Leipzig 26th January

Evolutions in vessel closure

“Smaller profile devices in EVAR & TEVAR. How do they change practice”

Dr. W. Lansink  ZOL GENK BELGIUM
“Smaller profile devices in EVAR & TEVAR. How do they change practice”

Disclosures: Travel fee & speakers fee:
- Abbott
- Bard
- Cook
- Gore
- Medtronic
“Smaller profile devices in EVAR & TEVAR. How do they change practice”

The short answer is: They didn’t do it for us

we started big hole vessel closure in 1998
with the Prostar device

changed in 2004 to the “double proglide technique”

we did not change strategy P- Evar vs S - Evar
because of the French Size

Dr. W. Lansink ZOL GENK BELGIUM
“Smaller profile devices in EVAR & TEVAR. How do they change practice”

The varicoloured answer is:

with smaller profile devices we:
- can treat patients with smaller access arteries
- can treat more calcified arteries
- therefor can treat more patients with EVAR
- see less complications ……?
Smaller profile devices in EVAR & TEVAR

We use:

- **Gore Excluder** reduced French size over the years between 10 – 33 %
  - Trunk-Ipsi Leg 31 mm device: Reduction 20→18 Fr 10 %
  - Trunk-Ipsi Leg 23/26 mm device: Reduction 18→16 Fr 11 %
  - Contralateral Leg 27 mm device: Reduction 18→15 Fr 17 %
  - Contralateral Leg 23 mm device: Reduction 18→14 Fr 22 %
  - Contralateral Leg 16/18/20 mm device: Reduction 18→12 Fr 33 %

- **Gore Tag** did not change much and the today French size is
  - 21 mm device 18 Fr
  - 21-28 mm device 20 Fr
  - 31-34 mm device 22 Fr
  - 37-45 mm device 24 Fr
Smaller profile devices in EVAR & TEVAR

We use:

- **Cook Zenith AAA:**
  - 1999: Zenith Flex 20-22 Fr
  - 2010: Zenith Low Profile 16 Fr
  - 2014: Zenith Alpha Abdominal 16 Fr

- **Cook Zenith TAA**
  - 2006: Zenith TX2 20-22 Fr
  - 2013 Zenith Alpha Thoracic 16-18-20 Fr

So we get ride of the big 22-24 Fr Devices
Less complications with smaller profile devices?

Pub med:
- not one RCT,
  only two non RCT studies

that mentioned french size as independent factor for failure or success

1: N=113 Ye P in Nan Fang Yi Ke Da Xue Xue Bao 2014 May; 34 (5)
2: N=279 Lee WA in J. Vasc Surg 2007 Jun;45(6)
Less complications with smaller profile devices?

Pub med: french size as independent factor for failure or success
N=113, Ye P in Nan Fang Yi Ke Da Xue Xue Bao 2014 May; 34

24 Fr n=37
22 Fr n=29
20 Fr n=24
18 Fr n=25
16 Fr n=12
14 Fr n=38

Four access related adverse events:
- AV-fistula
- Acute femoral thrombosis
- Bleeding
- Lower extremity ischemia

Occured in 4 cases = 2.4%

He reports:
- ≤ 18 Fr 99 % success
- ≥ 20 Fr 81 % success

P= significant
Less complications with smaller profile devices?

Pub med: french size as independent factor for failure or success
N = 279, Lee Wa et al., J Vasc Surg 2007 Jun;45(6)

37% ≤ 16 Fr  16 Failures
63% ≥ 18 -24 Fr

He reports:
≤ 16 Fr  99.0 % success
≥ 18 Fr  91.4 % success

P= significant
Less complications with smaller profile devices?

Pub med: RCT, independent factors for failure or success

- Anterior Femoral artery calcification > 50% is major risk factor
  J Vasc Surg 2013 Nov
- Severe fibrosis of the access vessel
  J Endovasc Ther 2009; 16
- Learning curve !!
  J Endovasc Ther 2009; 16
  Eur J Vasc Endovasc Surg 2010
  J Vasc Surg 2013 Nov,
  PLoS One 2015 Apr 22
- Use of ultrasound by punction
  - Cardiovasc Intervent Radiol 2013 Jun;36(3)
- Avoid punction above circumflex arteries (ext hypogastric)
- Age and Female gender

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Early and late pe-EVAR results.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
</tr>
<tr>
<td>1st period (1999–2008)</td>
<td>917</td>
</tr>
<tr>
<td>2nd period (2008–2010)</td>
<td>884</td>
</tr>
<tr>
<td>Total</td>
<td>1801</td>
</tr>
</tbody>
</table>

^a Reported on pre-close technique femoral access entry site basis.
Yes, because in the same time we:

- passed the learning curve !!
- start using ultrasound to puncture
- avoid punction above circumflex arteries
- developed a "bail out strategy"
Tips & Tricks to improve your results

1- Inform your patients before the procedure about:

Cost of the device and
Potential side effects!

Hematoma, retroperitoneal bleeding, pseudoaneurysm,
AV-fistula, vessel damage/thrombosis, Infection,
Nerve entrapment

If you read the patients experience at

the biggest complaint is not being informed!!!
Tips & Tricks to improve your results

2 – Study preoperative ct-scan very carefully concerning the CFA:

- exclude severe calcified arteries
- find the right spot in the CFA

Very calcified at the typical puncture place in the mid CFA
Tips & Tricks to improve your results

3 – Use Duplex ultrasound !!!
find the best puncture place in the CFA
- non diseased area
- with at least 5 mm diameter
Tips & Tricks to improve your results

4 – UNDERSTAND THE DEVICE FULLY
in order to interpret the feedback of the vessel locator.
AND
don’t deploy if you don’t have the right feedback.
Tips & Tricks to improve your results

5 - Have a Bailout strategy!

BE PREPARED
- Perform in a surgically equipped room with adequate lighting

BE RESOURCED
- Have surgical equipment (clamps, sutures, endarterectomy instruments) available

BE SAFE
- Leave a wire in place
- If fails try another Proglide
- If this fails reinsert a sheath to achieve hemostasis
- Perform cutdown/femoral artery repair with big sheath for haemostasis

Source: Ramon Varcoe Sydney Presentation Linc Asia pacific
“Smaller profile devices in EVAR & TEVAR. How do they change practice”

Conclusions:

1 French size and obesity are not major factors in failure (almost all studies exp2)

2 Percutaneus vs Surgical Endovascular Aortic Aneurysm repair:

   showed noninferiority in (PEVAR trial) =mrct J. Vasc Surg 2014
   showed in 6 of 7 studies PEVAR vs SEVAR better results for PEVAR
   or-time, time to ambulation, time hospital stay, groin & vessel complications

3 Overall technical success rate (after learning curve)
   in right indication must be above 95 % !!
"Smaller profile devices in EVAR & TEVAR. How do they change practice"

Future: One Single Proglide Device?


Safety and utility of total percutaneous endovascular aortic repair with a single Perclose Proglide closure device

Ichihachi T et al.

Methods: 50 Pevar vs 96 Sevar

Results: complication 4% in Pevar vs 8% in Sevar, or-times 153 vs 211 minutes, hospital lengths of stay 6.7 vs 9.3 days

Conclusions: Compared with SEVAR, PEVAR with a single Proglide device is a safe procedure with shorter operating room time and hospital stay, without increasing access site complications
A device you would like to have invented yourself !!!
Leipzig 26th January

Evolutions in vessel closure

“Smaller profile devices in EVAR & TEVAR. How do they change practice”