FREEDOM

Pilot study of the feasibility and safety of early walking after manual compression in patients treated for peripheral artery disease by endovascular repair with 5F catheter


Department of vascular surgery, University Hospital of Nantes, France
Potential conflicts of interest

Speaker's name: Yann Goueffic

☑️ I have the following potential conflicts of interest to report:

Consultant: COOK, MEDTRONIC, PEROUSE.
Rationale for same-day discharge

- Increased demand of hospital care (population is aging)
- Hospital budgets constraints (pressure to reduce stay / cost)
- Patients more informed (ask for safe/effective solutions + prompt recovery)

Find ways to optimize the resources **BUT**, without compromising quality, **safety** and **efficiency** of patient care
Are same-day discharge procedures safe and efficient for PAD patients?

Original Studies

Assessment of Clinical Outcomes related to Early Discharge after elective Percutaneous Coronary Intervention: COED PCI

Purushothaman Muthusamy,1,2,3* MD, Denise K. Busman,2,3 MSN, RN, Alan T. Davis,1,4 PHD, and David H. Wohns,2,3 MD, FACC, FSCAI

Assessing Patient-Reported Outcomes and Preferences for Same-Day Discharge After Percutaneous Coronary Intervention: Results From a Pilot Randomized, Controlled Trial

Michael Kim, Paul Muntner, Samin Sharma, James W. Choi, Robert C. Stoler, Mark Woodward, Devin M. Mann and Michael E. Farkouh

Circ Cardiovasc Qual Outcomes 2013;6:186-192; originally published online March 12, 2013;
DOI: 10.1161/CIRCOUTCOMES.111.000069

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Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg, 2006*

**Inclusion criteria**
- Claudicant
- Adequate home support
- Ambulating without assistance

**Procedure**
- Femoral approach
- Heparin 5000 UI (wo reversion)
- Stent at the discretion of the physician
- ACD (Angioseal®, St Jude)
- Ambulation 1h after the procedure

**Follow up**
Duplex scan evaluation at 6 w and every 3 mo for the 1st year and every 6 mo after.

**Prospective ✓ Registry ✓ Single center ✓ In-tent to treat ✓ Published ✓**
112 procedures / 97 patients
74y ± 9y - 49 men / 48 females

Preoperative clinical status
R. stage 2: 38%
R. stage 3: 63%

SFA:
TASC A/B: 77%
TASC C/D: 22%

Stenting: 77%
6F sheath: 83%

Ambulatory success: 92%

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<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>88</td>
<td>(78.6)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>61</td>
<td>(54.5)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>57</td>
<td>(50.9)</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>50</td>
<td>(44.6)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>31</td>
<td>(27.7)</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>9</td>
<td>(8.0)</td>
</tr>
<tr>
<td>Renal disease*</td>
<td>5</td>
<td>(4.5)</td>
</tr>
</tbody>
</table>

*Defined as serum creatinine >2.0 mg/dL.

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<table>
<thead>
<tr>
<th>Location</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Iliac</td>
<td>20</td>
<td>(17.9)</td>
</tr>
<tr>
<td>External Iliac</td>
<td>18</td>
<td>(16.1)</td>
</tr>
<tr>
<td>Common femoral</td>
<td>4</td>
<td>(3.6)</td>
</tr>
<tr>
<td>Superficial femoral</td>
<td>53</td>
<td>(47.3)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>41</td>
<td>(36.6)</td>
</tr>
</tbody>
</table>

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Inclusion criteria (SFAR 2009)

- ASA 1, 2, 3 stable
- Good understanding of study constraints
- Patient who could be accompanied for intervention, FU visit, and during the following night
- Patients living at less than 1h far from an health care structure
- Accept to stay overnight if needed
- FU Phone call at 24h post intervention
<table>
<thead>
<tr>
<th>Symptomatology</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudication</td>
<td>90</td>
</tr>
<tr>
<td>Rest pain</td>
<td>(45)</td>
</tr>
<tr>
<td>Trophic disorder</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Renal artery stenosis</td>
<td>2 (1)</td>
</tr>
<tr>
<td>IC</td>
<td>91.5</td>
</tr>
<tr>
<td>CLI</td>
<td>8.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multiples and complex lesions</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac</td>
<td>70</td>
</tr>
<tr>
<td>Femoropopliteal</td>
<td>68</td>
</tr>
<tr>
<td>Infraopopliteal</td>
<td>4</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>64</td>
</tr>
<tr>
<td>Bilateral lesions</td>
<td>30</td>
</tr>
<tr>
<td>Multilevel lesions</td>
<td>36</td>
</tr>
</tbody>
</table>

Retrograde femoral approach: 94%
Cross over: 60%
Same-day discharge peri-operative morbi-mortality: 16% (n=8)

All the adverse events were observed in the operating room or in the recovery room.

Clinical improvement @ 1 month: 98%

None reintervention - None rehospitalization
Issues for the development of outpatients?

Clinical issues
Lower profile devices 4-5 F
ACD / Manual compression

Economic issues
Diagnosis Related Groups modifications?

