Experience Sharing of Debulking Technology in Complicated PAD

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Disclosure

Speaker name:

Mingjin GUO

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

✓ I do not have any potential conflict of interest
Aortoiliac Occlusive Disease

Aortoiliac occlusive disease (AIOD) typically begins at the aortic terminus or common iliac artery origins and slowly progresses proximally and distally over time. Progression is variable but may ultimately result in total aortic occlusion.
Complicated PAD

Type C lesions

- Bilateral CIA occlusions
- Bilateral EIA stenoses 3–10 cm long not extending into the CFA
- Unilateral EIA stenosis extending into the CFA
- Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA
- Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA

Type D lesions

- Infra-renal aortoiliac occlusion
- Diffuse disease involving the aorta and both iliac arteries requiring treatment
- Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA
- Unilateral occlusions of both CIA and EIA
- Bilateral occlusions of EIA
- Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

HOW TO TREAT?

- Supervised exercise
- Medical therapy
- Bypass operation
- Endovascular Revascularization
### Table 3. Six-Month End Points and Risk Factors

<table>
<thead>
<tr>
<th></th>
<th>OMC (n=20)</th>
<th>SE + OMC (n=38)</th>
<th>ST + OMC (n=41)</th>
<th>SE vs OMC [95% CI] (P)</th>
<th>ST vs OMC [95% CI] (P)</th>
<th>SE vs ST [95% CI] (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary end point</strong></td>
<td></td>
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</tr>
<tr>
<td>Change of PWT from baseline to 6 mo, mins</td>
<td>1.2±2.6 (−4.1, 8.6)</td>
<td>5.8±4.6 (−0.4, 16.9)</td>
<td>3.7±4.9 (−4.7, 14.6)</td>
<td>4.6 [27−6.5] (&lt;0.0001)*</td>
<td>2.5 [0.6−4.4] (0.021)*</td>
<td>2.1 [0.0−4.2] (0.042)*</td>
</tr>
<tr>
<td>P, nonparametric analysis</td>
<td></td>
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<tr>
<td>Multiple imputation analysis</td>
<td>1.0±2.8 (−9.5, 8.60)</td>
<td>6.1±4.6 (−0.4, 16.9)</td>
<td>3.6±4.9 (−4.7, 14.6)</td>
<td>5.1 [45−5.7] (&lt;0.001)*</td>
<td>2.6 [2.0−3.2] (0.017)*</td>
<td>2.5 [1.9−3.1] (0.028)*</td>
</tr>
<tr>
<td><strong>Secondary end points</strong></td>
<td></td>
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<tr>
<td>Change in COT from baseline to 6 mo, min</td>
<td>0.7±1.1 (−0.6, 3.3)</td>
<td>3.0±2.9 (−0.8, 10.7)</td>
<td>3.6±4.2 (−0.3, 17.9)</td>
<td>2.2 [1.2−3.3] (0.003)</td>
<td>2.9 [1.5−4.3] (0.006)</td>
<td>0.7 [0.9−2.3] (0.425)</td>
</tr>
<tr>
<td>Change in hourly free-living steps from baseline to 6 mo, n†</td>
<td>−5.6±109.4 (−268.2, 168.9)</td>
<td>72.8±138.7 (−185.2, 425.7)</td>
<td>114.3±273.9 (−192.6, 976.4)</td>
<td>78.3 [0.7−157.2] (0.0625)</td>
<td>120.0 [3.5−238.5] (0.1024)</td>
<td>41.7 [73.4−156.8] (0.4661)</td>
</tr>
<tr>
<td>Change in ABI from baseline to 6 mo</td>
<td>0.01±0.10 (19) (−0.24, 0.12)</td>
<td>0.03±0.11 (36) (−0.23, 0.37)</td>
<td>0.29±0.33 (40) (−0.12,1.59)</td>
<td>0.0 [0.0−0.1] (0.578)</td>
<td>0.3 [0.2−0.4] (&lt;0.001)</td>
<td>0.3 [0.2−0.4] (&lt;0.001)</td>
</tr>
<tr>
<td><strong>Risk factors (change from baseline)</strong></td>
<td></td>
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</tr>
<tr>
<td>LDL cholesterol, mg/dL</td>
<td>−4.4±42.3</td>
<td>−3.6±17.4</td>
<td>−9.3±24.7</td>
<td>P=0.813</td>
<td>P=0.686</td>
<td>P=0.474</td>
</tr>
<tr>
<td>HDL cholesterol, mg/dL</td>
<td>7.9±15.4</td>
<td>5.6±8.4</td>
<td>0.4±8.5</td>
<td>P=0.551</td>
<td>P=0.661</td>
<td>P=0.013</td>
</tr>
<tr>
<td>Hemoglobin A1c, %</td>
<td>−0.09±0.27</td>
<td>0.01±0.50</td>
<td>0.01±0.35</td>
<td>P=0.344</td>
<td>P=0.303</td>
<td>P=0.977</td>
</tr>
<tr>
<td>Fibrinogen, g/dL</td>
<td>31.7±64.1</td>
<td>−15.0±84.5</td>
<td>−2.0±89.1</td>
<td>P=0.043</td>
<td>P=0.151</td>
<td>P=0.541</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>−5.8±20.7</td>
<td>−0.95±19.1</td>
<td>−5.6±21.9</td>
<td>P=0.381</td>
<td>P=0.974</td>
<td>P=0.323</td>
</tr>
</tbody>
</table>

