**Abstract**

Lower-extremity peripheral artery occlusive disease (PAOD), which is causing by atherosclerosis, occurs in 12 to 21% of the adult population. A total 40 patients undergoing outpatient department will be enrolled in the prospective study between January 2006 and January 2007. All patients featured ankle-brachial index less than 0.9. All patients receive Cilostazol therapy. Upon enrollment, they completed a set of questionnaires, including the peripheral artery questionnaire and short form-36, a rest vascular Doppler examination, and functional measures. According to PAOD questionnaire data analysis, the physical limitations, social limitations, clinical symptoms and treatment satisfactions were significant improved after 3 months Cilostazol treatment. Therefore, PAOD questionnaire can be useful to evaluate the quality of life after Cilostazol treatment.

**Introduction**

Lower-extremity peripheral artery occlusive disease, which is causing by atherosclerosis, occurs in 12 to 21% of the adult population. The prevalence of peripheral artery occlusive disease increases with advancing age. Approximately one third of patients with peripheral artery occlusive disease have typical claudication. In patients with claudication, the severity of the condition increased slowly; 25% have worsening claudication, and 5% undergo an amputation with 5 years. Less than 5 to 10% of patients have critical leg ischemia, but their risk of limb loss is substantial. In patients with peripheral artery occlusive disease, the major mortality and morbidity were from cardiovascular events that including coronary artery disease, cerebrovascular disease, and death from vascular causes. The severity of peripheral artery occlusive disease is correlated with the risk of cardiovascular events. Patients with peripheral artery occlusive disease having the lower ankle-brachial index were associated with the greater risk of cardiovascular events. However, despite the high prevalence of peripheral artery occlusive disease and its strong association with cardiovascular morbidity and mortality, the disease has received relatively little attention, and these patients are less likely to receive appropriate treatment for their atherosclerotic risk factors than those with coronary artery disease. Not only increased cardiovascular morbidity and mortality,
but also functional status is often severely impaired in those with peripheral artery occlusive disease. 13, 14 The limited ability to ambulate leads to disability that is particularly detrimental to quality of life, because both leisure and work activities are often severely curtailed. 15 The different treatments for patients with peripheral artery occlusive disease, including medications, percutaneous peripheral revascularization, and surgery, may help improve functional capacity and patient’s quality of life. How to quantifying the patient’s perspectives of the treatment benefits received will be essential. The peripheral arterial questionnaire is a new disease-specific measure for patients with peripheral arterial occlusive disease. It may prove to be a useful endpoint in clinical trials and a potential aid in the management of peripheral arterial occlusive disease. 16 The present prospective study will evaluate and compare health status in patients with peripheral arterial occlusive disease receiving Cilostazol by short form-36 and peripheral artery questionnaire.

**Methods**

A total of 40 patients undergoing outpatient department were enrolled in the prospective study between January 2006 and January 2007. All patients featured ankle-brachial index (ABI) less than 0.9. Upon enrollment, they completed a set of questionnaires, including the peripheral artery questionnaire and short form-36, a rest vascular Doppler exam. Two weeks later, the peripheral artery questionnaire is given again in order to obtain the reliability data. Patients also start to receive Cilostazol 50 mg twice a day. If patients are able to tolerate low-dose Cilostazol, Cilostazol will titrate up to 100 mg twice a day after another 2 weeks. Three months after their treatment, patients are encouraged to return for set of repeat questionnaires and a repeat vascular Doppler exam.

Measurement of the ABI: Systolic blood pressure is measured by Doppler ultrasonography in each arm and in the dorsalis pedis and posterior tibial arteries in each ankle. The higher of the two arm pressures is selected, as is the higher of the two pressures in each ankle. The right and left ABI values are determined by dividing the higher ankle pressure in each leg by the higher arm pressure. The ranges of the ABI values are shown, with a ratio greater than 1.30 suggesting a non-compressible, calcified vessel. In this condition, the true pressure at that location cannot be obtained, and additional tests are required to diagnose peripheral arterial disease. Patients with claudication typically have ABI values ranging from 0.41 to 0.90, and those with critical leg ischemia have values of 0.40 or less.

The peripheral artery questionnaire was first described by Spertus et al in 2004. We translated this peripheral artery questionnaire to Chinese language and showed in appendix.

All parameter values were expressed as mean ± standard deviation. Comparison between two groups was performed by paired-samples t test. There was significant difference while p < 0.05.

