Intermittent Claudication: An Objective Office-Based Assessment

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OBJECTIVES
We sought to compare standard lower extremity vascular laboratory treadmill exercise with the office-based active pedal plantarflexion technique.

BACKGROUND
Intermittent claudication is relatively common in elderly patients and is an important predictor of cardiovascular morbidity and mortality. Noninvasive testing using resting and posttreadmill exercise ankle:brachial systolic blood pressure indices is often required to confirm the diagnosis and objectively assess the severity of lower extremity arterial occlusive disease. This is traditionally performed in a formal vascular laboratory setting.

METHODS
Fifty consecutive patients (100 lower extremities) with known or suspected intermittent claudication referred for lower extremity treadmill exercise testing were also tested with active pedal plantarflexion using a prospective, randomized crossover design. Supine ankle:brachial systolic blood pressure indices were measured immediately before and after each form of exercise.

RESULTS
There was an excellent correlation (r = 0.95, 95% confidence interval 0.93 to 0.97) between mean postexercise ankle:brachial systolic blood pressure indices for treadmill exercise and active pedal plantarflexion. There was no significant difference in outcome based on the order of testing or the severity of arterial occlusive disease. Symptoms of angina or dyspnea occurred in 11 patients (22%) with treadmill exercise versus zero patients with active pedal plantarflexion.

CONCLUSIONS
Active pedal plantarflexion is an office-based test that compares favorably with treadmill exercise for the noninvasive, safe, objective and economical assessment of lower extremity arterial occlusive disease. (J Am Coll Cardiol 2001;37:1381–5) © 2001 by the American College of Cardiology
Vascular Laboratory for assessment of PAOD. Prior experience had demonstrated that there would be significant numbers of both normal and abnormal test results in such a population. If normal is defined as a post-treadmill exercise ABI $>0.90$, then there were 34 normal limbs and 66 abnormal limbs in the study. Exclusion criteria included noncompressible vessels (ankle systolic blood pressure $>300$ mm Hg or $>50$ mm Hg higher than brachial systolic blood pressure), critical limb ischemia and inability to walk on a treadmill or perform active pedal plantarflexion.

**Testing protocol.** A crossover design was used so that all subjects underwent both treadmill and APP testing. The schema is illustrated in Figure 1. The order of testing was randomized. Rest periods of 15 and 30 min were allowed before and after the first test, respectively. Ankle:brachial indices were performed immediately before and within the first minute after each form of exercise. Ankle systolic blood pressures were obtained using a Doppler stethoscope (MedaSonic, Minnetonka, Minnesota) with an appropriately sized blood pressure cuff placed just above the ankle. Blood pressure cuffs were kept consistent throughout the study. The posterior tibial artery, because it is easier to locate, was used preferentially over the dorsalis pedis artery whenever possible. Optimum signal position was marked with a temporary ink skin dot to facilitate rapid relocation of the pulse following exercise. The same pedal artery was used for both tests. If no pedal artery Doppler signal was detected, the ABI was taken to be zero. Brachial artery systolic blood pressures were obtained manually using standard auscultation technique. The higher of the two brachial artery systolic blood pressures was used to calculate the ABI.

The treadmill protocol consisted of a 5-min walk on a 10% grade at 2 miles per hour (mph). If the subject was unable to walk at 2 mph, the speed was reduced to 1.5 or 1.0 mph as required. Treadmill exercise was symptom-limited so that premature termination of exercise was permitted if the subject was experiencing undue lower extremity discomfort, angina, dyspnea or significant arrhythmia.

The APP protocol (Fig. 2), also symptom-limited, consisted of up to 50 consecutive repetitions of active ankle plantarflexion while standing. The knees were to be kept fully extended. Subjects were allowed fingertip support against a wall to assist with balance.

**Statistics.** The means and standard deviations of the baseline and post-test ABIs for APP and treadmill testing were calculated, along with the means and standard deviations of the paired differences. Paired $t$ tests tested whether the paired difference means were significantly different from zero. Pearson correlation coefficients were calculated to assess the agreement between APP and treadmill mean ABIs. Subgroups were compared to assess the effects of order of testing and disease severity. Also, a Bland-Altman plot, which plots the difference versus the mean of the APP and treadmill post-test ABIs, was constructed to examine the difference between the two tests as a function of the level of ABI in that subject.

