Objectives. To study the usefulness of a new laser Doppler (LD) device as compared with photoplethysmography (PPG) to measure toe systolic blood pressures (TBP) in patients suspected of arterial insufficiency of the legs.

Design. Prospective comparative clinical study.

Materials and Methods. Seventy patients (121 legs) referred to our vascular laboratory for TBP measurements were investigated using a standard PPG and a new LD instrument, incorporating a cuff inflator and probe heater.

Results. Mean toe pressures with the PPG, unheated LD, and heated LD (37°C) were 68.1, 67.2, and 75.5 mmHg, respectively. TBP with heated LD was systematically higher than with PPG (7.7 mmHg; p < 0.001). Intra-class correlations between PPG vs. unheated LD and PPG vs. heated LD were good: 0.91 and 0.93, respectively. However, a considerable variation existed between PPG and LD (95% confidence interval: 45 mmHg), which were unrelated to the value of the TBP. Kappa values of agreement between PPG and unheated and heated LD to detect critical ischaemia (TBP below 30 mmHg) were good (κ = 0.77 and 0.63, respectively).

Conclusions. The new LD device appears a good alternative to standard PPG measurements to assess TBP, despite a rather wide variation.

Key Words: Toe blood pressure; Laser Doppler; Photoplethysmography; Leg ischaemia.

Introduction

Toe systolic blood pressure (TBP) measurements are useful in the diagnostic workup of patients suspected of peripheral arterial disease, particularly when ankle blood pressure measurements cannot be assessed reliably.1 This may occur in diabetics and patients with media sclerosis, which can cause the ankle arteries to be poorly compressible,2 or when application of an ankle cuff or Doppler probe is hampered by the presence of local ulcers. TBP measurement can be an aid in the diagnosis of critical leg ischaemia (CLI) to assess distal perfusion,3 in the decision as to which patient needs a vascular intervention4,5 and in the prediction of the need for an amputation.6

The Transatlantic Inter-Society Consensus (TASC) document advocates TBP measurements to assess peripheral arterial insufficiency and recommends a cut-off value to diagnose CLI of 30 mmHg.7 This is a low value, which requires an accurate and reproducible measurement technique, especially in the low pressure range. Standard techniques to measure TBP have been strain-gauge plethysmography,8 followed by photoplethysmography (PPG),9 which make use of the pulsatility of the digital blood flow. TBP measurements using PPG were shown to have an acceptable reliability,10 but are difficult to attain in cold, ischaemic toes, which is the very condition of interest. To overcome this drawback, the TBP measurement technique may be improved by warming of the foot or emptying the leg veins, which make routine TBP measurements more cumbersome.

The laser Doppler (LD) technique, detecting non-invasively skin microcirculatory perfusion, was proposed to apply for TBP measurements. A few studies have shown the feasibility and possible advantage of the LD to detect lower toe pressures, notably in diabetics, because LD appeared more sensitive to perfusion changes than PPG, probably because of its different measurement principle.11–13 However, this technique also has its drawbacks, as it needs a separate cuff and inflator and is still troubled by the low-flow state of cold, ischaemic toes.

More recently, a new laser Doppler device has become available, which incorporates an inflator as
well as local heating module, which might overcome the negative effect of cold toes on TBP measurements. Hence, in this study we investigated how this new LD device compares with PPG in a routine clinical setting to measure TBP in patients with different stages of peripheral arterial insufficiency.

Patients and Methods

Patients

Patients referred to our Vascular Laboratory between July 2001 and July 2003 for routine assessment of the presence and severity of peripheral arterial insufficiency were eligible for inclusion in the study. Only patients for whom a vascular surgeon requested a TBP measurement were included in this study.

Photoplethysmography (PPG)

PPG is based on detecting changes in blood filling of the digit. The PPG sensor emits infrared light that penetrates the tissue under the probe and is reflected by red blood cells. The more red blood cells present, the higher the reflected signal. The PPG used was part of a Doppler instrument (PV-lab, Stöpler, EDI, Burbank, CA, USA). It incorporates an unheated probe and an inflatable digital cuff with a width of 2.5 cm. The PPG signal (AC mode) is displayed on a paper recorder, the cuff pressure on a numerical display.

