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Fioranelli, Alexandre; Razuk Filho, Álvaro; Castelli Júnior, Valter; Karakhanian, Walter; Pereira de Godoy, José Maria; Caffaro, Roberto Augusto

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Mortality within the endovascular treatment in Stanford type B aortic dissections

Mortalidade no tratamento endovascular nas dissecções aórticas tipo B

Alexandre FIORANELLI[1], Álvaro RAZUK FILHO[1], Valter CASTELLI JÚNIOR[2], Walter KARAKHANIAN[1], José Maria Pereira de GODOY[3], Roberto Augusto CAFFARO[4]

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Abstract

Background: **Endovascular stent-graft repair of aortic dissections is a relatively new procedure, and although apparently less invasive, the efficacy and safety of this technique have not been fully established.**

Objective: **To evaluate mortality in patients with complicated Stanford type B aortic dissections submitted to endovascular treatment.**

Methods: **Clinical, anatomical, imaging and autopsy data of 23 patients with complicated type B aortic dissections were reviewed from November 2004 to October 2007. The main indications for transluminal thoracic stent-grafting included: persistent pain in spite of medical therapy, signs of distal limb ischemia, signs of aortic rupture, progression of aneurismal dilation of the descending aorta during follow-up (defined as a diameter > 50 mm) and the diameter of descending thoracic aorta of 40mm or larger at the onset of aortic dissection. Data were analyzed statistically; all p-values were two-tailed and differences < 0.05 were considered to indicate statistical significance. Continuous variables were expressed as mean (± SD), and medians were compared by the Student's t test. Differences in categorical variables between the groups were analyzed by the Chi-square or Fisher's exact test.**

Results: **The procedure presented primary technical success in 82.6% of patients. Four patients (17.4%) had an incomplete proximal entry seal. Three patients (13%) died within 30 days of the procedure and eight patients (34.8%) died after 30 days.**

Conclusion: **Endovascular correction of complicated Stanford type B aortic dissections is a feasible and effective treatment option.**

Descriptors: **Stents. Mortality. Aortic Diseases/surgery. Aneurysm, Dissecting.**

Resumo

Introdução: **O tratamento endovascular na dissecção de aorta é um procedimento relativamente novo e, embora aparentemente menos invasivo, a eficácia e a segurança dessa técnica não estão totalmente estabelecidas.**

Objetivo: **Avaliar a mortalidade e complicações nos pacientes submetidos a tratamento endovascular na dissecção de aorta tipo B de Stanford.**

Métodos: **Foram revisados, a partir de novembro de 2004 a outubro de 2007, em estudo clínico, anatômico, de imagens e dados da autopsia de 23 pacientes com dissecção aórtica tipo B. As principais indicações para o procedimento foram: dor persistente apesar da terapia médica, sinais de isquemia distal do membro, sinais de ruptura da aorta, progressão da dilatação do aneurisma da aorta descendente, durante o seguimento (definida como um diâmetro > 5 cm) e descendente da aorta torácica de 40 mm ou mais de diâmetro no início da dissecção aórtica. Os dados foram analisados estatisticamente considerados erro alfa de 5%. As variáveis**

1. Doutor; Professor Assistente do Departamento de Cirurgia Vascular da Faculdade de Medicina da Santa Casa-SP, São Paulo, SP, Brasil.
2. Doutor; Professor Adjunto do Departamento de Cirurgia Vascular da Faculdade de Medicina da Santa Casa-SP, São Paulo, SP, Brasil.
3. Professor Livre Docente do Departamento de Cirurgia Vascular da Faculdade de Medicina da Santa Casa-SP, São Paulo, SP, Brasil.
4. Doutor; Chefe do Departamento de Cirurgia Vascular da Faculdade de Medicina da Santa Casa-SP, São Paulo, SP, Brasil.

Work carried out at Santa Casa de São Paulo-Departamento Cirurgia Vascular, São Paulo, SP, Brazil.

