**Part Two: Against the Motion. Young Patients with Good Risk Factors Should not be Treated with EVAR**

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**INTRODUCTION**

Surgical repair is indicated for large asymptomatic abdominal aortic aneurysms (AAA) in patients with an acceptable operative risk. Following Parodi’s landmark paper, early results of randomized controlled trials (RCTs) have demonstrated lower peri-operative mortality after endovascular aortic aneurysm repair (EVAR) compared with open surgical repair (OSR). However, some years later, the mid-term results of these RCTs have shown equivalent mortality after either EVAR or OSR, with a significantly higher re-intervention rate after EVAR, failing to support evidence favoring its use as first-line therapy, especially in young and/or fit patients. The goal of this debate is to compare early and late outcomes in patients younger than 65 years receiving OSR or EVAR.

**THE PROBLEM**

Over the last decade, EVAR has radically changed the approach for treating AAA. In the USA EVAR rose from 11,171 procedures in 2001 to 21,725 procedures in 2006. The same paradigm shift was observed in France, regardless of patient age, with 777 EVAR procedures in 2006 compared with 372 in 2001. Currently, in the USA, 60% of AAAs are repaired by EVAR. But the use of EVAR in young patients calls into question the long-term benefits and durability of this procedure. To answer these questions, analysis of the survival rate, of the risk of device-related complications, including radiation exposure by computed tomography (CT) scan, and cost-effectiveness with regard to devices and re-interventions are essential (Table 1).

**THE EVIDENCE**

Comparison of EVAR with OSR in patients deemed fit for surgery is available in four RCTs (Table 2). EVAR 1 involved 1,252 patients from 1999 to 2004. This trial demonstrated an initial benefit in terms of aneurysm-related mortality in favour of EVAR at 6 months. But this benefit vanished after 4 years, and the risk of aneurysm-related death, around 7%, was equivalent for the two groups at 6 years. In addition, there were more re-interventions and complications in the EVAR group. At 8 years, the complication rate was 52% for EVAR versus 15% for OSR (p = .01), and the re-intervention rate was 28% for EVAR versus 10% for OSR. In addition, 25 aortic ruptures, with 18 deaths, occurred in the EVAR group (4%) and none in the OSR group. These late ruptures outweighed the initial benefits of EVAR.

The DREAM trial demonstrated the same initial benefits for EVAR, with a lower rate of in-hospital mortality (1.2% vs. 4.6% for OSR; p < .05), but with a higher rate of cardiovascular-related death in the EVAR group at 1 year, which outweighed its initial benefit in terms of survival at 2 years. There were also more re-interventions in the EVAR group (29.6% for EVAR vs. 18.1% for OSR; p = .03) with an increased rate of re-interventions after 4 years in the EVAR group, 75% of which were related to stent graft failure.

The OVER trial also showed a significant decrease in hospital mortality in favour of EVAR compared with OSR (0.5% vs. 3%, respectively; p = .004), which remains significant at 3 years. In contrast to the EVAR 1 and DREAM trials, there was no difference in the rate of re-interventions between EVAR and OSR during this study. In this trial, mortality was analysed according to several risk factors, including age, and showed an advantage for EVAR in young patients (<70 years) compared with OSR, even if a higher incidence of cancer in the OSR group could explain this difference and even though six AAA ruptures with three deaths occurred in the EVAR group.

The results of the ACE (Anévrysme de l’aorte abdominale, Chirurgie versus Endoprothèse) trial comparing OSR (n = 149) with EVAR (n = 150) in low-to-moderate-risk patients showed no significant difference in in-hospital mortality between the two groups (0.6% for OSR vs. 1.3% for EVAR; p = 1.0). However, there was a higher rate of re-interventions in the EVAR group (16% vs. 2.7%; p < .0001), with three ruptures resulting in two deaths versus no rupture in the OSR group. The absence of early benefit of EVAR in this trial was explained by the low mortality rate of the OSR group.

**WHAT HAVE WE LEARNED FROM THESE STUDIES?**

These four RCTs did not investigate the performance of EVAR amongst different age groups. The mean age of patients in these RCTs did not match with the definition of young patients, and calls into question the applicability of their conclusions for young patients. Other studies have concentrated exclusively on the elderly population. However, with the development of AAA screening there will surely occur an...
Table 1. Reasons for skepticism regarding endovascular aortic aneurysm repair (EVAR) as a first-line therapy for young patients.

