Long-Term Complications of Endologix AFX2 Insights from Two Case Studies

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Introduction

Endovascular aneurysm repair (EVAR) has demonstrated superior early survival benefits compared to surgical repair. However, the need for vigilant surveillance arises due to late-onset complications associated with EVAR, including a higher incidence of aneurysmal sac enlargement and aneurysm-related mortality in the long term. The Endologix AFX endograft system distinguishes itself with a unique structure, securing its main element at the aortic bifurcation, unlike other stent grafts with supra-renal fixation. The US Food and Drug Administration had previously issued warnings about the earlier generation of the Endologix AFX stent graft due to an increased risk of type IIIa/IIIb Endoleak. Technical advancements in the Endologix AFX2, as observed in the LEOPARD trial, appeared to address these concerns. However, long-term follow-up cases, particularly beyond five years, reveal persistent challenges. This report discusses two cases highlighting the long-term complications associated with the Endologix AFX2 stent graft.

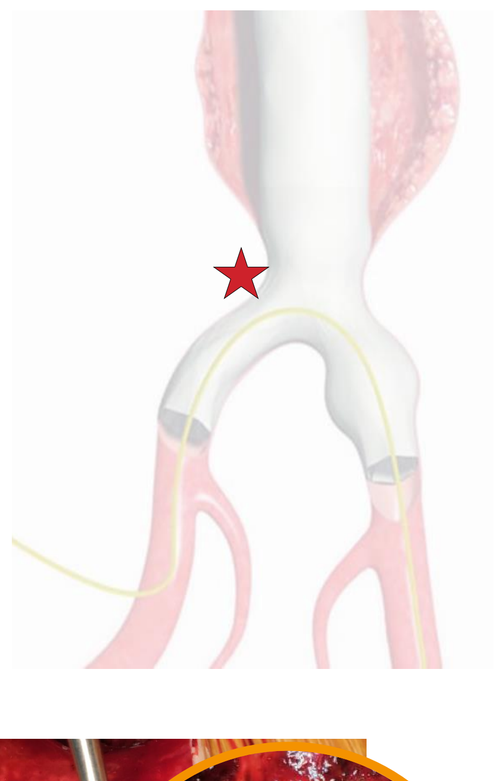
Case 1. Late-Onset Type IIIb Endoleak

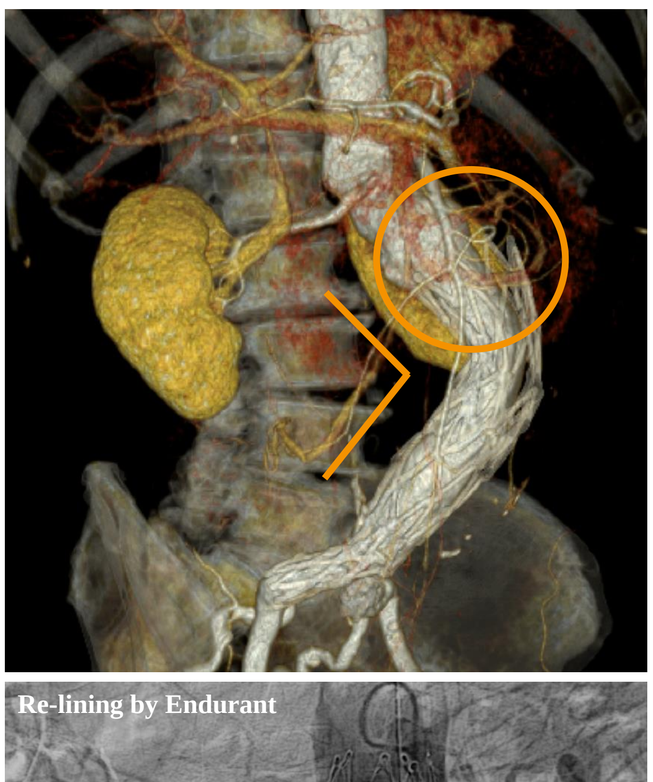
A 68-year-old male had an infrarenal AAA measuring 62mm, for which an Endologix AFX2 was implanted in 2018. The patient had a neck angle of 40 degrees and a neck length of 35mm, indicating a non-hostile neck, and met the IFU criteria. There were no significant issues in the immediate follow-up. However, the patient was lost to follow-up and returned five years later with symptoms. A CT scan at that time revealed an aneurysmal sac enlargement up to 97mm. Additionally, within the aneurysmal sac, there was no clear endoleak point, but rather an amorphous delayed enhancement, leading to suspicions of either endotension or a delayed type IIIb Endoleak in the bifurcated area of the Endologix stent graft, a known issue. An open conversion surgery confirmed a fabric tear in the bifurcated stent graft.

This is thought to be due to the endoskeleton structure of Endologix, which, along with continuous direct contact with the aorta wall, may lead to fabric tear.

Case 2. Delayed Migration of Aortic Cuff

An 80-year-old male had a 65mm infrarenal fusiform AAA (neck angle: 40 degrees), for which an Endologix AFX2 was implanted in 2018. The immediate follow-up CT showed no endoleak or notable findings. Annual surveillance was conducted, and in 2023, the aneurysmal sac had enlarged to 85mm, and delayed migration of the aortic cuff was observed. There were no occurrences of Type 1a or Type IIIa Endoleak yet. Additionally, there was a 95-degree angulation between the bifurcated main body and the aortic cuff. Considering the risk of complications such as fabric tear, a 3-piece Endurant II stent graft was implanted inside the AFX2 endograft. Subsequently, the stent graft remained patent without any endoleak. This phenomenon is observed in cases with a neck angle of 30 degrees and large fusiform AAAs of over 60mm. **It is explained as minimal prosthetic graft dilation due to the flow direction effect caused by angulation, along with the shortening of the lower part of the bifurcated main body. This is also thought to be a specific phenomenon of the Endologix stent graft, which features active sealing.**





Conclusion

The Endologix AFX2 endograft is a useful option for low-profile and narrow aortic bifurcations. However, its design has inherent limitations that can lead to late-onset complications, making it difficult to say that it has completely resolved the issues of type III endoleak found in earlier generations. These cases underscore the necessity for ongoing surveillance due to the potential for late-onset complications, including fabric tear and graft migration, even with the advancements in the AFX2 design. We conclude that while the AFX2 offers benefits for specific anatomical challenges, its design limitations require vigilant long-term follow-up.

Declaration of interest

No conflicts of interest to declare