Less Invasive EVAR
Transitioning to a Fast-Track Protocol

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Disclosure

Speaker name: Mario Lachat, MD

- I have the following potential conflicts of interest to report:
  - Consulting - TriVascular
Fast-track surgery

- «Same day home», «day surgery», «outpatient surgery», «surgery in out clinic patient»
  - Well investigated pathways
  - Significant clinical and economical advantages

- Fast-track EVAR?
TriVascular LIFE Study
Least Invasive Fast-Track EVAR Study

SUMMARY

• Prospective
• Nonrandomized
• Multicenter post-market registries in Europe and the US
  – Enrolling over 450 subjects
• Purpose to demonstrate Ovation System’s clinical and economic benefits
• Fast-track EVAR protocol
  – **Bilateral percutaneous access**
  – No general anesthesia
  – No postoperative ICU admission
  – Next-day discharge
TriVascular LIFE Study
Least Invasive Fast-Track EVAR Study

ENDPOINTS

• Primary Endpoint:
  – **MAE within 1 month** of the procedure, as determined by independent Clinical Events Committee (CEC)

• Secondary Endpoints:
  – **Treatment success** defined as percent of subjects who successfully follow less invasive protocol through discharge
  – **Additional endpoints** include: vascular access complications, technical success, hospital stay (ICU, Recovery Room, total duration), quality of life, pain, resource utilization of hospital staff, etc.

• Follow-up: 1 month
TriVascular European LIFE Study
Least Invasive Fast-Track EVAR Study

HIGHLIGHTS

- 200 subjects
- 6 Countries / 19 sites
  - Belgium (3 sites)
  - Italy (5 sites)
  - Netherlands (3 sites)
  - Poland (2 sites)
  - Switzerland (1 site)
  - United Kingdom (5 sites)
Why PEVAR?

- Technology continues to drive towards less invasive solutions
- Fewer complications
- Cost pressures growing
- Patient satisfaction and HCAPS
Single-Center Experiences with PEVAR

Percutaneous Endovascular Aortic Aneurysm Repair: A Prospective Evaluation of Safety, Efficiency, and Risk Factors

W. Anthony Lee, MD, Michael P. Bozic, MD, James M. Seeger, MD, Gainesville, Fl., USA

Objective: Percutaneous access during a stent-mediated closure device (Preclose technique) is to examine the late outcomes of methods. The Preclose technique is a closure device deployed in the femoral artery profunda arteriotomy by tying down knots of the Preclose device. The study was performed in 23 patients who underwent endovascular aneurysm repair and were assessed for long-term success. Follow-up protocol consisted of ultrasound imaging at 6 months and annually thereafter. All Preclose patients had a diagnosis of abdominal aortic aneurysm with a minimum of 5 cm in diameter. Results: A total of 292 patients underwent stent-mediated closure device. Two hundred seventy-eight (93.4%) were closed successfully with no complications. In the remaining 34 patients, who had adequate postoperative CT scans, there were no complications. There were no in-hospital deaths, with an in-hospital complication rate of 1.2%. Of the 292 cases, 289 (98.9%) were discharged, with a median length of stay of 3 days. Conclusions: Percutaneous closure of femoral arteriotomies is a low incidence of early and late complications. 96% success in 168 pts.

94% success in 292 pts.
96% success in 500 pts.
96% success in 168 pts.

Midterm outcomes of percutaneous endovascular aneurysm repair

Gabriel Elzer, Bjorn Solheim, Dennis G. Nyman
Department of Vascular Surgery, University Hospital of Bergen, Bergen, Norway

Objective: To evaluate midterm outcome of stent-graft repair using the Preclose technique. Methods: The Preclose technique has been used in our department for endovascular repair of abdominal aortic aneurysms since 2003. Between 2003 and 2015, 2003 patients underwent endovascular aneurysm repair using the Preclose technique. Results: The overall success rate of the Preclose technique was 89% in 23 patients. In 95 patients, who had adequate postoperative CT scans, there were no complications. There were no in-hospital deaths, with an in-hospital complication rate of 1.2%. Of the 2003 cases, 1974 (98.6%) were discharged, with a median length of stay of 3 days. Conclusions: Percutaneous closure of femoral arteriotomies is a low incidence of early and late complications.
Single-Center Experiences with PEVAR