**Results**

A total 40 patients was enrolled into this prospective study. The mean age was 73.1±5.6 years. Comparison reliability data or responsiveness data was with the same group in different time, not between two groups. There were 21 patients with mild intermittent claudication (ABI between 0.7 and 0.89), 12 patients with moderate intermittent claudication (ABI between 0.4 and 0.69), and 7 patients with severe intermittent claudication. The risk factors
included 30 diabetes mellitus patients, 14 cigarette smoking patients, 12 dyslipidermia patients, and 17 hypertension patients. The PAOD had coexistent coronary artery disease in 13 patients and prior ischemic stroke in 6 patients.

Table 1 revealed the reliability data of PAOD questionnaire. The physical limitation, symptoms, social limitation and treatment satisfaction showed the similar scores between baseline data and 2 weeks data. There were no significant changes in scores over 2 weeks before treatment with Cilostazol. Therefore, the PAOD questionnaire is reliable for clinical utility in the present study.

Table 2 showed the responsiveness analysis of PAOD questionnaire and SF-36 questionnaire. According to PAOD questionnaire data analysis, the physical limitations, social limitations, clinical symptoms and treatment satisfactions were significant improved after 3 months Cilostazol treatment. General health, mental health, daily activity, and vitality were no significant changes after 3 months Cilostazol treatment, however.

**Discussion**

Schroll and Munck2 reported that the prevalence of PAOD was 16% of men and 13% of women aged 60 years. Criqui et al1 showed that the prevalence of PAOD was 5.6% of persons aged 38 to 59 years, 15.9% of persons aged 60 to 69 years, and 33.8% of persons aged 70 to 82 years. In the Cardiovascular Health Study,17 PAOD was present in 13.9% of 2214 men aged 65 years and in 11.4% of 2870 women aged 65 years without cardiovascular disease. Modifiable risk factors that predispose to PAOD include cigarette smoking, diabetes mellitus, hypertension, dyslipidemia, increased plasma homocysteine levels. In a study of 1886 men and women, mean age 81 years, 270 of 468 persons (58%) with PAOD had coexistent coronary artery disease and 159 of 468 persons (34%) with PAOD had prior ischemic stroke.8 In the present study, we also found that PAOD is likely to occur during old age, cigarette smoking, diabetes mellitus, hypertension, and dyslipidemia.

Cilostazol is an inhibitor of phosphodiesterase type 3 and thereby inhibits platelet aggregation and causes vasodilation. A meta-analysis of 8 RCTs involving 2702 patients demonstrated that cilostazol improved maximum walking distance and pain-free walking distance.18 Although cilostazol has not been associated with the increase in cardiac mortality seen with other phosphodiesterase inhibitors such as milrinone (which was developed for the treatment of heart failure), it remains contraindicated in patients with PAOD who have coexistent cardiac failure. In the present study, the PAOD questionnaire is dramatically improved in physical limitations, social limitations, clinical symptoms and treatment satisfactions after 3 months treatment. Therefore, PAOD questionnaire can be useful to evaluate the quality of life after Cilostazol treatment.

致謝

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**Reference**


Table 1. Reliability analysis of peripheral artery disease questionnaire

<table>
<thead>
<tr>
<th>Questionnaire scores</th>
<th>Baseline</th>
<th>2 weeks</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical limitation</td>
<td>19.3 ± 4.5</td>
<td>19.8 ± 4.7</td>
<td>NS</td>
</tr>
<tr>
<td>Symptoms</td>
<td>12.8 ± 3.1</td>
<td>12.5 ± 2.8</td>
<td>NS</td>
</tr>
<tr>
<td>Social limitation</td>
<td>10.3 ± 2.4</td>
<td>10.5 ± 2.7</td>
<td>NS</td>
</tr>
<tr>
<td>Treatment satisfaction</td>
<td>6.8 ± 2.3</td>
<td>6.3 ± 2.5</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS: non-significant

Table 2. Responsiveness analysis of patients with peripheral arterial occlusive disease (PAOD)

