Endovascular ThoracoAbdominal Aneurysm Repair

The French Prospective Multicenter Trial 1 Year Follow Up



Disclosure Statement

None

STRATO

The French Prospective Multicenter Study 1-Year Follow-up

Enrollment: April 2010 - February 2011 – 10 centers

23 pts (4 female, 19 male), Age 76y \pm 11y (59-93y)



CT imaging at 1-3-6-12 months Corelab (CERC – France)

C Vaislic, JN Fabiani, S Chocron, JM Alsac, Y Glock, H Rousseau, P Leprince, J Robin, T Unterseeh, JP Villemot, V Costache, M Sapoval,

STRATO The French Prospective Multicenter Study 1-Year Follow-up

Non expert centers No learning curve First generation MFM

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Clinical Event Commitee

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Primary efficacy endpoint :

Aneurysm exclusion Collateral patency

Primary safety endpoint :

All cause Mortality

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Secondary endpoints:

Type I or III endoleaks Secondary open or endovascular procedure Spinal cord ischemia Stent migration or loss of stent integrity aneurysm rupture major adverse events Change of size Maximum Diameter Volume (thrombus and flow)

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- Age >=80
- ASA >=3
- Hx of Aortic Surgery
- CAD
- Cardiac Renal or Respiratory
 Insufficiency
- Hostile Abdomen / Thorax

Pt History



Previous Aortic Intervention



Aneurysm Description

- 10 Crawford Type II (43.5 %)
- 13 Crawford Type III (56.5 %)
- Mean Diameter: 65 mm (46 85mm)
- Length: 162.5 mm (36-408mm)



Procedural Data

Acute Procedural Data	STRATO	HAS Report (Fenestrated endoprosthesis)
Average Deployment time (mean (range))	4.5 min (2-10min)	_
Duration of Procedure (min)	84 min	237 min
(mean (range))	(45-125min, n=19)	(85-600, 6 studies)
Duration of Fluoroscopy	19 min	60 min
(min) (mean (range))	(5-120min, n=22)	(5-117min, 7 studies)
Contrast Volume (cc)	129 cc	199 cc
(mean (range))	(50-300ml, n=21)	(9-400ml, 9 studies)
Estimated blood loss (cc) (mean (range))	68 cc (0-250ml, n=21)	

No Aneurysm Rupture, No Migration, No Stent Fracture

Rupture	1 month	6 months	12 months
	0% (0/22)	0% (0/22)	0% (0/21)

Major Adverse Events

Device related	
	1 branch occlusion
	1 partial opening of the distal part of the MFM (ballooning)
Procedure related	
	2 vascular trauma during insertion (iliac rupture, hematoma)
	1 stroke
	5 endoleaks
Other	
	1 death at 11 months
	1 non-occlusive endoluminal obstruction at 2 days not visible at 15 months

Mortality

Mortality	30 days	6 months	12 months	Cumulative Mortality
All-cause	0	0	1	1

Progression of TAA 3 Months After Initial Procedure

- 2 Multilayer stents have been added at the distal end at 3 months
- With 1 CVA
- CVA at 4 months
- Sudden death at 11 months
- Pt not treated
- « Overlapping would have imposed to implant the larger stent inside »





No Spinal cord ischemia
 No respiratory, renal or peripheral complications

Visceral Branch Patency

Branch Patency	12 months
Number of patients	n=20
Celiac Trunk Patency	93% (13/14)
Secondary Patency	100% (14/14)
Superior Mesenteric Artery Patency	94% (15/16)
Secondary Patency	100% (16/16)
Left Renal artery Patency	100% (13/13)
Right Renal Artery	100% (15/15)

At 12 months in 20pts; 2 occluded branches / 57 covered branches (96,5 %)

