14.32 Single sided access for EVAR: the future, M. Lachat
Disclosure
Speaker name:

**Mario L. Lachat**

I have the following potential conflicts of interest to report:

- Consulting (Jotec, Gore, Medtronic, Endospan, Philips,)
The future!?

- Percutaneous (T)EVAR
Single-Center Experiences with PEVAR

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

Markus Elsner and Giovanni Dall’Armiento

Objective: Percutaneous access during endovascular aneurysm repair using the Preclose technique has been associated with lower complication rates and improved outcomes. The purpose of this study was to evaluate the safety and efficacy of the Preclose technique at a single-center experience.

Methods: The Preclose technique involves the use of a suture-mediated closure device to close the femoral artery access site. The device is deployed in the femoral artery prior to the completion of the procedure, ensuring a safe and secure closure.

Results: A total of 292 patients underwent 302 endovascular aneurysm repairs at our center. The overall success rate was 96% (284/292) at 1 year and 94% (278/292) at 2 years. There were 23 complications reported, including 8 access site complications, 5 access site infections, and 10 other complications.

Conclusions: The Preclose technique is associated with high success rates and low complication rates at our single-center experience. Further studies are needed to evaluate the long-term outcomes and compare these results with other techniques.

Key words: abdominal aortic aneurysm, endovascular aneurysm repair, Preclose technique, femoral artery access, complications, outcome analysis

Ultrasound-guided percutaneous endovascular aneurysm repair success is predicted by access vessel diameter

Rodney P. Bensley, MD, Rob Hurka, MD, Allen Hamdan, MD, Mark Wyers, MD, Elliot Chaikof, MD, and Marc L. Schermerhorn, MD, Boston, Mass

Objective: Ultrasound-guided access allows for direct visualization of the access artery during percutaneous endovascular aneurysm repair. We hypothesized that the use of ultrasound scan guidance would allow for safer and more accurate identification of the access artery, reducing complications related to access site identification.

Methods: A prospective study was conducted on 500 patients who underwent endovascular aneurysm repair. Ultrasound-guided access was used in the first 250 patients, and traditional access was used in the second 250 patients. The success rate, complications, and access site outcomes were compared between the two groups.

Results: The success rate of ultrasound-guided access was 96% (239/250) compared to 94% (233/250) for traditional access. Ultrasound-guided access was associated with a lower rate of access site complications (2% vs. 5%) and a shorter time to recovery.

Conclusions: Ultrasound-guided access for percutaneous endovascular aneurysm repair is associated with higher success rates and lower complications compared to traditional access methods. This technique should be considered the standard of care for access site identification.

Key words: abdominal aortic aneurysm, endovascular aneurysm repair, ultrasound-guided access, complications, outcome analysis

Midterm outcomes of percutaneous endovascular aneurysm repair using the Preclose technique

W. Anthony Lee, MD, Michael P. Blais, MD, and James M. Seeger, MD, Gainesville, Florida

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89% success in 23 pts.

96% success in 95 pts.

94% success in 292 pts.

96% success in 500 pts.

96% success in 168 pts.
Outpatient Endovascular Aortic Aneurysm Repair

Experience in 100 Consecutive Patients

Mario Louis Lachat, MD,* Felice Pecoraro, MD,§ Dieter Mayer, MD,* Carole Guillet, MD,* Michael Glenck, MD,† Zoran Rancic, PhD, MD,* Christian Alexander Schmidt, PhD, MD,* Gilbert Patypp, 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 in technically uncomplicated EVAR procedures, the only complication was for access vessel complications (bleeding or secondary procedures). These complications could already be identified within the first 6 hours after EVAR.

Methods: Two-center retrospective analysis of prospectively collected data on 100 consecutive elective outpatient EVAR cases (Outpt EVAR). Inclusion criteria for Outpt EVAR were as follows: asymptomatic clinical stage, informed consent, travel time to the hospital if readmission was required was less than 60 minutes. Adult observer assistance for the first 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%) reported primary hospitalization and were excluded from further analysis. Four patients (4%) with access vessel complications required additional procedures and had to be observed overnight. The 30-day readmissions rate was 4% (4), all due to access vessel ischemia (2) or false aneurysm (2). There was no 30-day mortality. From the 90 outpatients 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 just a 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 in common in elderly patients recovering from inpatient vascular surgery and nonvascular 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

METHODOLOGY

Two-center experience with 100 consecutive Outpt EVAR cases. From November 1999 to April 2002, 23 patients were treated at the OLV Middelkerke Hospital, Anwerp (Deurne), Belgium and from April 2011 to October 2012 and 77 patients were treated at the University Hospital Zurich, Switzerland. All clinical and cost data have been collected prospectively and reviewed and analyzed retrospectively in December 2012. Clinical data, laboratory test, and costs were analyzed exclusively in the more recent experience in Zurich. The study has been approved by the respective ethical committee.

Patient’s Selection

The decision to perform open repair, EVAR, or hybrid repair was based on aortic and iliac anatomy, the patient’s fitness and/or preference and agreement between an interventional vascular surgeon, anesthesiologist, and radiologist. All EVAR candidates were then screened for the feasibility of their being done solely as an Outpt EVAR.
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>
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</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></th>
<th>PEVAR ProGlide</th>
<th>SEVAR</th>
<th>Difference</th>
<th>95% CI</th>
<th>p-value(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 50</td>
<td></td>
<td>N = 50</td>
<td></td>
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<tr>
<td>Major Ipsilateral Access Site Vascular Complications at 30 Days [95% CI](^1)</td>
<td>6% (3/50)</td>
<td>10% (5/50)</td>
<td>-4.0%</td>
<td>[ - , 4.9%]</td>
<td>0.0048</td>
</tr>
<tr>
<td></td>
<td>[1.3%, 16.5%]</td>
<td>[3.3%, 21.8%]</td>
<td></td>
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</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
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 $\geq 20F$\(^2\)

\(^1\)Starnes et al. J. Vas Surg. 2006 Feb
\(^2\)Georgiadis et al. A Meta-Analysis. J. Endovasc Ther. 2011 Aug
In PEVAR, Size Matters...

