usually leaves patients with no treatment options. Autologous bone marrow cells may have potential to reduce the instances of amputation and improve quality of life for these patients.

Methods: 49 patients with thromboangiitis obliterans resulting in CLI were treated with a composition of concentrated bone marrow nucleated cells. A total of 240 mL of aspirate was processed using a point of care centrifuge (Harvest Technologies, Plymouth, MA) to yield 40 mL of treating volume. The patients were divided equally into two treatment groups. Group 1 received forty 1 mL direct intramuscular injections in the ischemic regions below the knee and Group 2 received twenty 1 mL direct intramuscular injections below the knee and an intra-arterial infusion of 20 mL down the SFA into the lower leg. An evaluation of these patients was conducted at 12 and 26 weeks.

Results: All patients enrolled were men with the following demographics: mean age 44.9, all smokers. There were six adverse events in each treatment group. None were considered to be related to the biologic treatment. No patients died. Limb salvage was 87.5% and all major endpoints showed statistically significant improvement over baseline: Quality of Life assessment (Rand-36 questionnaire) p=0.0009; perception of pain p=0.0001; TcPO2 and ABI measurement p=0.0001 & p= 0.0003 respectively. There was 100% reduction in pain medications. Mean number of nucleated cells delivered 3.63x10^6. The delivery method showed no statistical difference.

Conclusions: Based on these results, this bone marrow composition may be considered safe and has shown potential to reduce amputation rates. This study has also shown that both the methods of delivery are equally effective and safe.

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SS2.

Congestive Heart Failure with Systolic Dysfunction Is Associated with Decreased Patency after Endovascular Intervention for Symptomatic Peripheral Arterial Disease

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Objectives: Congestive heart failure (CHF) predicts morbidity and mortality after treatment of peripheral arterial disease. The impact on procedural success, however, remains unknown. We hypothesized that CHF with reduced left ventricular ejection fraction (LVEF) results in a diminished perfusion pressure and a low-flow state that could predispose arterial interventions to fail.

Methods: A prospective database identified patients with CHF who underwent endovascular arterial intervention from 2004-2009. Demographics, co-morbidities, intervention, LVEF, and outcomes were recorded. Patients were followed clinically and by duplex ultrasound. Kaplan-Meier survival analysis and Cox Regression were used.

Results: Of 1220 patients undergoing intervention, 271 patients (22%) with documented CHF underwent intervention for claudication (23%) or critical limb ischemia (CLI) (77%). Primary patency at 1 year was 51.9±2.5% among those with CHF, compared to 64.6±1.3% in controls (p<0.001). In the setting of CHF, 1 year patency was 56.6±4.1% if LVEF>40% vs 43.2±3.5% if LVEF<40% (p<0.001). (Table 1). Among those with CLI, limb salvage rates were equivalent between controls and patients with CHF and LVEF>40%, but worse with LVEF<40% (p=0.01) and LVEF<20% (p<0.001).

Conclusions: CHF is an independent risk factor for failure of endovascular intervention. Specifically, low LVEF (<40%) predicts loss of patency. The inverse association between patency and LVEF needs further assessment.

Table 1. Primary Patency

<table>
<thead>
<tr>
<th></th>
<th>Patency at 12 months</th>
<th>Patency at 24 months</th>
<th>Patency at 36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>64.6 ± 1.3</td>
<td>53.1 ± 1.4</td>
<td>47.5 ± 1.6</td>
</tr>
<tr>
<td>CHF</td>
<td>51.9 ± 2.5</td>
<td>42.8 ± 2.7</td>
<td>38.5 ± 2.8</td>
</tr>
<tr>
<td>LVEF&gt;40%</td>
<td>56.6 ± 4.1</td>
<td>45.9 ± 4.4</td>
<td>36.0 ± 4.8</td>
</tr>
<tr>
<td>LVEF&lt;40%</td>
<td>43.2 ± 3.5</td>
<td>26.9 ± 3.7</td>
<td>16.8 ± 4.9</td>
</tr>
</tbody>
</table>

P-Values

Control vs CHF  <.001*   <.001*  <.001*  
Control vs CHF  (LVEF<40%)  <.001*  <.001*  
Control vs CHF  (LVEF>40%)  0.03*  0.051  0.057  
LVEF>40% vs LVEF<40%  0.008*  <.001*  <.001*  

*Statistically Significant.


VS1.

Video Presentation
Endovascular Management of an Aorto-Iliac Occlusion Utilizing an IVUS Guided Re-entry Device

Ali Amin. Surgery, Reading Hospital and Medical Center, Reading, PA

Background: 43 yr old female. pain bilateral lower extremity for 8 months. Pain worse right side, can only walk few feet. pain at night, chronic numbness right foot. Hypertension, COPD, HIV+ smoker Absent femoral/pedal pulses. ABI right .36 left .64 Abdominal duplex: