Endovascular repair of thoracic and thoraco-abdominal aortic lesions

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BACKGROUND: *We report our "real-world" experience of endovascular repair of thoracic/thoraco-abdominal aortic lesions in patients treated from May 2002 to May 2017.*
METHODS: *Data of all consecutive treated patients were retrospectively collected in a database and analyzed. Patients were divided into 4 groups: atherosclerotic thoracic/thoraco-abdominal aneurysms (TAA/TAAA) and floating thrombus (group A); acute complicated type B dissection (TBD), penetrating aortic ulcers (PAU) and intra-mural hematomas (IMH) in group B; chronic TBD evolving in TAA (group C); traumatic injuries (group D). Mortality, reinterventions and occurrence of neurological complications, both at 30 days and in the long term, were analyzed as primary outcomes for each group.*
RESULTS: *Ninety-four patients were treated complessively, most for a TAA (55.3%). Thirty-days deaths and neurological complications were observed in group A only (5 cases each, 5.3%). A reintervention was necessary in 6 patients (6.4%) of group A. At 5 years, in group A survival was 62.8%±6.3% and freedom from neurological complication was 88.3%±4.2%. Neither deaths nor neurological complications were recorded in the other groups. No late aortic ruptures were recorded. Freedom from reintervention in group A was 54.7%±7.6% at 5 years and a reintervention was needed in all patients of group D. Overall, the main cause for reintervention was a type I endoleak.*
CONCLUSIONS: *The endovascular repair of thoracic/thoraco-abdominal aortic lesions had acceptable mortality and neurological complication rates, both at 30 days and in the long term. Reinterventions in the long term occurred more frequently after TAA/TAAA and traumatic injuries, and were mainly required for a type I endoleak.*

KEY WORDS: Endovascular thoracic repair, Endovascular thoraco-abdominal repair, Thoracic aneurysms

Introduction

Since the publication of Dake and Coll. [1], in the last twenty years, the endovascular techniques have totally revolutionized the treatment of aortic diseases, especially in the thoracic region.
On one hand, the endovascular techniques are now universally recognized as the gold standard for the treatment of thoracic aortic lesions (TEVAR), overcoming the open techniques with the advantage of reduced postoperative mortality and morbidity [2,3].
On the other hand, thanks to the improvement of materials, they have recently been extended to complex segments such as the thoraco-abdominal region, making it possible to treat "high risk patients" that previously would have been totally excluded from surgery.
In the literature, however, some issues are still being debated. A major issue is about the strategies of prevention of dangerous neurological complications such as perioperative stroke and paraplegia. Another important topic regards the need to revascularize the left subclavian artery in case of intraoperative coverage with

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proximal landing zone of the endograft. Eventually, the reintervention rate in the long term is the Achilles heel of TEVAR, similarly to what happens for the abdominal aortic district [4]. To contribute to a better understanding of these issues, it is important to report the real clinical experience, which could be useful in the daily practice.

Aim of the study was to report our "real-world" retrospective and monocentric experience of patients undergoing endovascular exclusion of thoracic and thoraco-abdominal aortic lesions from May 2002 to May 2015.

Materials and Methods

Ethics approval was obtained from our Institution.

We retrospectively reviewed data of all consecutive patients who underwent endovascular exclusion of either a thoracic or a thoraco-abdominal aortic lesion from May 2002 to May 2017 in our institution.

Data were obtained through a retrospective research on medical records and patients' radiological imaging. For each patient we considered preoperative data (such as demographics, information about the aortic disease, comorbidities), intraoperative data and complications at 30 days and in the long term. Follow-up information were collected through the review of outpatient visits and telephonic interview.

All patients underwent a preoperative angio-computed tomography (angio-CT) scan of the thoraco-abdominal aorta, which was mandatory for the correct pre-procedural planning. A duplex ultrasound scan of supra-aortic vessels was performed in all cases (except for emergent procedures) to assess carotid, vertebral and subclavian artery patency and flow, especially in case of aortic dissection.

All procedures were performed by vascular surgeons in the operating theatre.

For the prevention of spinal cord ischemia (SCI), a cerebrospinal fluid drainage (CSFD) was positioned by the anesthesiologist at least 1 hour before the procedure in selected patients, such as in case of previous aortic surgery, when there was the need to cover a long segment of aorta (>30 cm), when the aortic endograft would cover the region between T8 and L1, or when there was the need to cover the left subclavian artery (LSA)[5]. The CSFD was usually removed at least 48 hours after the procedure when there were no signs of SCI. Otherwise, it was left in place as indicated by the neurologist. Drainage of the CSF was performed when the liquoral pressure was higher than 15 mmHg.

The LSA was kept patent whenever possible. When the coverage of the LSA was necessary for the achievement of a proper proximal landing zone of the endograft, however, elective pre-procedural or intra-procedural revascularization was performed in selected cases, such as young patients, when there was no adequate collateral flow from the contralateral vertebral artery or the hypogastric arteries, or in case of previous aortic-iliac surgery. The revascularization was obviously mandatory in presence of a hemodialytic arterial-venous fistula or a coronary artery bypass graft with left internal mammary artery[6]. In case of landing of the proximal edge of the endograft in either zone 0 or zone 1 (Ishimaru's classification), a rapid sequence pacing was used to facilitate the precise placement of the graft itself.