Correspondence address:
Alexandre Fioranelli. Rua Conselheiro Fernandes Torres, 110/72 – São Paulo, SP, Brazil – ZIP code: 01235-020.
E-mail: alezpa@terra.com.br

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contínuas foram expressas como média (± dp) e medianas e comparadas pelo teste t Student. As diferenças entre os grupos em variáveis categóricas e analisadas pelo chi-quadrado ou teste exato de Fisher.

Resultados: **O procedimento apresentou sucesso técnico primário em 82,6% dos pacientes. Quatro (17,4%) pacientes tinham um selo de entrada incompleto proximal. Três (13%) pacientes morreram antes de 30 dias e oito (34,8%), após 30 dias do procedimento.**

Conclusão: **Os procedimentos endovasculares são factíveis na dissecção da aorta torácica tipo B, na qual as complicações das causas de mortalidades alertam sobre a gravidade da doença e de intercorrências das próteses como no caso das fistulas.**

Descritores: **Stents. Mortalidade. Doenças da Aorta/ cirurgia. Aneurisma Dissecante.**

INTRODUCTION

Aortic dissection represents the most common aortic emergency, affecting 3 to 4 per 100,000 people per year and is still associated with a high mortality. Twenty percent of patients with aortic dissection die before reaching hospital and 30% die during hospital admission [1].

Acute uncomplicated Stanford type B aortic dissection (TBAD) is optimally managed with medical treatment [1,2]. However, surgery and thoracic endovascular aortic repair (TEVAR) are occasionally indicated, particularly when end-organ ischaemia develops [2]. The advent of TEVAR has improved outcomes but still carries considerable morbidity, with distinct patterns between mode of presentation and anatomic extent [3].

Several single center reports have shown the technical feasibility and clinical safety of this procedure, but data from larger scale or multi-centre controlled trials are not yet available [2-4]. Although endovascular treatment is gaining popularity, limited information on the midterm results is available. Despite the initially promising results this method has its own inherent risks and complications. Nonetheless, current data, including multiple reports proposing a variety of predictive factors, suggest that there may be a subset of higher-risk patients with acute uncomplicated dissections who could benefit from TEVAR [5].

The objective of the current study was to evaluate the mortality and complications in patients with complicated Stanford type B aortic dissections submitted to endovascular treatment.

METHODS

Following proper IRB approval, a total of 23 patients with complicated Stanford type B aortic dissections were treated at a tertiary teaching institution using endovascular techniques with transluminal thoracic stent-grafts from November 2004 to October 2007. All patients consented to participate in the study after carefully informing them of the objectives, potential risks and benefits of the procedures involved. Patients' clinical health status was evaluated according to the classification of the American Society of Anesthesiologists (ASA) [6].

The dissection was considered acute when the patient presented within 14 days of onset and chronic if more than 14 days had elapsed. Ten (43.5%) patients were treated in the acute phase, and 13 (56.5%) were treated in the chronic phase.

The interval between diagnosis and stent-grafting ranged from one hour to 14 days (mean, 5.7 ± 3.9 days) in the acute group and from 15 days to 24 months (mean, 9.2 ± 8.5 months) in the chronic group.

The main indications for transluminal thoracic stent-grafting included: persistent pain in spite of medical therapy, signs of distal limb ischemia, signs of aortic rupture, progression of aneurismal dilation of the descending aorta during follow-up (defined as a diameter > 5 cm) and the diameter descending of the thoracic aorta of 40 mm or larger at the onset of aortic dissection (Table 1).

None of the patients had Marfan's syndrome or a prior know history of aortic disease.

