TAA Morphology Matters: Fusiform versus Saccular

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Potential Conflict
Medtronic: consulting, speaking/training

TAA

Distal arch TAA – “ductus aneurysm”

saccular

>fusiform

>30%
Hybrid endovascular repair with preliminary cervical arterial bypass debranching of the aortic arch.

Regulatory Approval:

IFU and Labeling

Approved indications for commercially available thoracic stent-graft devices are delineated with clarity in the Instructions for Use (IFU) and include all forms of true aortic aneurysms, both fusiform and saccular, as well as penetrating aortic ulcers (PAU). These lesions were defined as the appropriate targets for endovascular treatment in the investigational protocols authorizing the various clinical trials that tested device safety and efficacy before approval could be granted by the US Food and Drug Administration and regulatory agencies around the world.

The all-important anatomical requirements are also described in the protocols and the IFU. Above all, successful stent-graft placement necessitates the presence of adequate landing zones (necks), both proximally and distally, in order to achieve secure fixation and a blood-tight seal. These must be of a certain diameter and length, the latter generally amounting to 20 mm or more. While all types of true aortic aneurysms and PAU lesions deemed to be appropriate indications, it is noteworthy (but not surprising) that most patients enrolled in the clinical trials have been reported to have fusiform aneurysms, with only a minority fitting the saccular or PAU designations. Moreover, most aneurysm models used for preclinical device testing feature the fusiform configuration. Strikingly, though, these two main aneurysm types (saccular and PAU) are characterized by distinct morphologies as the aortic contour (circumference) remains essentially intact and largely uninvolved in saccular lesions (Fig. 1A), but it is completely distorted by definition when the aneurysm is fusiform (Fig. 1B). Grouping together such different pathological entities became the accepted investigational plan as all stakeholders agreed that it would facilitate patient enrollment and accelerate the regulatory path to approval and subsequent commercialization.

15-20mm long neck required as per IFU

Z1-Z4: No debranching
**Risks of carotid-LSA bypass:**
- Nerve injuries
- Lymphatic complications
- Stroke
- Death
- 5-10% overall


**Saccular Aneurysms**

However, it is not unusual to find a length of 10 to 15 mm of intact aorta for proximal landing beyond the left common carotid artery (in arch zone 2) and, at times, even distal to the left subclavian artery (zone 3). Such an aortic length is frequently exceeded when dealing with a saccular lesion. The saccular lesion may be treated by grafting a small window of communication with the main aortic lumen and, therefore, a largely intact aortic contour throughout. The end-to-end graft device should have no difficulty affixing itself securely and achieving a seal as long it is appropriately oversized (Fig. 3A). The fusiform morphology, on the other hand, clearly requires more generous landing zones (Fig. 3B).
Off-label vs. On-label

Testing the above-described hypothesis would be most interesting and hopefully confirmatory. In the meantime, it would be worthwhile to sharpen our focus on the distinction nature of aneurysm morphologies and their significance vis-à-vis the suitability of the various treatment options. In such context, saccular aneurysms and PAVM lesions occurring in the arteries may create situations in which off-label use can result in measurable benefit in some cases.

Are saccular aneurysms inherently more dangerous... thereby justifying repair regardless of size??

MAYBE...
- Pressures and engineering concepts
- Bio-mechanical modeling, etc.

BUT... absolutely no supportive clinical evidence