OMC indicates optimal medical care; SE, supervised exercise; ST, stent revascularization; CI, confidence interval; PWT, peak walking time; COT, claudication onset time; ABI, ankle-brachial index; LDL, low-density lipoprotein; and HDL, high-density lipoprotein. Values are mean±SD (minimum, maximum) when appropriate. P values are based on ANCOVA with adjustment for study center, baseline cilostazol use, and baseline value of the end point. *One-sided P value.
†Adjusted with pedometer logs.

Table 4. Six-Month Leg Symptoms and Quality of Life

<table>
<thead>
<tr>
<th>Measure</th>
<th>OMC (n=20)</th>
<th>SE+OMC (n=38)</th>
<th>ST+OMC (n=41)</th>
<th>P, SE vs OMC</th>
<th>P, ST vs OMC</th>
<th>P, SE vs ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-12 physical</td>
<td>31.6±10.5</td>
<td>32.3±8.8</td>
<td>34.3±9.3</td>
<td>0.001</td>
<td>0.366</td>
<td>0.463</td>
</tr>
<tr>
<td>SF-12 mental</td>
<td>52.4±8.3</td>
<td>54.2±9.3</td>
<td>53.1±11.4</td>
<td>0.441</td>
<td>0.834</td>
<td>0.711</td>
</tr>
<tr>
<td>WIQ pain severity</td>
<td>28.4±20.8</td>
<td>30.2±25.9</td>
<td>33.7±27.5</td>
<td>0.842</td>
<td>0.423</td>
<td>0.292</td>
</tr>
<tr>
<td>WIQ walking distance</td>
<td>22.9±26.8</td>
<td>12.7±11.6</td>
<td>17.9±15.5</td>
<td>0.023</td>
<td>0.359</td>
<td>0.066</td>
</tr>
<tr>
<td>WIQ walking speed</td>
<td>26.5±20.8</td>
<td>21.4±16.9</td>
<td>26.3±18.3</td>
<td>0.252</td>
<td>0.930</td>
<td>0.190</td>
</tr>
<tr>
<td>WIQ stair climbing</td>
<td>33.5±30.0</td>
<td>30.3±22.1</td>
<td>33.2±23.7</td>
<td>0.542</td>
<td>0.889</td>
<td>0.561</td>
</tr>
<tr>
<td>PAQ physical limitation</td>
<td>32.9±27.0</td>
<td>28.9±18.0</td>
<td>30.5±19.5</td>
<td>0.366</td>
<td>0.621</td>
<td>0.897</td>
</tr>
<tr>
<td>PAQ symptoms</td>
<td>43.3±19.7</td>
<td>41.0±19.0</td>
<td>48.2±21.1</td>
<td>0.585</td>
<td>0.434</td>
<td>0.114</td>
</tr>
<tr>
<td>PAQ social limitation</td>
<td>50.7±32.3</td>
<td>55.6±25.5</td>
<td>55.0±26.5</td>
<td>0.636</td>
<td>0.438</td>
<td>0.718</td>
</tr>
<tr>
<td>PAQ treatment satisfaction</td>
<td>75.0±26.5</td>
<td>74.0±20.2</td>
<td>79.3±22.0</td>
<td>0.876</td>
