Digital Photoplethysmography in the Diagnosis of Suspected Lower Limb DVT: Is It Useful?

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Objective: to determine the role of digital photoplethysmography (D-PPG) in the diagnosis of deep-vein thrombosis (DVT), in comparison to the “gold standard” of either contrast ascending venography (ACV) or colour-flow duplex imaging (CFDI).

Method: prospective study of 100 hospital inpatients (103 legs) referred to the X-ray department for ACV or CFDI with clinically suspected lower limb DVT in a district general hospital. Each patient was assessed by either ACV or CFDI, and D-PPG.

Results: thirty-seven limbs were found to have DVT as demonstrated by ACV or CFDI. All patients with a venous refilling time (RT) of greater than 20 s and venous pump (VP) of greater than 35 had a normal ACV or CFDI. Using RT of less than 21 s as the optimal cut-off point, D-PPG achieved a sensitivity of 100%, negative-predictive value of 100%, specificity of 47% and positive-predictive value of 51%. By using VP of less than 36 as the optimal cut-off point, a sensitivity of 100%, a negative-predictive value of 100%, a specificity of 35% and positive-predictive value of 46% were achieved.

Conclusions: these results validate the use of portable D-PPG as a useful screening tool for the diagnosis of clinically suspected lower limb DVT. A positive test requires further confirmation by one of the “gold standard” methods, whereas a negative test effectively excludes DVT.

Key Words: Digital photoplethysmography (D-PPG); Light-reflection rheography (LRR); Deep-vein thrombosis (DVT); Venous refilling time; Colour-flow duplex imaging (CFDI); Venography.

Introduction

Deep-vein thrombosis (DVT) is a common condition among the general population, which, if left untreated, can lead to fatal pulmonary embolism (PE); therefore the diagnosis of DVT is essential. A recent study revealed that 10% of mortality in general hospitals in the United Kingdom was from pulmonary embolism.

Ascending contrast venography (ACV) as well as colour-flow duplex imaging (CFDI) are the “gold standard” investigations for diagnosing DVT. CFDI has been shown to be comparable to ACV in detecting proximal DVT (sensitivity 97% and specificity 99%) and distal DVT (sensitivity 87% and specificity 91%).

Despite these investigations being the current “gold standard” for the diagnosis of DVT, they are not without limitations. ACV is invasive, involves radiation exposure, and is associated with risk of significant morbidity such as thrombogenesis and adverse reactions to intravenous contrast agents. Although safe, CFDI is technically demanding, requiring expertise in performing the test and interpreting the results. In addition, both tests involve a considerable expense, in terms of time and cost. Of those patients with clinically suspected DVT, only about 20–30% who undergo these tests are found actually to have the condition. Thus, the remaining patients would have undergone ACV and/or CFDI unnecessarily.

Photoplethysmography is a non-invasive optical technique which has been widely used as a simple clinical method for assessing venous function. Digital photoplethysmography (D-PPG) is a further development of analogue light-reflection rheography (LRR), based on the principle of PPG. It differs from LRR in that it is assisted by microprocessor and possesses an inbuilt calibration mechanism, which regulates the intensity of infra-red light emitted from the light emitting diode (LED). The ability to calibrate allows for the correction of differences in colour and thickness of the skin, as well as the initial volume of the dermal microcirculation. For instance, the light intensity will increase with darker skin and decrease...
with lighter skin. With this technique, the venous refilling time measurement is standardised and, by measuring the extent of blood displacement from the calf, assessment of the calf pump efficacy is also possible. Although LRR has been shown by some studies to be a useful non-invasive screening test for patients with suspected lower limb DVT,5,13 to the best of our knowledge, there have been no studies validating the use of D-PPG in the assessment of DVT.