Outpatient Endovascular Aortic Aneurysm Repair
Experience in 100 Consecutive Patients

Mario Louis Lachat, MD,* Felice Pecoraro, MD,‡ Dieter Mayer, MD,* Carole Guillet, MD,* Michael Gienck, MD,‡ Zoran Rancic, PhD, MD,* Christian Alexander Schmidt, PhD, MD,* Gilbert Paippe, MD,‡ Frank Junior Veith, MD,¶ Jacques Bleyen, MD,¶ and Dominique Bettex, MD‡

Objectives: To present the safety, feasibility, costs, and patient satisfaction of outpatient endovascular aneurysm repair (EVAR).

Background: Our experience in more than 1000 patients indicated that technically uncomplicated EVAR procedures, the operation was for access vessel complications (bleeding or secondary procedures). These complications could also be anticipated within the first 3 hours after EVAR.

Methods: Two-center retrospective analysis of prospectively gathered data on 100 consecutive elective outpatient EVAR cases (Outpt EVAR). Indications for Outpt EVAR were as follows: asymptomatic clinical status, informed consent, travel time to the hospital if readmission was required, one of 24 hours, and a technically uncomplicated EVAR procedure. EVAR was mostly performed under local anesthesia and with percutaneous access. Patients were discharged home after 4 to 6 hours of observation and checked the next morning and on the fifth postoperative day in the outpatient clinic.

Results: From 104 patients selected, 4 (3.8%) preferred primary hospitalization and were excluded from further analysis. Four patients (4%) with access vessel complications required additional procedures and had to be hospitalized overnight. The 30-day readmission rate was 4% (4), all due to access vessel stenosis (2) or false aneurysm (2). There was no 30-day mortality. From the 96 patients who completed Outpt EVAR, 93 (97%) would undergo Outpt EVAR again and would recommend it to others. Cost comparison showed in 42 matched contemporary patients treated with standard stent graft that costs were significantly lower in 21 Outpt EVAR patients than in 21 inpatient EVAR.

Conclusions: Elective Outpt EVAR can be performed safely, provided certain criteria are fulfilled and specific precautions are taken. In this series, Outpt EVAR morbidity was minimal, especially relevant common in elderly patients recovering from inpatient vascular surgery and nosocomial infections did not occur. Finally, patient satisfaction was high and costs were less than with standard inpatient EVAR.

Keywords: ambulant, day, endovascular aneurysm repair, EVAR, fast-track, outpatient, surgery

Since its introduction, endovascular aneurysm repair (EVAR) has proven to be less invasive and offering significant perioperative morbidity and mortality advantages over traditional open repair. In our institution, 88% of all Aneurysm EVAR cases were performed as outpatient procedures, with a success rate of 96%.

PEVAR: 96% success in 88 pts.
In PEVAR, Size Matters...

- Lower profile devices are associated with higher success rates and fewer complications

  - Success rate for patients with sheath size $\geq 20F$ was 78% compared to 98.4% success rate for patients with sheath size $\leq 18F^1$

  - Risk of conversion to cutdown increased by 78% with sheaths $\geq 20F^2$

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1 Starnes et al. J. Vas Surg. 2006 Feb
In PEVAR, Size Matters...

- Growth of PEVAR is complemented by decrease in sheath delivery sizes
- Experience includes both Prostar®XL and ProGlide® SMCDs

Comparison of EVAR Delivery Systems*

- **Lombard Aorfix™**: 22F OD
  - Addresses 27% of AAA population

- **Gore Excluder®**: 20F OD
  - Addresses 40% of AAA population

- **Medtronic Endurant® / Cook Zenith® LP**: 18F OD
  - Addresses 59% of AAA population

- **Endologix Nellix®**: 17F OD
  - Addresses 63% of AAA population

- **TriVascular Ovation Prime® / Cordis Incraft®**: 14F OD
  - Addresses 83% of AAA population

* Patient’s Access Vessel Size Distribution for CE Mark devices
  (Derived from M2S Measurement Database of 43,000 CT Scans)
CLINICAL TRIAL EXPERIENCE WITH PEVAR
In the Ovation pivotal trial, subjects (43%) undergoing percutaneous access (PEVAR) achieved similar clinical outcomes, but with fewer MAEs and less time spent related to anesthesia, procedure and hospitalization.