<td>0.495</td>
<td>0.253</td>
</tr>
<tr>
<td>PAQ quality of life</td>
<td>44.4±25.5</td>
<td>44.0±18.4</td>
<td>46.1±19.4</td>
<td>0.915</td>
<td>0.853</td>
<td>0.664</td>
</tr>
<tr>
<td>PAQ summary</td>
<td>45.6±23.3</td>
<td>42.8±16.2</td>
<td>45.3±18.3</td>
<td>0.960</td>
<td>0.840</td>
<td>0.587</td>
</tr>
<tr>
<td>Change from baseline to 6 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-12 physical</td>
<td>1.2±11.0</td>
<td>5.9±10.1</td>
<td>6.6±8.5</td>
<td>0.047</td>
<td>0.023</td>
<td>0.958</td>
</tr>
<tr>
<td>SF-12 mental</td>
<td>−2.4±8.0</td>
<td>−2.2±11.5</td>
<td>−1.7±9.9</td>
<td>0.810</td>
<td>0.713</td>
<td>0.882</td>
</tr>
<tr>
<td>WIQ pain severity</td>
<td>16.3±34.7</td>
<td>26.3±36.3</td>
<td>40.4±43.9</td>
<td>0.251</td>
<td>&lt;0.001</td>
<td>0.014</td>
</tr>
<tr>
<td>WIQ walking distance</td>
<td>−0.5±26.0</td>
<td>25.1±27.6</td>
<td>43.8±42.2</td>
<td>0.007</td>
<td>&lt;0.001</td>
<td>0.029</td>
</tr>
<tr>
<td>WIQ walking speed</td>
<td>1.47±15.69</td>
<td>16.5±19.7</td>
<td>30.8±31.0</td>
<td>0.007</td>
<td>&lt;0.001</td>
<td>0.007</td>
</tr>
<tr>
<td>WIQ stair climbing</td>
<td>10.2±29.3</td>
<td>24.0±20.9</td>
<td>29.3±39.1</td>
<td>0.071</td>
<td>0.051</td>
<td>0.539</td>
</tr>
<tr>
<td>PAQ physical limitation</td>
<td>0.6±22.5</td>
<td>16.2±19.2</td>
<td>28.1±30.9</td>
<td>0.012</td>
<td>&lt;0.001</td>
<td>0.043</td>
</tr>
<tr>
<td>PAQ symptoms</td>
<td>1.0±17.2</td>
<td>16.3±21.4</td>
<td>29.2±27.4</td>
<td>0.008</td>
<td>&lt;0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>PAQ social limitation</td>
<td>−10.6±29.6</td>
<td>8.8±30.0</td>
<td>17.6±30.2</td>
<td>0.016</td>
<td>&lt;0.001</td>
<td>0.156</td>
</tr>
<tr>
<td>PAQ treatment satisfaction</td>
<td>−8.1±19.1</td>
<td>4.6±20.7</td>
<td>4.0±25.9</td>
<td>0.013</td>
<td>0.010</td>
<td>0.323</td>
</tr>
<tr>
<td>PAQ quality of life</td>
<td>0.8±26.7</td>
<td>17.3±20.8</td>
<td>30.4±28.3</td>
<td>0.011</td>
<td>&lt;0.001</td>
<td>0.006</td>
</tr>
<tr>
<td>PAQ summary</td>
<td>−3.1±18.6</td>
<td>13.8±17.0</td>
<td>28.0±26.4</td>
<td>0.001</td>
<td>&lt;0.001</td>
<td>0.002</td>
</tr>
</tbody>
</table>