After treatment all patients were discharged on antiplatelet therapy (either ASA 100 mg daily or Clopidogrel 75 mg daily all lifelong) unless they were already on anticoagulant therapy for preoperative comorbidities.

All collected data were inserted in a database and analyzed as appropriate.

Patients were grouped according to the different etiology of the aortic lesions: atherosclerotic thoracic aneurysms (TAA) or thoraco-abdominal aneurysms (TAAA) and floating thrombus were gathered in group A; acute complicated type B dissection (TBD), penetrating aortic ulcers (PAU) and intra-mural hematomas (IMH) in group B; chronic TBD evolving in TAA in group C; traumatic injuries in group D. Mortality, reinterventions and occurrence of neurological complications, both at 30 days and in the long term, were analyzed as primary outcomes, with respect to the different type of pathology. Secondary outcomes were the occurrence of post-implantation syndrome (PIS) and of left arm ischemia in patients in whom the left subclavian artery was intraoperatively covered by the endograft without elective revascularization.

Statistical analysis was performed using the software JMP® 5.1.2 (SAS Institute, Inc., Cary, NC, USA). The data were reported as median and interquartile ranges (IQR) for variables with non-Gaussian distribution (Shapiro-Wilk test) and mean ± 2SD for Gaussian variables. Categorical variables were presented as n (%). Kaplan-Meier method was used to estimate survival, freedom from neurological events and freedom from reinterventions. The Wald test was performed to assess if age could affect the raw survival. Chi-square test (Pearson correlation), logistic regression and One-way ANOVA were used as appropriate to assess any possible factor which could affect outcomes. P values <.05 were considered statistically significant. When a correlation was found, the strength of the correlation was reported through R2.

In case of any statistically significant results, ROC curves were also analyzed for the determination of cut-off values which could be highly associated with the occurrence of follow-up events.

Results

From May 2002 to May 2017 a total of 94 patients (74 males, 78.7%), median age 73 years (IQR 68-79

TABLE I - *Characteristics of the patients*

	n=94
Male Sex	74 (78.7%)
Median Age, years (IQR)	73 (68 – 79)
Etiology of the lesion	
Group A:	
Atherosclerotic TAA	*59 (62.7%)*
Atherosclerotic TAAA	*5 (5.3%)*
Aortic floating thrombus	*2 (2.1%)*
Group B:	
Complicated acute Type	*6 (6.4%)*
B dissectionPAU	*11 (11.7%)*
IMH	*3 (3.2%)*
Group C:	
Chronic type B dissection evolving in TAA	*4 (4.2%)*
Group D:	
Post-Traumatic lesion	*2 (2.1%)*
Comorbidities	
Current or previous smoke	38 (40.4%)
COPD	33 (3.1%)
CAD	29 (30.8%)
Hypertension	78 (83%)
Dyslipidemia	48 (51.1%)
Diabetes	12 (12.8%)
Chronic renal failure	41 (43.6%)
Previous neoplasm	18 (19.1%)
Stroke	1 (1.06%)
Transient Ischemic Attack	2 (2.1%)
Concomitant AAA	14 (14.9%)
Previous AAA repair	32 (34%)
Emergent setting	15 (15.9%)

Legend: TAA = Thoracic Aortic Aneurysm; TAAA = Thoraco-Abdominal Aortic Aneurysm; PAU = Penetrating Aortic Ulcer; IMH = IntraMural Hematoma; COPD = Chronic Obstructive Pulmonary DiseaseCAD = Coronary Artery Disease; AAA = Abdominal Aortic Aneurysm

TABLE II - *Intraprocedural and in-hospital data (Mean+SD; Median, IQR)*

	n=94
Anesthesia	
General	74 (78.7%)
Local + conscious sedation	3 (3.2%)
Locoregional	17 (18.1%)
Vascular Access	
Surgical femoral	82 (87.3%)
Abdominal aorta	7 (7.4%)
Surgical Iliac	5 (5.3%)
Percutaneous brachial (additional)	12 (12.7%)
Percutaneous contralateral femoral (additional)	27 (28.7%)
CSF drainage	27 (28.7%)
Trans-esophageal echocardiography	16 (17%)
LSA coverage	18 (19.1%)
Time of operation (min; median, IQR)	105 (70-140)
Amount of contrast (cc)	45.2 + 1.5
Fluoroscopy time (min)	34.3 + 1.6
Blood loss (cc)	143 + 12
Proximal landing zone (Ishimaru's class)	
Zone 0	1 (1.1%)
Zone 1	1 (1.1%)
Zone 2	18 (19.1%)
Zone 3	24 (25.5%)
Zone 4	50 (53.2%)
Total endograft length (median, IQR)	130 mm (125-180 mm)
Length of stay (days; median, IQR)	6 (4-8)
ICU (days; median, IQR);	4 (2-6)

Legend: LSA = Left subclavian artery; CSF = cerebro-spinal fluid

years) were treated consecutively for either a thoracic or a thoraco-abdominal aortic lesion.

