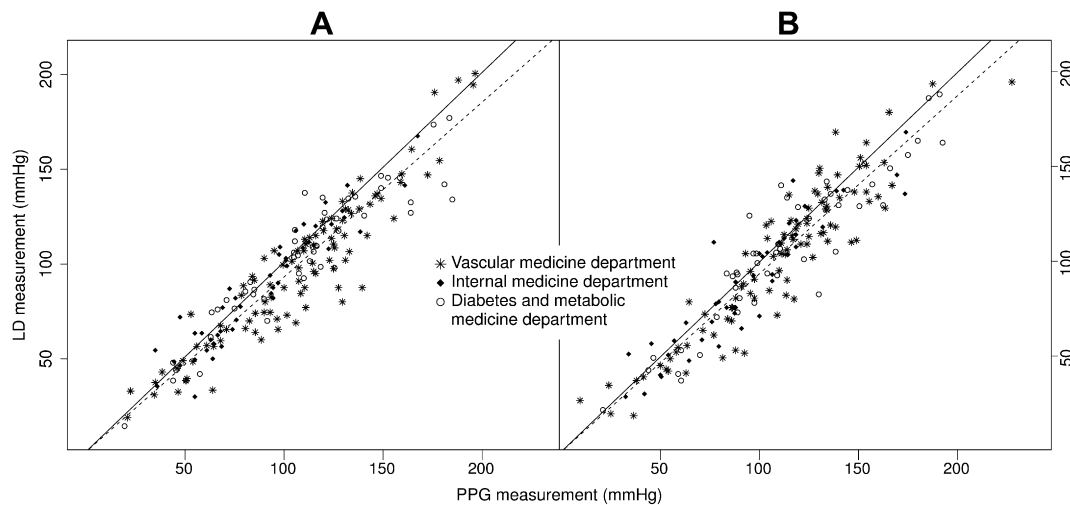
Figure 2 Plot of laser Doppler (LD) toe pressure measurement versus photoplethysmography (PPG) toe pressure measurements (A) for the right lower limb and (B) for the left lower limb. The full line is the 45° line through the origin which represents the perfect situation of concordance. The best linear regression model explaining LD measurement values as a function of PPG values was the model without constant. The equation of the regression line (dotted line) was LD = 0.922 PPG for the right lower limb and LD = 0.939 PPG for the left lower limb.

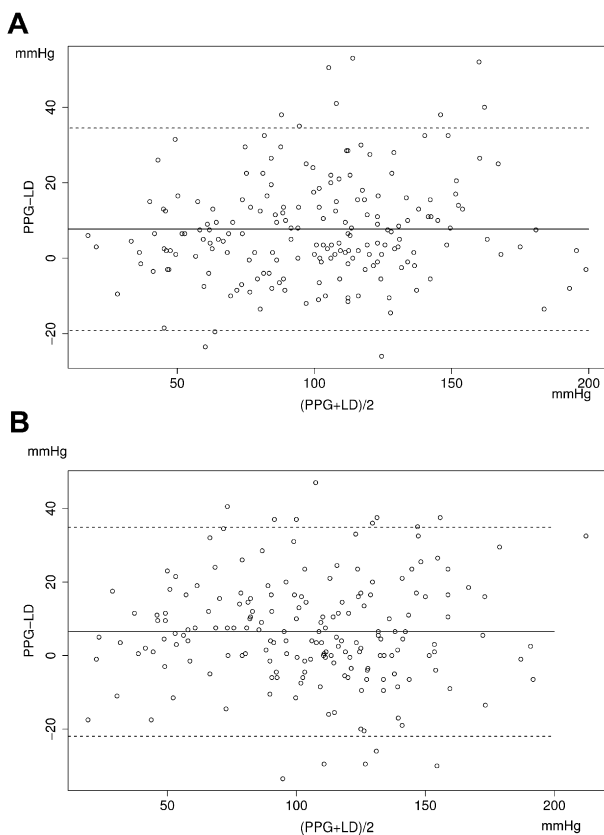**Figure 3** Bland—Altman plot showing the difference between photoplethysmography (PPG) and laser Doppler (LD) toe blood pressure measurement at the right (A) and the left (B) lower limb in dependency of the mean value of PPG and LD in each measurement.

precluded its use in out-clinics, outside vascular laboratories. Several devices are available, most of them using either PPG or LD sensors. During the past few years, some authors have developed automated monitors for TBP assessment.[24] Among them, the PresTo®, first validated in 2002, has been more recently tested in 16 diabetic patients with ischaemic leg by comparing the automatic software detection of blood perfusion return to the visual assessment of LD signals.[25] In the present study, we compared values provided by automatic software detection of blood perfusion return on PPG and on LD signal, and obtained quite satisfactory results.

In addition, the small PPG device we used is portable, battery powered, with fully automated reading of blood pressure, and also of pulp blood draining and occlusion cuff inflation and deflation, which are either not implemented or manual on the other systems.

We tested the accuracy of our device over a large range of pressure values, in patients with or without PAD and co-morbidities or cardiovascular risk factors. In all groups and subgroups, the reliability suited the clinical needs, and the reproducibility was satisfactory.

Although this device requires little formal training, its reliability implies the adherence to strict methodological recommendations such as warm room temperature and supine rest. The cuff width also influences the toe pressure value and needs to be taken into account in patients with a very large first toe, or when measurements have to be performed on another toe because of first toe amputation or ulceration.[26] In addition, the PPG sensor must be precisely placed with full and stable contact with the skin. The use of two-sided adhesive tape is useful.

In conclusion, fully automated PPG measurement of TBP with a small portable device is reliable and accurate. This technique seems perfectly suitable for large-scale screening, evaluation, and follow-up of PAD in at-risk patients, particularly diabetics.

Conflict of Interest

Acknowledgements

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