Most EVAR procedures should be done under local anaesthesia.

D. Böckler
Department of Vascular and Endovascular Surgery
University Hospital Heidelberg
Disclosures

• Consultant
  – Arsenal, Cook, Endologix, Gore, Medtronic, Cook

• Research Grant / research support
  – Cook, Gore, Maquet, Medtronic, Siemens

• Advisory Board
  – Endologix, Gore, Medtronic, Siemens

• Paid speaker
  – Cook, Endologix, Gore, Maquet, Medtronic, Siemens

• Major stakeholder
  – none

No conflict of interest
Access for EVAR

- Cut-down
- Fascia closure
- Percutaneous
Cut-down: Surgical access

- Longitudinal
- Transverse
Surgical access – complications

• Incidence in the literature: 5-15%

• Study * with 186 patients
  – Infection 8%
  – Wound necrosis 6.5%
  – Lymphocele 4.8%
  – Haematoma 1%

Percutaneous EVAR (pEVAR) - Why?

• **Potential advantages**
  – Fast mobilisation
  – Reduced in-hospital stay
  – Reduced operating time
  – Less wound infections / lymphatic fistula
  – Reduction in costs per case
  – Less invasive

• **Disadvantages**
  – Device specific complications
  – Technical failure
Percutaneous EVAR (pEVAR) - Why?

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 Puippe, MD,†
Frank Junior Veith, MD,* Jacques Bleyn, 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 need for hospitalization was for access vessel complications (bleeding or occlusion) requiring secondary procedures. These complications could always be identified 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). Inclusion criteria for Outpt EVAR were as follows: asymptomatic clinical state, informed consent, travel time to the hospital if readmission was required of 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.

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 experienced centers, 30-day mortality of elective EVAR in low-risk patients is clearly less than 1%. Our 16-year experience with more than 1000 EVAR cases indicated that in technically uncomplicated EVAR procedures the only need for postoperative hospitalization was for access vessel complications (bleeding or occlusion) requiring secondary procedures. These latter complications could always be identified within the first 3 hours after EVAR. We also noted that the often older EVAR patients complained after their EVAR procedure about the stresses of staying in the hospital and expressed the wish to go home as soon as possible. On the basis of these facts and motivated by the oral communications of Jacques Bleyn about his initial experience of EVAR performed as “day procedure,” we decided to offer this technique to our Zurich patients. We herein report an
Selected Example - Perclose Technique

Proglide / Abbott
Prostar XL
Technique: Ultrasound-guided puncture

Kurisu K, Osanai T, Kazumata K, Nakayama N, Abumiya T, Shichinohe H, Shimoda Y, Houkin K.
Fluoroscopy
Clinical results
Non Randomised Trial, n=80

<table>
<thead>
<tr>
<th></th>
<th>pEVAR</th>
<th>Cut-down</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tech. success</strong></td>
<td>35/38</td>
<td>38/42</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td>3 failure (2 heamorrhage)</td>
<td>1 dissection 3 lymphocele</td>
<td></td>
</tr>
<tr>
<td><strong>Op. time (min)</strong></td>
<td>130</td>
<td>122</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>In-hospital stay (Tage)</strong></td>
<td>5.8</td>
<td>7.8</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Costs (Euros)</strong></td>
<td>5580</td>
<td>7503</td>
<td>0.04</td>
</tr>
</tbody>
</table>
# Clinical Results

Randomised single center study  n=55

<table>
<thead>
<tr>
<th></th>
<th>pEVAR</th>
<th>cutdown</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complications</strong></td>
<td>1 Thrombosis, 1 cut-down</td>
<td>1 Thrombosis, 3 Lymphocele</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Op. time (min)</strong></td>
<td>86</td>
<td>107</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Mobilisation in hours</strong></td>
<td>20</td>
<td>33</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Torsello et al, JVS 2003;38:78-82
# US Randomised Trial