In particular, 63 patients underwent thoracic endovascular aortic repair (TEVAR) for either an atherosclerotic TAA or an aortic floating thrombus (group A, see Table I). Of them, 6 TAA had been symptomatic for a contained rupture, 4 TAA had either hemophtoe or dysphonia (2 patients each) and 5 had been symptomatic for chest pain. One patient who had an aortic floating thrombus presented with bilateral acute lower limb ischemia. Five more patients of group A underwent a total endovascular exclusion of a thoraco-abdominal aneurysm (4 type II according to Crawford's classification and one type IV) using a fenestrated endograft in 3 patients. A multilayer flow modulator stent-graft was employed for "compassionate use" in 2 patients who were excluded from other treatments because of high surgical risk and hostile anatomy.

For patients with aortic aneurysms, the median diameter of the lesion was 65 mm (IQR 60-79.5; range 30-93).

Group B included 3 patients who presented with chest pain and IMH, 11 PAU (being 2 of them symptomatic for chest pain) and 6 patients who underwent TEVAR for an acute complicated TBD which caused either acute limb/visceral ischemia (5 patients) or irrepressible chest pain (1 patient).

Four patients underwent TEVAR for a chronic TBD (type IIIA according to De Bakey's classification) evolving into TAA with an aortic diameter greater than 50 mm (Group C), and 2 patients were treated for a traumatic rupture at the isthmus (Group D).

As described in Table I, patients mainly had a history of hypertension. Fourteen patients had a concomitant infrarenal abdominal aortic aneurysm (AAA) which was under regular follow-up, while 32 had already undergone either endovascular or open aortic repair of an AAA (4 patients and 28 patients respectively).

At preoperative anesthetic assessment, most of the patients was in ASA (American Society of Anesthesiologists) class 3 (55.7%) and 4 (30%).

Technical success, defined as the correct deployment of the endograft without any immediate endoleak, was achieved in 96.8% of the cases overall. In 2 patients of group A, a type Ia endoleak at the end of the proce-

dure was immediately corrected with a proximal cuff, with good results. In the latter case, the procedure was interrupted for the occurrence of a severe ischemic stroke of the posterior cerebral circulation during the delivery of the graft for the repair of a TAA. The patient was then immediately referred to the ICU and died after 28 days.

As described in Table II, the procedures were manly performed using general anesthesia (78.7%).

A CSFD was selectively used in 27 patients (being all 5 cases of TAAA, 1 case of acute complicated TBD, all 6 cases of chronic TBD and 15 cases of TAA). The CSFD was left in place for a median of 50 hours (IQR 48-56 hours). In 7 of these cases, active drainage was performed because the liquoral pressure rose up to more than 15 mmHg.

Endovascular repair was performed via surgical femoral access in 82 patients, while in the remaining 12 cases a different vascular access was needed, due to the presence of either small or highly calcified femoral-iliac arteries (Table II). A percutaneous transluminal angioplasty or femoral arterectomy was necessary in 11 patients before the endograft could be successfully delivered. An additional percutaneous femoral or percutaneous brachial access was performed for the diagnostic angiography in 27 and 12 patients respectively. In particular, a percutaneous brachial access was used in the 3 patients who underwent the endovascular exclusion of TAAA using the fenestrated endografts, in all cases of acute TBD and in 3 cases of chronic TBD.

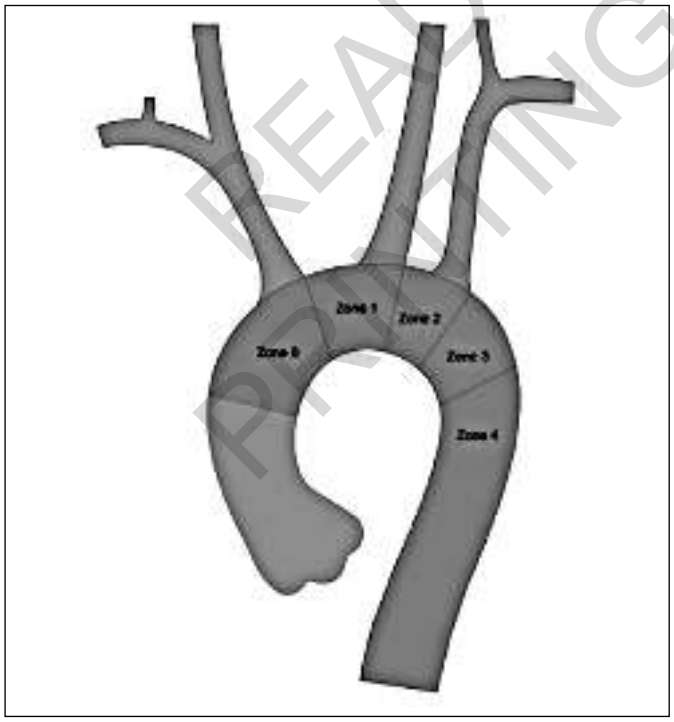

Fig. 1: Ishimaru's classification of aortic arch and thoracic aorta.