OMC indicates optimal medical care; SE, supervised exercise; ST, stent revascularization; SF-12, Short Form-12; WIQ, Walking Impairment Questionnaire; and PAQ, Peripheral Artery Questionnaire. Values are mean ± SD. P values for baseline scores are based on ANCOVA with adjustment for study center and baseline clofazimine use. P values for change from baseline to 6 months are based on ANCOVA with adjustment for study center, baseline clofazimine use, and baseline score. P values for change from baseline to 6 months for PAQ symptom stability score are based on ANCOVA with adjustment for study center and baseline clofazimine use only. The physical and mental summary scores from the SF-12 correlate highly with those obtained from the SF-36 and are scaled to a US population mean of 50 and SD of 10 (higher scores are better). Multiple groups have suggested minimal clinically important changes in SF-12 summary scores to be ≥2 to 2.5 points and moderate changes to be ≥5 points.23 The WIQ grades symptom severity and patient ratings of their walking distance, walking speed, and ability to climb stairs on scales of 0 to 100, with higher scores indicating lesser symptoms and greater functional capacity. The PAQ assesses PAD-related physical limitations, symptoms, quality of life, social function, and treatment satisfaction, also on scales of 0 to 100; higher scores are better. For the PAQ summary scale, a difference of 8 points has been proposed as clinically important.4 The minimum clinically important difference has not been established for the WIQ.
Overall, according to this RCT, in claudication patients caused by aortoiliac disease, supervised exercise results in superior walking performance than revascularization, however, the latter shows better patient-reported quality of life.

In China, when admitted to hospital, many patients suffered critical limb ischemia because of thromboembolism combined with AIOD, and cannot tolerate supervised exercise. Besides, supervised exercise in China is quite difficult.
1. Debulking technic (CDT) ---- the key initial treatment
2. PTA, stenting, DCB or bifurcated endograft

- Debulking
  - Catheter-directed thrombolysis
    - Rotarex
    - TurboHawk

- PTA
  - POBA/DCB

- Stenting
  - Bare metal stent
  - Covered stent
  - Unibody bifurcated stent-graft
M, 34 y.

Chief complaint: intermittent claudication in both lower extremity for 3 years, paresthesia and pain in right lower extremity for 3 days.

Diagnosis: Aortoiliac occlusive disease
case 1

Treatment Strategy

- Medical treatment?
- Aortic iliac bypass?
- PTA?
- STENT?
  - Bare or covered?
- Debulking?
- Popliteal arterial disease?
case 1

bilateral femoral access

PTA+CDT
case 1

Catheter-directed thrombolysis for 5 days

CDT +5 days
case 1
Left lower extremity (Rotarex+DCBs for popliteal artery)
case 1
Right lower extremity (DCBs for anterior tibial artery)
Followup Angiography after 6 months

No paresthesia and pain

Walking distance > 500m
case 1

1 year later after OR

Paresthesia and pain in left lower extremity
case 1

DCBs for common iliac artery; Turbo Hawk and DCBs for popliteal artery
M, 64y.

Chief complaint: intermittent claudication in both lower extremity for 6 years.

Diagnosis: Aortoiliac occlusive disease
case 2

CDT for 5 days + unibody bifurcated stent-graft
case 2

Followup Angiography after 7 months

Walking distance > 500m
M, 76 y.
Chief complaint: intermittent claudication in both lower extremity for 4 years.
Past medical history: atrial fibrillation for 10 years, diabetes for 12 years.
case 3

CDT 1w+PTA+unibody bifurcated stent-graft
Our data review

• 26 AIOD patients were treated in recent 3 years.
  • CDT + PTA 3 cases
  • CDT + Unibody bifurcated endograft 7 cases
  • CDT + Bare STENT 10 cases
  • CDT + Viabahn 6 cases

• Technical success rate 100%;
• No major amputation (above the ankle);
• 1 minor amputation (below the ankle);
• No perioperative cardiovascular and cerebrovascular event;
• No major bleeding
• No perioperative death
1. Peripheral artery diseases are usually rather complicated in China.

2. The complex situation of the patient should be estimated more carefully.

3. Debubling technique such as CDT can achieve amazing results if used appropriately.

4. DCBs is very useful especially combined with debulking technique.

5. Be aware of CDT’s complications such as hemorrhage and distal embolism.
THANKS!!
Experience Sharing of Debulking Technology in Complicated PAD

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