*primary endpoint*

<table>
<thead>
<tr>
<th></th>
<th>PEVAR ProGlide</th>
<th>EVAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 50</td>
<td>N = 50</td>
<td></td>
</tr>
<tr>
<td>Access complications within 30 days</td>
<td>6% (3/50)</td>
<td>10% (5/50)</td>
<td>0.048</td>
</tr>
</tbody>
</table>

*US Randomised Trial: Nelson et al; J Vasc Surg 2014*
US Randomised Trial
secondary endpoint

<table>
<thead>
<tr>
<th></th>
<th>PEVAR ProGlide</th>
<th>SEVAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 50</td>
<td>N = 50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>106+/-44</td>
<td>141+/-73</td>
<td>0.0056</td>
</tr>
<tr>
<td>Time to coagulation(min)</td>
<td>10+/-17</td>
<td>23+/-23</td>
<td>0.0023</td>
</tr>
</tbody>
</table>

*Note: Nelson et al; J Vasc Surg 2014*
MRCT: PEVAR-Trial
(Nelson et al, JVS 2014)

- 121 pat. randomized
- Percut. Vs. Ccut down
- Outcome @30 day and 6 mths.
- Non-inferiority for PEVAR
- Shorter time to hemostasis
- Shorter procedure time
- Less pain, more QOL
Metaanalysis of 21 Studies (n=193)
Haulon et al, EJVES 2011

- Technical success 624/692 (92%)
- Operating time: 66 min. faster than cut-down
- Reduced in-hospital stay
- Reduced costs
Results pEVAR vs. Surgical Access

No difference regarding

- Mortality
- Wound infection
- Haematoma/Bleeding

> pEVAR: reduced operating time (30 min)
Device specific complications

- Case-dependent factors:
  - Sheath size
  - Obesity
  - Hostile groin
  - Difficult access vessel: calcification

- Surgeon’s experience
  - Learning curve
Technical success: 96.1%

Risk factors:
- Calcification
- Surgeon’s experience (<30)
- Hostile groin
- Sheath size
Predictors for technical failure

Calcification > patient selection

Predictors for technical failure

- Experience
- Learning curve


Predictors of percutaneous access failure requiring open femoral surgical conversion during endovascular aortic aneurysm repair.
### Predictors for technical failure

**Table 2**  
Uni and multifactorial analysis for successful percutaneous access.\(^a\)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Success (n = 81)</th>
<th>Failure (n = 9)</th>
<th>P value (Univariate analysis)(^c)</th>
<th>P value (Multivariate analysis)(^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>74.0 ± 7.7</td>
<td>77.1 ± 9.4</td>
<td>0.26</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>Female (%)</td>
<td>11</td>
<td>0</td>
<td>n/a(^b)</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.1 ± 3.6</td>
<td>28.7 ± 5.5</td>
<td>0.31</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>DM (%)</td>
<td>8.6</td>
<td>33.3</td>
<td>0.21</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>Cr &gt;120 (%)</td>
<td>23.5</td>
<td>33.3</td>
<td>0.08</td>
<td>0.38</td>
</tr>
<tr>
<td>Groin scarring (%)</td>
<td>13.6</td>
<td>11.1</td>
<td>0.40</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>CFA depth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>41.3 ± 15.3</td>
<td>53.7 ± 23.0</td>
<td>0.03</td>
<td>0.33</td>
</tr>
<tr>
<td>Min</td>
<td>29.4 ± 9.5</td>
<td>35.8 ± 12.7</td>
<td>0.07</td>
<td>0.85</td>
</tr>
<tr>
<td>CFA diameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>12.7 ± 2.0</td>
<td>14.0 ± 2.6</td>
<td>0.07</td>
<td>0.32</td>
</tr>
<tr>
<td>Min</td>
<td>9.6 ± 1.6</td>
<td>10.8 ± 1.1</td>
<td>0.04</td>
<td>0.34</td>
</tr>
<tr>
<td>CFA length</td>
<td>47.2 ± 11.4</td>
<td>47.4 ± 10.1</td>
<td>0.94</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>Anterior calcification</td>
<td>2.9 ± 4.0</td>
<td>1.4 ± 1.7</td>
<td>0.29</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>Post calcification</td>
<td>8.3 ± 9.0</td>
<td>4.6 ± 5.2</td>
<td>0.26</td>
<td>n/a(^b)</td>
</tr>
<tr>
<td>Experienced surgeon (%)</td>
<td>66.7</td>
<td>44.4</td>
<td>0.00</td>
<td>0.05</td>
</tr>
</tbody>
</table>