Table III - *Type of endografts used in our series*

Type of endograft	N (%)
Relay Bolton	50 (53.7%)
Gore Tag	8 (8.6%)
Endomed Endofit	2 (2.1%)
Cook TX2	17 (18.3%)
Cook Z-FEN	3 (3.2%)
Medtronic Valiant	7 (7.5%)
Jotec E-Vita	5 (5.4%)
Medtronic Talent	1 (1%)
Cardiatis MFM	2 (2.1%)

According to Ishimaru's classification (Fig. 1), the proximal landing zone for the endograft was mainly 3 and 4 (24 and 50 patients respectively). The LSA was intentionally covered in 20 patients (all of them in group A), 6 of whom underwent elective revascularization due to either previous aortic surgery or young age (3 patients each). In 2 cases, the flow to the LSA was restored through a left common carotid artery (LCCA)-to-LSA prosthetic bypass graft (Dacron). In one of these patients, also LCCA was covered to achieve a proper proximal landing zone for the endograft (Ishimaru's zone 1), so both LCCA and LSA were revascularized using a prosthetic right common carotid artery (RCCA)-to-LCCA-to-LSA bypass graft. In the remaining case, the lesion involved the aortic arch so the endograft was placed with a proximal land in Ishimaru's zone 0 after a total debranching of the supra-aortic trunks and reconstruction on the ascending aorta had been performed through sternotomy.

A single endograft was used in 78 cases, 2 endografts in 14 patients and 3 endografts in one patient, with a median length of covered aortic region of 130 mm (IQR 125-180 mm, range 50-430 mm).

A Bolton Relay™ tubular graft was mostly used (Table III). The five thoraco-abdominal aneurysms were excluded using a Cardiatis Multiflow Modulator Stent in 2 cases and a Cook Z-Fen in the remaining 3 cases (Fig. 2).

Post-procedural median length of stay (LOS) was 6 days (IQR 4-8 days, range 0-31). Intensive Care Unit (ICU) stay was needed in 22 cases, with a median length of stay of 4 days (IQR 2-6 days, range 2-28 days).

Overall median follow-up was 25.6 months (range 1 – 97.7 months).

Thirty-Days Complications

Mortality

Five patients of group A died within 30 days (5.3%). The first was an 88-years-old man who arrived at Emergency Department for a contained rupture of a thoracic aneurysm. He immediately underwent the endovas-

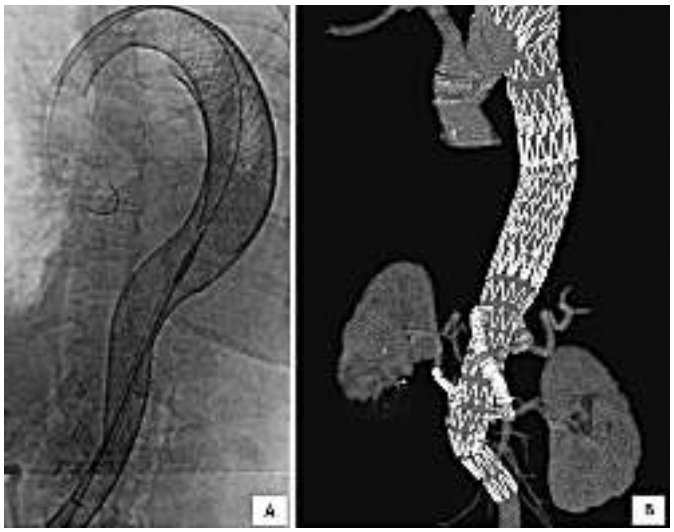

Fig. 2: Endovascular treatment of thoraco-abdominal aneurysm using a Cardiatis Multiflow Modulator Stent (A, on the left side) Cook Z-Fen (B, on the right side).

cular repair but a cardiopulmonary arrest occurred in the following 24 hours.
The second patient (a 77 female) died for a visceral ischemia in postoperative day (POD) 1 after an emergent exclusion of a thoracic aneurysm which had been symptomatic for hemophtoe and thoracic pain.
The third death was caused by a severe ischemic stroke of the posterior cerebral circulation which occurred intraoperatively during the delivery of the graft. The patient was then immediately referred to the ICU and died after 28 days.
The fourth case of death was recorded after a frontal stroke which occurred in POD 2nd in a 86-years-old male patient who underwent endovascular exclusion of a thoracic aneurysm.
The last patient died for a congestive heart failure 10 days after he had been discharged. He had undergone elective endovascular exclusion of a thoracic aneurysm.
No more deaths were recorded within 30 days among the remaining groups.

Neurological complications

There were 5 (5.3%) neurological complications in group A, being 2 cases of major strokes and 3 cases of SCI. The two strokes (one frontal and one in the posterior cerebral circulation) occurred in POD 2nd and intraoperatively respectively, both of them leading to death (see "Thirty-days mortality").
One of the three cases of SCI completely resolved 48 hours later after CSFD and administration of corticosteroids, while the remaining two required prolonged spinal rehabilitation but eventually the paraplegia completely resolved respectively after 4 and 8 months.
The occurrence of perioperative stroke was related to the presence of a symptomatic aortic lesion (P=.02; R^2=0.24). It was also more frequent in older patients (P=.05; R^2=0.004) with a higher probability in patients older than 86 years (AUC 97% at ROC curve analysis). There was no evidence of any correlation with preoperative comorbidity or with the intraoperative coverage of the LSA.
As regards the risk of SCI, it was associated with the length of covered aortic segment (P=.007; R^2=0.0039), being a greater risk of SCI for covered segment longer than 230 mm (AUC 94%). The occurrence of SCI on the other side did not seem to be affected by the presence of CSFD, the coverage of the LSA or a previous abdominal aortic surgery.
There were also two cases of post-dural puncture headache, which resolved with hydration, analgesia and administration of corticosteroid therapy.
No neurological complications occurred postoperatively in group B, C and D.