<table>
<thead>
<tr>
<th></th>
<th>Cut-Down (S-EVAR) N=92</th>
<th>Percutaneous (P-EVAR) N=69</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Adverse Event @ 30 Days</td>
<td>3.3%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Anesthesia Time (mean)</td>
<td>191 minutes</td>
<td>149 minutes</td>
</tr>
<tr>
<td>Procedure Time (mean)</td>
<td>118 minutes</td>
<td>98 minutes</td>
</tr>
<tr>
<td>Hospitalization (median)</td>
<td>2 days</td>
<td>1 day</td>
</tr>
<tr>
<td>Treatment Success @ 1-year</td>
<td>98.9%</td>
<td>100%</td>
</tr>
</tbody>
</table>
# Endologix PEVAR Trial\(^1\)

First FDA Approved, Prospective, Multicenter, Randomized, Controlled Trial of Totally Percutaneous EVAR

<table>
<thead>
<tr>
<th>Major Ipsilateral Access Site Vascular Complications at 30 Days [95% CI](^1)</th>
<th>PEVAR ProGlide N = 50</th>
<th>SEVAR N = 50</th>
<th>Difference 95% CI(^2)</th>
<th>p-value(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6% (3/50) [1.3%, 16.5%]</td>
<td>10% (5/50) [3.3%, 21.8%]</td>
<td>-4.0% [ - , 4.9%]</td>
<td>0.0048</td>
<td></td>
</tr>
</tbody>
</table>

This trial revealed that PEVAR is safe and offers lower vascular morbidity than surgical access and repair

\(^1\)Nelson et al. J. Vas Surg. 2014 Jan

©2015 TriVascular, Inc. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
PEVAR potential benefits across the health care spectrum

<table>
<thead>
<tr>
<th>Patient Benefits</th>
<th>Physician Benefits</th>
<th>Hospital Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Minimally Invasive</em></td>
<td><em>No delay for anesthesia</em></td>
<td><em>Patient satisfaction</em></td>
</tr>
<tr>
<td>Avoiding complications of general anesthesia</td>
<td><em>Improved patient satisfaction</em></td>
<td><em>Lower infection rates</em></td>
</tr>
<tr>
<td>Less blood loss</td>
<td><em>Improved efficiency from quicker procedure time</em></td>
<td><em>Lower cost by avoiding anesthesia</em></td>
</tr>
<tr>
<td>Fewer groin complications</td>
<td></td>
<td><em>Less need for blood transfusion</em></td>
</tr>
<tr>
<td>Less pain</td>
<td></td>
<td>Better utilization of hospital resources</td>
</tr>
<tr>
<td>Quicker recovery time</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PEVAR potential benefits across the health care spectrum

<table>
<thead>
<tr>
<th>Costs comparison (Euro)</th>
<th>Costs for Outpt EVAR</th>
<th>Costs for Inpt EVAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician fees</td>
<td>2125 ± 908</td>
<td>1789 ± 1492</td>
<td>0.38</td>
</tr>
<tr>
<td>Nurse fees</td>
<td>185 ± 73</td>
<td>1023 ± 483</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medical services costs</td>
<td>1657 ± 637</td>
<td>1254 ± 422</td>
<td>0.02</td>
</tr>
<tr>
<td>-Outpatient Clinic</td>
<td>510 ± 605</td>
<td>57 ± 38</td>
<td>0.01</td>
</tr>
<tr>
<td>Material cost</td>
<td>8042 ± 3615</td>
<td>9467 ± 1596</td>
<td>0.10</td>
</tr>
<tr>
<td>Ward costs</td>
<td>33 ± 7</td>
<td>258 ± 96</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Management costs</td>
<td>1690 ± 511</td>
<td>2112 ± 751</td>
<td>0.04</td>
</tr>
<tr>
<td>Total costs</td>
<td>13732 ± 5543</td>
<td>15903 ± 4813</td>
<td>0.05</td>
</tr>
</tbody>
</table>

