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# Evaluation of chronic venous insufficiency with PPG prototype instrument

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**Abstract - Photoplethysmography (PPG) is a non-invasive optical technique for measurement of blood volume changes inside an organ or body part. In presented study, a chronic venous insufficiency (CVI) of 25 individuals (38 legs) was measured using PPG prototype instruments. The results of PPG evaluation were compared to results of Doppler ultrasound, which is the gold standard for diagnosis of CVI. The sensitivity and specificity of PPG prototype instrument in amount of 82% and 81%, respectively was calculated.**

## INTRODUCTION

Plethysmography is the term given to the recording of changes in limb size due to tissue fluid or pooled blood within the veins. This measurement can be undertaken in a variety of ways, fluid displacement, electrical impedance, electronic strain gauge, gravimetric methods and PPG [1]. Historically, the diagnosis of venous insufficiency was performed by invasive ambulatory venous pressure measurements (AVP), which has been described as the ideal diagnostic standard [2,3] or as the 'gold standard'[4]. Early investigations using infra-red radiation to identify fluctuations in dermal blood flow resulted in the introduction of PPG. Hertzman [5] described the method of measuring circulation through the skin using photoelectric plethysmography by relating the blood content of the skin to the amount of light reflected. AVP is a comparatively invasive technique, as it involves

cannulation of the dorsal foot vein. It has been described as painful and cumbersome [6], associated with complications such as bleeding or haematoma formation [7] and unsuitable for repeated use on the same patient or for screening purposes [8]. In contrast, PPG is described as easy to undertake, without risk and user-friendly [9]. PPG has increased in popularity due to the ease and speed of the investigation; this method depends on the absorption of light by haemoglobin in the red cells. Increasingly this was developed to investigate the venous haemodynamics of the lower limb and was renamed light reflection rheography (LRR). A light emitting diode is placed 5-10 cm above the medial malleolus to measure the speed at which the capillary bed becomes filled with blood following calf muscle exercise. In the normal subject refill time may take between 20 and 45 seconds and a reduction in this refill time identifies degrees of venous insufficiency.

Ineffective venous return from the lower legs leads to a condition of venous hypertension in the superficial venous system [10,11,12], which frequently results in ulceration[11]. It has been reported that 1% of the adult population suffer from leg ulcers [10], which has placed a large financial burden on the health service [13].

## METHOD

Thirtyeight legs in 25 patients with evidence of CVI were studied prospectively by physical examination, PPG and duplex ultrasound scanning in Vascular

laboratory of General Hospital Novo mesto during a 12-month period from October 2015 to September 2016. Data were recorded after a single examination. The patients were currently seeking care by a vascular surgeon for worsening of CVI symptoms. They were examined by one senior vascular surgeon.

PPG was performed with our prototype instrument. After an area of skin 5 cm superior to the medial malleolus was cleaned, a small piece of tape was used to secure the transducer to this site. Patients wore loose-fitting clothing to prevent impedance of outflow from the leg, and all patients were barefoot. The leg to be examined was placed in a dependent position over the side of the examination table for a few minutes to allow lower extremity blood volume to stabilize. The patient was then instructed to forcefully dorsiflex the foot ten times in rapid succession and then to relax the foot (Fig.1). The time taken from the beginning of relaxation until reestablishment of the baseline was documented as the venous refilling time (VRT). A refill time of greater than 20 seconds was used as the normal value.

A PPG prototype instrument for CVI was designed, fabricated and characterized together with customized readout electronics. Readout electronics provides photovoltaic operating mode of silicon photodiode, transforms photocurrent to measured voltage and serves as constant current source for LED. After laboratory characterization of each component, fabricated PPG prototype was clinically

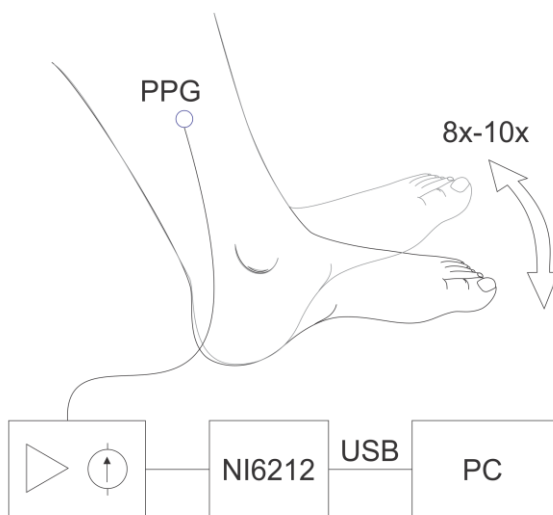


Figure 1: Measurement setup during clinical test

tested on 53 patients. Details of PPG prototype fabrication and characterisation are published elsewhere [14].