Like LRR and classical photoplethysmography, D-PPG detects the changes in the blood content of dermis by measuring the infra-red light reflected from the dermal microcirculation of the leg. The photoplethysmographic refilling time has been shown to have good correlation with the venous pressure refilling time (direct intravenous pressure measurement).10±13 In a normal subject, activation of the calf muscle pump (dorsiflexion of foot) will result in reduction of venous pressure and dermal blood volume. On the D-PPG, these physiological changes translate as decrease in light absorption and increase in light reflection. The efficacy of calf pump depends on the percentage of displacement of initial blood volume, which is represented on the D-PPG by the percentage change of light absorption and light reflection. Displacement of blood will be reduced or restricted in patients with venous valvular14 or venous obstructive disease as in DVT.15,16 The light absorption and reflection signals return to baseline on completion of the exercise as venous refilling occurs. Time taken for venous filling after exercise in a normal subject depends entirely on the arterial inflow.16 Normal venous refilling time has been reported to range from 18 to 40 s by direct invasive venous measurement15 but, in the presence of valvular incompetence in the superficial or deep veins, venous reflux reduces the refilling time of the dermal microcirculation. On the other hand, in DVT with obstruction to the deep veins, the rate at which blood empties from the calf and skin slows down and consequently venous refilling times become shorter.

Aims

The aim of this study was to determine the role of D-PPG in the diagnosis of DVT, by comparison to the “gold standard” of either ACV or CFDI. The possibility of additional confounding factors affecting the D-PPG measurements was also analysed.

Methods

This was a prospective study of 100 consecutive inpatients (103 legs) between August 1997 and July 1998 in a district general hospital, referred to the radiology department for ACV or CFDI with clinically suspected DVT, able to comply with the exercise programme (ten successive foot dorsiflexions) as required by D-PPG. There were no standard criteria used for the clinical diagnosis of DVT. The study protocol was approved by Wrexham Ethics Committee, North Wales Health Authority. All patients gave full consent for the study.

D-PPG was performed either before ACV and CFDI or within 24 h after ACV and CFDI. D-PPG was carried out mainly on the ward as a bedside test by one of the authors (YT). All ACVs were performed and reported by consultant radiologists, whereas all CFDIs were performed by consultant radiologists and a trained ultrasonographer, with the results of CFDIs being interpreted by the former. Neither the investigators using reference methods of diagnosis nor the D-PPG investigator were aware of each other’s findings.

The D-PPG device used in this study (Rheo Dopplex II PPG Huntleigh Diagnostics Ltd., Cardiff, U.K.) is also a fully functional, vascular bi-directional Doppler with appropriate probe. It is battery-driven and fully portable, weighing about 300 g including probe and battery. The probe is smaller and lighter (5 g) compared to LRR. It contains two light-emitting diodes (LED) and two adjacent photodetectors to permit continuous recording of the relative amount of blood in the dermal microcirculation resulting from venous emptying and refilling. Infra-red light with transmitting wavelength of 950 nm is beamed into the dermal microcirculation, and is then absorbed by the red blood cells. The amount of light absorption is dependent on the number of red blood cells in the circulation. The remaining unabsorbed light is reflected back to the sensor, and is then converted into a digital signal.

For the D-PPG examination, the patient was examined in the sitting position with the foot resting flat on the floor and knee flexed at an angle of about 110 degrees. The patient’s foot was insulated by a towel, in order to maintain a stable temperature. The sensor was attached to an area of skin approximately 10 cm superior to the medial malleolus with a double-sided adhesive tape. The D-PPG unit was then switched on. Calibration of the D-PPG unit normally took between 30 s to 1 min. The patient was then instructed to dorsiflex the foot in succession for 10 times in 15 s (venous emptying phase) in time to an audible metronome. The exercise was followed by resting the foot completely for 45 s when the metronome indicated the completion of the exercise (venous refilling phase). After completing the exercise, the patient was requested to refrain from
D-PPG in the Diagnosis of Suspected Lower Limb DVT

Venous refilling time (RT) = 39 s
Venous pump (VP) = 48
Half amplitude time = 25 s

Venous refilling phase (during rest)
Venous emptying phase (during exercise)

(a) (b)

Fig. 1. (a) PPG curve of a normal patient with normal venous refilling time (RT); (b) PPG curve of a patient with DVT confirmed by ACV/CFDI.

talking, deep breathing or moving, as these may distort the venous refilling. On completion of the test, venous refilling time (RT) and venous pump (VP) (efficacy of calf pump as represented by the amplitude of D-PPG curve) were automatically displayed on the LCD. A printout of the results with D-PPG curve was obtained at the same time or later (see Fig. 1) to be kept in the patient’s note for documentation purposes. A second set of D-PPG results was obtained for each patient immediately following the first examination, and both sets of results recorded separately for each patient.