Laser Doppler (LD)

The LD perfusion signal is derived from the Doppler shift the emitted infra-red laser light (wavelength 780 nm) undergoes after reflection by moving particles. These particles are mainly erythrocytes in the arterioles, venules and AV-shunts of the microcirculation in the upper 1.5 mm layer of the skin. The LD device (PF5000, Perimed, Stockholm, Sweden) incorporates a laser light generator (PF5010), a toe cuff inflator (PF5050), which deflates with a speed of 3 mmHg/s, a thermostat unit (PF5020), and a small heater-probe, which can record the unheated skin temperature and can be heated up to 44 °C. This device uses the same digital cuffs as the PPG does (Hokanson, Bellevue, WA, USA). The LD and cuff pressure signals were fed into a data acquisition system (AcqKnowledge III and MP 100WSW, Biopac System Inc., Santa Barbara, CA, USA) and displayed on a computer screen.

Measurement protocol

All patients were examined in a temperature-controlled room with a temperature of 22 ± 1 °C. Patients were acclimatised for approximately 15 min before the TBP measurement. The blood pressure of the big toes was measured first using PPG and subsequently LD, before and after heating of the LD probe to at least 37 °C. Patients were investigated in the supine position, with the legs covered. This implied that the toes were slightly above heart level, which is the regular position for this measurement. When a stable signal was obtained, the digital cuff was inflated until disappearance of the PPG and LD signals, respectively, usually at 200 mmHg. Using PPG, the actual TBP was obtained during gradual deflation of the cuff at the moment the pulsatile signal reappeared. TBP using LD was found off-line after the whole procedure by scrolling on-screen towards the point where the LD signal started to rise from the baseline value, during release of the arterial occlusion. This point yielded the corresponding pressure (Fig. 1). The measurements were performed by vascular technologists with at least 4 years experience, as part of a routine procedure, in which repetition of the measurement was performed only in doubt (e.g. when the pressure recording was unclear due to noise).

Statistical analysis

Mean values of TBP as assessed by means of PPG and LD were compared using a paired t-test. The inter-measurement agreement between PPG and (un)heated LDF to detect critical ischaemia (i.e. a toe pressure below 30 mmHg) was expressed as a kappa value, which is a chance-corrected measure of agreement. The correlation between the TBP as obtained by means of PPG and heated and unheated LD were expressed as intraclass correlation coefficients (ICC) and their 95% confidence intervals (95% CI). These ICCs also give information about any systematic error. Scatter plots according to Bland and Altman were made to depict the differences in TBP between PPG and LD measurements across the range of values. For the statistical analysis SPSS for Windows version 11.5 (SPSS Inc., Chicago, IL, USA) was used.

Results

During the study period 70 patients, comprising 121 legs, were investigated. Their mean age was 64 years (range 20–96 years). Of these, 51% were males and
44% had diabetes. Their clinical symptoms were intermittent claudication (28%), rest pain and/or ulceration (31%), or not based on arterial insufficiency (41%). Their mean ankle-brachial blood pressure index was 85% (range: 0–143%).

Using the LD for TBP measurements gave the investigators the impression of a more accurate assessment, because the exact moment of reappearance of the perfusion could be assessed off-line, which was not possible with the PPG. A typical TBP recording using the laser Doppler is shown in Fig. 1. However, poor signals in the lower pressure range were difficult to discern with both techniques, due to background noise of the PPG and due to the biological zero perfusion of the LD.

Mean toe pressures as measured with the PPG, unheated LD, and heated LD were 68.1, 67.2, and 75.5 mmHg, respectively. Unheated toe skin temperatures varied between 27 and 34 °C. The heated LD yielded significantly higher TBP values than PPG ($p < 0.001$), whereas, the unheated LD results did not differ significantly from the PPG results.

The overall correlations between PPG vs. unheated LD and PPG vs. heated LD were good: ICCs were 0.91 (95% CI: 0.88–0.94) and 0.93 (95% CI: 0.90–0.95), respectively. The relation between PPG and unheated LD results are plotted in Fig. 2. There was no systematic difference between the two parameters, but the variation was rather large: 95% of the cases showed a difference of up to 45 mmHg, which was unrelated to the value of the TBP. Heated LD yielded a systematically higher TBP (7.7 mmHg) than PPG (Fig. 3). Again, the variation was considerable (95% of the cases had a difference of up to 42 mmHg) and was not related to the height of the TBP.

In the subgroup of patients with rest pain or ulceration, similar results were observed. In three out of the 10 legs (30%) in which PPG found a zero pressure, the heated LD found a TBP above 0 mmHg. There was a good agreement between PPG and unheated LD to detect CLI, defined as a TBP below 30 mmHg (kappa = 0.77; 95% CI: 0.59–0.95). This agreement was slightly less between PPG and heated LD (kappa = 0.63; 95% CI: 0.38–0.88). The comparisons in diabetics and non-diabetics showed similar results.