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\(^a\) Percutaneous access with large vessel closure for endovascular aortic surgery: experience and predictors of technical success.

\(^b\) Data not available.

\(^c\) Univariate analysis.

\(^d\) Multivariate analysis.
Clinical results

*Prospective Evaluation* (n=903)

- Technical success 868/903 (96.1%)
- 35 secondary interventions <1 week
  - Postoperative Bleeding 28
  - Pseudoaneurysm 4
  - Arterial thrombosis 3
- Predictors for technical failure
  - Sheath size
  - Previous groin access

*Elsenack et al, J Endo Ther 2009;16:708-13*
Clinical Results: Big Sheath Size

Prospective Evaluation in 118 TEVAR (up to 26 Fr)

- Primary technical success 92%
- 7 Conversions
- Predictors for technical failure
  - Arterial hypertension
  - Age
  - Obesity
- No late complications

Skagius et al, EJVES 2013;46:558-63
Relative Contraindications

- Calcification CFA
- Previous groin acces
- High femoral bifurcation (inguinal ligament)
- Small vessel diameter + big sheath size
- Stenosis: iliac/aortic bifurcation
- Many sheath changes?
- Connective tissue disease?
- Obesity?
Preliminary Summary

pEVAR

- Faster
- Reduced complications following learning curve
- Reduced costs
- Device: Proglide (best data availability, extravasal, suture)

Of note:

- Learning curve (> 30)
- Patient selection
Local Anaesthesia for Endovascular Repair of Infrarenal Aortic Aneurysms


Abstract

Objective: The study aimed to analyse and report the results of a 'local anaesthesia first' approach in elective endovascular aneurysm repair (EVAR) patients.

Material and Methods: Between January 2007 and August 2010, a total of 217 consecutive patients (187 men, median age 76 years, range 52–94 years) underwent elective EVAR using this approach, with predefined exclusion criteria for local anaesthesia (LA). A retrospective analysis regarding technical feasibility, mortality, complication and endoleak rate was performed. The results are reported as an observational study.

Results: LA was applied in 183 patients (84%), regional anaesthesia (RA) in nine patients (4%) and general anaesthesia (GA) in 25 patients (12%). Anaesthetic conversion from LA to GA was necessary in 14 patients (7.6%). Airway obstruction (n = 4) and persistent coughing (n = 3) were the most common causes for conversion to GA. Thirty-day mortality in the LA group was 2.7%, with 16/183 patients (8.7%) experiencing postoperative complications. All type I endoleaks (n = 5, 2.7%) occurred in patients with LA and challenging aneurysm morphologies.

Conclusions: A 'local anaesthesia first' strategy can successfully be applied in 75% of patients undergoing EVAR. The use of LA can impact imaging quality and thus precise endograft placement, which should be considered in patients with challenging aneurysm morphologies.

