Treatment of type B aortic dissection: endoluminal repair or conventional medical therapy?

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Abstract

Objective: To evaluate the mid-term results of endovascular stent-grafting for type B aortic dissection, in comparison with those of standard medical therapy in uncomplicated cases. Methods: Between January 1999 and 2004, among 56 patients (mean age 59.5 ± 11.5 years) with type B aortic dissection, hypotensive medical therapy was the only treatment in 28 uncomplicated cases, (group A), while stent-graft implantation was performed in 28 patients with uncontrolled hypertension, persistent pain or evidence of dissection progression or complication (group B). In 14 cases (50%) the procedure was performed in an acute setting. Stent-grafting procedures were monitored with intraoperative trans-esophageal echocardiography and cine-angiography. CT scan and trans-esophageal echocardiography were performed before hospital discharge, at 6 and 12 months and then yearly. Results: Follow-up (range 1–61 months, average 18.1 ± 16.9 months) was 100% complete. In-hospital mortality was 10.7% (three patients, all belonging to Group B; P = 0.24). No spinal cord injuries were observed. Early endoleak occurred in one patient (3.5%). Mid-term mortality was lower in Group B, although the difference was not significant (10.7 versus 14.3% in Group A, P = 0.71). Follow-up CT scans evidenced complete thrombosis of the false lumen in 75% cases in Group B, 10.7% in Group A (P = 0.0001), and an aneurismal dilatation of the descending aorta in 3.5% cases in Group B, 28.3% in Group A (P = 0.02). Conclusions: Although with still considerable early mortality, endovascular stent-graft implantation is an effective option for the treatment of complicated type B aortic dissection. Endovascular treatment achieved a better mid-term fate of the descending thoracic aorta than medical therapy alone, even in patients with worse preoperative conditions. © 2005 Elsevier B.V. All rights reserved.

Keywords: Descending aorta; Aortic dissection; Endovascular stent-graft; Hypotensive therapy

1. Introduction

Aortic dissection originating after the left subclavian artery and extending into the descending aorta, also known as Stanford type-B dissection (TBD), remains a therapeutic dilemma. Surgical management still represents a valid option in spite of the dramatic improvement in operative techniques and in methods of spinal protection. However, postoperative mortality remains high, ranging in published series from 6 to 67% [1,2]. Thereby, medical therapy is indicated in case of uncomplicated TBD, and yields an early mortality rate of 10%, a 1-year mortality of 20% and a need for surgical operation during the long-term follow-up reaching 20% [3,4]. Both mortality and aortic events requiring operation are thought to be related to scarce response to hypotensive therapy, a condition clinically associated to aortic dissection itself [5]. Endovascular stent-graft (EVG) implantation is the most recently introduced therapeutic approach and it has been gaining space in this field thanks to its less-invasive nature when compared to surgery, and after the demonstration in the first series [6-9] of a high incidence of false lumen late thrombosis. Patency of false lumen is known to represent a risk factor for dissection-related death or adverse events in patients surviving the acute phase of TBD, whereas the thrombotic obliteration of the false lumen is associated with better long-term outcomes [10].

The aim of the present retrospective study was to evaluate the results of medical therapy and, in comparison, those of EVG therapy, in terms of persistence or thrombosis of the false lumen as well as aneurysm development.

2. Materials and methods

2.1. Study design

This is a retrospective study analysing the experience over 5 years in the treatment of TBD. From January 1999 and 2004, a total of 64 patients were referred to the Department...
Table 1

Characteristics of the study groups

<table>
<thead>
<tr>
<th></th>
<th>Group A (medical therapy)</th>
<th>Group B (EVG)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>28</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>56.5 ± 8.0</td>
<td>60.8 ± 8.3</td>
<td>0.85</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>24 (85.7)</td>
<td>23 (82.1)</td>
<td>0.9</td>
</tr>
<tr>
<td>History of hypertension (%)</td>
<td>23 (82.1)</td>
<td>22 (78.5)</td>
<td>0.9</td>
</tr>
<tr>
<td>Optimal pressure control in the f-u (%)</td>
<td>11 (39.2)</td>
<td>13 (46.4)</td>
<td>0.78</td>
</tr>
<tr>
<td>Previous aortic surgery (%)</td>
<td>1 (3.5)</td>
<td>0</td>
<td>0.9</td>
</tr>
<tr>
<td>Intramural haematoma (%)</td>
<td>4 (14.2)</td>
<td>3 (10.7)</td>
<td>0.9</td>
</tr>
<tr>
<td>Maximal aortic diameter (cm)</td>
<td>3.95 ± 0.45</td>
<td>4.13 ± 0.76</td>
<td>0.52</td>
</tr>
</tbody>
</table>

f-u = follow-up of medical therapy (prior to EVG in group B).