**Discussion**

For the diagnostic workup of patients suspected of severe leg ischaemia, the new laser Doppler device appeared a simple and easy alternative to standard PPG measurements to assess TBP. It showed a good agreement despite a rather wide variation. Local heating of the skin facilitated the measurement and led to slightly higher TBP values.

The common problem of cold toes hampering the TBP measurement is overcome by the heater element incorporated in the probe, which is a quicker solution.
than warming the feet. The still small probe size allows for easy application to even smaller toes. Local heating up to a standard value reduces the temperature-induced variability in perfusion. The induced dilatation of the superficial vessels allows for a more substantial reperfusion to be detected after the period of arterial occlusion. It furthermore facilitates detection of the baseline signal in case the resting perfusion without local heating is very low, which was illustrated by the cases in which the laser Doppler could detect a perfusion signal, whereas the PPG could not. This is in agreement with previous findings.\textsuperscript{12} The heated laser Doppler yielded systematically higher (7.7 mmHg) TBP values than the PPG, as was seen earlier.\textsuperscript{10} Similar results were also found when using the older strain-gauge technique as comparative

Fig. 2. Scatter plot of mean toe pressure versus difference in toe pressure between PPG and unheated LD.

Fig. 3. Scatter plot of mean toe pressure versus difference in toe pressure between PPG and heated LD.
method.17,18 In the present study this systematic difference obviously lowered the correlation between the two methods in the detection of CLI patients. This suggests the PPG generally underestimates the actual TBP, as it is known that low blood pressures (e.g. below 20 mmHg) may remain undetected with PPG and are therefore regarded as zero due to the poor signal to noise ratio, while on the other hand the laser Doppler is a sensitive detector of changes in microcirculatory blood perfusion. Given this difference, a higher cut-off value for the detection of CLI might be considered when using the laser Doppler for TBP measurements, for instance 35 instead of 30 mmHg. However, a gold standard for the TBP is lacking to corroborate this.

Measurement variation may be due to a variety of causes. In the present as well as previous studies,5,12 as many factors as possible were standardised, such as device, cuff, and interpreter. However, these studies were performed under more experimental conditions, which are usually quite dissimilar from routine clinical practice, in which different vascular technicians perform the tests. To reduce this uncertainty, repetition of a measurement will help reducing the variability as it causes regression to the mean, i.e. will give a better estimate of the true value after averaging the two results. This holds, irrespective of when the measurement is repeated, but the variation may be larger with a greater interval between both measurements, because of patient-related factors. Hence, we advise to repeat any measurement as soon as possible when in doubt about the validity of the result, and to be aware of the variability and reproducibility in one’s own diagnostic setting. Ideally, the measurement should be performed more than once during the same session and the results averaged.

The observed variation between PPG and LD measurements was influenced neither by local heating nor by the height of the TBP, and was larger than in other studies.12,13 A possible reason for this could be that PPG and LD measurements were not performed simultaneously and by different vascular technicians, and could therefore be influenced by inter-observer and physiological patient variability. A second explanation could be that the feet were not warmed prior to the PPG measurement, and thirdly because of intra-observer variability, which was found to be ± 10 mmHg for the PPG.10 An additional source of variability might be the difficulty in detecting the moment of signal reappearance. The PPG signal has to be read on-line from the paper recorder, while the laser Doppler signal, even though it can be read off-line, can be difficult to discern form baseline artefacts during arterial occlusion.

Display of the laser Doppler and cuff pressure signals requires a computer monitor, which reduces the portability. In addition, TBP measurements are usually combined with ankle blood pressure measurements. This combined measurement, which requires different devices, is less practical to carry out, especially when patients need to be investigated outside the vascular laboratory, e.g. on the ward or the outpatient clinic. Hence, a further improvement of the laser Doppler method would be integration in the standard equipment for routine vascular diagnostics, comprising a Doppler device for arterial and venous application.

In conclusion, the new laser Doppler device with heatable probe is a simple, useful alternative to PPG measurements of the toe blood pressure. It overcomes the reduction in reliability due to cold toes as with PPG, and appears to more accurately measure toe blood pressures. There is, however, a considerable measurement variation to be taken into account. Hence, repetition of the measurement is advisable to ascertain a diagnosis.

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References

9 YAO JS, FLINN WR, BERGAN JJ. Noninvasive vascular diagnostic...

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