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http://dx.doi.org/10.1016/j.ejvs.2015.07.024

Part Two: Against the Motion. Fenestrated EVAR Procedures are not Better than Snorkels, Chimneys, or Periscopes in the Treatment of Most Thoracoabdominal and Juxtarenal Aneurysms

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Endovascular aneurysm repair (EVAR) has rapidly overtaken open surgery worldwide for the treatment of anatomically suitable aortic aneurysms. It was inevitable that endovascular technology and strategies would be developed to further treat juxtarenal (JAA) and thoracoabdominal (TAAA) aneurysms. Centers of excellence and early adopters outside the USA and US centers with physician-sponsored investigator device exemptions gained much experience in using fenestrated and branched (FEN-BR) devices with excellent results. However, the lack of widespread availability of branched devices and the only recent US Food and Drug Administration approval of fenestrated technology in mid-2012 have encouraged an alternative strategy utilizing parallel, or snorkel, periscope, and chimney grafts (CH-EVAR). The snorkel/chimney/periscope technique has gained increasing popularity since the first publications in 2003 and 2007.1,2 These techniques have emerged from the basic idea of creating a “snorkel/chimney” conduit from above or a “periscope” conduit from below using available “off-the-shelf” stents deployed into target visceral branches adjacent to the main intra-aortic stent-graft. Initially described as a bail-out technique for inadvertent coverage
or emergent situations, several major centers have reported excellent short- and mid-term outcomes comparable with the published literature for FEN-BR technology.\(^8\) To best address the oft-debated question of FEN-BR versus Ch-EVAR it is useful to understand first that the best results of FEN-BR come from only a handful of centers with the longest access and most experience with the devices. Critics of Ch-EVAR claim it remains difficult to obtain a clear picture of outcomes and its potential applications, owing to nonstandardized protocols and a heterogeneous mix of devices used. Concerns raised about Ch-EVAR include overall technical success, gutter-related type Ia endoleaks requiring re-interventions, chimney stent patency, long-term renal dysfunction, and long-term durability. Short of a randomized prospective trial, however, a direct comparison of these techniques is challenging given publication biases, conflicts of interest, and varying lengths of follow-up time of a given available generation of stent-graft. A review of numerous meta-analyses and a newly published international registry of Ch-EVAR provide the most current evidence that it is a viable and often complementary strategy compared to FEN-BR repairs in the treatment of patients with JAA and TAAA.\(^8\)–\(^11\)

Available data prior to the PERICLES registry have shown no statistically significant difference between Ch-EVAR and FEN-BR with regard to technical success, target branch vessel patency, early mortality, type I endoleak, post-operative renal dysfunction, or need for secondary intervention.\(^11\),\(^12\) Still, critics of the Ch-EVAR strategy claim the majority of the published data are short-term, small in number, and from single-center experiences. To address this concern, the PERICLES registry recently reported on 517 patients with 898 chimney stents from 13 international centers. With regard to overall mortality rates following FEN-BR, a pooled 30-day mortality of 2.1% was calculated and noted in a recent systematic review,\(^13\) which included nine studies treating 629 patients. This is slightly better when compared with the PERICLES registry with its 30-day mortality of 4.9% (3.7% if ruptured Ch-EVAR was excluded). In an earlier meta-analysis of published reports of Ch-EVAR up to 2012,\(^9\) an overall pooled 30-day mortality of 3.4% was noted in 14 studies covering 176 patients. All of these mortality results are acceptable as most patients with JAA have significant comorbid medical conditions, and the postoperative mortality is often linked to cardiopulmonary issues. Interestingly, in one of the few head-to-head propensity-matched comparisons of endovascular to open surgery for JAA, FEN-BR had a mortality rate as high as 9.5%, indicating there is a range of mortality for FEN-BR depending on center experience, as well as patient selection.\(^14\)