Table 1. Causes leading to transluminal thoracic stent-graft in the 23 patients with complicated Stanford type B thoracic aortic dissections

Cause	Phase at the time of treatment		
	Acute Phase (n = 10)	Chronic Phase (n = 13)	Total (n = 23)
Dilation	0 (-)	9 (69.2%)	9 (39.1%)
Rupture	6 (60%)	2 (15.38%)	8 (34.8%)
Persistent thoracic pain	1 (10.0%)	0 (-)	1 (4.4%)
Thoracic pain + Dilation	1(10%)	1 (7.7)	2 (8.7%)
Lower Limb Ischemia	2 (20.0%)	1 (7.7%)	3 (13%)

Hypertension was the most common preoperative risk factor (100%) followed by cigarette smoking (6.2%), coronary artery disease (17.4%), and renal failure and diabetes mellitus (13% each) (Tables 2 and 3).

Before stent-graft placement, all patients underwent contrast enhanced computed tomography angiography (CTA). The CTA scan was used to measure the landing zone diameter and also offered anatomical landmarks (Table 4). A stent-graft with a larger diameter (usually 10% for acute cases and 20% for chronic cases) than the diameter of the true lumen immediately proximal to the entry tear was chosen. Special attention was given to the determination of the true diameter of the femoral and iliac arteries, which were used for stent-graft implantation.

Self-expanding endoprostheses was used in all patients. The stent-grafts were available in standard configurations. Four types of stent-graft systems were used: Talent /Talent Valiant (Medtronic Inc, Florida, USA) was used in eleven patients, Tag (Gore, Inc, California, USA) was used in seven patients, Zenith (Cook, Inc, Bloomington, USA) was used in four patients, and Endofit (Endomed, Inc, Phoenix, USA) was used in one patient.

Stent graft implantation was performed in the vascular intervention suite (Philips Integris V 3000, Hamburg, Germany) by a team of trained vascular surgeons of a tertiary teaching hospital. The designated strategy was to seal the proximal major entry tear.

General anesthesia was used in all patients and the procedure was performed in the supine position. Cefthriaxone (2g) was administered intravenously prior to the procedure. Blood pressure was monitored by a right radial artery catheter.

A 5F sheath was inserted into the left axillary artery. A calibrated 5F pigtail catheter (Cook) was introduced into the ascending aorta through the left subclavian artery.

Only one of the femoral arteries was exposed by surgical dissection via a longitudinal groin incision (the less tortuous or the one with the widest lumen).

Table 2. Demographic and clinical data of the 23 patients submitted to endovascular treatment of complicated Stanford type B thoracic aortic dissections

Demographic Variables	Phase at the time of treatment		
	Acute Phase (n = 10)	Chronic Phase (n = 13)	Total (n = 23)
Mean age (years)	56.3 ± 12.3	60.8 ± 10.8	58.8 ± 11.4
Gender:			
Male	8 (80.0%)	10 (76.9%)	18 (78.3%)
Female	2 (20.0%)	3 (23.1%)	5 (21.7%)

Table 3. Clinical data of the 23 patients submitted to endovascular treatment of complicated Stanford type B thoracic aortic dissections

Clinical Variables *	Phase at the time of treatment		
	Acute (n = 10)	Chronic (n = 13)	Total (n = 23)
Co-morbidities, isolated or associated risk factors:			
Arterial hypertension (AH)	10 (100.0%)	13 (100.0%)	23 (100.0%)
Smoker	7 (70.0%)	8 (61.5%)	15 (65.2%)
Diabetes Mellitus (DM)	0 (-)	3 (23.1%)	3 (13.0%)
Renal Failure (RF)	1 (10.0%)	2 (15.4%)	3 (13.0%)
Coronary Failure (CF)	3 (30.0%)	1 (7.7%)	4 (17.4%)
Congestive Heart Failure (CHF)	0 (-)	2 (15.4%)	2 (8.7%)
Dyslipidemia	0 (-)	2 (15.4%)	2 (8.7%)
Chronic Obstructive Pulmonary Disease (COPD)	0 (-)	1 (7.7%)	1 (4.3%)
Clinical Status (ASA):			
II	2 (20.0%)	5 (38.5%)	7 (30.4%)
III	5 (50.0%)	7 (53.8%)	12 (52.2%)
IV	3 (30.0%)	1 (7.7%)	4 (16.7%)

