The use of strain-gauge plethysmography in the functional assessment of chronic venous disease: five-year experience at a single centre

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Abstract

Objective: Plethysmography can be used in the diagnosis and evaluation of chronic venous disease in the lower extremities. This study aimed to evaluate the applicability and reliability of strain-gauge plethysmography (SGP) in the functional assessment of chronic venous disease.

Methods: This descriptive study was conducted between 2016 and 2021 at a single centre. Four hundred and thirty-two patients with symptomatic chronic venous disease were included in the study. All participants were diagnosed initially with Doppler ultrasonography. SGP was then performed to evaluate venous outflow capacity, venous reflux and muscle pump function.

Results: The average age was 45.16 ± 12.54 years (median age 46 years; range 20–78 years), and 239 (55.3%) women and 193 (44.7%) men were included in the study. The age groups, diagnosis, pathological distribution and risk factors were quantitatively determined according to gender. Localisation and lateralisation statistics of the pathologies are given. SGP measurements, including venous volume (V), venous emptying (VE), expelled volume ratio in four seconds (EV4/V), half refilling time (t½) and refilling volume (RV) of each lower extremity, were done individually to compare the involved extremity with the normal contralateral side. SGP measurements of each affected lower limb were also compared separately by gender, age group and disease onset. The correlation between t½ values and skin discolouration or oedema of the affected limb was examined. Finally, receiver operating characteristic curve analyses of the V, VE, EV4/V, t½ and RV values were done, and the cut-off values of each parameter were defined accordingly.

Conclusion: High reliability and consistent results indicate that SGP is a practical and sensitive test for quantitative functional assessment of patients with chronic venous disease. It can be used as an effective method in diagnosing and following up chronic venous disorders. As there are no currently accepted cut-off values, we suggest that ours can be used as new reference values for SGP measurements.

Keywords: plethysmography, diagnostic techniques, cardiovascular, venous insufficiency, venous thrombosis
photoplethysmography, where SGP and APG can quantitatively
determine both venous outflow and venous valve function.11 SGP is a non-invasive test for CVD, determining the venous
capacitance, venous outflow rate, and venous refilling time (a measure of valvular competence).12 The procedure is also simple, painless and easily performed in about 20 minutes, with a rapid result.10 The strain gauge is wrapped around the larger circumference of the calf. Volumetric changes in calf circumference cause proportional change in gauge length and, therefore, in its electrical resistance.11 This study researched the convenience and reliability of SGP in the assessment of patients with CVD.

Methods

This was a descriptive study conducted in the Department of Cardiovascular Surgery, Faculty of Medicine, Kafkas University, between June 2016 and May 2021. The study included 432 patients referred to the vascular clinic owing to symptomatic CVD diagnosed with DUS imaging. The study was approved by the Kafkas University Research Ethics Committee (issue nr. 2016/0071) and conducted according to the Helsinki Declaration.

There were 193 (44.7%) men and 239 (55.3%) women, with a mean age of 45.16 ± 12.54 years (range 20–78). The inclusion criteria were the presence of a CVD diagnosed with DUS and a signed informed consent form showing the patients were willing to volunteer for participation. The exclusion criteria were unwillingness to participate in the study, lack of or doubtful CVD, and conditions in which the simultaneous SGP measurements failed.

The researchers prepared the data-collection form to register the patients’ data and SGP measurements. According to a detailed physical examination, the patients’ data, disease staging, and oedema or pigmentation were noted in this form. Lastly, bilateral lower-extremity measurements were done in each patient with the SGP. In this study, a single SGP device (Venometer® V3, Amtec Medical Ltd, Antrim, UK) and its indium gallium strain gauges were used for the examination of all patients. All measurements were taken following the operating manual.13 According to the manual, the positioning of the patient is critical. The patients should lie down in a supine position and horizontally with minimum back lift. They should also keep stationary in this position during the measurements as the SGP is extremely precise in recording unwanted movements, resulting in diagnostic variables being wrongly measured. During the test, the arms should also be relaxed and lie next to the patient.