Reinterventions

A total of 6 patients in group A required 6 procedures. One patient with TAA required an emergent correction of a type Ia endoleak in POD 3rd for distal migration of the endograft. A second patient underwent a left thoracotomy for a hemothorax following an emergent endovascular exclusion of a ruptured TAA. A LCCA-to-LSA bypass was required in a third patient with TAA for the occurrence of a subacute left arm ischemia, the fourth patients underwent an evacuation of hematoma of the femoral access. An exploratory laparotomy was performed in POD 1st in a woman who developed intestinal ischemia due to possible embolism. The remaining patient underwent a Fogarty embolectomy for acute lower right limb ischemia due to thrombosis of the femoral access.
Postoperative course was uneventful in the remaining groups. In particular, symptoms disappeared in all patients who underwent TEVAR for acute complicated TBD. In these latter patients, an angio-CT scan at discharge showed the complete thrombosis of the false lumen with regular patency of the visceral and renal vessels in all cases.

Long-Term Complications

Mortality

Survival in group A was 87 %± 3.7% and 62.8%±6.3% at 1 and 5 years respectively (Fig. 3), which was significantly affected by age (P=.004), history of renal failure (P=.005) and history of coronary artery disease (P=.02). In particular, in patients affected by chronic renal failure, a preoperative serum creatinine level more than 1.22 mg/dL seemed to be a predictive factor for

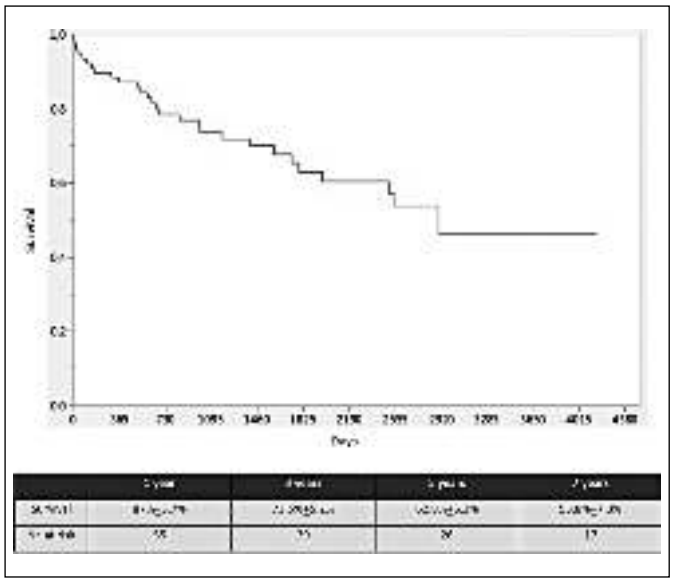

Fig. 3: Kaplan-Meier analysis with estimated long-term raw survival of group A.

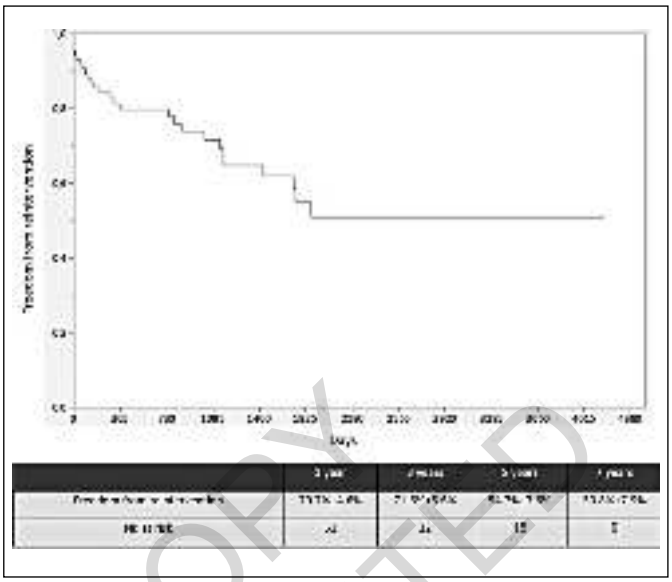

Figure 4. Kaplan-Meier analysis with estimated long-term freedom from reintervention of group A.

TABLE IV - *Details of reinterventions at long term*

Group	Patient (sex, age)	Primitive Patology	Time of reintervention (postop months)	Cause of reintervention	Type of reintervention
A	Male 69 y.o.	TAA	3	Endoleak Ia	Debranching + proximal cuff
A	Male 72 y.o.	TAA	50	Distal dilatation à Endoleak Ib	Distal cuff
A	Male 79 y.o.	TAA	53	Endoleak Ia	Debranching + proximal cuff+Plug in LSA
A	Male 71 y.o.	TAA	2	Retrograde dissection	Debranching + proximal cuff
A	Male 82 y.o.	TAA	10	Endoleak Ia	Proximal cuff
A	Male 63 y.o.	TAA	47	Endoleak Ia	Proximal cuff
A	Male 84 y.o.	TAA	4	Endoleak Ia	Debranching + proximal cuff
A	Male 63 y.o.	TAA	39	Endoleak Ia	Ascending aorta prosthetic replacement
A	Male 74 y.o.	TAAA	10	Endoleak Ia + Ib	Proximal and distal cuff
A	Male 65 y.o.	TAA	38	Distal dilatation → Endoleak Ib	Distal cuff
A	Male 65 y.o.	TAA	58	Distal dilatation → Endoleak Ib	Distal cuff
A	Male 76 y.o.	TAA	26	Endoleak II	Plug in LSA
A	Male 78 y.o.	TAA	28	Endoleak Ib	Distal cuff
A	Male 80 y.o.	TAA	25	Endoleak Ib	Distal cuff
A	Male 72 y.o.	TAA	12	Endoleak Ib	Distal cuff
A	Male 84 y.o.	TAAA	34	Endoleak Ia + Ib	Proximal and distal cuff
A	Male 70 y.o.	TAA	39	Endoleak Ia	Proximal cuff
A	Male 81 y.o.	TAA	3	Endoleak Ia	Proximal cuff
A	Male 71 y.o.	TAA	2	Left arm claudication	LCCA to LSA bypass
A	Male 64 y.o.	TAA	3	Left arm claudication	LCCA to LSA bypass
B	Male 67 y.o.	PAU	58	Endoleak Ia	Proximal cuff
B	Male 63 y.o.	Acute Complicated TBD	2	Renal malperfusion	Renal artery angioplasty
D	Male 53 y.o.	Traumatic rupture	7	Endoleak Ia	Proximal cuff
D	Male 40 y.o.	Traumatic rupture	5	Infolding	Relining