1. Failure to improve survival during long-term follow-up
2. New devices are more likely used outside instructions for use with worse effects on durability
3. Longer life expectancy of young patients increases the risk of endograft-related complications after EVAR, including the risk of late abdominal aortic aneurysm rupture
4. Need for follow up by computed tomography scan with radiation exposure and increased cancer risk
5. EVAR is not cost-effective for patients fit for surgery

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procedures after 8 years of follow-up was higher for EVAR ($23,153) than for OSR ($18,586). This raw analysis could be unfair, as the costs of some laparotomy-related complications were not taken into account in the cost analysis. However, even in recent series, EVAR continues to cost more than OSR and an updated report from the French Health Agency designed to evaluate the cost-effectiveness of EVAR in France concluded that EVAR was not a viable economic solution, especially in patients fit for surgery.30

CONCLUSION

There is no evidence in the recent literature to support EVAR as the first-line therapy in patients younger than 60 years. Open repair remains the best option for the majority of them.

REFERENCES


Table 2. Randomized controlled trials comparing endovascular aortic aneurysm repair (EVAR) with open surgical repair (OSR) for abdominal aortic aneurysms (AAA).

<table>
<thead>
<tr>
<th>References</th>
<th>Patients (n)</th>
<th>Age (mean ± SD) (y)</th>
<th>Follow up (y)</th>
<th>Peri-operative mortality</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR 1, 2005,1 201010</td>
<td>539 with OSR 543 with EVAR</td>
<td>74 ± 6.1 74.2 ± 6.0</td>
<td>6</td>
<td>OSR: 6.2% EVAR: 2.1% (p = .001)</td>
<td>Overall aneurysm related death: 1.2/100/year with OSR vs. 1/100/year with EVAR (p = .73) Overall mortality: 7.1/100/year with OSR vs. 7.2/100/year with EVAR (p = .61) Re-intervention rate: 1.7/100/year with OSR vs. 5.1/100/year with EVAR (p &lt; .001) No AAA rupture after OSR and 25 after EVAR (4.6%)</td>
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<tr>
<td>DREAM, 2005,4 2010</td>
<td>174 with OSR 171 with EVAR</td>
<td>69.6 ± 6.8 70.7 ± 6.6</td>
<td>6.4</td>
<td>OSR: 4.6% EVAR: 1.2% (p = .01)</td>
<td>Overall mortality: 30.1% with OSR vs. 31.1% with EVAR (NS) AAA-related mortality: 4.49% with OSR vs. 1.15% with EVAR (p &lt; .001) Re-intervention rate: 18.1% after OSR vs. 29.6% after EVAR (p = .003)</td>
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<tr>
<td>OVER, 2009,2 20126</td>
<td>437 with OSR 444 with EVAR</td>
<td>70.5 ± 7.8 69.6 ± 7.8</td>
<td>5.2</td>
<td>OSR: 3% (p = .004) EVAR: 0.5%</td>
<td>Overall mortality: 33.4% after OSR vs. 32.9% after EVAR (NS) AAA-related mortality: 3.7% after OSR vs. 2.3% after EVAR (NS) AAA rupture: 0 after OR vs. 6 (1.4%) after EVAR (p = .03) Re-intervention rate: 17.8% after OSR vs. 22.1% after EVAR (NS)</td>
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<tr>
<td>ACE, 201112</td>
<td>149 with OSR 150 with EVAR</td>
<td>70 ± 7.1 68.9 ± 7.7</td>
<td>3</td>
<td>OSR: 0.6% EVAR: 1.3% (p &gt; .05, NS)</td>
<td>Overall mortality: 8% after OSR vs. 11.3% after EVAR (NS) AAA-related mortality: 0.6% after OSR vs. 4% after EVAR (NS) AAA rupture: 0 after OSR vs. 3 (2.0%) after EVAR (NS) Re-intervention rate: 2.7% after OSR vs. 16% after EVAR (p &lt; .0001)</td>
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Note. NS = not significant.