The foot positioner apparatus supports the feet with an adequate flexion degree of the femur. If the femur’s flexion is not sufficient, and if the patients feel a lack of support underneath, they tend to maintain the leg position with the muscular tonus. This muscle contraction may be impossible for a geriatric patient; however, a young individual unconsciously balances the leg position with maintained muscle tonus. In both cases, muscle tonus leads to vasoconstriction and decreases the venous blood flow as in DVT, causing misdiagnosis. The foot positioner may be supported if it is needed to be more stable.

The contralateral extremity may be positioned on or under the foot positioner. Some patients may feel more comfortable if mild analgesia is applied before the procedure. Patient comfort is essential for accurate results. If the patient is nervous, feels chilly, or has pain, the venous system may close itself, leaving a venous disease undiagnosed. Finally, the strain-gauge cuff is wrapped around the calf muscle and tightened with velcro. A cable connection is then made with the plethysmography device to start the measurements.

The following five parameters were measured:

- **venous volume (V):** the volume during venous occlusion under 60 mmHg pressure of inflated cuff in the capacitance mode (ml/100 ml)
- **venous emptying (VE):** time of venous outflow (ml/100 ml/min)
- **expelled volume ratio in four seconds (EV4/V):** the ratio of expelled blood volume in four seconds over the total volume, indicating the venous outflow
- **half refilling time (t½):** filling time of half of the venous volume, indicating the venous reflux (seconds), which alters with exercise
- **refilling volume (RV):** this is another parameter altered with exercise, indicating the muscle pump function (ml/100 ml).

The patients were requested to shake their legs 15 times before taking the t½ and RV measurements.

Statistical analysis

The SPSS 20.0 for Windows (SPSS, Inc; Chicago, USA) statistical software was used for statistical analyses. The descriptive values are defined as number (n), percentage (%), average (Avr), standard deviation (SD) and median. Pearson’s chi-squared test was used for the comparison of categorical variables. Continuous variables were compared with non-parametric Mann–Whitney U- and Kruskal–Wallis tests as they were unsuitable for the normality assessment done with Kolmogorov–Smirnov and Shapiro–Wilk tests. The Spearman correlation test was used for the correlation between continuous variables. Diagnostic features of the measurement values over CVD diagnosis were analysed with receiver operating characteristics (ROC) curves.

In the presence of significant limiting values, the sensitivity and specificity values were calculated. Statistical significance was accepted as p < 0.05.

Results

Four hundred and thirty-two patients, including 239 (55.3%) women and 193 (44.7%) men, were included in the study. The average age was 45.16 ± 12.54 years (median age 46 years; range 20–78 years). The age groups were determined as 20–29 years (56 patients; 13.0%), 30–39 years (114 patients; 26.4%), 40–49 years (102 patients; 23.6%), 50–59 years (101 patients; 23.4%) and above 60 years (59 patients; 13.6%).

All participants initially underwent DUS imaging and were diagnosed with DVT (49.8%), CVI (40.0%), thrombophlebitis (5.6%) and DVI (4.6%) (Table 1). The pathological distributions were quantitatively determined in women as DVT (46.9%), CVI (42.2%), thrombophlebitis (6.3%) and DVI (4.6%), and in men as DVT (53.4%), CVI (37.3%), thrombophlebitis (4.6%) and DVI (4.7%). There was no significant difference regarding the diagnostic distribution between the genders (p = 0.559).

Localisation and lateralisation statistics of the pathologies revealed that left-sided involvement was slightly more
predominant, although the right greater saphenous vein (GSV) was the most affected site (Table 2). The pathologies were located mainly on the left side in both women (53.6%) and men (50.8%). There was no significant difference regarding localisation and lateralisation between the genders ($p = 0.316$).

Among the various risk factors, immobilisation, genetic factors and smoking were the leading causes (Table 3). The three major risk factors in the men were smoking (17.6%), immobilisation (15.0%) and genetic factors (11.9%). However, in women, the three primary risk factors were pregnancy (16.3%), oral contraceptives plus smoking (12.6%) and immobilisation (11.3%). Regarding the course of CVD, chronic cases were predominant (49.5%). The rest of the cases were acute (39.1%) and acute exacerbation on a chronic background (11.3%) (Table 4).