Legend: y.o. = years old; TAA = thoracic aortic aneurysm; LSA = left subclavian artery; PAU = penetrating aortic ulcer; TBD = type B dissection; TAAA = thoraco-abdominal aneurysm; LCCA = left common carotid artery

long-term mortality (ROC curve, AUC 65%). In patients treated for aneurysmal disease, a preoperative sac diameter greater than 70 mm (ROC curve, AUC 69%) also seemed to be a predictive factor for mortality.

Deaths in the long-term were not aortic-related and no aortic rupture were detected during follow-up. There was no deaths in the long-term among the remaining groups of patients.

Neurological complications

Three more strokes were recorded in the long term only in group A. They did not seem to be affected by any preoperative neither intraprocedural factors. Not any other neurological complications were recorded in the remaining groups.

Reinterventions

Freedom from reinterventions in group A (Fig. 4) was 79.7%±4.6% and 54.7%±7.6% at 1 and 5 years respectively, being significantly affected by the coverage of the LSA (P= .03). Reinterventions were also more likely to occur in patients who underwent an urgent procedure (P=.04).
Two out of the 5 patients who underwent TEVAR for TAAA required a reintervention in the long-term (Table IV), in particular both patients in whom the Cardiatis Multi-Flow Modulator stent was used. The Cook TX2 endograft (P= .01) and the Cardiatis MFM (P=.02) endoprostheses were more associated with the occurrence of reinterventions.
In patients affected by aneurysmatic lesions, a diameter greater than 67mm seemed to be a predictive factor for the need of secondary procedures (ROC curve, AUC 64%).
One patient of group B required a renal angioplasty (Table IV) because of a severe stenosis with renal malperfusion due to the remodeling of the thrombosed false lumen. In fact, the intimal flap at the time of presentation involved the origin of the renal artery. Another patient who was treated for a PAU developed a type Ia endoleak after 58 months, due to aneurysmal evolution of the aortic region just at the proximal end of the graft. A proximal cuff was then placed, with optimal results.
In the patients of group B treated for acute TBD, the false lumen was completely excluded and no aneurysmal evolution of the aorta was recorded.
No reinterventions were needed in the long-term for patients of group C. In particular, a shrinkage of the aneurysmal sac was observed in all cases.
Both patients of group D required a reintervention for either a type Ia endoleak or a graft infolding[7] (1 patient each, Table IV).
The main cause for a reintervention was the occurrence of a type I endoleak (a total of 18 patients, Table IV). Five more endoleaks occurred in the long term in group A, being 4 type II endoleaks (1 from a covered LSA, which required the placement of a plug in the LSA, and 3 from intercostal arteries, which are still under surveillance) and a type V endoleak which is still in follow-up. In patients treated for aneurysmal disease, an endoleak of any type was more likely to occur when the preoperative sac diameter was greater than 86 mm (ROC curve, AUC 70%).

Post-Implantation Syndrome (PIS)

A total of thirty-seven patients out of 94 (39.4%) experienced a postoperative fever, which lasted for a median of 3 days (IQR 2-4 days; range 1-11 days) and with a median body temperature of 38.5°C (IQR 38-38.8°C; range 37.7-39.5°C). However, a real PIS as described for EVAR[7] was not detected, as white blood cells count did not raise significantly. Irrespectively from the etiology of the disease, fever occurred most frequently in men (P= .01, R^2=0.04), which was probably due to the higher prevalence of male patients in our series.

Left arm ischemia

Two of the 14 patients (14.3%) in whom LSA was covered without elective revascularization reported a left arm ischemia within 30 days. The former patient (a 82 years-old woman with an asymptomatic TAA), experienced paresthesia and mild hypothermia of her left arm in POD 2nd, which spontaneously resolved after medical therapy with prostanoid. The latter patient (a 58 years-old male who underwent emergent exclusion of a symptomatic TAA) had a claudication of his left arm and in POD 18th underwent a LCCA-to-LSA bypass graft.
In the long-term, two more patients in whom the LSA was intraoperatively covered by the endograft without elective revascularization required a LCCA-to-LSA bypass for a left arm severe claudication which occurred respectively two and three months after the first procedure.
Coverage of the left subclavian artery was the only factor which significantly affected the occurrence of left arm ischemia (P=.0001, R^2 0.41).

