

Title: ANCHOR Study: ESAR is More than Reinforced Proximal Seal
Participants: Prof Michel Reijnen
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- My name is Michel Reijnen, I'm a Vascular Surgeon from the Rijnstate Hospital in Arnhem, which is located in Netherlands. And beside that, I'm a Professor at the University of Twente in Enschede also in Netherlands.

Study Background

The ANCHOR study was a prospective observational international multi-center registry study, that was led by my colleague, Jean-Paul de Vries from Europe and Dr. William Jordan from the US, and it enrolled patients that were treated with EndoAnchors an adjunct to EVAR from April, 2012 to December, 2019. And these patients were followed for five years. Some are still in follow up. And for this particular analysis, we looked at patients that had a wide infrarenal aortic neck and this defines the neck diameter of 28 millimetres or more.

It is not about long term EVAR outcomes is that there is a relation of hostile neck anatomy, and unfavourable outcomes and a wide neck diameter, which is typically defined as a diameter of 28 millimeters or more. Is one of the definitions of hostile neck.

When we look at the literature and what has been published on wide necks, we see that wide necks are related to more reinterventions, more stent expansion, more endoleaks, and also more ruptures.

So there is an unmet need in the treatment of this patient group. Another problem with standard EVAR in wide necks, is that wide necks are related to neck expansion in time. This is very likely to be multifactorial, so it's progression of disease, but also the outward force of the endograft. And independent risk factors for second neck expansion are a wide neck and excessive over sizing.

Study Design and Cohort

Overall in the ANCHOR registry, there were 1032 patients enrolled. 771 of these were the so-called primary arm in EndoAnchors which was used in adjunct to EVAR treat complication during surgery or preventive. And then there were 261 in the revision arm. And for this particular analysis we took the primary arm, and in these patient group, we looked for patients that had a infrarenal neck diameter between 28 and 32 millimetres.

Overall, there were 72 patients in this cohort and consequently there were 699 patients with a non-wide infrarenal neck.

Key Results

But when we look at this cohort, patients were age 73 years old, almost 90% were male, and when you look at the baseline anatomy the infrarenal neck diameter was on average 29.5 mms.

He had a considerable neck length of 18 millimetres, 23% had a conical neck and the angulation was 33 degrees. The aneurysm itself had a maximum diameter on average of 61 millimetres, but we looked at the treatment. This patients got the vast majority 71% was treated with the Endurant device and the remaining which was auto devices.

But mostly with either the Zenith or the endograft. We have followed these patients three years, in the end 42 patients actually got their three year follow up. So it's relatively a small sample size, but then when you look at the results, they were very positive. There was a freedom aneurysm relative mortality of almost 99%. There were no conversions. The freedom from secondary interventions overall, was 87%. There were no ruptures, and then we're looking at more, specifically at the neck related complications. The freedom for migration in this group was 100%. The freedom from type one endoleaks was 98.5% in effect. There was only one patients that had a procedural type one endoleak, that spontaneously disappeared on the next imaging modality, and did not come back afterwards. And consequently there were no reinterventions performed with type one endoleak. So these were all very good results.

What we do know nowadays is that, sac dynamics after EVAR are important as there seems to be a relation between sac regression and long term survival. When we look at the sac behaviour after EVAR in this group, we saw at three years that 60% had a sac regression, 30% had a

stable aneurysm and 8.7% had a growing aneurysm. These were 2 out of 23 patients. And when you compare this to another patient group with a more beneficial anatomy, you see that the same rates have been reached as in these groups.

Take-home Messages for Clinicians

Well, the take home messages are that wide necks are a risk factor for late failure of EVAR, and with the use of EndoAnchors. The neck related complications could be reduced. There are some limitations, however, it's a small patient cohort with a limited number with actual three year follow up. And also the imaging protocol was, for standard of care of the hospitals, which means that sometime duplex ultrasound was used instead of CT scans.

And this is the main reason that these data need to be confirmed with the prospective comparative trial. Later this year, we will start this trial which is called the HERCULES trial. And in this trial, we will enrol 300 subjects globally, both in the US and Europe and will be randomised between treatment with the Endurant endograft, or the Endurant endograft with EndoAnchors as adjunctive treatments. The composite at endpoint that one year will be freedom from type-one endoleak or migration or aneurysm sec growth. And the patients will be followed for five years follow up. And hopefully this will confirm the data that we've seen in the anchor registry.