SGP measurements of each lower extremity were done individually to compare the involved extremity with the normal contralateral side. Measurements of patients with right-sided involvement are provided in Table 5. According to these measurements, mean VE of the right leg was $90.45 \pm 9.35$ ml/100 ml/min and of the left leg, it was $101.69 \pm 6.75$ ml/100 ml/min; V of the right leg was $6.45 \pm 0.14$ ml/100 ml/min and of the left leg, it was $6.18 \pm 0.06$ ml/100 ml/min; EV4/V of the right leg was $0.63 \pm 0.07$ and of the left leg, it was $0.73 \pm 0.05$; R V of the right leg was $6.45 \pm 0.14$ ml/100 ml; t½ of the right leg was $6.30 \pm 0.06$ and of the left leg, it was $6.20 \pm 0.06$ seconds, R V: refilling volume, t½: half refilling time, R: right, L: left, SD: standard deviation.

Measurements of patients with left-sided involvement are provided in Table 6. According to these measurements, the mean VE of the right leg was $105.08 \pm 3.66$ ml/100 ml/min and of the left leg, it was $87.99 \pm 9.49$ ml/100 ml/min; V of the right leg was $6.20 \pm 0.09$ ml/100 ml/min and of the left leg, it was $6.58 \pm 0.22$ ml/100 ml/min; t½ of the right leg was $6.50 \pm 0.34$ and of the left leg, it was $6.00 \pm 0.34$ seconds, R V: refilling volume, t½: half refilling time, R: right, L: left, SD: standard deviation.
0.22 ml/100 ml; EV4/V of the right leg was 0.73 ± 0.05 and of the left leg, it was 0.63 ± 0.08; RV of the right leg was 1.49 ± 0.16 ml/100 ml and of the left leg, it was 1.29 ± 0.34 ml/100 ml; t½ of the right leg was 11.94 ± 0.16 s and of the left leg, it was 6.65 ± 0.80 s. Statistically significant difference was present in all five parameters between the affected left and the unaffected right leg.

The SGP measurements of each affected lower limb are compared separately by gender in Table 7. In the right-sided pathologies, EV4/V (p = 0.009), RV (p = 0.017) and t½ (p = 0.005) were statistically significantly different between the genders. In the left-sided pathologies, only EV4/V was statistically significantly different (p = 0.020) between the genders.

In Table 8, SGP measurements of each affected lower limb are compared in different age groups. According to these values, in right-sided pathologies, VE (p = 0.002), V (p = 0.026), EV4/V (p < 0.001), RV (p = 0.002) and t½ (p < 0.001) were statistically significantly different between the age groups. Similarly, in left-sided pathologies, VE (p = 0.022), V (p = 0.096), EV4/V (p = 0.085), RV (p = 0.007) and t½ (p = 0.003) were also statistically significantly different between the age groups. This table also demonstrates that V was increased by advanced age, whereas VE, EV4/V, RV and t½ values decreased with advanced age.

In Table 9, SGP measurements of each affected lower limb are compared with different disease onsets. According to these values, all measurements, including both limbs, were statistically significantly different in terms of disease onset.

The correlation between t½ values and skin discolouration or oedema of the affected limb is provided in Table 10. According to these values, t½ did not correlate with the presence of oedema in the right-sided pathologies and had a negative correlation with skin discolouration (r = –0.38, p < 0.001). In other words, skin discolouration increased when the t½ shortened, and
skin discolouration decreased when $t_{1/2}$ was lengthened. In the left-sided pathologies, $t_{1/2}$ had a negative correlation with both oedema ($r = -0.31$, $p < 0.001$) and skin discolouration ($r = -0.26$, $p < 0.001$). In other words, more oedema and skin discolouration were observed in patients with a low $t_{1/2}$ value.