Discussion

In the last twenty years, the endovascular techniques have totally revolutionized the treatment of aortic diseases, especially in the thoracic region, overcoming the open techniques with the advantage of reduced postoperative mortality and morbidity[2]. In our real-world experience, the endovascular techniques allowed the treatment of a wide variety of aortic pathologies, ranging from atherosclerotic TAA, to acute and chronic TBD, traumatic lesions and even 5 patients with TAAA. Each and every type of pathology has its pro's and con's towards TEVAR, and this was the main reason why results were reported taking into account the different etiology of the lesion. Irrespectively of the kind of the aortic disease, however, a proper preoperative selection of the patient is mandatory, to optimize the long-term benefit survival of TEVAR.
In our study, the long-term survival after TEVAR for aneurysmal atherosclerotic disease was influenced by comorbidities such as coronary artery disease and

chronic renal failure. The latter is in fact a well-known predictive factor for mortality after TEVAR [9]. In our series, mortality was also affected by the preoperative diameter of the sac in patients undergoing treatment for aneurysms. This variable could be linked to the severity of both the aortic pathology and the cardiovascular comorbidities, as it was reported for patients undergoing endovascular repair for infrarenal aortic aneurysm [10]. There weren't any predictive factors of mortality in the other groups, as numbers were too low to allow a proper statistical analysis.

The risk of neurological complication after TEVAR is another major topic, in particular concerning the risk of stroke and SCI.

As regarding the risk of perioperative stroke, Sullivan and Stundt reported an incidence of stroke after TEVAR of 2.2% [11], which was higher in patients with a history of renal failure or previous cerebrovascular events [12], an excessive intraoperative manipulation of devices within the aortic arch, a prolonged operative time, when there was the need to cover the LSA or in case of debranching of supra-aortic trunks.

Our results compared favorably with those reported in the Literature. In our analysis, albeit limited by the small sample size, the occurrence of postoperative stroke in patients of group A was affected by age, especially in patients older than 86 years, and by the presence of preoperative aortic symptoms.

The incidence of SCI following TEVAR is estimated at around 3-5%, depending on the studies [5]. The main risk factors for this complication have been identified in the concomitant or previous surgery of the abdominal aorta, in the history of acute dissection or aneurysm rupture, in the extensive coverage in the thoraco-abdominal aorta with the graft, in the coverage of the LSA, in the history of chronic renal failure and in the history of diabetes. Also hemodynamic factors such as systolic hypotension and perioperative anemia seemed to play an important role in the occurrence of SCI [5]. Among the strategies for prevention of SCI, the use of CSFD in TEVAR is still under discussion, without any unequivocal conclusion [13,14]. According to Hiratzka and Coll., placement of CSFD is recommended in selected patients deemed to be at high risk of SCI [15]. In our results we did not found a significant difference in the occurrence of SCI between patients with CSFD and those without. The only risk factor which significantly affected the occurrence of this complication was the total length of the prosthetic coverage, with a cutoff of 230 mm above which the risk seemed to be significantly increased. For these reasons, in our experience the prevention strategies of SCI include:

– selective placement of CSFD in high risk patients;
– a two-staged treatment of extensive aortic lesions (as for thoraco-abdominal aneurysms) to allow for an enhancement of collateral circulation;
– maintaining an adequate blood volume, hemoglobin and mean arterial pressure (greater than 90mmHg);
– close monitoring of the motility of the lower limbs.

A third major issue regards the risk of reintervention and endoleaks in the long term and strategies aimed at reducing their frequency. Reintervention and endoleaks are closely related, being the latter the main cause for reinterventions, as it was in our series.

In our experience, the type of endograft seemed to play an important role in the occurrence of reinterventions during follow-up, in particular with a stronger correlation when either Cook TX2 or Cardiatis MFM endoprostheses were used.

We tried to explain this finding by analyzing the technical features of these grafts. The first version of the Cook TX2, was not so conformable to the aortic arch curvature and many studies in the literature showed that over the years the first stent could detach from the inner curvature, causing the so-called "bird-beak" effect [16] and consequently leading to type Ia endoleaks. The new delivery system, along with changes of the graft itself, have made the device more conformable to the anatomy.

The Cardiatis MFM, on the other side, showed a low compliance to the native aorta and a tendency to shrink after release, with consequent loss of sealing and the need for secondary procedures in both patients of our series, who underwent endovascular correction of type Ia and Ib endoleaks.

In our experience reinterventions occurred also more frequently in case of urgent aortic repair and in all cases of traumatic etiology of the disease. One of the possible explaining for these correlations could be the fact that usually the aortic repair for traumatic injuries is performed in an emergent setting [17], without a precise preoperative planning. Moreover, the low blood pressure that often accompanies the patient, could represent a bias in the measurement of aortic diameters on CT angiography, underestimating the real size and consequently leading to an excessive oversizing of the graft. Furthermore, an emergent aortic repair usually aims to stabilize the patient's life, leaving possible cause of secondary minor procedures to a later time. Finally, most endografts have been developed for the treatment of degenerative aortic diseases such as aneurysms and dissections, with large diameters and poor conformability which do not adapt to a young and otherwise healthy aorta, with an increased risk of either infolding of the graft or dilation of the native vessel [18] and consequent occurrence of endoleaks and migration of the device.