Legal issues
in case of complications?
Arterial closure device vs Manual compression

+ Decrease of hemostasis and procedural time
+ More rapid resumption of walking

- No difference in terms of complications.
- More complications (Hematoma, false aneurysm)
- Redo surgery at the femoral puncture point which presents a greater risk after the ACD

The use of increasingly small diameter instruments would tend to render manual compression sufficient

Cost

Upponi SS, Eur J Radiol., 2007
Koreny JAMA 2004
FREEDOM trial

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- Prospective ✔
- Single center ✔
- Cohort ✔
- Ethic committee ✔
- Completed ✔

Flowchart:

1. Information
2. Inclusion criteria met
3. Inclusion
4. Endovascular procedure
5. Evaluation at H3, H4, H5, D1 and M1
Patients (n=30)

Inclusion criteria
- Age > 18 years
- Endovascular examination or treatment compatible with a 5F sheath
- Walking ability
- Patient affiliated with a social security scheme
- Patient's signed informed consent form

Exclusion criteria
- Contraindication to endovascular treatment
- Use of a 6F or greater sheath
- Morbidity contraindicating same-day walking
- History of open common femoral artery surgery at the puncture site
- Radial or brachial approach
- Bilateral femoral approach
- Antegrade femoral puncture
- Acute ischemia
- Anticoagulant treatment
- Allergy to Elastoplast® type adhesive strips
- Life expectancy of less than one month
- Participation in another therapeutic trial
- Pregnant woman
Primary endpoint: walking ability @ H5

It consists in a walking test in the department's corridor, the patient being asked to walk for 100 meters on flat ground within the department. All of this is conducted under medical and paramedical supervision.

Secondary endpoints

- Occurrence of major punctured femoral artery events during the perioperative period, requiring prolongation of hospitalization, repeat hospitalization or repeat surgery
- Occurrence of minor punctured femoral artery events during the perioperative period, not requiring prolongation of hospitalization, repeat hospitalization or repeat surgery
  - Time to onset of complications
    - Puncture point pain
  - Quality of life evaluation
  - Compression and dressing time
Entrust™ delivery system with EverFlex™ self-expanding peripheral stent (Medtronic®)

- 5F delivery system
- Triaxial design
- Compatible with a 0.035” wire
- Shafts: 80, 120 and 150-cm
- One-handed handle
- Last generation of SE:
  - Good trackability
  - Good radial force
  - Clinical and morphological proven performance (Durability II, Durability 200)
Freedom screening diagram
Mars to August (5 months)

129 screened patients from May to August 2015

93 screen failed

6 patients were excluded for:
- non respect of inclusion criteria (2)
- 6F procedure (4)

30 Freedom procedures
# Exclusion causes*

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of a 6F or greater sheath</td>
<td>38.95%</td>
</tr>
<tr>
<td>Bilateral femoral approach</td>
<td>21.05%</td>
</tr>
<tr>
<td>Radial or brachial approach</td>
<td>17.89%</td>
</tr>
<tr>
<td>Same-day walking contraindicating</td>
<td>15.79%</td>
</tr>
<tr>
<td>Age &gt;85y</td>
<td>11.58%</td>
</tr>
<tr>
<td>Others</td>
<td>9.47%</td>
</tr>
<tr>
<td>Antegraded femoral puncture</td>
<td>7.37%</td>
</tr>
<tr>
<td>Participation in another therapeutic trial</td>
<td>6.32%</td>
</tr>
<tr>
<td>Anticoagulant treatment</td>
<td>5.26%</td>
</tr>
<tr>
<td>Patient's signed informed consent form</td>
<td>3.16%</td>
</tr>
</tbody>
</table>

*Some patients presented two or more exclusion criteria*
<table>
<thead>
<tr>
<th>Demographic data</th>
<th>30 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (y) - Sex ♂ (%)</td>
<td>66±11 - 77</td>
</tr>
<tr>
<td>ASA 2 – 3 – 4 (%)</td>
<td>60 – 37 – 3</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>17</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>63</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>37</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>47</td>
</tr>
<tr>
<td>Renal failure (%)</td>
<td>3</td>
</tr>
<tr>
<td>CAD (%)</td>
<td>50</td>
</tr>
<tr>
<td>Statins (%)</td>
<td>xx</td>
</tr>
<tr>
<td>Antiplatelet drug (%)</td>
<td>xx</td>
</tr>
<tr>
<td>ACE inhibitors (%)</td>
<td>xx</td>
</tr>
</tbody>
</table>
### Intraoperative data

<table>
<thead>
<tr>
<th>Procedure</th>
<th>30 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local anesthesia + sedation (%)</td>
<td>100</td>
</tr>
<tr>
<td>Retrograde approach (%)</td>
<td>100</td>
</tr>
<tr>
<td>45cm-5F sheath (%)</td>
<td>100</td>
</tr>
<tr>
<td>Arteriography for diagnosis (%)</td>
<td>0</td>
</tr>
<tr>
<td>Angioplasty alone (%)</td>
<td>13</td>
</tr>
<tr>
<td>Femoropopliteal treatment</td>
<td>87</td>
</tr>
<tr>
<td>Stenting (%)</td>
<td>87</td>
</tr>
<tr>
<td>Mean procedure duration (mn)</td>
<td>63±24 (29-120)</td>
</tr>
<tr>
<td>Mean manual compression duration (mn)</td>
<td>12.8±4.1 (9-25)</td>
</tr>
</tbody>
</table>
Walking ability @5 hours

n=28 (93.3%)
- Arythmia
- False aneurysm @ the puncture site

Perioperative complications

n=4 (13%)
False aneurysm @ the puncture site (reintervention)
Calf hematoma
Leg hematoma
Arythmia
1-month FU

- 100% FU
- No further reintervention
- No further local complications
- No MACE
- Significant improvement of life quality
  (Mean EQ5D score baseline vs 1 mo: 72±17 vs 60±16; p=0.001)
Take home message

- Manual compression after endovascular repair with 5F compatible devices allows early walking

- Manual compression could be an alternative to the use of arterial closure devices for same day discharge procedures for PAD patients
FREEDOM

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