Because data on both legs of each subject were pooled for analysis, the assumption of independence was in question.

### Abbreviations and Acronyms
- **ABI** = ankle:brachial index
- **APP** = active pedal plantarflexion
- **PAOD** = peripheral arterial occlusive disease
- **r** = Pearson correlation coefficient
- **SD** = standard deviation

![Figure 1. Schema of study design. ABI = ankle:brachial index; APP = active pedal plantarflexion.](image1)

![Figure 2. Active pedal plantarflexion technique. The subject begins standing flat-footed and raises his heels as high as possible while keeping the knees straight. He then immediately lowers his heels and repeats the cycle for up to 50 consecutive repetitions.](image2)
Table 1. Effect of Order of Testing

<table>
<thead>
<tr>
<th>First Test</th>
<th>Time</th>
<th>n</th>
<th>APP ABI Mean ± SD</th>
<th>Treadmill ABI Mean ± SD</th>
<th>p Value</th>
<th>r Value</th>
<th>Mean Difference</th>
<th>SD of Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>APP</td>
<td>Baseline</td>
<td>50</td>
<td>0.97 ± 0.28</td>
<td>0.97 ± 0.26</td>
<td>0.67</td>
<td></td>
<td>0.0069</td>
<td>0.084</td>
</tr>
<tr>
<td></td>
<td>Post-test</td>
<td>50</td>
<td>0.73 ± 0.34</td>
<td>0.75 ± 0.33</td>
<td>0.11</td>
<td></td>
<td>0.022</td>
<td>0.098</td>
</tr>
<tr>
<td>Treadmill</td>
<td>Baseline</td>
<td>50</td>
<td>0.92 ± 0.20</td>
<td>0.88 ± 0.20</td>
<td>0.0002</td>
<td></td>
<td>-0.048</td>
<td>0.083</td>
</tr>
<tr>
<td></td>
<td>Post-test</td>
<td>50</td>
<td>0.60 ± 0.35</td>
<td>0.59 ± 0.36</td>
<td>0.61</td>
<td></td>
<td>-0.0095</td>
<td>0.13</td>
</tr>
</tbody>
</table>

ABI = ankle:brachial index; APP = active pedal plantarflexion; n = number of subjects; p = statistical significance; r = Pearson correlation coefficient with 95% confidence interval; SD = standard deviation.

Bootstrap sampling of subjects was performed to assess the impact of the lack of independence on the standard error of the mean difference between the two methods. The bootstrap standard errors were not much different from the standard errors obtained assuming independence between limbs of each subject. Consequently, mean and standard deviations based on the independence assumption are reported.

RESULTS

The 50 subjects consisted of 28 men and 22 women with a mean age of 71 years (range 52 to 83 years). Subjects completed a mean of 43 APP repetitions (standard deviation [SD] = 10) with 30 (60%) completing the full 50 repetitions. Those who stopped prematurely did so because of lower extremity fatigue or discomfort. Subjects walked a mean of 3.5 min (SD = 1.4) or 160 yards (SD = 88) on the treadmill, with 20 subjects (40%) completing the full 5-min protocol.

The mean and standard deviations of the baseline and post-test ABIs for APP and treadmill testing can be found in Tables 1 to 3 along with the paired t test p values and Pearson correlation coefficients (r value) with 95% confidence intervals. Listed are subgroups divided with respect to order of testing (Table 1), disease severity evident at baseline (Table 2) and combined results for all subjects (Table 3). The combined results for all subjects are also graphically illustrated in Figure 3.

The post-test ABI is the single most important value in assessing the severity of PAOD; therefore, a Bland-Altman plot of the difference versus the average for the post-test ABIs for each individual subject is shown in Figure 4. This also illustrates the broad range of disease severity studied.

DISCUSSION

In our prospective, randomized crossover study of a consecutive series of patients, we found that active pedal plantarflexion compared favorably with treadmill exercise for the noninvasive objective assessment of PAOD.

