Long term results of EVAR for AAA, are the RCT results still valid?

Piergiorgio Cao, MD, FRCS
Disclosure

Speaker name:

**Piergiorgio Cao**

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

I do not have any potential conflict of interest
### RCTs

<table>
<thead>
<tr>
<th>Study</th>
<th>Perioperative mortality</th>
<th>Follow-up years</th>
<th>Risk of Overall mortality</th>
<th>Risk of AAA-related death</th>
<th>Risk of Reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EVAR-1</strong> 2016</td>
<td>0.8%</td>
<td>EVAR: 1.8%</td>
<td>OR: 76.2%</td>
<td>OR: 20%</td>
<td>OR: 20.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EVAR: 83.2%</td>
<td>EVAR: 17.1%</td>
<td>EVAR: 35.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P = 0.001</td>
<td>P = 0.001</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td><strong>DREAM</strong> 2010</td>
<td>4.6%</td>
<td>6.4</td>
<td>OR: 31.1%</td>
<td>OR: 3.7%</td>
<td>OR: 18.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EVAR: 31.1%</td>
<td>EVAR: 2.3%</td>
<td>EVAR: 29.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P ns</td>
<td>P ns</td>
<td>P ns</td>
</tr>
<tr>
<td><strong>OVER</strong> 2012</td>
<td>3%</td>
<td>5.2</td>
<td>OR: 33.4%</td>
<td>OR: 3.7%</td>
<td>OR: 17.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EVAR: 32.9%</td>
<td>EVAR: 2.3%</td>
<td>EVAR: 22.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P ns</td>
<td>P ns</td>
<td>P ns</td>
</tr>
<tr>
<td><strong>ACE</strong> 2011</td>
<td>0.6%</td>
<td>3</td>
<td>OR: 8%</td>
<td>OR: 0.6%</td>
<td>OR: 2.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EVAR: 11.3%</td>
<td>EVAR: 4%</td>
<td>EVAR: 16%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P ns</td>
<td>P ns</td>
<td>P &lt; 0.0001</td>
</tr>
</tbody>
</table>

**EVAR 1**

After 8 y aneurysm-related mortality  OR : 3% vs EVAR 5%  p<0.005
1996: EVT, Ancure

Un-supported body,
Uni-modular device.
High risk of limb kink /occlusion
First generation endografts

Management of Abdominal Aortic Aneurysm: A Decade of Progress

Timothy A.M. Chuter, MD¹; Juan C. Parodi, MD²; and Michael Lawrence-Brown, FRACS³

J Endovasc Ther 2004;11(Suppl II):II-82–II-95
Device migration after endoluminal abdominal aortic aneurysm repair: Analysis of 113 cases with a minimum follow-up period of 2 years

Piergiorgio Cao, MD, Fabio Verzini, MD, Simona Zannetti, MD, Paola De Rango, MD, Gianbattista Parlani, MD, Luciano Lupattelli, MD, and Agostino Maselli, MD, Perugia, Italy


Fig. 4. Probability of device migration of current study cohort. Numbers of patients at risk for different intervals are shown.
Striving for: low profile devices, thinner and durable fabrics, active fixation
January 1997 – December 2011
1412 consecutive pts
Elective EVAR

TABLE 1
Type of Devices Used in the Old and New Stent-Graft Groups

<table>
<thead>
<tr>
<th>Old Stent-Grafts (n=530)</th>
<th>New Stent-Grafts (n=882)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AneuRx</td>
<td>Endurant</td>
</tr>
<tr>
<td>Talent</td>
<td>Zenith</td>
</tr>
<tr>
<td>First-generation</td>
<td>Second-generation</td>
</tr>
<tr>
<td>Excluder</td>
<td>Excluder</td>
</tr>
<tr>
<td>First-generation</td>
<td>Second-generation</td>
</tr>
<tr>
<td>Anaconda</td>
<td>Anaconda</td>
</tr>
<tr>
<td>Fortron</td>
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</tr>
</tbody>
</table>
EVAR TODAY

✔ Evolution of technique and materials

Abdominal Aortic Endografting Beyond the Trials: A 15-Year Single-Center Experience Comparing Newer to Older Generation Stent-Grafts

Fabio Verzini, MD, PhD, FEBVS ; Giacomo Isernia, MD ; Paola De Rango, MD, PhD, FEBVS ; Gioele Simone, MD ; Gianbattista Pariani, MD ; Diletta Loschi, MD ; and Piergiorgio Cao, MD, FRCs