Re-interventions and branch vessel patency are likely the main durability issues of any endovascular treatment, and, particularly for Ch-EVAR and FEN-BR, these issues are related to type Ia endoleaks and branch patency. Extremely durable results have been published by the world’s most experienced FEN-BR center, the Cleveland Clinic, and comparison of these results with those of the PERICLES registry is worthwhile.\(^15\) In the Cleveland Clinic experience, excellent long-term durability of endovascular repair in 650 patients (1,679 target vessels) undergoing complex repair with branched or fenestrated devices between 2001 and 2010 are reported. The 30-day, 1-year, and 5-year freedoms from branch re-intervention were 98.0%, 94.0%, and 84.0%, respectively. These numbers from this single institution are better than those which the PERICLES registry reports. Overall primary chimney-graft patency was 94.1% with patency estimates of 94.9%, 91.8%, 89.2%, and 87.0% at 6 months, 1 year, 2 years, and 3 years, respectively, in the 13 centers participating in the registry. However, these excellent Cleveland Clinic branch patency numbers for FEN-BR are not corroborated by meta-analyses of published reports when more centers are included, suggesting that “real-world” data cannot match those of the most experienced operators. The earlier-mentioned meta-analysis of FEN-BR, which included nine studies encompassing 629 patients and a total of 1,622 target vessels, documented a pooled technical success rate of 90.7% and an estimated re-intervention rate of 17.8% during a follow-up period of 15–25 months.\(^13\) More importantly, branch vessel patency was found to be 93.2%, renal function decline 22.2%, and all-cause morality 16% at the 15–25 month follow-up range—numbers nearly identical to PERICLES registry results. Because renal function decline is related not only to primary patency, but also to complexity of the technical aspects of repair, more consistent reporting standards are likely necessary to truly compare renal outcomes between FEN-BR and Ch-EVAR. Fortunately, renal function decline after Ch-EVAR measured by the strictest criteria (stages of glomerular filtration rate decline range between 17.5% in the registry and 32.6% in a recent single-center report) is in line with reported values for FEN-BR.\(^16\)

In a more recent systematic review and meta-analysis of FEN-BR the outcomes of 12 studies involving a total of 776 patients and > 1,728 target vessels calculated a pooled estimate for 30-day mortality of 2.5%, technical success of 92.8%, a short-term 12-month type I endoleak rate of 7.9%, target vessel patency of 94.5%, and a secondary intervention rate of 17.6%.\(^17\) Over 70.0% of the re-interventions occurred during the first year following fenestrated EVAR and loss of renal artery patency was the leading reason for re-intervention (24.1%). These pooled results clearly highlight the learning curve necessary for FEN-BR or any other complex EVAR strategy. They also emphasize that the results from the most experienced centers may not be achievable everywhere.

While the data reviewed above have mainly surrounded JAA treatment, the Ch-EVAR techniques for TAAA typically involve various sandwich/terrace configurations of which extremely limited data exists. Most of these series are case reports in the setting of urgent or ruptured thoracoabdominal pathology, and likely not ready to be analyzed in comparison with the small experience of a few centers of excellence with access to branched devices for TAAA. It remains to be seen whether these strategies that address aortic pathology well above the visceral segment
will have the same early success that Ch-EVAR has had for juxtarenal pathology.

One final word that deserves mention is the off-the-shelf availability of the Ch-EVAR strategy, making it applicable immediately. While technology related to FEN-BR will continue to disseminate to all aortic surgeons, the regulatory hurdles, complex planning required, and the custom-designed wait period will make it challenging to treat urgent or ruptured patients. Ch-EVAR naturally adapts to whatever anatomy and situation that is present, and therefore should be in the armamentarium of the endovascular aortic specialist.

In summary, Tables 1 and 2 review findings from several studies cited through the meta-analyses presented above to document the clinical equipoise we have between these two complementary techniques. The popularity and early reporting of acceptable outcomes for Ch-EVAR are now validated in a large registry of 13 centers that demonstrates comparable technical success, early mortality, overall survival, freedom from aneurysm-related death, mid-term branch patency and durability, endoleak rates, and secondary interventions. Perhaps the most intriguing question to come from this debate is whether there will be any impetus to perform a head-to-head controlled comparison.