Two previous small pilot studies have also suggested significant correlation between these two tests. A study of five patients (10 limbs) found 100% concordance in immediate post-stress ABIs after both treadmill and APP. The authors also found an excellent correlation between APP and postobstructive reactive hyperemia, an uncomfortable, infrequently used test for PAOD (5). Another study examined 14 patients (21 limbs) with intermittent claudication and resting ABIs over 0.8. There was no significant difference in percent pressure change postexercise between APP and treadmill exercise (6).

The mean pre- and post-test ABIs for APP and treadmill exercise in the current study are virtually identical. Neither order of testing nor baseline ABI significantly affected outcome (post-test ABI) when comparing the two tests. The Bland-Altman plot of post-test ABIs showing each individual subject illustrates some expected scatter. However, it is important to note the distribution is approximately equal above and below the zero line. This indicates that within the population studied, neither test consistently produced a greater or lesser drop in ABI than the other test.

Table 2. Effect of Disease Severity

<table>
<thead>
<tr>
<th>Baseline ABI</th>
<th>Time</th>
<th>n</th>
<th>APP ABI Mean ± SD</th>
<th>Treadmill ABI Mean ± SD</th>
<th>p Value</th>
<th>r Value</th>
<th>Mean Difference</th>
<th>SD of Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 0.8</td>
<td>Baseline</td>
<td>64</td>
<td>1.09 ± 0.14</td>
<td>1.07 ± 0.12</td>
<td>0.17</td>
<td></td>
<td>0.016</td>
<td>0.093</td>
</tr>
<tr>
<td></td>
<td>Post-test</td>
<td>64</td>
<td>0.86 ± 0.25</td>
<td>0.86 ± 0.27</td>
<td>0.89</td>
<td></td>
<td>-0.0020</td>
<td>0.12</td>
</tr>
<tr>
<td>≤ 0.8</td>
<td>Baseline</td>
<td>36</td>
<td>0.68 ± 0.13</td>
<td>0.66 ± 0.12</td>
<td>0.039</td>
<td></td>
<td>0.028</td>
<td>0.078</td>
</tr>
<tr>
<td></td>
<td>Post-test</td>
<td>36</td>
<td>0.32 ± 0.22</td>
<td>0.33 ± 0.23</td>
<td>0.46</td>
<td></td>
<td>-0.014</td>
<td>0.11</td>
</tr>
</tbody>
</table>

ABI = ankle:brachial index; APP = active pedal plantarflexion; n = number of subjects; p = statistical significance; r = Pearson correlation coefficient with 95% confidence interval; SD = standard deviation.
The variability of the ABI must be considered when interpreting these tests. A mean range in a series of daily ABI measurements of 0.18 (SD = 0.07) has been reported in a group of 35 clinically stable claudicants (7). Testing found 95% confidence intervals of ±16% for single measurements of ABI in a sample of 24 patients with PAOD and 12 normal subjects (8). Given these data, it would seem reasonable not to consider a difference in ABI significant unless it is greater than 0.10 to 0.15. When viewed in this light of “clinical” (vs. statistical) significance, the already excellent correlation between APP and treadmill exercise is further strengthened. Although there are several p values <0.05 in Tables 1 to 3 for differences in mean baseline ABI that meet the definition of statistical significance, they represent such small differences in ABI that they fall far short of clinical significance.

Our experience with APP has left us enthusiastic with respect to its potential clinical utility. The complete APP test can be performed in <10 min and requires only BP cuffs and a hand-held Doppler probe. No specialized vascular laboratory or testing facility is required. Cardiac monitoring is not required, nor is it necessary to have a physician in attendance. It was much simpler for patients to perform APP testing than treadmill testing. Active pedal plantarflexion was well tolerated by patients who almost uniformly reported it as being preferred to the treadmill. No subjects had symptoms suggestive of myocardial ischemia during APP, as opposed to nine patients who developed dyspnea and two patients who developed angina on the treadmill. Of those 11 subjects with treadmill-induced symptoms, three had definite cardiac ischemia on their treadmill electrocardiograms. We recognize that the assessment of coronary artery disease may be a secondary advantage of treadmill testing for lower extremity ischemia; however, the workload achieved during most PAOD treadmill protocols is inadequate for proper assessment of coronary artery disease. Furthermore, PAOD patients often require pharmacologic cardiac stress testing because claudication prevents them from exercising to an adequate workload.