Endoleaks

Endoleaks	Discharge-3 months	6 months	12 months
All Endoleaks (any and persistent)	30,3% (7/23)	30% (6/20)	20% (4/20)
Type I (Proximal)	21,7% (5/23) ¹	20% (4/20)	20% (4/20)
Type I (Distal)	4,3% (1/23) ²	5% (1/20)	0% (0/20)
Type III (Mis- overlapping)	4,3% (1/23) ³	5% (1/20)	0% (0/20)

Endoleak was reported in 5 (20%)

- <u>1 corrected by stent-graft</u>
- <u>2 corrected with secondary intervention (MFM)</u>
- <u>1 corrected with secondary intervention (MFM) after 12 m fu</u>

3 Type I Endoleaks

Causes :

- Always linked to wrong placement
- Gap between the stent and the arterial wall
- Small stent in the big one
- Aneurysm not completely covered

Gap + small MFM in the big one for 1 patient

Patient 2 - IC0308_FRA_91_01



Diameter Evolution IC0308_FRA_91_01







Clinical Success

Clinical Success	6 months	12 months
Aneurysm Exclusion	65% (13/20)	75% (15/20)
Aorta and MFM Patency	100% (20/20)	100% (20/20)

Change in Size

Change in Size	Baseline	12 months
Maximal Diameter ¹ (mean (range) (nb patients))	68mm (5,3 – 8,1mm) (N=21)	72mm (5,4 – 9,0mm) (N=20)
Increase (>10mm/year)	_	10% (2/20) ²
Stable (<10mm/year)	-	90% (18/20)
Decrease (>10mm/year)	-	0% (0/20)
Aneurysmal Flow Volume / Total Volume (% / range (nb patients) ¹	16,3% (2,2 - 42,9%) (N=19)	10,1% (0 - 31,7%) (N=17)
Thrombus Volume / Total Volume (% (range) (nb patients)) ¹	43,9% (17,1 - 80%) (N=19)	55,2% (37,9 - 79,4%) (N=17)

Evolution of the Max Diameter (Patient with endoleak)

	Mean (cm)	Min (cm)	Max (cm)	SD (cm)
Discharge	7,23	6,94	7,60	0,30
1 Year	8,23	7,48	8,99	0,70



The aneurysm increased about 1 cm at 1 year due to

Evolution of the Max Diameter (Patients without endoleak)

	Mean (cm)	Min (cm)	Max (cm)	SD (cm)
Discharge	6,66	5,26	8,07	0,85
1 Year	6,96	5,36	8,46	0,93



The diameter comparison between discharge and 1 year shows a non significant increase (3 mm) with a p-value > 0,05

Thrombus and Circulating Lumen Change (Patients without endoleak)







STRATO Study: 1-year Results

Criteria	STRATO
Aneurysm Exclusion	75% (15/20)
Aorta Patency	100% (23/23)
Primary Branch Patency	96.5% (55/57 covered visceral branches)
Migration	0%
Fracture	0%
Kinking	0%
Endoleaks	22% (5/23)
Re-interventions	22% (5/23: 4 endovascular (for endoleak) – 1 surgery)
Maximal Diameter	Baseline: 68mm (53-81mm) – 1 year: 72mm (54-90mm)
Change (≠ 10mm)	≌ 0% ; ➔ 90% ; ᄏ 10% (Endoleaks)
Residual Flow Vol. Ratio	Baseline: 14.2% - 1 year: 10.1%
Thrombus Volume Ratio	Baseline: 45.5% - 1 year: 55.2%
Paraplegia/Paraparesia	0%
Aneurysm Rupture	0%

Results at One Year

CMFM is reliable device for TAA treatment in term of aneurysm thrombosis, stent and side branches patency and diameter stabilisation

In order to obtain these results, it is mandatory:

- Antiplatelet therapy
- Treat concomitant stenosis of collateral vessels
- Adequate overlapping
- Proper proximal and distal landing zones

Results at One Year

Collateral, in particular when arising from both sac and neck, delay exclusion (>12 months)

Longer FU is needed to evaluate device durability and persistency of the results