– Multilayer Flow Modulator Endografts –
Is The MLFM Stent A Valid Treatment
In High Risk 80- and 90-Year Olds With Paravisceral And TAAAs?

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Multilayer
- Flow Modulator or Flow Diverter
- Chromium-Cobalt alloy
- 3D structure
- Transforms turbulent into laminar flow
- Excludes the aneurysm in a physiological way, preserving branch patency

Objective
- Create a simple solution for a complex disease:

Thoraco Abdominal Aortic Aneurysms

How?
- Reducing the vortex velocity
- Providing laminar flow to the branchess
- Optimizing sistemic blood pressure in the perfused vessels

But, it works?
Experimentally, it is proved that it works!

In neurointervention, the rationale of flow diversion gains increasing acceptance!

**RATIONALE FOR USE OF THE MULTILAYER ENDOGRAFT IN OCTO AND NONAGENARIAN PATIENTS**

Para visceral degenerative aortic aneurysm in a 90y man - diameter 103 mm.

Traditionally, open surgical treatment has not been offered to octa and nonagenarian patients, due to the high risk of complications and mortality in this subgroup with high incidence of comorbidities.

Para visceral degenerative aortic aneurysm in a 90y man - diameter 103 mm.

With the increasing number of elderly population, there is a subgroup of individuals with thoracoabdominal and paravisceral aneurysms that are not fit for treatment with fenestrated, branched or open techniques.

Most of this patients will be dead within a year if left untreated.

In January 2013 we started a prospective registry of patients with this characteristics, to be treated with the Multilayer Endograft.

Para visceral degenerative aortic aneurysm in a 90y man - diameter 103 mm.

Thoracoabdominal & paravisceral aortic aneurysms

**INDICATIONS OF TREATMENT**

- Patients unfit for open procedure
- Patients at prohibitive risk for endo procedures
- Patients that do not accept any risk of paraplegia

A thorough and detailed Informed Consent was explained to all patients and their families, and signed before the procedure.

Para visceral and abdominal degenerative aortic aneurysm in a 90y man - diameter 103 mm. Previous TEVAR, with prolonged paraparesis.

**SELECTION OF PATIENTS**

- Thoracoabdominal or paravisceral AA with at least 6,5 cm in diameter
- Life expectancy of at least two years
- Judged UNFIT to undergo the standard procedures by our intensive care and anesthesiology team

Para visceral and para anastomotic symptomatic aortic aneurysm in a 80y man – diameter 72 mm.

**MATERIAL**

- Fourteen patients
- Mean age – 84,6y (80-97y)
- Sex – 13 males (93%); 1 female (7%)
- Previous aortic surgery – 64%

**ANEURYSM CHARACTERISTICS**

- All degenerative
- Toracoadominal – 64%
- Para visceral – 36%
- Diameter – 65-103 mm (mean 76,6 mm)
- Form: Fusiform – 47%; Sacular – 43%

Para visceral and para anastomotic symptomatic aortic aneurysm in a 80y man – diameter 72 mm.
Co Morbidities and Risk Factors ABOUNDed in this population:

- High risk for paraplegia: 85%
- Systemic hypertension: 78%
- Coronary artery disease: 71%
- Previous aortic surgery: 64%
- COPD: 64%
- Non-dialytic renal insufficiency: 57%
- Previous neoplasm(s): 50%
- Thrombocytopenia: 42%
- Atrial fibrillation: 28%
- History of heavy smoking: 100%

Other important co morbidities were present in 71% of the patients.

THE PROCEDURE

- 7 cases with single MLFM implant – Op time: 122' (75-225')
- 7 cases concomitant to other endo procedures - Op time: 243' (150-360')
- In 71% of the cases only one MLFM was implanted.

CONTRAST USED

- None – 1 case (7%)
- CO₂ – 1 case (7%)
- Iodinated – 12 cases (86%) – 15-100 ml (mean 43ml)

Strict IFU were observed only in 35% of the cases; in 65%, the MLFM was anchored either proximally or distally in pre existing grafts.

EARLY RESULTS

- Technical success: 100%
- Operative mortality: Zero
- 30 day complications
  - Thrombocytopenia
  - GI hemorrhage
  - Pneumonia
  - Intestinal obstruction
- 30 day mortality: 1 (7.1%)
  - Intestinal obstruction - same patient

PARAPLEGIA: ZERO!
No early or late visceral ischemia was observed. Renal function remained stable in 93% of cases; one non-dialytic patient evolved to HD and one additional required PTA+stent of a progressively stenosing renal artery. No aneurysmal growth in the series. Death causes in the 1-34 mo period – Pneumonia; GI hemorrhage; Pulmonary embolism.

Lessons learned:
• Careful selections of patients is key!
• Patients must adhere to strict antiplatelet regimen.
• Anchoring within dacron grafts seems to be safe.
• Anchoring within endografts seems to be safe.
• Most aneurysms have a slight decrease in size, but their shape changes from circular to oval – depressurization of the wall?

Multilayer Flow Modulator:
• MLFM is not a mechanical barrier
• MLFM is a dynamic barrier
• reduces stress forces on aneurysmal wall
• decreases flow velocity in the aneurysmal sac
• maintains laminar flow in main arteries
• maintains laminar flow in side branches

MLFM is contraindicated in acute expanding and ruptured aneurysms.

Thank You
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