A 6F pigtail catheter was then introduced into the ascending aorta through the femoral artery. Angiography was performed, usually in two projections, one left anterior oblique and one anterior-posterior. First, confirmation that the 6F pigtail catheter was in the true lumen was attained and then the precise location of the primary tear was identified. By using the calibrated pigtail catheter, the diameter of the landing zone was measured and compared to that of the CTA. Before the deployment of the stent-graft, heparin (1 mg/kg) was given intravenously.

An extra-stiff guide wire (Amplatz Super Stiff, Boston Scientific or Lunderquist, Cook, USA) was threaded into the ascending aorta through the pigtail catheter.

The delivery system was introduced to the appropriate position over the extra-stiff guide wire. After the systolic blood pressure was decreased to less than 100 mmHg and the heart rate reduced to less than 90 beats/min, the stent-graft was deployed under fluoroscopy. Angiography was performed again to confirm the correct position.

If a type I endoleak was discovered, a balloon catheter was used to dilate the end of the stent graft to provide a leak-proof seal. When the primary entry was found to be incompletely sealed, a proximal cuff was added.

A total of 31 stent-grafts were used in the 23 patients: two required proximal extensions (Talent Valiant and TAG) for proximal endoleaks, and six cases had distal extensions. Five of the latter had extensions placed in the descending aorta (2 Talent, 1 Talent Valient, and 2 TAG), and one had a contralateral (Talent) extension placed in the left common iliac artery (Table 5).

Complete occlusion of the left subclavian artery was necessary for eleven patients as the distance between the primary tear and the opening of the left subclavian artery was less than 2 cm.

Patients were monitored in the intensive care unit after the operative procedure with rigorous control of the systolic blood pressure, which was kept below 120 mmHg using sodium nitroprusside.

Causes of early and late mortality were assessed by medical records (in-patient, out-patient, and autopsy reports).

Follow-up CT images were obtained with triple rule-out 64-slice biphasic injection computed tomography angiography (Philips, Eindoven, Holland) at 1 month, 3 months, 6 months, and 1 year, and once every year thereafter. At the workstations, three-dimensional oblique multiplanar reconstructions were performed in order to analyze the aortic anatomy.

Procedural success was defined as the technically successful placement of the endoprosthesis at the intended target location and no evidence of leaks.

Table 4. Anatomical parameters of the 23 patients submitted to endovascular treatment of complicated Stanford type B thoracic aortic dissections (measured in millimeters - mm)

Anatomical parameters	Phase at the time of treatment		
	Acute (n = 10)	Chronic (n = 13)	Total (n = 23)
Diameter of the proximal neck)	29.0 ± 3.2	31.5 ± 3.9	30.4 ± 3.8
Extension of the proximal neck	15.6 ± 6.7	15.9 ± 5.6	15.8 ± 5.9
Smallest diameter of the true lumen	18.8 ± 6.2	19.8 ± 5.5	19.3 ± 5.7
Greatest diameter of the false lumen	42.3 ± 12.5	59.6 ± 16.8	52.0 ± 17.2 *
Extension of the Dissection:			
- subclavian – iliac	5 (50.0%)	11 (84.6%)	16 (69.7%)
- subclavian – above the celiac branch	1 (10.0%)	0 (-)	1 (4.3%)
- subclavian – visceral	4 (40.0%)	2 (15.4%)	6 (26.0%)
Origen of the aortic branches at the false lumen:			
- right renal artery	2 (20.0%)	1 (7.7%)	3 (13.0%)
- left renal artery	5 (50.0%)	4 (30.8%)	9 (39.1%)
- celiac branch	1 (10.0%)	2 (15.4%)	3 (13.0%)
- superior mesenteric artery	0 (-)	1 (7.7%)	1 (4.3%)