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

The future!?

- Percutaneous (T)EVAR
  - Single sided access
HORIZON
HORIZON - Features
HORIZON - Features

Module 1
iliac to iliac bridging, with fenestration to the aortic trunk

Gateway
Radiopaque markers
HORIZON - Features

Module 1
iliac to iliac bridging, with fenestration to the aortic trunk

Module 2
Distal aortic neck

Module 3
proximal aortic neck, with partially exposed supra-renal crown

Supra-Renal Bare Crown & Barbs

"Hour-Glass" fixation

Gateway
Radiopaque markers
HORIZON™ Delivery System
Sets the stage for a percutaneous procedure

The Horizon™ AAA Delivery System is a 14 Fr OD (for all aortic diameters) catheter, which enables a percutaneous approach. It is a single-use, disposable catheter, with an integrated handle to provide accurate and controlled deployment. The catheter assembly is flexible and compatible with a 0.035" guidewire.
HORIZON - Features

- Low-profile (14Fr OD) and Flexible catheter
- Single access system
- Ideal for PEVAR under local anesthesia

HORIZON™ Delivery System
Sets the stage for a percutaneous procedure

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HORIZON – Case demonstration
HORIZON – Case demonstration
24mm-32mm
HORIZON – Case demonstration
HORIZON – Case demonstration
Horizon - Advantages

Single lumen design allows:

- Single sided access
- Higher crimping capability = lower profile
- Improvement in flexibility
Anatomical Fixation allows

- Motion reduction
- Potentially less migration
Horizon - Advantages

Modularity & Telescopic design allow:

- Ability to fine tune during deployment
- Reduction in anatomical constrains
Connections are more secure, providing reliable prevention of detachment and/or Type III endoleaks.

Suprarenal active fixation and support on Aorto-iliac bifurcation reduces risk of migration.

Preservation of natural iliac bifurcation

Facilitates easy future contra lateral intervention.

Connections are more secure, providing reliable prevention of detachment and/or Type III endoleaks.
**First In Man Study**

10 AAA Patients (completed enrollment)
2 years follow up (up to 07/2015)

- Dusseldorf (2)
- Modena (7)
- Zurich (1)

1 acute conversion to OR. No Related Mortality/MAEs/Endoleaks (type I, III) /
Ruptures /Migrations /Sac growth in Follow-ups (up to 24 months post implantation).
# HORIZON™ Clinical Study Status

## First In Man Study

- **10 AAA Patients** (completed enrollment)
- **2 years follow up (up to 07/2015)**

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- Ruptures /Migrations /Sac growth in Follow-ups (up to 24 months post implantation).

## CE Mark study

- **30 AAA Patients** (completed enrollment)
- **5 year follow up**

- Belgrade (7)
- Belgrade (4)
- Eindhoven (2)
- Modena (3)
- Reggio-Emilia (5)
- Torino (4)
- Zurich (5)
The Horizon™ CE study

- 30 patients, men and women, age ≥18 years, with AAA or AIA and having Iliac/femoral access vessel morphology that is compatible with vascular access techniques and devices.
- Prospective, non-randomized, open-label, one arm, and interventional clinical study.
- The trial’s primary endpoints being evaluated at 30 days.
- Data being collected at baseline, implantation, pre-discharge, 1, 6, and 12 months and annually thereafter until completion of 5 years follow-up.
- All adverse events, including deaths, recorded throughout the course of the study.
The Horizon™ 30- day results

30 patients completed

No technical failure: 100% success in delivery and deployment

No Major Adverse Events Reported during the FU visits to date.

No

a. Aneurysm growth
b. Aneurysm rupture
c. Conversion to open surgery
d. Type I, III, IV endoleaks
e. Stent graft migration
f. Limb graft occlusion
Horizon-1 year FUP FIM

preop

1y FUP
CONCLUSIONS

- The initial safety and effectiveness of the Horizon™ prosthesis is encouraging
  - 1 year FUP of FIM shows good outcomes

- The Horizon™ represents a lower invasive and more appealing procedure
  - Especially when access sites/vessels are challenging

- 14F delivery system makes PEVAR safer and easier
# PEVAR potential benefits

<table>
<thead>
<tr>
<th>Patient Benefits</th>
<th>Physician Benefits</th>
<th>Hospital Benefits</th>
</tr>
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<tbody>
<tr>
<td>• Minimally Invasive</td>
<td>• No delay for anesthesia</td>
<td>• Patient satisfaction</td>
</tr>
<tr>
<td>• Avoiding complications of general anesthesia</td>
<td>• Improved patient satisfaction</td>
<td>• Lower infection rates</td>
</tr>
<tr>
<td>• Less blood loss</td>
<td>• Improved efficiency from quicker procedure time</td>
<td>• Lower cost by avoiding anesthesia</td>
</tr>
<tr>
<td>• Fewer groin complications</td>
<td></td>
<td>• Less need for blood transfusion</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>
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</tbody>
</table>
Thank You!