Two different stent graft devices were used: Talent™ (Medtronic, World Medical Manufacturing Corp, Sunrise, FL) in 19 patients and Excluder® (Gore, Sunnyvale, CA) in nine patients. Once the stent graft was released, an arteriogram was performed to verify the complete closure of the proximal intimal tear and the absence of peri-graft leakage. In all cases, intra-operative transesophageal color-Doppler echocardiography was performed to identify the site of intimal tear for correct EVG positioning and to verify the success of the procedure.

2.3. Follow-up

All patients have been followed-up by our laboratory of echocardiography before discharge, at 6 and 12 months after hospital discharge and then, in the absence of complications, yearly. At every follow-up visit the patient’s history was updated, arterial pressure controlled at each arm and TEE was performed. At TEE, descending thoracic aorta diameter was measured and the possible presence of intimal tears sought for; flow characteristics in the true and false lumen were investigated. The expansion rate of the descending aorta was calculated as the difference between the current diameter and the last follow-up measurement divided by the time interval between the two examinations. In group B patients graft position was checked and possible endoleaks searched for. When quality of TEE images was unsatisfactory, further information was needed, or the procedure was not tolerated or refused by the patient, 3-mm section spiral angio-TC scan with longitudinal reconstructions was performed. Early mortality and morbidity included events occurring within 30 days of treatment (EVG positioning in group B; beginning of medical therapy in group A), either in hospital or after discharge. Information about patients was obtained both from retrospective chart review and by contacting patients or their treating physicians. The follow-up was 100% complete.

2.4. Statistical analysis

Continuous variables were expressed as means ± SD and were compared by the Student’s t test. Differences between the groups in categorical variables were analyzed by the χ² test or Fisher’s exact test. Actuarial survivals (Kaplan-Meyer method) were compared with the log-rank test. All P values were two-tailed, and a P value of less than 0.05 was considered to indicate statistical significance.

3. Results

3.1. Operative outcomes

In group B, EVG procedure was successfully carried out in 100% of cases. In three cases (10.7%) the site of sealing was too close to the left subclavian artery origin to spare it and the exclusion of the artery was necessary, requiring subsequent carotid-subclavian by-pass. In five cases (17.8%) multiple graft implantation was required in a “telescope” fashion. Total graft length averaged 153.2 ± 28.9 cm, ranging from 102 to 270 cm. All patients who...
underwent medical treatment were discharged in overall good conditions within 7 days of admission.

3.2. Early results

In no case postoperative paraplegia occurred. No hospital (30-days) death was observed in group A. Thirty-days mortality in Group B was 10.7% (P = 0.24): all three patients died within 24 h of procedure. Two of them had undergone EVG implantation for complicated chronic dissection, both with a Talent type graft prosthesis. In the first patient, a new tear developed at the site of EVG proximal sealing soon after deployment, generating retrograde dissection: a second, more proximal stent was implanted, occluding the origin of the subclavian artery and requiring subsequent carotid-subclavian by-pass: the patient never awoke and died on the 27th post-operative day. Hemorrhagic shock due to aortic rupture occurred while positioning a second stent for false lumen persistence after first EVG implantation in the other patient with complicated chronic dissection. Both those patients had signs of particularly severe atherosclerosis of the aortic wall at TEE and CT scan. In the third patient, who had developed hemorrhagic shock few hours after admission, the procedure was performed in the acute phase, using an Excluder EVG model and easily managing to obliterate the false lumen: nevertheless, multiorgan failure, including hepatic, renal and respiratory failure, caused death 12 h after the procedure.

3.3. Late results

Optimal pressure control with hypotensive therapy was found during the follow-up in only 11 patients from group A and 13 from group B. Mean follow-up time was 18.1 ± 16.9 months (range 1-61 months); it reached 19.4 ± 13.2 months in group A, 17.5 ± 13.0 in group B (P = NS). Among group A patients, 4 (14.3%) died during the follow-up. In one of them the cause of death was acute aortic rupture (aortic diameter at the last control was 5.6 cm: the patient, who had several co-morbidities, including chronic pulmonary disease, diabetes and coronary artery disease, did not give his consent to invasive treatment), in 1 acute myocardial infarction, in two sudden death. In this group 1, 3 and 5 years survival, considering both in-hospital and follow-up deaths, was 90.8, 84.3, 84.3% versus 86.3, 86.3 and 86.3% in group B (P = 0.71) (Fig. 1). In no patients from group B an endoleak was evidenced in the follow-up time. Only in one patient the persistence of the false lumen at CT scan suggested the presence of an endoleak; however, an accurate TEE evaluation revealed that the flow in the false lumen was due to the persistence of an intimal tear proximally to the sealing site. The patient underwent a new EVG implantation successfully.