<table>
<thead>
<tr>
<th>Questionnaire scores</th>
<th>Baseline</th>
<th>3 months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAOD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical limitation</td>
<td>19.3 ± 4.5</td>
<td>27.8 ± 5.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Symptoms</td>
<td>12.8 ± 3.1</td>
<td>17.8 ± 4.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Social limitation</td>
<td>10.3 ± 2.4</td>
<td>13.5 ± 2.9</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Treatment satisfaction</td>
<td>6.8 ± 2.3</td>
<td>11.5 ± 3.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SF-36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health</td>
<td>8.3 ± 2.1</td>
<td>7.8 ± 2.2</td>
<td>NS</td>
</tr>
<tr>
<td>Mental health</td>
<td>10.5 ± 2.5</td>
<td>11.3 ± 2.3</td>
<td>NS</td>
</tr>
<tr>
<td>Physical function</td>
<td>15.3 ± 2.7</td>
<td>21.5 ± 3.1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Daily activity</td>
<td>4.3 ± 1.5</td>
<td>4.8 ± 1.3</td>
<td>NS</td>
</tr>
<tr>
<td>Social function</td>
<td>2.3 ± 0.7</td>
<td>3.8 ± 0.9</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Vitality</td>
<td>36.8 ± 5.5</td>
<td>39.3 ± 5.8</td>
<td>NS</td>
</tr>
<tr>
<td>Body pain</td>
<td>2.0 ± 0.5</td>
<td>4.3 ± 0.8</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

NS: non-significant

Appendix. The peripheral artery questionnaire in Chinese

週邊動脈疾病問卷調查表

此問卷調查可以反映你的週邊動脈疾病情況，請詳讀並回答下列問題，答案沒有對或錯，請你選擇其中一個最適合你的答案。(請在□打勾)

1. 下肢動脈阻塞時，稱為週邊動脈疾病，不同的人會有不同程度症狀表現，有些人會感覺腳痛，有些人會感覺腳無力，有些人會有腳痙攣情形，你感覺那隻腳讓你最不舒服？
   1右腳  2左腳  3雙腳  4都沒有

2. 請你回憶四週前，腳不舒服症狀如何限制你的生活？

<table>
<thead>
<tr>
<th>活動</th>
<th>極度限制</th>
<th>非常限制</th>
<th>中度限制</th>
<th>輕度限制</th>
<th>沒有限制</th>
<th>未從事此活動</th>
</tr>
</thead>
<tbody>
<tr>
<td>家中走路</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>走1到2街口平路</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>走3到4街口平路</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>走1到2街口上坡路</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>快走或趕路</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>運動或勞動</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
3. 和四週前比較，腳不舒服症狀是否改善或變壞?
   1. 翻壞很多 2. 輕微翻壞 3. 沒有改變
   4. 輕微改善 5. 改善很多 6. 沒有不舒服

4. 在過去四週，腳不舒服症狀發生幾次？
   1. 一直都舒服 2. 一天好幾次
   3. 一天一次 4. 一星期三至四次
   5. 一星期一至二次 6. 一星期少於一次

5. 在過去四週，腳不舒服症狀是否困擾你？
   1. 極度困擾 2. 中度困擾 3. 輕微困擾
   4. 沒有困擾 5. 沒有不舒服

6. 在過去四週，你是否因腳不舒服半夜醒來？
   1. 每晚醒來 2. 一星期三至四次
   3. 一星期一至二次 4. 一星期少於一次
   5. 未曾醒來

7. 對於你所將可能接受的週邊動脈疾病治療是否滿意？
   1. 非常不滿意 2. 不滿意 3. 差強人意 4. 滿意
   5. 非常滿意

8. 對於醫護人員針對你病情解釋是否滿意？
   1. 非常不滿意 2. 不滿意 3. 差強人意
   4. 滿意 5. 非常滿意

9. 對於目前你所接受治療週邊動脈疾病的情況是否滿意？
   1. 非常不滿意 2. 不滿意 3. 差強人意
   4. 滿意 5. 非常滿意

10. 在過去四週，週邊動脈疾病是否影響你的生活？
    1. 極度限制 2. 非常限制 3. 中度限制
    4. 輕微限制 5. 沒有限制

11. 如果從現在開始你必須跟週邊動脈疾病奮鬥一輩子，你是否滿意？
    1. 非常不滿意 2. 不滿意 3. 差強人意
    4. 滿意 5. 非常滿意

12. 在過去四週，你是否因週邊動脈疾病而沮喪？
    1. 一直非常沮喪 2. 大部分時間沮喪
    3. 偶而沮喪 4. 很少沮喪 5. 未曾沮喪

13. 在過去四週，週邊動脈疾病是否限制你的活動？

<table>
<thead>
<tr>
<th>活動</th>
<th>極度限制</th>
<th>非常限制</th>
<th>中度限制</th>
<th>輕微限制</th>
<th>沒有限制</th>
<th>未從事此活動</th>
</tr>
</thead>
<tbody>
<tr>
<td>喝茶</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>拜訪朋友</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>工作或打掃</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

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