NOTE:

** Student-t Test for the comparison of averages found a statistically significant difference between patients treated during the acute and chronic phases of the dissection for the parameter "greatest diameter of the false lumen" (p = 0.0130).*

*** No statistically significant differences were found between patients treated in the acute and chronic phases of the dissection regarding the anatomical parameters (Chi-square test comparing frequencies)*

Table 5. Type of endoprosthesis implanted in the 23 patients submitted to endovascular treatment of complicated Stanford type B thoracic aortic dissections

Characteristics of the endoprosthesis	Total (n = 23)
Proximal diameter of the endoprosthesis	Size of the Implant (mm)
Minimum	32 mm
Maximum	44 mm
Average (± SD)	38 ± 4 mm
Median	38 mm
Length of endoprosthesis	
Minimum	120 mm
Maximum	216 mm
Average (± SD)	183 ± 26 mm
Median	200 mm

Treatment failure was defined as the presence of a proximal endoleak (blood flow outside the stent-graft but within the aortic false lumen) or the patient not surviving the procedure.

Early death was defined as that occurring within 30 days of the procedure and late death thereafter.

To characterize the patient sample, categorical demographic variables are presented as frequencies and percentages for each category; continuous variables are presented as means, standard deviations, medians and minimum and maximum values.

The values expressed as frequencies were compared using the Chi-square Test and its variants (Fisher's exact test and generalization of Fishers exact test for small sample sizes). The Student t-test was used to compare continuous variables (age).

Univariate analysis was used to analyze risk factors associated with mortality. The odds ratio (odds ratio) and 95% confidence interval (CI) were also calculated. Data were tabulated and analyzed using the SAS computer program version 9.1.

Data were analyzed statistically; all p-values were two-tailed and a *P*-value of less than 0.05 was considered to indicate statistical significance.

RESULTS

Stent-graft placement was successfully performed without conversion to open surgical or proximal leaks in 19 patients (82.6%).

In four (17.4%) cases, the primary tears were incompletely sealed and a proximal endoleak remained despite the correct placement of the stent-graft across the entry site, additional balloon dilation and proximal extension. However, substantial reduction of blood flow in the false lumen and shrinkage of the false lumen were observed. In all four cases the left subclavian artery was occluded due to a short neck.

The left subclavian artery was intentionally occluded in 11 (47.8%) patients. One (4.3%) patient had transient left arm ischemia on the first postoperative day. In 10 (43.5%) patients it was necessary to occlude the left subclavian artery with placement of a stent covering the ostium as the proximal neck was less than 10 mm.

In four patients, the proximal entry was sealed incompletely and thus constituted treatment failure. The incidence of proximal leak was 17.4%. Of these patients, two were treated in the chronic phase and two in the acute phase of dissection. The left subclavian artery was occluded in the four cases due to short proximal necks. In one patient treated in the acute phase and in another treated in chronic phase, the leak persisted even after placement of a proximal extension although a reduction in blood flow was evidenced. All four patients died; for three of them the causes of death (retrograde dissection, aorto-esophageal fistula and renal failure) were related to the proximal leak.

No left upper extremity ischemia or brain steal phenomena occurred in the other patients.

The 30-day mortality rate observed in the current series was 13% (three patients), all with complicated acute type B aortic dissections. One patient died immediately after the procedure and the others on the 3rd and 12th post-procedural days. Two patients had a massive hematoma in the pleural space caused by rupture of the false lumen of the distal aorta on the first postoperative day. The other patient presented a retrograde aortic dissection with cardiac tamponade.