The potential cost savings of APP versus treadmill exercise are significant. The 1999 Medicare fee for a peripheral vascular study with exercise and monitoring was $132.88. This is in contrast to the fee of $65.10 for a peripheral vascular circulation study of two extremities without exercise or monitoring (9). An APP fee set midway between these two fees could represent cost savings of approximately 25%, assuming that testing is performed in properly accredited facilities by competent personnel.

Another less obvious advantage of APP testing is the identification of patients at increased risk for adverse cardiovascular or cerebrovascular events. An abnormal ABI identifies patients at increased risk. The National Cholesterol Education Program recommends a goal low-density lipoprotein cholesterol level ≤100 mg/dL for patients with atherosclerosis (10). Patients with PAOD fall into this category. This is perhaps especially relevant in light of the recently recognized benefits of “statin” drugs in the prevention of myocardial infarction, stroke and death in this high risk population (11–15).

**Study limitations.** Both our study and the APP technique have limitations. Orthopedic conditions of the ankle or foot

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**Table 3. Comparison of APP and Treadmill for All Subjects Combined**

<table>
<thead>
<tr>
<th>Time</th>
<th>n</th>
<th>APP ABI Mean ± SD</th>
<th>Treadmill ABI Mean ± SD</th>
<th>p Value</th>
<th>r Value</th>
<th>Mean Difference</th>
<th>SD of Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>100</td>
<td>0.94 ± 0.24</td>
<td>0.92 ± 0.24</td>
<td>0.023</td>
<td>0.93</td>
<td>−0.021</td>
<td>0.088</td>
</tr>
<tr>
<td>Post-test</td>
<td>100</td>
<td>0.66 ± 0.35</td>
<td>0.67 ± 0.36</td>
<td>0.58</td>
<td>0.95</td>
<td>0.0064</td>
<td>0.12</td>
</tr>
</tbody>
</table>

ABI = ankle:brachial index; APP = active pedal plantarflexion; n = number of subjects; p = statistical significance; r = Pearson correlation coefficient with 95% confidence interval; SD = standard deviation.

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**Figure 3.** Mean baseline and post-test ABIs ± 1 standard deviation for all subjects’ APP and treadmill exercise results. ABI = ankle:brachial index; APP = active pedal plantarflexion.

**Figure 4.** Bland-Altman plot of post-test ABIs for APP and treadmill exercise testing. The reference lines drawn at ±0.15 on the y-axis represent what might be considered reasonable guidelines for clinically significant differences in ABI (see text). Abbreviations as in Figure 3.
may preclude adequate pedal plantarflexion, but still allow treadmill testing. The variability of the ABI may complicate interpretation of results. Doppler signals from the pedal arteries can be difficult to locate and detect, especially in the presence of severe PAOD. For example, a signal that is absent immediately after exercise and takes 1 min to reappear can be difficult to differentiate from a faint signal that is always present but takes 1 min to find. Therefore, operator skill and experience become potential confounding variables.

Active pedal plantarflexion does not incorporate either segmental pressures or pulse volume recording and is thus unable to localize the level of arterial occlusive disease. Patient cooperation is always a concern when subjects have to push themselves to perform an exercise test. One patient in our study actually managed to raise his heels by flexing his knees, instead of using his gastrosoleus muscles, thereby producing post-test ABIs of dubious validity.

One of the advantages of treadmill exercise is that provoking lower extremity pain may aid in establishing the diagnosis, such as differentiating vascular claudication from neurogenic claudication. Active pedal plantarflexion generally does not reproduce the lower extremity symptoms brought on by walking. However, a normal ABI following APP should exclude significant PAOD as a cause of lower extremity discomfort.

Conclusions. We conclude that APP is a safe, simple, accurate, portable and inexpensive bedside test for the noninvasive objective assessment of patients with known or suspected PAOD. We recommend APP as an extension of the physical examination for patients at risk for PAOD, and potentially as a tool for following those with established disease.

Acknowledgment

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REFERENCES