Debate 4: Complex endovascular aortic repair will make open surgery obsolete
Definition

• Complex aortic pathology (aneurysms/dissection)
  – Involvement of thoracic and/or abdominal aorta involving visceral branches (celiac, SMA, renals)
  – Involvement of hypogastric arteries
Repair options

- Open repair
- Endovascular repair
Repair options:
- General anesthesia
- Single lung ventilation
- Cardiopulmonary bypass (in selected patients)
- Hypothermic circulatory arrest
- Spinal drainage
Repair options: Open
- Operative time: 3 to 15 hours
- ~ 2 weeks in hospital (3-5 days in ICU)
- 2-4 days on ventilator
- Up to 27% risk for pulmonary complications
- Need for dialysis in up to 15%
- Mortality (30 days) 5-15%; 1 year up to 30%
- Paraplegia 3-10% risk

High volume centers
Thoraco-abdominal incision

Thoraco-abdominal incision
Repair options: Open

- Higher risk, long duration, slow recovery
- “more fun” for the surgeon
- Not so much for the patient!!
Repair options: Endovascular aortic repair

- General or local anesthesia
- Percutaneous or limited groin incision (+/- brachial puncture)
- Spinal drainage
- Operative times 1-4 hours
- Hospital stay 1-5 days

- Lower operative risk, shorter operations, rapid recovery for patients
- "more fun" for the right surgeon
- **Patients love it!!!**
I rest my case here...
Since this is a debate...

Lets talk evidence
Let's see what Dr. Stokes has to say.

- Technology not available to us
- Not applicable to all anatomy
- Long term outcomes favor open surgery
- Better for older patients
- Learning curve
- Expensive
- Not an option for vasculitis, connective tissue disorder, infection, etc.

STOP EXCUSES
Myth #1

- Technology is not available
- Endovascular technology is available for only specific anatomy
## Technology is available here!

<table>
<thead>
<tr>
<th></th>
<th>Patient specific design</th>
<th>Off the shelf</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Currently approved</strong></td>
<td>Zenith Fenestrated</td>
<td>Heli-FX Endoanchors</td>
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<td></td>
<td></td>
<td>Gore Iliac branch device</td>
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<tr>
<td><strong>Under trial</strong></td>
<td>Cook Fenestrated/Branched Endografts</td>
<td>TAMBE (Gore)</td>
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<td></td>
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<td>Cook P branch</td>
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<td></td>
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<td>Cook T branch</td>
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<tr>
<td></td>
<td></td>
<td>Thoracic Branch Devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Cook, Gore, Bolton, Medtronic)</td>
</tr>
<tr>
<td><strong>Physician modified</strong></td>
<td>In situ fenestration</td>
<td>Parallel branch endografts</td>
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<tr>
<td></td>
<td>Back-table modification</td>
<td>(Chimney, Snorkel, Periscopes)</td>
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</table>
Thoracic branch devices (Cook, Gore, Medtronic, Bolton), PMEGs

TAMBE, Z fen, Patient specific fenestrated/branched endografts, CHIMPS, PMEGs

Low profile TEVAR

Heli-FX endoanchors

Iliac branch endoprosthesis
Myth #2

• Long term data favors open surgery
Long term clinical outcomes

EVAR 1 Trial (1999-2004)
1252 pt, 37 UK centers
15 years outcome
No significant difference in mortality at 15 years
EVAR better in short term

Long term clinical outcomes

DREAM trial (2000-03)
178 OR, 173 EVAR
No significant difference at 12 years

Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS(Gen Surg), and Alun H. Davies, DM, FRCS, London, United Kingdom

Background: Open repair is the gold standard management for juxtarenal aneurysms. Fenestrated endovascular aneurysm repair (FEVAR) is indicated for high-risk patients. The long-term outcomes of FEVAR are largely unknown, and there is no Level I comparative evidence. This systematic review and meta-analysis of case series compares elective juxtarenal aneurysm surgery by open repair and FEVAR.

Methods: A systematic literature search was conducted for all published studies on elective repair of juxtarenal aneurysms by FEVAR and open repair. The MEDLINE, EMBASE, and Cochrane databases were searched from 1947 to April 2013. The exclusion criteria were case series of <10 patients or ruptured aneurysms. The primary outcomes were perioperative mortality and postoperative renal insufficiency. The secondary outcomes were secondary reinterventions and long-term survival.