@ University Hospital Zurich
Stanford Criteria for Fast-Track EVAR

Pre-operative Criteria

• Functionally independent, performing all activities of daily living
• Social support with someone available to stay with the patient for the first 24 hours postprocedure
• Absence of significant baseline comorbidities (unstable angina, congestive heart failure, severe chronic obstructive pulmonary disease)
• Normal renal function
• Favorable aortic anatomy (no angulated iliac or aortic portions or significant thrombus)

Peri-procedural Criteria

• Uncomplicated PEVAR with a procedural duration < 2 hours
• Uneventful 4-hour observation period following the procedure
• Able to tolerate a regular oral diet
• Pain controlled with oral analgesics

Source: EndoVascular Today The Least-Invasive Approach: Transitioning to a fast-track EVAR protocol, Brant W. Ullery, MD and Jason T. Lee, MD, September 2014
# University of Zurich Criteria for Fast-Track EVAR

## TABLE 1. Selection Criteria for Outpt EVAR

**Inclusion**
- Asymptomatic patient
- Anatomy suitable for EVAR
- Transfer time to hospital for eventual readmission of <60 min
- Adult observer assistance the first 24 hrs
- Informed consent
- Technically successful procedure

**Exclusion**
- Any serious intraoperative complication
- Procedural time >4 hrs
- Incomplete sealing of access vessels
Outpt EVAR - Methods

Outpatient pathway

1. Informed consent
2. Procedure
3. Postoperative checks
### University of Zurich Criteria for Fast-Track EVAR

**TABLE 2. Main Differences Between Inpatient and Outpatient Pathways**

<table>
<thead>
<tr>
<th></th>
<th>Outpt EVAR</th>
<th>Inpt EVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative</strong></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Admission, quick check</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Day of surgery</strong></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Admission, quick check</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovery room</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Bedroom</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Discharge</td>
<td>Same day</td>
<td>3rd POD</td>
</tr>
<tr>
<td><strong>Follow-up in OPC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st POD</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Wounds, laboratory, ABI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5th POD</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Wounds, laboratory, ABI, CTA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CASE STUDY REVIEW

70 yo female
Diagnosis

- **AAA 56mm (rapidly growing)**
  - Positive family history of rAAA (brother, sister)
Diagnosis

- **AAA** 56mm (rapidly growing)
  - Positive family history of rAAA (brother, sister)
- Peripheral occlusive disease (ABI 0.6)
- Facioscapulohumeral muscular dystrophy
  - 1979
  - Tetraparesis (atonic)
- CAD
  - AMI, PCI 2000
- RVD: 50%-70% RRA stenosis
- COPD (GOLD 3, risk-group C)
  - smoker
- Migrain
Outpt EVAR @ UHZ (2011)

- Hybrid OR
PEVAR Technique @ UHZ

- **Identify potential troubles on CTA**
  - Calcifications, atherome, stenosis

- **US guided puncture**

- **Prox. access site**
  - >2 cm above Bifurcation
Unsuccessful closure
Distal CFA re-access
Outpt EVAR @ UHZ (2011)

- Hybrid OR

- Recovery bed room
Summary

- EVAR continues to evolve into an increasingly safe, less-invasive, and efficacious therapeutic alternative to open AAA repair.
- Led by the low-profile 14-F Ovation Prime Stent Graft, the trend toward lower-profile devices has enabled the transition toward a fast-track EVAR protocol characterized by routine percutaneous access and the potential to avoid general anesthesia.
- Results of the LIFE study will significantly contribute to the existing literature in the near future and add momentum to the inevitable transition toward a fast-track, next-day-discharge EVAR protocol.
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