ACV was performed using the standard procedure as described by Hemingway. 17 Fifty millilitres of low osmolar and non-ionic iodine contrast medium (Nipam 100) was used. The diagnosis of DVT was made by the presence of filling defect(s) and non-filling of the veins in the presence of collateral flow. Patients were considered to have proximal DVT if proximal veins (femoropopliteal) were involved, irrespective of involvement of calf veins.

CFDI (Diagnostic Ultrasound System, Model SSA-270A, Toshiba, Harrogate, U.K.) was performed as follows: the common and superficial femoral veins were assessed with the patient in supine position. The popliteal vein was examined with the patient lying on either side. The calf veins were studied with the patient sitting on the side of the table. Transducer probes of 7.5 MHz and 5 MHz were used. Pressure was applied, using the transducer probe, over the veins to check their compressibility. CFDI with flow augmentation and inspection of the vein during direct compression was also performed. The presence of DVT was indicated when the vein failed to be compressed or there was absence of colour in the vein lumen even with flow augmentation.

Additional data was recorded for each patient including age, previous history of DVT, patient’s anticoagulation status, presence of varicose veins, competency of saphenofemoral junction (SFJ) and saphenopopliteal junction (SPJ), as assessed by continuous-wave Doppler using the standard methods described by Mitchell, 18 and clinical assessment of lower limb peripheral pulses. For the purpose of this study, all positive ACV and positive CFDI examinations were termed “gold standard-positive”. The anticoagulation status of each patient was noted at the time when D-PPG was performed. Peripheral pulses assessed on the affected limb included femoral, popliteal, posterior tibial and dorsalis pedis pulses.

Statistical Analysis

Comparison between the new test (D-PPG) and the “gold standard” was performed. Sensitivity, specificity, predictive value of a positive and negative test and Fisher’s exact test were determined using $2 \times 2$ tables. 19,20 Unpaired data were analysed using Mann-Whitney test. 20 Receiver operating characteristic (ROC) 21 curves were constructed for each parameter. The area under each curve was calculated to reveal their discriminatory power for the new test. The Bayes theorem 22 was applied to calculate the post-test probability of a patient with and without DVT. Repeatability of the test was also assessed applying...
Bland–Altman plots. Multiple regression analysis was used to identify any additional factors that affect the RT and VP. A p value of <0.05 was considered as statistically significant. Statistical analysis was performed using STATA, V.4.0 (Stata Corporation, Texas 77840, U.S.A.).

Results

A total of 103 lower limbs in 100 patients with suspected DVT were assessed in the study. Of all the patients enrolled in the study, none were excluded due to unsatisfactory D-PPG results. Patients were referred from medical (including referral from Accident & Emergency department and General Practitioners) (77), surgical (15), orthopaedic (five), obstetrics and gynaecology (three) departments. The study sample of 68 females and 32 males had a median age of 61 years (range 26–91) and 59 years (27–88), respectively. The prevalence of DVT in this study was 36% (pre-test probability of 0.36).

The choice of either ACV or CFDI was left to the discretion of the individual consultant radiologist. ACV was performed on 45 limbs and CFDI was performed on 58 limbs. DVT was confirmed by ACV in 23 cases (proximal 17, distal six), whilst CFDI confirmed the presence of DVT in 14 cases (proximal 10, distal four). The demographic profile of the study sample is demonstrated in Table 1. Of those 10 patients with distal DVT, one calf vein was involved in three patients, two calf veins were involved in two patients and three calf veins were involved in five patients. One of the patients in the latter group was also found to have varicose veins clinically.

The RT and VP were the parameters of D-PPG used to compare with the “gold standard” methods. The higher value of each parameter, from both sets of data for each patient, was used in the analysis. This was meant to increase the safety margin by preventing patients with true DVT from being “ruled out” by the test.