Results: We identified 35 case series with data on 2326 patients. Perioperative mortality was 4.1% in open repair and FEVAR case series (odds ratio for open repair with FEVAR, 1.059; 95% confidence interval, 0.642-1.747; P = .822). Postoperative renal insufficiency was not significantly different (odds ratio for open repair with FEVAR, 1.136; 95% confidence interval, 0.754-1.713; P = .542). FEVAR patients had higher rates of secondary reintervention, renal impairment during follow-up, and a lower long-term survival compared with open repair patients.

Conclusions: FEVAR and open repair have similar short-term outcomes but have diverging long-term outcomes that may be secondary to the selection bias of FEVAR being offered to high-risk patients. FEVAR is a favorable option in high-risk patients, and open repair remains viable as the gold standard. (J Vasc Surg 2015;61:242-55.)
Open repair versus fenestrated endovascular aneurysm repair of juxtarenal and infra-renal aneurysms by Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCR, Alun H. Davies, DM, FRCS, London, United Kingdom

Metanalysis of 35 series comparing FEVAR (750) and Open repair (1575)
- published upto 2013
- similar short term mortality, AKI, dialysis (favors FEVAR)

<table>
<thead>
<tr>
<th>Description</th>
<th>Odds ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>p-Value</th>
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<tr>
<td>Perioperative Mortality</td>
<td>1.059</td>
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<td>1.747</td>
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<td>Open Repair versus FEVAR</td>
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<td>Postoperative renal insufficiency</td>
<td>1.136</td>
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<td>1.713</td>
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Open repair versus fenestrated and branched endografts repair of juxtarenal aneurysm

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS, Alun H. Davies, DM, FRCS, London, United Kingdom

Metanalysis of 35 series comparing FEVAR (750) and Open repair (1575)

- Similar survival at 5 years
- Target vessel patency in FEVAR 95-98% in long term
- Type I and III endoleak 5.8% and 3.2%

Kaplan Meier Survival Curves of Pooled Open Repair and FEVAR Studies


Cum Survival

0.0 0.2 0.4 0.6 0.8 1.0

Time (Months)

0 12 24 36 48 60
Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on suprareciac sealing zones

Gustavo S. Oderich, MD, Mauricio Ribeiro MD, PhD, Jan H. Hekster, MD, Julia Chini, Thanila A. Macedo, MD, and Peter Gloviczki, MD

ABSTRACT

Purpose: To investigate outcomes of manufactured fenestrated and branched endografts based on suprareciac sealing zones to treat pararenal and thoracoabdominal aneurysms (TAAAs).

Methods: A total of 127 patients (91 male; mean age, 75 ± 10 years; mean body mass index, 27.1 ± 4.4 kg/m2) were enrolled in a single-center study using manufactured F-BEVAR (November 2013-July 2016). The suprareciac sealing zone in all patients with ≥ four vessels in 111 (89%). Follow-up included duplex ultrasound, and computed tomography imaging at discharge. Adverse events were adjudicated by independent clinical event committee including mortality, stroke, paraplegia, acute kidney injury, respiratory failure, re-intervention, and branch-related instability (occlusion, stenosis, endoleak, target vessel patency, sac aneurysm enlargement, and aneurysm rupture).

Results: There were 47 pararenal, 42 type IV, and 38 type I-III TAAAs with mean diameter of 59 ± 17 mm. A total of 496 renal-mesenteric arteries were incorporated by 352 fenestrations, 125 directional branches, and 19 celiac scallops, with a mean of 3.9 ± 0.5 vessels per patient. Technical success of target vessel incorporation was 99.6% (n = 495/496). There were no 30-day or in-hospital deaths, dialysis, ruptures or conversions to open surgical repair. Major adverse events occurred in 27 patients (21%). Paraplegia occurred in two patients (one type IV, one type II TAAAs). Follow-up was >30 days in all patients, >6 months in 79, and >12 months in 34. No patients were lost to follow-up. After a mean follow-up of 9.2 ± 7 months, 23 patients (18%) had renal artery stents were occluded, five patients had type la or III endoleaks, and none had aneurysm sac enlargement. Primary and secondary target vessel patency was 96% ± 1% and 98% ± 0.7% at 1 year. Freedom from any branch instability and any reintervention was 93% ± 2% and 93% ± 2% at 1 year, respectively. Patient survival was 96% ± 2% at 1 year for the entire cohort.

Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with suprareciac sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2017;65:1249-59.)
Prospective, nonrandomized study to evaluate repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on Mayo Clinic prospective study

127 patients (47 pararenal, 42 type IV, 38 type I-III) aneurysms repaired with patient specific endografts

- 1.5% paraplegia
- 96% survival at 1 year

Follow-up (months)

Patient Survival (%)

97 ± 2
(94-100)

Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with supraceliac sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2017;65:1249-59.)
Mayo Clinic prospective study
- Low reintervention
- Target vessel patency 98%
- 89% without renal dysfunction

Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with suprarenal sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2017;65:1249-59.)
Myth #3

Endovascular surgery only applicable for elderly patients with short term survival
EVAR for younger patients

Prospectively collected data for pts < 60 years in Canada (119 open and 50 EVAR)
- No difference in survival / interventions at 1 yr, 5 yr and 10 yr
- More laparotomy for OR and endo interventions for EVAR

Durability and survival are similar after elective endovascular and open repair of abdominal aortic aneurysms in younger patients Journal of Vascular Surgery 2015 61, 636-641 DOI: (10.1016/j.jvs.2014.10.012)
Myth #4

Endovascular surgery has a steep learning curve
Learning curve for FEVAR

A **CUSUM Graph**
(Death or Any Major Complication)

B **Adjusted CUSUM Graph**
(Death or Any Major Complication)

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Aortic surgery in the US

<table>
<thead>
<tr>
<th>Year</th>
<th>OAR, No.</th>
<th>EVAR, No.</th>
<th>FEVAR/BREVAR, No.</th>
<th>Total, No.</th>
</tr>
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<tbody>
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<td>N/A</td>
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<td>15,895</td>
<td>29,769</td>
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<tr>
<td>2011</td>
<td>10,039</td>
<td>35,028</td>
<td>722</td>
<td>45,788</td>
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</table>

Decreasing OPEN REPAIR and increasing ENDO REPAIR

Trends in open aortic repair

“When combined with the increase in vascular surgery trainees and lower number of open repairs, vascular fellows will complete about 10 OAR cases in 2015 and five OAR cases in 2020.”

Myth #5

Endovascular repair is expensive
If willingness to pay thresholds of €20,000 or €80,000 per QALY gained are used, EVAR has a high probability (95.0% and 87.5%, respectively) of being cost-effective compared with OSR.
Cost effectiveness

- Data remains unclear in US literature
- QALY added by EVAR not studied well so far in the US system.
- Similar outcomes for complex EVAR are not available
Myth #6

Endovascular surgery is not an options for infection, connective tissue disorders, vasculitis
Nationwide Study of the Treatment of Mycotic Abdominal Aortic Aneurysms Comparing Open and Endovascular Repair

EVAR for mycotic aneurysms

Paradigm shift in treatment of MAAA in Sweden
EVAR was associated with improved short-term survival in comparison with OR, without higher associated incidence of serious infection-related complications or reoperations.
Infections, CTD and Vasculitis

• Endovascular repair is being applied for challenging medical conditions worldwide
• Careful planning, staging and diligent follow up allows for safe outcome with these conditions
Conclusion

Complex EVAR is
- Available for all anatomy
- Safe, effective and durable
- Applicable for all patient population (young age, vasculitis etc)
- Comparable in cost
- READY FOR PRIME TIME!!!
Complex endovascular aortic repair will make the open aortic surgery obsolete.
BRACE YOURSELVES

THE EXCUSES ARE COMING
THANK YOU
Outcomes

http://www.jvascsurg.org/article/S0741-5214(17)30381-6/fulltext
http://www.jvascsurg.org/article/S0741-5214(16)31286-1/fulltext
http://www.jvascsurg.org/article/S0741-5214(18)30257-X/fulltext
http://www.jvascsurg.org/article/S0741-5214(16)30290-7/fulltext
http://www.jvascsurg.org/article/S0741-5214(14)01634-6/fulltext