Table 1. Summary of current literature on snorkel/chimney endovascular aortic aneurysm repair.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients (n)</th>
<th>Target vessels (n)</th>
<th>Technical success (%)</th>
<th>30-d mortality (%)</th>
<th>Type 1A endoleak (%)</th>
<th>Re-intervention (%)</th>
<th>Primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ohrlander et al. (2008)</td>
<td>6</td>
<td>10</td>
<td>100</td>
<td>0.0</td>
<td>0.0</td>
<td>33.3</td>
<td>100 (2.0 mo)</td>
</tr>
<tr>
<td>Hiramoto et al. (2009)</td>
<td>8</td>
<td>8</td>
<td>100</td>
<td>0.0</td>
<td>12.5</td>
<td>NR</td>
<td>100 (12.5 mo)</td>
</tr>
<tr>
<td>Bruen et al. (2011)</td>
<td>21</td>
<td>37</td>
<td>97.3</td>
<td>4.8</td>
<td>4.8</td>
<td>NR</td>
<td>84 (12.0 mo)</td>
</tr>
<tr>
<td>Coscas et al. (2011)</td>
<td>16</td>
<td>26</td>
<td>100</td>
<td>12.5</td>
<td>12.5</td>
<td>12.5</td>
<td>NR</td>
</tr>
<tr>
<td>Resch et al. (2012)</td>
<td>25</td>
<td>48</td>
<td>100</td>
<td>12.0</td>
<td>8.0</td>
<td>8.0</td>
<td>98 (10.0 mo)</td>
</tr>
<tr>
<td>Donas et al. (2012)</td>
<td>39</td>
<td>38</td>
<td>100</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>3.3</td>
</tr>
<tr>
<td>Lee et al. (2012)</td>
<td>28</td>
<td>56</td>
<td>98.2</td>
<td>7.1</td>
<td>7.1</td>
<td>7.1</td>
<td>3.6</td>
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<tr>
<td>Scali et al. (2014)</td>
<td>41</td>
<td>76</td>
<td>98.7</td>
<td>4.9</td>
<td>7.3</td>
<td>7.3</td>
<td>4.0</td>
</tr>
<tr>
<td>Banno et al. (2014)</td>
<td>38</td>
<td>60</td>
<td>97.4</td>
<td>7.9</td>
<td>5.3</td>
<td>5.3</td>
<td>26.3</td>
</tr>
<tr>
<td>Lee et al. (2015)</td>
<td>517</td>
<td>898</td>
<td>97.1</td>
<td>4.9</td>
<td>2.9</td>
<td>2.9</td>
<td>6.6</td>
</tr>
</tbody>
</table>

Note. NR = not reported.

Table 2. Summary of current literature on fenestrated endovascular aortic aneurysm repair.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients (n)</th>
<th>Target vessels (n)</th>
<th>Technical success (%)</th>
<th>30-d mortality (%)</th>
<th>Re-intervention (%)</th>
<th>Primary patency (%)</th>
<th>1-y patency (%)</th>
</tr>
</thead>
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<tr>
<td>Halak et al. (2006)</td>
<td>17</td>
<td>35</td>
<td>94.1</td>
<td>0.0</td>
<td>NR</td>
<td>94.3</td>
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<td>Muhs et al. (2006)</td>
<td>38</td>
<td>87</td>
<td>94.0</td>
<td>2.6</td>
<td>7.9</td>
<td>96.0</td>
<td>96.0</td>
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<td>O’Neill et al. (2006)</td>
<td>119</td>
<td>302</td>
<td>100</td>
<td>0.8</td>
<td>11.8</td>
<td>100</td>
<td>97.0</td>
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<tr>
<td>Semmens et al. (2006)</td>
<td>58</td>
<td>116</td>
<td>82.8</td>
<td>3.5</td>
<td>24.1</td>
<td>99.1</td>
<td>89.0</td>
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<tr>
<td>Ziegler et al. (2007)</td>
<td>60</td>
<td>119</td>
<td>87.3</td>
<td>0.0</td>
<td>20.6</td>
<td>96.7</td>
<td>90.5</td>
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<td>Scurr et al. (2007)</td>
<td>45</td>
<td>117</td>
<td>100</td>
<td>2.2</td>
<td>13.3</td>
<td>98.3</td>
<td>96.6</td>
</tr>
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<td>Bicknell et al. (2008)</td>
<td>15</td>
<td>40</td>
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<td>97.0</td>
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<td>96.3</td>
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<td>Greenberg et al. (2009)</td>
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<td>100</td>
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<td>92.2</td>
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<td>52</td>
<td>149</td>
<td>94.2</td>
<td>5.7</td>
<td>11.5</td>
<td>NR</td>
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<td>Amiott et al. (2010)</td>
<td>134</td>
<td>403</td>
<td>NR</td>
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<td>9.0</td>
<td>98.8</td>
<td>NR</td>
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<tr>
<td>Verhoeven et al. (2010)</td>
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<td>275</td>
<td>94.0</td>
<td>1.0</td>
<td>9.0</td>
<td>98.9</td>
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<td>Tambyraja et al. (2011)</td>
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<td>37.9</td>
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<td>Manning et al. (2011)</td>
<td>20</td>
<td>68</td>
<td>NR</td>
<td>10.0</td>
<td>NR</td>
<td>96.0</td>
<td>NR</td>
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<td>Donas et al. (2012)</td>
<td>29</td>
<td>44</td>
<td>97.7</td>
<td>0.0</td>
<td>10.3</td>
<td>96.6</td>
<td>NR</td>
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<td>53</td>
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<td>Lee et al. (2014)</td>
<td>15</td>
<td>25</td>
<td>96.0</td>
<td>0.0</td>
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<td>194</td>
<td>97.4</td>
<td>6.3</td>
<td>NR</td>
<td>93.7</td>
<td>NR</td>
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</table>