Post-Implantation Syndrome (PIS)

The occurrence of fever after endograft implantation despite antimicrobial therapy, together with leukocytosis (WBC>12,000/mm^3) and the raise of inflammatory markers without any evidence of infection [19] is known in the literature as post implantation syndrome (PIS). This clinical entity has been widely described after EVAR

using particular kinds of abdominal endografts [8], but little has been reported after TEVAR so far. Akowuah and Coll. [20] reported the occurrence of an inflammatory response after TEVAR but without the presence of a leukocytosis more than 12.000 WBC/mm^3, as requested for the definition of PIS.
In our series also, the occurrence of early post-procedural systemic inflammatory response did not correspond closely to the definition of PIS, as described for EVAR.

Management Of LSA

The management of the LSA when covered during TEVAR has been an issue of great controversy in the Literature.
In support of a routine revascularization, Zamor and Coll. [21] reported a significant reduction in perioperative rates of stroke upper limb ischemia in patients with previous revascularization than in those without. Furthermore, in the EUROSTAR registry [22] the coverage of the LSA without previous revascularization (along with the total length of the prosthetic implant) was identified as a risk factor for SCI.
Authors who perform a selective revascularization of the LSA argue that the coverage of the vessel does not increase significantly the risk of neurological complication or upper limb ischemia, while revascularization is not free from complications itself [23].
In our series, the coverage of the LSA did not affect the occurrence of neurological complications at 30 days. Nevertheless it was found to be the only factor affecting the occurrence of left arm ischemia.
Considering our findings and data reported in the literature, our policy regarding the management of the LSA aims to avoid its coverage whenever possible. Otherwise, revascularization is performed selectively. In case of occurrence of left arm ischemia, postoperative revascularization can be performed without any particular complications.
In conclusion, in our experience, the endovascular repair of either thoracic or thoraco-abdominal aortic lesions was a safe and effective technique, with acceptable mortality and neurological complication rates, both at 30 days and in the long term.
Mortality after TEVAR for either atherosclerotic aneurysmal disease or floating thrombus was significantly affected by age and a history of either renal failure or coronary artery disease. In group A, the occurrence of postoperative stroke was affected by age, especially in patients older than 86 years, and by the presence of preoperative aortic symptoms. The occurrence of early postoperative SCI was affected by the total length of the prosthetic coverage.
Reintervention in the long term occurred more frequently after endovascular repair of either TAAA or traumatic injuries, and were mainly required for a type I endoleak.
A post-implantation syndrome was not clearly detected. Coverage of the left subclavian artery significantly affected the occurrence of left arm ischemia, irrespectively from the type of the aortic disease, but not the occurrence of SCI.

Conclusion

The endovascular repair of thoracic/thoraco-abdominal aortic lesions had acceptable mortality and neurological complication rates, both at 30 days and in the long term. Reinterventions in the long term occurred more frequently after TAA/TAAA and traumatic injuries, and were mainly required for a type I endoleak.

Riassunto

Riportiamo la nostra esperienza nel trattamento endovascolare delle lesioni dell'aorta toracica e toraco-addominale nei pazienti consecutivamente sottoposti ad intervento da maggio 2002 a maggio 2017.
I dati relativi ai suddetti pazienti sono stati raccolti in un database in maniera retrospettiva, analizzati e divisi in 4 gruppi: aneurismi aterosclerotici dell'aorta toracica e toraco-addominale (AAT/ATA) e trombi flottanti (gruppo A); dissezioni acute complicate di tipo B (TBD), ulcere penetranti aortiche (PAU) ed ematomi intramurali (IMH) nel gruppo B; dissezioni croniche con evoluzione aneurismatica (gruppo C); lesioni traumatiche (gruppo D).
Per ogni gruppo sono stati analizzati come outcomes primari la mortalità, il tasso di reinterventi e l'insorgenza di complicanze neurologiche, sia a 30 giorni ed a lungo termine.
Il 55.3% dei 94 pazienti presi in esame sono stati sottoposti ad intervento per AAT. Eventi come mortalità a 30 giorni e complicanze neurologiche sono stati osservati solamente per il gruppo A (5 casi per ciascun indicatore, 5.3%).
Considerando il gruppo A, sei pazienti sono stati sottoposti a reintervento (6.4%), mentre la sopravvivenza a 5 anni è stata del 62.8%+6.3% e la libertà da complicanze neurologiche del 88.3%+4.2%. Nei restanti gruppi non sono stati registrati né decessi né complicanze neurologiche. Non si sono verificate rotture aortiche tardive. E' stato registrato un tasso di libertà da reinterventi a 5 anni del 54.7%+7.6% nel gruppo A, mentre almeno un reintervento è stato necessario per ciascun paziente del gruppo D. Tra tutte, la principale causa di reintervento è stata l'occorrenza di un endoleak di tipo I.
Questi dati confermano come la correzione endovascolare delle lesioni dell'aorta toracica e toraco-addominale sia gravata da tassi di mortalità e complicanze neurologiche accettabili, sia a 30 giorni che nel lungo termine. Nel lungo termine sono stati sottoposti a reintervento più

frequentemente i pazienti affetti da AAT/ATA e lesioni traumatiche, principalmente per endoleak di tipo I.

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