Evaluating the economic value of 5F systems for outpatients

Pr Yann Gouëffic, MD, PhD

Department of vascular surgery - University Hospital of Nantes, France
Disclosure

Speaker's name: Yann Goueffic

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

Consultant: COOK, CORDIS, COVIDIEN, MEDTRONIC, PEROUSE, TERUMO
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?

Clinical and Economic Evaluation of Ambulatory Endovascular Treatment of Peripheral Arterial Occlusive Lesions

Bénédicte Albert, Jean-Michel Davaine, Marie-Pierre Chaillet, Gaël Grimandi, Béatrice Guyomarch, Laure Azéma, Alain Costargent, Philippe Chaillou, Philippe Patra, and Yann Gouëffic, Nantes, France


Period: June 2008 - October 2010 (29 months)
Evaluation criteria

- **Primary endpoint:**
  perioperative morbimortality rate

- **Secondary endpoints**
  - Clinical improvement at 1 month
  - Cost (Angio-Seal® vs longer hospital stay)
Outpatients functional unit

- Patients scheduled
- Hospitalization at 7-7.30am
- Preparation and check of patients’ requirements
- Procedure done before 2 pm (6F/7F devices)
- Arterial closure device
- Patient leaving hospital not before 6pm, after authorization given by the surgeon and the anesthesiologist
- Clinical and duplex scan evaluation at 1 month
45 patients / 50 hospitalization stays

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>number</th>
<th>%</th>
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<tbody>
<tr>
<td>Sexe male</td>
<td>42</td>
<td>93%</td>
</tr>
<tr>
<td>Active smoking</td>
<td>26</td>
<td>58%</td>
</tr>
<tr>
<td>Inactive smoking</td>
<td>11</td>
<td>24%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>25</td>
<td>56%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8</td>
<td>18%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>23</td>
<td>51%</td>
</tr>
<tr>
<td>Family history</td>
<td>5</td>
<td>11%</td>
</tr>
<tr>
<td>BMI : obesity</td>
<td>4</td>
<td>9%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Preoperative renal function</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning renal failure</td>
<td>19</td>
<td>42%</td>
</tr>
<tr>
<td>Renal failure</td>
<td>8</td>
<td>18%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>45 patients</th>
<th>n</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Previous history of vascular surgery</td>
<td>18</td>
<td>40%</td>
</tr>
<tr>
<td>Previous history of cardiac pathology</td>
<td>10</td>
<td>22%</td>
</tr>
<tr>
<td>ASA 1</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>ASA 2</td>
<td>35</td>
<td>78%</td>
</tr>
<tr>
<td>ASA 3</td>
<td>9</td>
<td>20%</td>
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<tr>
<td>Preoperative treatment</td>
<td></td>
<td></td>
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<tr>
<td>2 antiplatelet</td>
<td>11</td>
<td>24%</td>
</tr>
<tr>
<td>VKA</td>
<td>3</td>
<td>7%</td>
</tr>
<tr>
<td>Symptomatology</td>
<td>%</td>
<td>(n)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Claudication</td>
<td>90</td>
<td>(45)</td>
</tr>
<tr>
<td>Decubitus pain</td>
<td>6</td>
<td>(3)</td>
</tr>
<tr>
<td>Trophic disorder</td>
<td>2</td>
<td>(1)</td>
</tr>
<tr>
<td>Renal artery stenosis</td>
<td>2</td>
<td>(1)</td>
</tr>
</tbody>
</table>

Claudication: 91.5%
CLI: 8.5%

<table>
<thead>
<tr>
<th>Multiples and complex lesions</th>
<th>%</th>
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<tbody>
<tr>
<td>Iliac</td>
<td>70</td>
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<tr>
<td>Femoropopliteal</td>
<td>68</td>
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<tr>
<td>Infraopopliteal</td>
<td>4</td>
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<tr>
<td>Thrombosis</td>
<td>64</td>
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<tr>
<td>Bilateral lesions</td>
<td>30</td>
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<tr>
<td>Multilevel lesions</td>
<td>36</td>
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<tr>
<td>Intraoperative data</td>
<td>%</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Antegrade puncture</td>
<td>6</td>
</tr>
<tr>
<td>Retrograde puncture</td>
<td>94</td>
</tr>
<tr>
<td>Cross over</td>
<td>60</td>
</tr>
<tr>
<td>Combined access</td>
<td>14</td>
</tr>
<tr>
<td>Stenting</td>
<td>90</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Angioseal® data</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angio-Seal® VIP 6F</td>
<td>93%</td>
</tr>
<tr>
<td>Angio-Seal® VIP 8F:</td>
<td>7%</td>
</tr>
</tbody>
</table>
Same-day discharge peri-operative morbi-mortality: 16% (n=8)

- Surgical conversion: 4% (n=2) – stent migration / rupture
- Leg hematoma: 2% (n=1) – procedure-related
- Hematoma at the puncture site: 4% (n=2) – introducer related
- Operator learning curve with VCD: 6% (n=3) – mis-deployment

All the adverse events were observed in the operating room or in the recovery room.
None re-hospitalization during peri-operative period.
Clinical improvement @ 1 month

- In 98% of the case

- Complications
  - 1 paresthesia
  - 1 Scarpa hematoma
  - 1 Leg hematoma

None reintervention - None rehospitalization
Economic evaluation

Saving of 44 hospitalization days: 10,971 €

Cost of 54 arterial closure device: 7,427 €

Saving: 3,544 €
Issues for the developpement 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

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

presents a greater risk after the ACD

Cost

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

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

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

Recruiting: 02/2015

- Endovascular examination or treatment compatible with a 5F catheter
- Entrust™ delivery system with EverFlex™ self-expanding peripheral stent
- Primary endpoint: Walking ability @ H5
Primary endpoint: walking ability @ H5

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

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
### Patients

**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
Entrust™ delivery system with EverFlex™ self-expanding peripheral stent (Covidien)

- 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)
Take home messages

1/ Same-day discharges procedures are safe and efficient

2/ Clinical, legal and economic issues should be investigated to enlarge the indication of same-day discharge procedures

3/ Manual compression based on the use of 5F devices could decrease the cost and increase the safety of same-day procedures
Evaluating the economic value of 5F systems for outpatients

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