1412 consecutive elective EVAR from 1997 to 2011

J Endovasc Ther 2014

freedom from reintervention

freedom from conversion

freedom from AAA growth >5mm
Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft

Fabio Verzini, MD, PhD, FEBVS,a Lydia Romano, MD,a Gianbattista Parlani, MD,a Giacomo Isernia, MD,a Gioele Simone, MD,a Diletta Loschi, MD,a Massimo Lenti, MD, PhD,a and Piergiorgio Cao, MD, FRCS,b

Perugia and Rome, Italy

J Vasc Surg Feb 2017

2000 - 2011

610 pts

Elective EVAR using the Zenith endograft (Cook)

Mean follow up 99.2 months (range 0-175)
Overall survival

70.1% ± 1.9% @ 5 y

37.8% ± 2.9% @10 y

24 % ± 4% @ 14 y
Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft

Fabio Verzini, MD, PhD, FEBVS,a Lydia Romano, MD,a Gianbattista Parlani, MD,a Giacomo Isernia, MD,a Gioele Simone, MD,a Diletta Loschi, MD,a Massimo Lenti, MD, PhD,a and Piergiorgio Cao, MD, FRCS,b Perugia and Rome, Italy

J Vasc Surg Feb 2017

Freedom from aneurysm-related death

98.4% ± 0.6 @ 5 y

97.3% ± 0.8 @10 and 14 y

Fig 4. Kaplan-Meier estimate of the cumulative probability of aneurysm-related death. The standard error did not exceed 10% at 14 years. Survival estimate is expressed as percent ± standard error.
Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft

Fabio Verzini, MD, PhD, FEBVS, a Lydia Romano, MD, a Gianbattista Parlani, MD, a Giacomo Isernia, MD, a Gioele Simone, MD, a Diletta Loschi, MD, a Massimo Lenti, MD, PhD, a and Piergiorgio Cao, MD, FRCS, b
Perugia and Rome, Italy

J Vasc Surg Feb 2017

Freedom from late reintervention

69.9% ± 5.2 @ 14 y

Fig 6. Kaplan-Meier estimate of the cumulative risk of overall late reinterventions (reintervention and conversion). The standard error did not exceed 10% at 14 years. Survival estimate is expressed as percent ± standard error.
California Office of Statewide Health Planning and Development inpatient database from 2001 to 2009:
23,670 patients

Medicare Beneficiaries from 2001 to 2008:
39,966 pairs of patients after propensity matching

From 2001 to 2008 perioperative mortality decreased by 0.8% in EVAR (P = 0.001) and by 0.6% in OPEN (P = 0.01)
The rate of open conversion after EVAR decreased from 2.2% in 2001 to 0.3% in 2008 (P<0.001)

Survival After Endovascular vs Open Aortic Aneurysm Repairs
Original Investigation | PACIFIC COAST SURGICAL ASSOCIATION

California Office of Statewide Health Planning and Development inpatient data from 2001 to 2009:
23,670 patients
Performance outside of controlled trials when anatomic limits pushed

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair
Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

(Circulation. 2011;123:2848-2855.)

Determinants of Aortic Aneurysm Sac Enlargement

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic neck diameter &gt;32 mm</td>
<td>2.07 (1.46–2.92)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Aortic neck angle &gt;60°</td>
<td>1.96 (1.63–2.37)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Age and preoperative clinical status

Debate: Whether young, good-risk patients should be treated with endovascular abdominal aortic aneurysm repair

“EVAR is as good as if not better than OR when early mortality is factored into the equation…”

“…there are potential risks of future secondary interventions with EVAR.”

“There is no evidence in the recent literature to support EVAR as the first line therapy in young patients aged <60 years. OR remains the best option for most of them.”
169 patients ≤ 60 years
50 EVAR: - only 13% outside IFU

- higher rate of hypertension (P=0.03) and poor left ventricular function (P=0.04)

Increased evidence that young AAA patients do not have the same life expectancy as patients without aneurysms...

- Late overall survival in AAA patients ranges 15/20% after 10ys

- New generation endograft significantly improve the long term results of EVAR, in terms of aneurysm related death and reintervention rates

- To what extent long term results from RCT’s trials have been affected by the early generation endograft has to be established
CONCLUSION

- However reinterventions rates remain high in the long term

- To treat or not with EVAR a “young” patient is still an open issue

- Imaging surveillance should be continued life-long in the EVAR patients
Long term results of EVAR for AAA, are the RCT results still valid?

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