Note. NR = not reported.

a Rate of successful target vessel cannulation.

b Early re-intervention within 30 days of operation.
of these two techniques. Understanding which strategy might be applicable to which scenario, anatomy, or patient cohort will likely have the longest positive influence on the care of these complex patients. Based on the available evidence at this time, FEN-BR is not always better than the well-planned Ch-EVAR case, particularly for juxtarenal aneurysms, and this review of published literature indicates that Ch-EVAR and other parallel graft techniques are a viable treatment method that deserve further study and potentially wider usage.

REFERENCES

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31 Chisci E, Kristmundsson T, de Donato G, Resch T, Setacci F, Sonesson B, et al. The AAA with a challenging neck: outcome of
Drs. Haulon and Lee have provided an extensive and broad comparison of two endovascular approaches to juxtarenal, pararenal, and thoracoabdominal aortic aneurysms, namely fenestrated/branched endovascular repairs (FEVAR) or snorkel/chimney (Ch-EVAR) repairs. Both are respected experts and leaders in the area of endovascular repair of complex aortic aneurysms and have advocated strongly for the responsible reporting and evaluation of the results of FEVAR and Ch-EVAR.

Although there has been no randomized trial, nor is one likely needed or possible, several meta-analyses have been performed to attempt a comparison between these approaches. Dr. Haulon highlights the difficulties in comparing these approaches as the patients and their anatomies preclude any meaningful and direct comparison. As both discussants report, single-center Ch-EVAR experiences tend to report higher mortality rates and rates of type I endoleaks and poorer target vessel patency than FEVAR reports. However, these differences lessen when emergency cases are excluded, which are treated in higher proportion in Ch-EVAR series, and technical features are considered. Both approaches have benefited from the expertise of our discussants as Dr. Haulon has optimized the fenestrated/branched approach and helps to lead the transition from solely custom-made devices to the more readily available off-the-shelf components. Dr. Lee provides important technical observations of the Ch-EVAR technique regarding the direct relationship with the number of parallel stents and risk of type I endoleak (so-called “gutter” endoleaks due to incomplete conformability of main body and parallel stents) and the inverse relationship between length of overlap and target vessel patency.

As expertise in both techniques has developed the differences in outcomes and results have become less apparent. This is evident in the recently published multicenter, international PERformance of the chimney technique for the treatment of Complex aortic pathoLogiES Registry (PERICLES) by Dr. Lee and colleagues.1 This registry reported on 517 patients treated in US and European centers over a 6-year period with a mean follow-up of 17.1 months. The results were commendable, but of particular interest was the variability in devices used. Different main bodies of commercially available transrenally fixed endografts were preferred by various centers and different parallel stents were also used. The uncertainly regarding the optimum devices is not unique to Ch-EVAR. Such issues as the use of fenestrations and/or directional side branches and which is the best bridging stent are issues with FEVAR that have yet to be fully elucidated. As procedure- or pathology-specific devices continue to be developed the results of both approaches should continue to improve.

Our debaters have eloquently outlined the strengths and weaknesses of both approaches at the present time. However, as fenestrated/branched endografts become more.

Editors’ Comment

Trans-Atlantic Debate: Are Branched/Fenestrated EVAR Procedures Better than Snorkels, Chimneys, or Periscopes in the Treatment of Most Thoracoabdominal and Juxtarenal Aneurysms?

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