ROC curve analyses of VE values are given in Fig. 1 (right leg) and Fig. 2 (left leg). The right-sided pathologies with a value of 81.00 showed 83.5% sensitivity and 78.8% specificity. The left-sided pathologies with a value of 80.50 showed 76.5% sensitivity and 89.6% specificity. However, the value of 79.00 showed 88.1% sensitivity and 44.8% specificity.

ROC curve analyses of V values are given in Fig. 3 (right leg) and Fig. 4 (left leg). The right-sided pathologies with a value of 6.57 showed 86.9% sensitivity and 82.3% specificity. The left-sided pathologies with a value of 6.77 showed 82.2% sensitivity and 97.1% specificity.

ROC curve analyses of EV4/V values are given in Fig. 5 (right leg) and Fig. 6 (left leg). The right-sided pathologies with a value of 0.57 showed 76.9% sensitivity and 82.3% specificity. The left-sided pathologies with a value of 0.54 showed 87.6% sensitivity and 25.8% specificity. However, the value of 0.56 showed 70.8% sensitivity and 80.2% specificity.

ROC curve analyses of RV values are given in Fig. 7 (right leg) and Fig. 8 (left leg). The right-sided pathologies with a value of 1.09 showed 78.2% sensitivity and 96.7% specificity. The left-sided pathologies with a value of 1.09 showed 75.2% sensitivity and 52.3% specificity.

ROC curve analyses of $t_{1/2}$ values are given in Fig. 9 (right leg) and Fig. 10 (left leg). The right-sided pathologies with a value of 5.25 showed 68.9% sensitivity and 99.7% specificity. The left-sided pathologies with a value of 5.40 showed 78.3% sensitivity and 99.3% specificity.

### Table 9. Comparing plethysmography measurements of right- and left-sided pathologies in different disease onsets

<table>
<thead>
<tr>
<th>Disease onset</th>
<th>VE (R)</th>
<th>VE (L)</th>
<th>V (R)</th>
<th>V (L)</th>
<th>EV4/V (R)</th>
<th>EV4/V (L)</th>
<th>RV (R)</th>
<th>RV (L)</th>
<th>t½ (R)</th>
<th>t½ (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>83.19</td>
<td>82.70</td>
<td>6.52</td>
<td>6.71</td>
<td>0.57</td>
<td>0.60</td>
<td>1.14</td>
<td>1.12</td>
<td>5.46</td>
<td>6.09</td>
</tr>
<tr>
<td>Number</td>
<td>94</td>
<td>75</td>
<td>94</td>
<td>75</td>
<td>94</td>
<td>75</td>
<td>94</td>
<td>75</td>
<td>94</td>
<td>75</td>
</tr>
<tr>
<td>SD</td>
<td>4.13</td>
<td>3.05</td>
<td>0.12</td>
<td>0.05</td>
<td>0.04</td>
<td>0.03</td>
<td>0.12</td>
<td>0.01</td>
<td>0.74</td>
<td>0.93</td>
</tr>
<tr>
<td>Median</td>
<td>83.00</td>
<td>84.00</td>
<td>6.55</td>
<td>6.75</td>
<td>0.56</td>
<td>0.60</td>
<td>1.10</td>
<td>1.12</td>
<td>5.00</td>
<td>6.00</td>
</tr>
<tr>
<td>Minimum</td>
<td>72.00</td>
<td>74.00</td>
<td>6.30</td>
<td>6.60</td>
<td>0.49</td>
<td>0.55</td>
<td>1.00</td>
<td>1.08</td>
<td>5.00</td>
<td>5.80</td>
</tr>
<tr>
<td>Maximum</td>
<td>100.00</td>
<td>89.00</td>
<td>7.00</td>
<td>8.80</td>
<td>0.77</td>
<td>0.75</td>
<td>1.60</td>
<td>1.15</td>
<td>9.00</td>
<td>14.00</td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>97.22</td>
<td>96.01</td>
<td>6.38</td>
<td>6.38</td>
<td>0.68</td>
<td>0.71</td>
<td>1.46</td>
<td>1.53</td>
<td>7.05</td>
<td>7.79</td>
</tr>
<tr>
<td>Number</td>
<td>109</td>
<td>105</td>
<td>109</td>
<td>105</td>
<td>109</td>
<td>105</td>
<td>109</td>
<td>105</td>
<td>109</td>
<td>105</td>
</tr>
<tr>
<td>SD</td>
<td>7.02</td>
<td>6.83</td>
<td>0.10</td>
<td>0.16</td>
<td>0.05</td>
<td>0.06</td>
<td>0.12</td>
<td>0.12</td>
<td>1.11</td>
<td>1.48</td>
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<tr>
<td>Median</td>
<td>98.00</td>
<td>94.00</td>
<td>6.35</td>
<td>6.35</td>
<td>0.68</td>
<td>0.70</td>
<td>1.50</td>
<td>1.60</td>
<td>6.50</td>
<td>7.00</td>
</tr>
<tr>
<td>Minimum</td>
<td>78.00</td>
<td>80.00</td>
<td>6.20</td>
<td>6.15</td>
<td>0.55</td>
<td>0.55</td>
<td>1.05</td>
<td>1.05</td>
<td>5.00</td>
<td>5.00</td>
</tr>
<tr>
<td>Maximum</td>
<td>108.00</td>
<td>115.00</td>
<td>6.78</td>
<td>6.78</td>
<td>0.80</td>
<td>0.82</td>
<td>1.60</td>
<td>1.65</td>
<td>10.00</td>
<td>10.00</td>
</tr>
</tbody>
</table>