A total of eight patients died after the 30th day (the late mortality rate was 34.8%). The causes of late death were:

- one case of fatal pressure – induced erosive rupture of the aneurysm sac into the esophagus caused by a huge thrombotic mass surrounding the stent-graft in the thoracic aorta;
- two cases of esophageal fistula where the necrosis was in the segment of the esophagus irrigated by arteries originating directly from the thoracic aorta under the left bronchus;
- one patient developed a major stroke with permanent neurological deficit within 1 day of the endovascular repair;
- one patient had a major stroke after a femoral-axillary bypass used to repair a proximal leak close to the brachioencephalic branch associated with rupture of the false lumen;
- one patient treated for acute aortic dissection sustained a fatal aortic rupture (confirmed by autopsy) 7 months after the initial repair;
- one patient evolved with renal failure associated to static obstruction involving the origin of the left renal artery, that was treated by the interposition of a stent in the renal artery after adequate sealing of the proximal entry of the descending aorta. However, the patient's renal failure

worsened and the patient died of multiple organ failure 5 weeks after the endovascular procedure;

• one patient died because a rupture of an abdominal aortic aneurysm 27 months after the procedure. Table 6 lists these causes.

Table 6. Time from procedure to death and cause of death

Time after procedure	Cause of death
40 days	Renal failure
2 months	Aortoesophageal fistula
2 months	Ischemic stroke
3 months	Aortoesophageal fistula
7 months	Rupture of the false lumen
7 months	Ischemic stroke
23 months	Aortoesophageal fistula
27 months	Abdominal aorta rupture

In all 3 cases of esophageal fistula, autopsy revealed necrosis of the esophageal wall. These patients presented upper gastrointestinal bleeding.

No femoral artery damage occurred in any of the 23 patients.

No paraplegia occurred after the procedure.

No differences were found on comparing patients who died and those that survived with regards to adverse clinical conditions such as diabetes mellitus, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, dyslipidemia and smoking. Additionally the ASA classification did not significantly affect the outcome.

In relation to renal insufficiency, the percentage of patients with this condition who died was significantly higher ($P = 0.093$) than patients without this condition.

The stage of disease (acute or chronic) during the treatment did not affect the outcome. Two thirds of the patients treated due to peripheral ischemia died and two thirds of patients with ruptures of the dissection survived. The indication for treatment, the proximal neck length, diameter of the false lumen, the extent of occlusion of left subclavian artery and distal reentry did not affect the outcome of patients.

Statistically significant differences were seen, however, between patients who survived and those who died in regards to the extent of dissection, the success of sealing the main entry point and the association between the extent of dissection and the presence of distal reentry.

There was a statistically significant inverse association between the reentry in the chest and thrombosis of the false lumen in the chest, where all patients with reentry in the chest did not evolve with complete thrombosis of the false lumen in the chest. Moreover, in the eight patients with thrombosis of the false lumen in the chest, four patients had visceral perfusion of at least one visceral artery through the false lumen. Of the remaining four patients, two had complete thrombosis of the false lumen in the chest and abdomen and had two reentry points in the distal aorta or iliac arteries.

The mean follow-up period was 14.8 months, ranging from 3 to 36 months.

DISCUSSION

Despite recent advances in surgical and anesthetic techniques, surgical resection of Stanford type B aortic dissections is technically challenging and presents high morbidity and mortality rates.

In 1999, an endovascular approach to Stanford type B dissections was proposed by Nienaber et al. [7] and Dake et al. [8], with the objective of achieving aortic remodeling using an endoprosthesis for proximal occlusion.

The current study analyzed the results of the endovascular treatment of complicated Stanford type B dissections (10 patients were treated in the acute phase and 13 cases in the chronic phase). In the current series the procedure was technically successful in 82.6% of patients versus 98.5% of the patients reported in the meta-analysis by Eggebrecht et al. [9], in 2006. The discrepancy in results may be explained by the fact that the authors of the 39 studies included in the aforementioned paper considered technical success to be a correct placement of the endoprosthesis, disregarding the presence of proximal leaks. This seems paradoxical if one considers that the primary objective of the procedure is the occlusion of the proximal entry. In the current series only those cases that achieved complete proximal occlusion were considered successful.

