VALUE OF MULTILAYER BARE STENTS (MLFM – ALLAY FROM INTRESSA) IN THE TREATMENT OF TBAD PATIENTS WITH OR AT HIGH RISK OF END ORGAN MALPERFUSION: LONG-TERM RESULTS

PREDICTORS OF POSITIVE REMODELING IN DISSECTION PATIENTS UNDERGOING ENDOVASCULAR TREATMENT WITH MULTILAYER STENTS

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Author disclosures

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2

BACKGROUND

TEVAR with stent-grafts for Type B Aortic Dissection (TBAD) generally leads to:

- Positive aortic remodeling in the aortic segment covered by the stent graft
- Continued aortic growth in the abdominal segment[1,2], even when treated with bare metal stents[3]

The continued aneurysmal degeneration of the dissection results in high re-intervention rates[4,5]

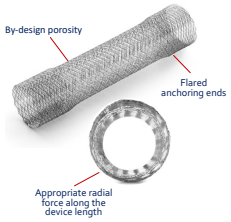
1: Famularo, et al. 2017; 2: Li, et al., 2022; 3: Lombardi, et al. 2022; 4: Zhang, et al. 2016; 5: Kotsun et al. 2017

3

BACKGROUND

Due to their properties (radial force, 3D porosity), multilayer stents have been investigated as a possible treatment option for the extensive treatment of the dissected aorta in TBAD

Initial results indicate that multilayer stents may reduce such aortic growth and the need for reintervention[6,7]



6: Sultan, et al. 2018; 7: Costache, et al. 2021

4

OBJECTIVE

Based on available data from both a prospective clinical study and retrospective real-world data collection in aortic dissection patients, identify predictors for positive aortic remodeling following multilayer stents implantation

5

METHODS - POPULATION

75 TBAD patients:

- treated with multilayer stents (MFM, Cardiatis, Belgium),
- either in the DRAGON prospective study (n=18) or in real-world off-label cases (n=57)
- followed-up for at least 30 days
- with CT-scans available pre- and post-procedure assessed by independent radiologists, and analyses performed by independent statisticians

6

METHODS - REGRESSION ANALYSES

Investigating the impact of relevant variables on the ENDPOINT: CHANGE IN MAX TA DIAMETER

Demographic	Dissection	Treatment	Follow-up
Age (years)	Pre-op max TA diameter (mm)	True Lumen (TL) reopening (mm)	# of days since procedure
Gender (M/F)	Extension into iliac arteries (Y/N)	Extensive coverage (Y/N)	False Lumen status
Presence of graft or stent graft (Y/N)			# of abdominal vessels fed through FL

7

RESULTS - POPULATION

Demographic	(N=75)
Age (Years)	56.7 ± 12.0
Max TA diameter (mm)	**52.7 ± 14.6**
Gender (%)	
Male	78.7% (59/75)
Female	21.3% (16/75)
Previous aortic treatment	
None	52.0% (39/75)
Yes	48.0% (36/75)
Ascending aorta	34.7% (26/75*)
Stent graft	18.7% (14/75*)
Extension into iliac arteries	
No	37.3% (28/75)
Yes	61.3% (46/75)
Unknown	1.4% (1/75)

*: 4 patients with both a graft and a stent-graft

8

RESULTS - POPULATION

Treatment and follow-up	(N=75)
Follow-up duration (days)	835 ± 724 (31 – 2618)
True Lumen reopening at PMC (mm)	10.7 ± 6.4
Change in Max TA diameter (mm)	3.1 ± 11.7
Extensive treatment:	
Yes	84.0% (63/75)
No	14.7% (11/75)
Unknown	1.3% (1/75)
Number of abdominal branches covered:	
None	25.3% (19/75)
1	40.0% (30/75)
≥ 2	33.4% (25/75)
Unknown	1.3% (1/75)
False Lumen (FL) status:	
Patent	**17.4% (13/75)**
Partially thrombosed	**80.0% (60/75)**
Completely thrombosed	1.3% (1/75)
Unknown	1.3% (1/75)

9

RESULTS – REGRESSION ANALYSIS

In univariate analysis, new predictor of positive remodeling identified: extensive treatment coverage with multilayer stent

Demographic	Dissection	Treatment	Follow-up
Age (years)	Pre-op max TA diameter (mm) p=0.010	True Lumen (TL) reopening (mm)	# of days since procedure p=0.002
Gender (M/F)	Extension into iliac arteries (Y/N)	Extensive coverage (Y/N) p=0.013	False Lumen status
Presence of graft or stent graft (Y/N)			# of abdominal vessels fed through FL

No predictor was identified through multivariate analysis

10

RESULTS - PAIRWISE COMPARISONS

In pairwise comparisons, extensive treatment coverage was the only significant variable predicting lack of aortic growth

Demographic	Dissection	Treatment	Follow-up
Age (years)	Pre-op max TA diameter (mm)	True Lumen (TL) reopening (mm)	# of days since procedure
Gender (M/F)	Extension into iliac arteries (Y/N)	Extensive coverage (Y/N) p=0.009	False Lumen status
Presence of graft or stent graft (Y/N)			# of abdominal vessels fed through FL

11

EXTENSIVE TREATMENT PREVENTS AORTIC GROWTH

>70% long-term stabilization of pre-op max TA total diameter over 5 years

	STABLE II* At the level of dissection stent		Multilayer Stent Real World	Multilayer Stent DRAGON
Nb of subjects	31	21	57	14
Follow-up duration (months) (mean ± sd)	24	60	21±21	54±14
Max TA Total diameter (mm) (mean ± sd)	Thoracic aorta: 39.6 ± 5.7 Abdominal aorta: 32.6 ± 4.9		55.5±14.9	43.3±9.2
% of subjects with TEVAR	100%	100%	18%	0%
% of subject with fully thrombosed FL	17%$	33%$	0%	7%
Remodelling - Change in max TA total diameter				
Increase:	45%$#	62%$#	30%@	21%#
Decrease:	7%$^	5%$^	35%€	29%^
No change:	48%$	33%$	35%	50%

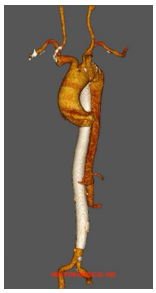
*: Lombardi et al. Five-year results of the STABLE II study for the endovascular treatment of complicated, acute type B aortic dissection with a composite device design. J Vasc Surg 2022;76:1189-97.

12

CONCLUSIONS

When patients with TBAD have their dissected aorta treated extensively with multilayer stents:

- the FL status and its perfusion of aortic side branches did not impact aortic remodeling
- extensive treatment with multilayer stents appears to be a key parameter to promote positive aortic remodeling, stabilizing disease progression, and thus potentially reducing the need for aortic reintervention



13

PERSPECTIVE

The ongoing prospective multicenter EXTENSO study is evaluating the effectiveness and safety of the Allay® Aortic Stent when used as an adjunctive endovascular treatment in patients with TBAD who are eligible for TEVAR with stent graft(s)

14

Thank you

15