Are DESs Ever Associated With Aneurysmal Degeneration: Is It Related To The Drug (Paclitaxel Or Limus) Or To The Fluoropolymer Excipient To Which The Drug Is Attached

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COI Disclosure

Speaker name :

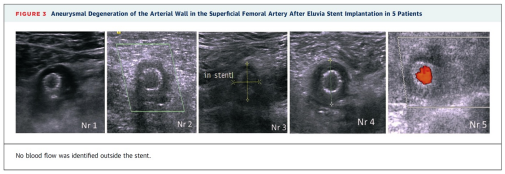
Osamu Iida, MD

I have the following potential conflicts of interest to report:

- ■ Consulting: Boston Scientific, Canon, NIPRO, Terumo
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- ■ Other(s) Honoraria: Medtronic, Boston Scientific, Gore, Terumo, NIPRO, Canon
- □ I do not have any potential conflict of interest

Aneurysmal degeneration after Fluoropolymer (FP)-Based Paclitaxel (PTX) DES implantation was firstly reported in the Münster registry

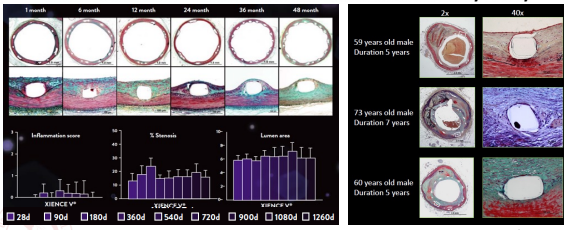
Münster All-Comers Registry was Small (62 patients) single-center retrospective study to evaluate the performance of Fluoropolymer-Based Paclitaxel DES (Eluvia™) in long and complex femoropoplíteal lesions.



1-year result of Münster registry highlighted that duplex ultrasound detected aneurysmal degeneration (mean diameter 14 mm) in 5 patients (8%), and all cases with aneurysmal degeneration were de novo chronic total occlusion (CTO) without any previous treatment with PTX-eluting technologies.

Bisdas T et al. JACC Cardiovasc Interv. 2018;11:957-966.

Fluoropolymer-based everolimus-eluting stent demonstrated absent or minimal inflammation in both swine and human coronary artery



The absence or minimal inflammation around the fluoropolymer, as observed in the pathological findings, suggests the presence of fluoropolymer would be associated with a low risk of aneurysm degeneration.

Otsuka F, et al. Circ Cardiovasc Interv. 2014;7:330-42.

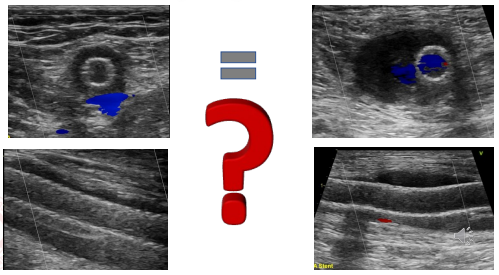
Incidence of aneurysmal degeneration after stent implantation

IMPREIAL trial	CAPSICUM registry	EMINENT trial
Eluvia DES: 33.7% Zilver PTX: 21.4% The prevalence rates did **NOT** differ significantly (P = 0.15).	Eluvia DES: 16.8% **NO** association with the 1-year risk of restenosis (OR:1.16, p=0.61)	Eluvia DES: 26.1% Bare metal stent: 17.9% The prevalence rates did **NOT** differ significantly (P = 0.21).

The presence of the aneurysmal degeneration is not limited to post-implantation of FP-DES. Furthermore, there is no association between the aneurysmal degeneration and restenosis occurrence.

Müller-Hülsbeck, et al Cardiovasc Intervent Radiol. 2021; 44:368-375. Iida O, et al. JACC Cardiovasc Interv. 2022;15:630-638. Gouëffic Y, et al. Circulation. 2022;146:1564-1576.

The halo sign and aneurysmal degeneration should be clearly distinguished from each other



The process of arterial repair varies among stents

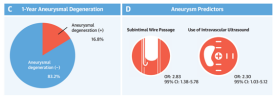
3 month post BMS Tx | 2-year post FP-DES Tx | 1 year post Stentgraft Tx

My speculation: Even if a halo sign occurs after BMS (bare metal stent) placement, the protective effect of neointimal proliferation would prevent the aneurysmal degeneration. In FP-DES, arterial repair would be delayed and the stent strut may not be fully covered, which increases the risk of aneurysmal degeneration.

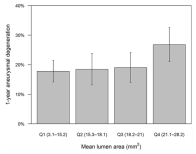
Aneurysmal degeneration is caused by medial injury and PTX?

1-Year Outcomes of Fluoropolymer-Based Drug-Eluting Stent in Femoropopliteal Practice

Predictors of Restenosis and Aneurysmal Degeneration



Impact of postprocedural minimum lumen area on clinical outcome after femoropopliteal drug-eluting stent implantation



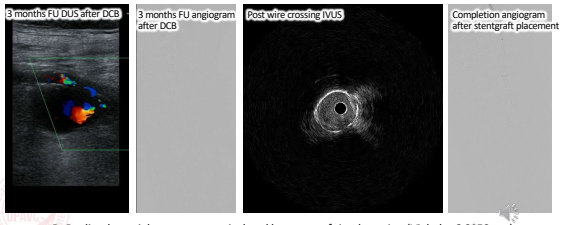
My speculation: 1) subintimal stenting would provoke sustained inflammation of the vessel wall (medial) owing to the influence of paclitaxel, which could potentially lead to aneurysmal degeneration. 2) IVUS use may encourage interventionalists to select larger devices and the use of larger balloons or stents may concomitantly accomplish larger minimum stent area and increase the risk of medial injury, which may lead to aneurysmal degeneration.

Iida O, et al. JACC Cardiovasc Interv. 2022;15:630-638.

Haraguchi T,et al. Vasc Med. 2023;28:412-421.

Case : Chronic total occlusion of Popliteal artery

Case: 57yo, female, HTN (+), DM (-), dialysis (-), claudication (Rutherford 3), rt ABI 0.65



Rt Popliteal arterial aneurysm was isolated by stentgraft implantation (Viabahn 6.0*50mm).

Take home message
(My speculation: mechanism of aneurysmal degeneration occurrence)