Acute exacerbation on chronic onset

| Average             | 72.00  | 78.28  | 7.00  | 6.80  | 0.50      | 0.52      | 1.00   | 1.03   | 5.00   | 5.00   |
| Number              | 3      | 46     | 3     | 46    | 3        | 46        | 3      | 46     | 3      | 46     |
| SD                  | 3.60   | 5.83   | 0.00  | 0.08  | 0.00     | 0.01      | 0.00   | 0.02   | 0.00   | 0.00   |
| Median              | 71.00  | 79.00  | 7.00  | 6.80  | 0.50      | 0.52      | 1.00   | 1.05   | 5.00   | 5.00   |
| Minimum             | 69.00  | 66.00  | 7.00  | 6.74  | 0.50      | 0.49      | 1.00   | 1.00   | 5.00   | 5.00   |
| Maximum             | 76.00  | 88.00  | 7.00  | 7.00  | 0.50      | 0.55      | 1.00   | 1.05   | 5.00   | 5.00   |

p-value* 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000

*Kruskal–Wallis test.


### Table 10. Correlation analyses between half refilling time ($t_{1/2}$) and the presence of oedema or skin discolouration in the affected limb

<table>
<thead>
<tr>
<th>Pathologies</th>
<th>Rank correlation coefficient ($r$)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right-sided pathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of oedema</td>
<td>–0.045</td>
<td>0.524</td>
</tr>
<tr>
<td>Presence of skin discolouration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left-sided pathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of oedema</td>
<td>–0.301</td>
<td>0.000</td>
</tr>
<tr>
<td>Presence of skin discolouration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Spearman’s correlation test.

of 81.00 showed 83.5% sensitivity and 78.8% specificity. The left-sided pathologies with a value of 80.50 showed 76.5% sensitivity and 89.6% specificity. However, the value of 79.00 showed 88.1% sensitivity and 44.8% specificity.

ROC curve analyses of V values are given in Fig. 3 (right leg) and Fig. 4 (left leg). The right-sided pathologies with a value of 6.57 showed 86.9% sensitivity and 82.3% specificity. The left-sided pathologies with a value of 6.77 showed 82.2% sensitivity and 97.1% specificity.

ROC curve analyses of EV4/V values are given in Fig. 5 (right leg) and Fig. 6 (left leg). The right-sided pathologies with a value of 0.57 showed 76.9% sensitivity and 82.3% specificity. The left-sided pathologies with a value of 0.54 showed 87.6% sensitivity and 25.8% specificity. However, the value of 0.56 showed 70.8% sensitivity and 80.2% specificity.