The early mortality rate of the current series was 13% and the late mortality rate was 34.8%. The cause of death was established in all cases. In large series, such as that of Leurs et al. [10], in 2004, with 131 patients who underwent endovascular correction of type B aortic dissections, 43% of those patients had no complaints, and the early mortality rate was 6.5% for elective cases and 12% for emergency cases. Another large series of 609 patients reported an early mortality rate of 5.3% and major complications occurred in 14 to18% [9].

Smaller series of patients treated with endovascular surgery seem to allow better analysis of management and outcome. The 24 cases of complicated Stanford type B dissections reported by Hansen et al. [11], in 2004, who were treated with endovascular surgery, presented a mortality rate of 13% (3/24), whereas the causes of death were false lumen rupture (one case) and retrograde dissection (two cases). Another study with 43 patients had a 7% early mortality rate (three cases presented retrograde dissection caused by the endoprosthesis with a proximal

free stent [12]. Dialetto et al. [13], in 2005, studied 28 patients with complicated dissections and found 10.7% of early mortality with retrograde dissection and rupture of the false lumen in two cases. Eggebrecht et al. [14], in 2005, treated 38 patients with complicated dissections (10 acute and 28 chronic) reporting 11% early mortality, with all these cases having acute onset. Thus, early mortality rates were similar in the different studies that compared similar clinical situations.

In the current study, all three cases that evolved to early mortality were treated during the acute phase of dissection and presented similar causes of death when compared to the literature. Five patients treated during the chronic phase of dissection and three during the acute phase presented late mortality (34.8%).The mean follow-up period in the current series was 14.8 months. Late mortality rates in literature range from zero up to 32% [15-17] however, the causes of death and the follow-up periods vary greatly in these reports. Although the late mortality rate in the current series is a little higher than the average reports in the literature, 47.8% of the patients were treated for rupture and peripheral ischemia.

No statistically significant difference was found between gender and age of patients that presented favorable outcomes when compared to those that died. Mackenzie et al. [18], in 2004, reported their 10-year experience in treating type B aortic dissections and found that prior renal failure was a statistically significant predictive factor of death (OR=8.72).

A successful proximal occlusion was significantly higher in patients with a favorable outcome. All four patients that presented persistent blood flow through the false lumen via the proximal entry died and in three of these patients the proximal leak was found to be the direct cause of death.

In 2004, Roseborough et al. [19] reported their 20-year experience in treating Stanford type B aortic dissections in 119 patients. The authors found a 13% mortality rate in the patients treated conservatively, 18% mortality rate in the surgical group, and 40% mortality rate in the endovascular group, where only percutaneous fenestration was carried out. Contrary to what would be expected, dissections of greater extension (IIIb) presented a lower mortality rate than those with smaller extension (IIIa). The latter had a greater percentage of ruptures and the former developed poor perfusion syndrome.

Shimono et al. [16], in 2002, described the importance of the extension of the dissection, as well. It was found that the retrograde flow to the thoraco-abdominal false lumen through the re-entry at the visceral level maintained the diameter of the false lumen, even when it was thrombosed, due to the constant pulse. According to the authors, this proved the importance of the thoracic re-entry in the progression of the false lumen.

This study shows that the endovascular procedure is a viable practice in the emergency phase of type B aortic dissections, both in acute and chronic phases. Early mortality occurred in acute dissections and late mortality was more evident in the correction of chronic dissections. However, the causes of mortality warn about the severity of the disease and complications of prosthesis, such as fistulae.

In Brazil, the effort of the Brazilian Society of Cardiovascular Surgery to report on and guide about this disease has steadily improved treatment [20-22].

CONCLUSIONS

Endovascular procedures are feasible in the treatment of type B aortic dissections; the causes of death and the complications related to prostheses such as fistulae, illustrate the severity of the disease.

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