Duplex scanning with Doppler colour flow imaging of the leg was performed with a GE scanner equipped. Duplex scanning is considered as “gold standard” for detecting CVI. Patients were placed in a 30-degree reverse Trendelenberg position with the limb externally rotated. Scanning was performed with a linear array transducer equipped with a 5 MHz pulsed-wave Doppler scanning. The saphenofemoral junction and the saphenous vein were insonated and evaluated for the presence of superficial venous reflux (SVR) with the Valsalva maneuver. SVR was defined as pathologic finding for CVI.

The results of PPG refill times were evaluated and compared with the duplex ultrasonography results and were evaluated for sensitivity, specificity and efficiency.

## RESULTS

In period between October 2015 and September 2016 38 limbs of 25 patients were prospectively evaluated with PPG and duplex ultrasonography. The group consisted of 16 women and 9 men with age range from 34 to 85 years (a mean of 61,4 years). Clinical examination was performed at initial presentation with the standard criteria.

The analysis results of PPG show the CVI in 18 limbs and missed the disease in 4 limbs. In addition, PPG results show 13 normal limbs, but missed 3 limbs.

**sensitivity** or true positive rate (TPR)

$$TPR = TP / (TP + FN)$$

**specificity** (SPC) or true negative rate

$$SPC = TN / (TN + FP)$$

TP - true positive, TN - true negative

FP - false positive, FN - false negative

(1)

The calculated sensitivity and specificity of the PPG was 82 % and 81 % respectively (1). The efficiency

of the PPG method was calculated in amount of 82 %.

## DISCUSSION

Venous function of the lower limb has proved to be a difficult concept to quantify. Many tests were developed in an attempt to separate normal from abnormal function, including ambulatory venous pressures, foot volumetry, photoplethysmography, and air plethysmography. The presence of complications of venous disease provides a means for a crude classification of venous disease and is the "best" "gold standard," on the assumption that the presence and severity of clinical disease reflects venous function. In particular, the accepted gold standard of ambulatory venous pressure demonstrates a large overlap in the values take. The VRT as measured by photoplethysmography not only reflects reflux but also efficiency of calf pump function because inadequately emptied veins will need a shorter period of time to refill [4]. In clinical practice, however, we found a large degree of overlap of the results with subsequent poor separation of normal from clinically abnormal limbs thus reducing the test's usefulness. We therefore undertook to improve the PPG trace in an attempt to enable a more accurate analysis. The goal of our study was to evaluate the new PPG prototype instrument for detecting chronic venous insufficiency.

Bays [15] showed low specificity (60%) of PPG refill times and low  $\kappa$  statistic for correlation between SVR and VRT. It was only 0.47. Darvall [16] showed the correlation between abnormal VRT correlated and presence of SVR on duplex (sensitivity 75%). Iafrati [17] showed that PPG provides a sensitivity of approximately 75%, with specificity near 90%. In our study the abnormal VRT correlated well with the presence of SVR on duplex (sensitivity 72%, specificity 81%).

## CONCLUSION

Although PPG can provide an assessment of the overall physiologic function of the venous system, it is most useful as a relatively simple and non-invasive measurement to detect the presence of venous reflux. Duplex ultrasonography provides detailed information on segmental reflux, and PPG provides an estimate of the global effect of reflux on the limb. Because of its inability to reliably grade

the severity of CVI, PPG has limited utility for assessing the results of corrective venous surgical procedures. Therefore, PPG is a reasonable measure of the presence or absence of CVI that is best used when no further information concerning the venous hemodynamic situation is desired. If information on the severity of CVI or evaluation of improvement after venous surgery is required, a quantitative test will be more useful [18].

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