ROC curve analyses of RV values are given in Fig. 7 (right leg) and Fig. 8 (left leg). The right-sided pathologies with a value of 1.09 showed 78.2% sensitivity and 96.7% specificity. The left-sided pathologies with a value of 1.09 showed 75.2% sensitivity and 52.3% specificity.

ROC curve analyses of $t_{1/2}$ values are given in Fig. 9 (right leg) and Fig. 10 (left leg). The right-sided pathologies with a value of 5.25 showed 68.9% sensitivity and 99.7% specificity. The left-sided pathologies with a value of 5.40 showed 78.3% sensitivity and 99.3% specificity.
Discussion
This study reveals that SGP can be used as an effective method for the diagnosis and follow up of CVD. It may become an alternative diagnostic tool for clinicians who have limited access to a radiology service or require additional information, obtained by imaging techniques. A detailed assessment of plethysmographic measurements in this study, with the largest patient population ever reported in the current literature, also provides new reference values.

A plethysmograph is a device for measuring volume changes within an organ or body part by detecting fluctuations in the blood volume. The word is derived from plethysmos, which in Greek means enlarging, increasing and becoming full.

SGP has been used for the detection and evaluation of venous incompetence of the lower extremities.\textsuperscript{11} It provides information about the degree of venous filling (venous capacitance) and the rate of venous emptying (venous outflow).\textsuperscript{12} The principles of venous occlusion SGP were first introduced in 1953 by Whitney, who used a mercury-in-rubber strain gauge.\textsuperscript{14} Clinical use of a computerised version of SGP was then introduced in the 1990s.\textsuperscript{11} At the same time, there was an increasing interest in non-invasive functional tests, which could quantitatively describe the exact
haemodynamic pathology, and providing additional information over imaging techniques. By using novel indium gallium strain gauges, SGP became easier to handle and a user-friendly instrument with better reproducibility than its predecessors. Our results demonstrate that SGP is a practical and sensitive method to define venous outflow capacity and to evaluate venous reflux and muscle pump function. The demographics and risk factors should first be described in order to accurately interpret the results of such a quantitative functional test.

This study represents five-year data of SGP measurements of 432 patients consisting of 239 women (55.3%) and 193 men (44.7%) in a single centre. There was an evident numerical predominance in favour of women. A similar study also revealed a 57% female predominance, and another reported 66%, with a 1:2 (male:female) ratio. This is thought to be because the risk factors pregnancy and oral contraceptive use occur only in women. Also sedentary lifestyle and obesity are more common risks in women compared to men. These risk factors may have caused women to predominate in these studies.

The average age was 45.1 years in this study. Similar studies have demonstrated nearly the same demographics, with an average age of 46.0 and 50.6 years, respectively. Although CVDs are seen in all age groups, it can be deduced that the middle age group is more affected by these diseases.

When we examined the location of pathologies in this study, it can been that the left side was slightly more predominant (52.3%), but the most common site was the right GSV. Similar results are presented in other studies, with a ratio of 71.4 and 55.7% dominancy in left-sided involvement. Venous outflow (VE, EV4/V), venous reflux (t½) and muscle pump function (RV) measurements were found to be significantly lower in legs with CVD compared to healthy legs. Oedema was detected in 82.4% and skin discolouration in 86.8% of all participants. Another article reported 74% oedema and 43% skin discolouration. Such findings are similarly associated with CVD.

Results of the SGP measurements performed on the involved extremity were compared according to gender. The values of EV4/V (p = 0.009), RV (p = 0.017) and t½ (p = 0.005) were found to be statistically significantly different between the genders in patients with right-sided pathology. However, only EV4/V (p = 0.020) was found to be significantly different between the genders in patients with left-sided pathology.

Results of the SGP measurements performed on the involved extremity were compared according to age group. In general, it was observed that the values of VE, EV4/V, RV and t½ decreased with older age, while the value of V increased with older age. In another study, although no significant difference was found between the genders, similar variables were higher as the age
increased. A possible reason for this may be atherosclerosis and decrease in valvular function as age increases.