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Influence of anesthesia type on outcome after endovascular aortic aneurysm repair: An analysis based on EUROSTAR data

Volker Ruppert, MD,^a^ Lina J. Leurs, MSc,^b^ Bernd Steckmeier, MD,^c^ Jacob Buth, MD,^b^ and Thomas Umscheid, MD,^d^ Munich, Germany; Eindhoven, The Netherlands; and Frankfurt, Germany

<table>
<thead>
<tr>
<th>Final completion angiogram</th>
<th>GA N = 3848 (69%)</th>
<th>RA N = 1399 (25%)</th>
<th>LA N = 310 (6%)</th>
<th>P* GA vs RA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak</td>
<td>682 (17.7)</td>
<td>210 (15.0)</td>
<td>29 (9.3)</td>
<td>0.0496</td>
</tr>
<tr>
<td>Proximal</td>
<td>105 (2.7)</td>
<td>52 (3.7)</td>
<td>8 (2.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Midgraft from prosth. fabric</td>
<td>52 (1.3)</td>
<td>17 (1.2)</td>
<td>2 (0.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Midgraft of limb prosth. connection</td>
<td>37 (1.0)</td>
<td>14 (1.0)</td>
<td>1 (0.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Distal</td>
<td>59 (1.5)</td>
<td>24 (1.7)</td>
<td>1 (0.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Perfusion from lumbar or IMA</td>
<td>400 (10.4)</td>
<td>102 (7.3)</td>
<td>10 (3.2)</td>
<td>.0356</td>
</tr>
<tr>
<td>Perfusion from int. iliac artery</td>
<td>24 (0.6)</td>
<td>5 (0.4)</td>
<td>—</td>
<td>NS</td>
</tr>
<tr>
<td>Complications intraoperatively</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device-related complications</td>
<td>196 (5.1)</td>
<td>67 (4.8)</td>
<td>11 (3.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Failure to complete procedure</td>
<td>67 (1.7)</td>
<td>14 (1.0)</td>
<td>3 (1.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Arterial complications</td>
<td>145 (3.8)</td>
<td>46 (3.3)</td>
<td>6 (2.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Complications from operation to discharge</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic complications</td>
<td>498 (13.0)</td>
<td>133 (9.5)</td>
<td>20 (6.6)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Cardiac</td>
<td>142 (3.7)</td>
<td>41 (2.9)</td>
<td>3 (1.0)</td>
<td>.0006</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>86 (2.2)</td>
<td>25 (1.8)</td>
<td>3 (1.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Renal</td>
<td>87 (2.3)</td>
<td>22 (1.6)</td>
<td>7 (2.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Sepsis</td>
<td>37 (1.0)</td>
<td>3 (0.2)</td>
<td>1 (0.3)</td>
<td>0.0432</td>
</tr>
<tr>
<td>Procedure &amp; device related</td>
<td>105 (2.7)</td>
<td>43 (3.1)</td>
<td>2 (0.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Access site &amp; lower limb complications</td>
<td>266 (6.9)</td>
<td>74 (5.3)</td>
<td>14 (4.6)</td>
<td>0.0059</td>
</tr>
<tr>
<td>Early death</td>
<td>93 (2.4)</td>
<td>32 (2.3)</td>
<td>6 (1.9)</td>
<td>NS</td>
</tr>
<tr>
<td>Early conversion</td>
<td>42 (1.1)</td>
<td>8 (0.6)</td>
<td>1 (0.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Early rupture</td>
<td>1 (0.03)</td>
<td>—</td>
<td>—</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are values (%).

GA, General anesthesia; RA, regional anesthesia; LA, local anesthesia.
EVAR – percutaneous + local anaesthetic = State of the Art
EVAR: percutaneous + LA: the new standard

- Technically feasible in most cases (>75%)
- Faster, reduced systemic complications, reduced costs
- Reduced in-hospital stay
- Advantageous in stable rAAA
- Patient’s demand of minimal-invasive technique
- Ability to compete with radiologists/cardiologists
- Global experience and evidence for Proglide/Perclose

Requirements:
- Surgeon’s experience
- Patient selection
- Low profile devices (TEVAR/BEVAR)
Most EVAR procedures should be done under local anaesthetic

D. Böckler
Department of Vascular and Endovascular Surgery
University Hospital Heidelberg