Why I Am Still Somewhat Skeptical About the MLFM Bare Stent

Mark Fillinger MD
Dartmouth-Hitchcock Medical Center
Lebanon, NH

Disclosure of Potential Conflicts of Interest
Speaker name: Mark Fillinger

Consulting (WL Gore, Cook, Endologix)
– none related to MLFM

How Could The Multilayer Stent Possibly Work?

- Alter shear stress
- Induce thrombosis of saccular outpouchings
- Develop tissue ingrowth (platelets, thrombus, laminated fibrin, neointima) which could theoretically become impermeable to pressure (or nearly so)

Saccular Aneurysm: Reduction of Shear Stress, In Vitro Model

Tissue Ingrowth Into Stents

S. Nishi, Y. Nakayama, H. Ueda, M. Ishikawa, and T. Matsuda

A New Stent Graft With Thin Walled Controlled Micropored Polymer Covering

Is This Important?

- Stent-grafts, coils and plugs are already known to work in small-diameter arteries with saccular aneurysms.
- Stent-grafts work in aortic aneurysms and dissections without branches.

What we want is something to treat aortic aneurysms with branches arising from the aneurysm sac ...
Wall SHEAR Stress

Wall shear stress is related to the velocity profile of blood flowing across the vessel surface.

Wall TENSILE Stress Causes Rupture

Wall tensile stress is related to the pressure, diameter, shape, and wall thickness—acts to pull the wall apart.

Thin-walled pressure vessels: \[ \text{Tension} = k \cdot PD/t \]

Tensile stress in an aortic aneurysm wall is >10 times shear stress.
Pressure and Flow Within the Sac

We know Pressure A>B>C

If Pressure C \approx SBP
Then Pressure B \approx SBP

If Pressure B = SBP
Then Pressure B1 = ?

Evidence to Date

- Single cases, small series, highly selected cases, and/or compilations of same
- Highly varied pathology:
  - Peripheral arteries
  - Aortic dissections
  - Aneurysms without major branches
  - Aneurysms with major branches
- Short term follow-up
- Mixed results, including ruptures

Evidence We Lack

What we have for aortic stent-grafts...
- A highly monitored, FDA-controlled clinical trial with core-lab follow-up
- Pathology of interest:
  - Aneurysms without major branches
  - Aneurysms with major branches
- Long-term follow-up with aneurysm volume

Conclusions

- Theoretical considerations suggest that Flow-diverting stents:
  - May work in peripheral arteries containing focal aneurysms without branches, and potentially more complex aortic cases
  - I remain skeptical that it can work as hoped in aortic aneurysms with major branches arising from the aneurysm