SGP measurements performed in the pathological extremity were compared according to onset of disease. All measurement results performed on both extremities showed that there was a statistically significant difference between disease onset and measurement values. In general, as the disease progressed from acute to chronic stages, the values of VE, EV4/V, RV and t½ increased, and the value of V decreased. This may represent adaptation of venous capacitance to the chronic status. As chronic disease predominated in the study population, this was expected to reflect the measurement results.

The correlation between t½ values and skin discolouration or oedema in the affected leg was examined. Although t½ values did not correlate with the presence of oedema in the right extremity, it was negatively correlated with skin discolouration \( (r = -0.38, p < 0.001) \). In other words, as t½ got shorter in the right extremity, the skin discolouration increased, and it decreased as t½ got longer.

In the left extremity, t½ was negatively correlated with both the presence of oedema and skin discolouration. In other words, the lower the t½ measurement, the more oedema and skin discolouration was observed in those individuals. In similar articles, t½ was also negatively correlated with oedema \( (r = -0.28, p < 0.05) \) and skin discolouration \( (r = -0.58, p < 0.001) \). These results indicate that CVD patients can be evaluated better by combining physical examination and SGP.

Since there was no control group in this study, the normal legs of participants, which had no pathology, were considered the control to demonstrate the diagnostic power of SGP. Venous DUS was taken as the gold standard, and sensitivity and specificity values of SGP were calculated accordingly.

Sample values are given as findings since there are currently no accepted SGP cut-off values. In fact, for VE measurements, a value of 81.00 had a sensitivity of 83.5% and a specificity of 78.8% in patients with right-sided pathology, and a value of 80.50 for patients with a left-sided pathology had a 76.5% sensitivity and 89.6% specificity.

For V measurements, the value of 6.57 had 86.9% sensitivity and 82.3% specificity for patients with right-sided pathology, and for patients with left-sided pathology, 6.77 had a sensitivity of 82.2% and a specificity of 97.1%. For EV4/V measurements, a value of 0.57 had a sensitivity of 76.9% and a specificity of 82.3% in patients with right-sided pathology, and a value of 0.54 had an 87.6% sensitivity and 25.8% specificity in patients with left-sided pathology.

For RV measurements, a value of 1.09 had a sensitivity of 78.2% and a specificity of 96.7% for patients with right-sided pathology, and for patients with left-sided pathology a value of 1.09 had a sensitivity of 75.2% and a specificity of 52.3%. For t½ measurements, 5.25 was found to have a 68.9% sensitivity and 99.7% specificity for patients with right-sided pathology, and for patients with left-sided pathology, 5.40 had a sensitivity of 78.3% and a specificity of 99.3%.

In another study, SGP had an 84.6% sensitivity and 83.9% specificity in diagnosing DVT. In a study conducted in England, the sensitivity was 93% and specificity was 80%. In the study conducted by Langford et al. in 2009, the sensitivity was 93% and the specificity was 95%. As can be seen from the results, SGP can be used in both the diagnosis and follow up of CVD, including DVT and other venous insufficiencies.

Although the results of this study cannot be adapted to the general population due to the limited number of patients and the absence of a control group, we consider SGP to be a good option for functional evaluation of patients with CVD. Replacement of the earlier strain gauges made of mercury with new indium gallium strain gauges gives SGP a more user-friendly design. This increased functionality makes SGP a cost-effective alternative to other plethysmographic devices used for similar purposes. Therefore SGP could be an alternative for clinicians who have limited access to a radiology service in remote settlements or require additional functional information obtained by clinical investigation and imaging techniques.

Conclusion

SGP was found to be an effective method in the diagnosis and follow up of CVD. In this study, we performed for the first time a detailed assessment of the influence of critical confounding factors and physiological variables on different plethysmographic measurements on the largest reported patient population in the literature. In addition, this study provides new reference values. As there are currently no accepted cut-off values, we suggest that ours can be used as new reference values for SGP measurements.

We believe these results show increased usefulness of SGP in the functional assessment of patients with CVD and provide vital information, which was lacking on SGP. Conducting more comprehensive studies on this subject and determining the cut-off values for SGP measurements could provide earlier diagnosis and information on the degree of progression of CVD.

References