Comparison of RT and VP values between patients without and with DVT were illustrated in Figs 2 and 3, respectively. Patients with DVT had a statistically significant shorter RT and lower VP when compared with those patients without DVT.

ROC curves were constructed for the RT and VP values (see Figs 4 and 5). The discriminatory power (area under the curve) of RT and VP were 75% and 74%, respectively. Because DVT is associated with significant morbidity and potentially fatal complications, missing a case is highly undesirable. Therefore, the optimal cut-off point for each parameter (i.e. RT and VP) obtained should achieve maximum true-positive rate (sensitivity) though compromising specificity (i.e. higher false-positive rate). RT of 21 s and VP of 36 were the optimal cut-off points obtained from the ROC curves based on the above criteria (see Figs 4 and 5). The sensitivity, specificity, positive-predictive value, negative-predictive value, likelihood ratio for positive and negative test, and of different cut-off points for RT and VP, are illustrated in Tables 2 and 3, respectively. By using RT of equal to or less than 20 s as the optimal cut-off point in indicating the presence of DVT, a sensitivity of 100% (95% confidence interval [CI], 91–100%), negative-predictive value of 100% (CI, 89–100%), specificity of 47% (CI, 35–60%), and positive-predictive value of 51% (CI, 39–63%) were achieved. By using VP of equal to or less than 36 as the optimal cut-off point, a sensitivity of 100% (CI, 91–100%), a negative-predictive value of 100% (CI, 85–100%), a specificity of 35% (CI, 23–48%) and positive-predictive value of 46% (CI, 35–57%) were achieved. Combining both RT and VP using the above cut-off points, a sensitivity of 100% (CI, 91–100%), a negative-predictive value of 100% (CI, 91–100%), a specificity of 56% (CI, 43–68%) and a positive-predictive value of 56% were obtained, whereby both specificity and positive-predictive value were improved. Thus, by employing the above optimal cut-off points, all patients with either proximal or distal DVT, confirmed by ACV/CFDI, were identified by D-PPG, though it also included some false-positives.

Fisher’s exact test using contingency tables comparing D-PPG and the “gold standard” methods (i.e. ACV/CFDI) for RT, VP and combination of RT and VP, using the optimal cut-off points, has yielded a p value of 0.0001 for each of those parameters. D-PPG also achieved a posterior probability for a positive test of 68%, 55% and 81% and a posterior probability for a negative test of 0% for RT, VP and combination of RT and VP, respectively.

By considering ACV and CFDI groups of patients separately, sensitivities of 100% and 100%, specificities of 54% and 43%, positive-predictive values of 69% and 35%, and negative-predictive values of 100% and 100% were achieved for RT respectively for ACV and CFDI. Using VP as the parameter, sensitivities of 100% and 100%, specificities of 45% and 29%, positive-predictive values of 65% and 31%, and negative-predictive values of 100% and 100% were obtained for ACV and CFDI, respectively. We analysed the influence of different independent variables on the RT and VP using step-wise backward multiple regression analysis. RT and VP were the dependent variables with age, presence of DVT, past history of DVT or affected lower limb,
Table 1. The demographic characteristics of study sample.

<table>
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<th>Gold standard-negative (n=66)</th>
<th>Total (n=103)</th>
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</tr>
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<td>60.7</td>
<td>60.9</td>
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<tr>
<td>Past DVT</td>
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<td>11</td>
</tr>
<tr>
<td>Presence of VV</td>
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</tr>
<tr>
<td>I</td>
<td>18</td>
<td>24</td>
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</tr>
<tr>
<td>II</td>
<td>2</td>
<td>10</td>
<td>12</td>
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<tr>
<td>III</td>
<td>3</td>
<td>2</td>
<td>5</td>
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<tr>
<td>IV</td>
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<tr>
<td>All present</td>
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<td>45</td>
<td>69</td>
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<tr>
<td>One absent</td>
<td>7</td>
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<tr>
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<td>6</td>
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<tr>
<td>More than two absent</td>
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<td>3</td>
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*Anticoagulation status (I) therapeutic (standard intravenous heparin infusion or clexane 1 mg/kg subcutaneously twice daily), (II) prophylactic (subcutaneous heparin 5000 units twice daily or subcutaneous clexane 40 mg once daily), (III) long-term anticoagulation (warfarin) for other reason(s), (IV) no anticoagulation.

Fig. 2. Box-whisker plot of RT in patients without and with DVT, confirmed by either ACV or CFDI. The median value is indicated by the horizontal line within the box. The lower (25%) and upper (75%) quartiles are represented by the box. The range is displayed by the “whiskers” of the diagram.

Fig. 3. Box-whisker plot of VP in patients without and with DVT, confirmed by either ACV or CFDI. The median value is indicated by the horizontal line within the box. The lower (25%) and upper (75%) quartiles are represented by the box. The range is displayed by the “whiskers” of the diagram.

presence of varicose veins, anticoagulation status, competency of SFJ and SPJ, and absence of peripheral pulses as the independent variables. Only age was significant (p < 0.001).

There were 50 patients with no evidence of venous disease (i.e. no DVT, past history of DVT and clinical evidence of varicose veins). RT and VP values in this group of patients reduced progressively with age. The correlation coefficients between RT and age, and VP and age have been calculated as -0.43 and -0.47, respectively, and they were statistically significant (Mann–Whitney p = 0.001 for both RT and VP) (see Figs 6 and 7).

Repeatability of D-PPG was assessed by using Bland–Altman plots.23 Repeated measurements from the original two sets of D-PPG results for RT and VP were examined. Plots showing difference (test 1–test 2) against mean for each patient were demonstrated

Eur J Vasc Endovasc Surg Vol 18, July 1999
in Figs 7 and 8. RT achieved a mean difference of 
-0.36, standard deviation of the differences of 5.68, 
and coefficient of repeatability of 11.36. On the other 
hand, VP achieved a mean difference of 1.83, standard 
deviation of the differences of 5.42 and coefficient of 
repeatability of 10.84.

Discussion

DVT is a widespread disease with an incidence of 
between 2.5% to 5% in the general population.25 It is 
estimated that 30±40% of patients with symptomatic 
DVT develop PE.25 Clinical diagnosis of patients with 
suspected DVT is notoriously unreliable, with only 
about 30% of patients shown to be positive on objective 
testing.4 Therefore, clinical diagnosis alone of sus-
pected DVT may result in unnecessary hospitalisation 
of patients and inappropriate anticoagulation therapy 
with potentially dangerous consequences.

Digital photoplethysmography (D-PPG) is a further 
development of light-reflection rheography (LRR), but 
with several advantages over LRR. D-PPG can be 
calibrated and it permits quantitative evaluation of 
blood displacement by compensating for different cu-
taneous optical densities as a result of skin colour, skin 
thickness and initial local blood volume. In addition, 
numerical results obtained with the D-PPG device are 
readily displayed on an LCD screen. This therefore 
obeviates bias introduced in LRR due to subjective 
interpretation for positive or negative results based 
on the shape of the curve and subjective measurement 
of a parameter from the graph. A limitation of the use 
of D-PPG is in groups of patients who are unable to 
comply with the exercise programme (i.e. performing 
ten successive foot dorsiflexions), due to confusion, 
paralysis or in those with foot trauma.

Table 2. Comparison of different RT cut-off points.

<table>
<thead>
<tr>
<th>Cut-off</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PVN*</th>
<th>PVP*</th>
<th>Fisher’s exact</th>
<th>Likelihood ratio</th>
<th>Posterior probability (%)</th>
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<td></td>
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<td>Positive Negative</td>
<td>Positive Negative</td>
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<tr>
<td>19</td>
<td>97%</td>
<td>49%</td>
<td>97%</td>
<td>51%</td>
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<td>1.89</td>
<td>0.05</td>
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<td></td>
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<td>(32/33)</td>
<td>(36/70)</td>
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<td></td>
</tr>
<tr>
<td>20</td>
<td>97%</td>
<td>47%</td>
<td>97%</td>
<td>51%</td>
<td>0.0001</td>
<td>1.83</td>
<td>0.06</td>
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<td>(31/32)</td>
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<td>21</td>
<td>100%</td>
<td>47%</td>
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<td>1.89</td>
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<tr>
<td></td>
<td>(37/37)</td>
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<td>(37/72)</td>
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<td>22</td>
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PVN = predictive value of negative test; PVP = predictive value of positive test.
Table 3. Comparison of different VP cut-off points.

<table>
<thead>
<tr>
<th>Cut-off</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PVN*</th>
<th>PVP*</th>
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<td>34</td>
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<td>40%</td>
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<tr>
<td>36</td>
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PVN = predictive value of negative test; PVP = predictive value of positive test.

Light-reflection rheography (LRR) has been demonstrated in various studies to be a useful non-invasive screening test in patients with suspected lower limb DVT. delta R/T (rate of venous emptying), achieved sensitivities of 96% and 96% and specificities of 71% and 78%, respectively. Abbott, using RT of 25 s as the cut-off point, achieved a sensitivity of 95.3% and a specificity of 53%. Thomas and Kuhlmann, however, using the shape of the LRR tracing, obtained sensitivities of 92% and 94.4%, and specificities of 84% and 68.4%, respectively.

In this study, with optimal cut-off points of RT and VP, D-PPG achieved a sensitivity and a negative-predictive value of 100% for both parameters, that is 0.43. Twenty-eight per cent (29 legs) of the study population have false-positive results using combination of RT and VP as the parameters. Of those with false-positive results, 12 of them had varicose veins with incompetency of both or either of the SFJ and SPJ in clinical. Studies have shown that venous refilling times are significantly reduced in patients with venous insufficiency. This is due to rapid refilling of dermal blood volume as a result of venous reflux. The specificity of D-PPG may therefore be improved in this group of patients by using below-knee tourniquet to abolish venous reflux, especially in those with primary varicose veins. Three patients had Baker’s cyst shown on ultrasound to be compressing the popliteal vein. This would have impeded the displacement of blood.
from the calf, resulting in a low VP and short RT. Two patients were in 36th (both legs) and 40th week of pregnancy, respectively, and it is well known that impairment of venous outflow due to compression of pelvic veins occurs in pregnancy. These three groups of patients would have low RT values due to either rapid venous filling or venous obstruction, regardless of presence or absence of DVT. However, our multiple regression analysis models showed that the presence of varicose veins did not significantly affect RT and VP values.

It is important to be aware that, as demonstrated by this study, RT and VP became progressively reduced with age in normal subjects, a finding also confirmed by Stacey.27 Consequently, the normality and abnormality of RT and VP become less distinct with age. This may be due to either inefficiency of the venous pump as a result of degenerative changes to valvular competency, reduced muscle mass or restricted mobility at the ankle joint, and thus contribute partly to the high false-positive rate.

The effect of reduced arterial inflow on venous refilling as measured by D-PPG was also assessed. The possibility of reduced arterial inflow due to arterial disease, which may have prolonged venous refilling time, has been questioned. If this is true, the presence of DVT could be missed. However, our multiple regression analysis models showed that clinical absence of peripheral pulses did not appear to influence venous refilling time as measured by D-PPG in our study. Stacey26 by employing ankle–brachial pressure index of <0.9, indicating the presence of arterial disease, has also confirmed this finding.

To our knowledge this is the first study to report repeatability on the D-PPG parameters (RT and VP), and this was shown that D-PPG is an acceptable measuring instrument. Its true application lies in its high negative-predictive value which enables confident exclusion of patients with DVT. However, because of its low specificity, it can never be substituted for ACV or CFDI. With the use of D-PPG, a significant number of patients (up to about 36% of our study population using combination of RT and VP) can be eliminated from having the invasive, expensive, technically specialised and time-consuming “gold standard” tests. This represents 56% of the non-DVT population in our study. Moreover, anticoagulation therapy, with its associated morbidity, can be avoided in these patients, with a beneficial effect in hospital bed resources. Overall, D-PPG is a satisfactory and reliable non-invasive screening test in the evaluation of DVT, as long as its shortcomings are understood.
D-PPG in the Diagnosis of Suspected Lower Limb DVT

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References


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