A complete obliteration of the false lumen was observed in three out of the 28 group A patients and in 18 of the 25 survivors from group B (10.7 versus 72%; P < 0.001) (Fig. 2). In three group B patients, there was a persistence of flow in the false lumen and distal tears were detected: in one patient the tear was already present at the time of EVG implantation and had not been treated since too close to the celiac tripod, while in the other two, the tears were new findings, being absent at the previous follow-up control. The analysis of the aortic diameters in the follow-up showed a significantly lower expansion rate in group B (0.15 versus 0.32 cm/year in group A; P = 0.02). The finding of a new aneurismal dilatation in the follow-up was registered in one patient from group B, who had a tear distally to the EVG stent, while it was noticed in six patients belonging to group A (21.4%; P = 0.04); in those patients with aortic dilation in the follow-up, the mean diameter at the last control was 4.82 ± 0.37 (range: 4.5-5.5); in no patient, except for one who has undergone surgical treatment at another Institution, the indication to treatment was posed, since the aortic dilatation had not reached 5 cm.

4. Discussion

As a recently introduced technique, EVG implantation for TBD of the aorta is currently recommended for complicated cases [11], as an alternative to the surgical method, and short- and mid-term studies performed so far have claimed encouraging results [6,8,12].

The present study confirmed the efficacy of EVG in the mid-term follow-up, with an overall survival at 5 years of 89.3%, which is comparable to that reported in recent studies [7,13]; all deaths notably occurred in the peri-procedural phase, indicating that maybe a more appropriate
patient selection, i.e. indications to EVG more accurately restricted to 'safer' anatomical situations, could have lead to better results. Moreover when looking at our mortality rate one should also consider that it includes the learning-curve period of our experience with EVG in the clinical setting of aortic dissection.

It is well-known that the appearance of complications in patients with TBD dramatically worsens the natural history of the disease and mandates intervention. From this point of view, due to the retrospective nature of this study, the reported outcomes must be viewed as the results of two different approaches, both applied according to the currently accepted guidelines [11], in two groups of patients characterised by profound clinical heterogeneity. Early mortality in group B (10.7%) was considerable: however, this result should be analysed in the light of the fact that 50% of EVG implantations were carried out in patients in whom acute complications had developed early (during first hospital admission). Although no analysis of risk factors for peri-procedural death could be performed due to the low numbers of this study, severe atherosclerotic degeneration of the aortic wall and, obviously, worse general conditions (preoperative hemorrhagic shock) seemed associated with the risk of lethal peri-procedural complications. In the other 50% patients, endoluminal treatment was performed after domiciliary medical therapy alone had failed preventing the progression of the disease. The evidence of a 5-year survival in group B patients being numerically comparable to that in group A suggests that EVG implantation can make the midterm prognosis of complicated TBD quite similar to that of uncomplicated TBD treated with hypotensive therapy alone, suggesting a possible absolute advantage of EVG over medical treatment. Only prospective randomized studies could assess the superiority of EVG to medical therapy when applied in the same clinical setting (for ethical reasons it could be considered to be unethical to perform EVG in patients without acute complications but likely more prone to worse long-term outcomes.

4.1. Study limitations

As already stated above, the two groups compared in this study were remarkably different as to pre-treatment conditions. This bias was inevitable for a retrospective comparison, considering the current guidelines for indication to EVG in patients with TBD. However, the aim of the analysis was to assess how EVG can modify the fate of the descending aorta in terms of false lumen obliteration and prevention of aneurismatic dilatation, and the only possible setting to compare was medically treated TBD.

4.2. Conclusions

Endovascular repair for complicated type B aortic dissection is a feasible option for the treatment of complicated TBD. Peri-procedural mortality can be considered, although lower than reported in some surgical series, but studies on EVG in the setting of uncomplicated TBD, that are so far lacking, could change this evidence. The endoluminal treatment resulted in a significant larger percentage of post-operative thrombosis of the false lumen compared to medical treatment. Aneurismatic dilatation of the aorta following EVG repair seems to be rare and this may represent an advantage over conservative treatment.

References

Appendix A. Conference discussion

Mr B. Keogh (Birmingham, UK): Who in your institution does the implantation of the stents? Is this a surgical procedure, is it a radiological one or a cardiological?

Dr Dialetto: We perform this implantation in the operating room. In our institution, the implantation of the endovascular stent graft is performed by the cardiologist and me.

Dr M. Turina (Zurich, Switzerland): A very interesting presentation and parallels our own experience. There are several questions. Is it true that since 1999 no surgery was performed for Type B aortic dissection in Monaldi Hospital anymore?

Dr Dialetto: The patients who underwent surgical treatment for Type B aortic dissection aren’t the object of this report, and from 1999 to today, about 12 patients, if I remember rightly, had surgical treatment for Type B aortic dissection.

Dr Turina: Because it would be interesting to know how you performed the selection for the endovascular graft versus operative treatment.

The second question is, what do you do when you intentionally cross the left subclavian artery? Do you obligatorily perform the carotid to subclavian bypass or do you just wait and see how the pressure develops in the artery?

Dr Dialetto: As regards the first question, when it is anatomically feasible in a complicated Type B aortic dissection to implant an endovascular stent graft, we implant an endovascular stent graft. Otherwise, the patient undergoes surgical treatment.

About the second question, in the early patients we performed a carotid to subclavian bypass in those patients in whom we believed the graft could close the left subclavian artery. Today in the patients in whom we think that the site of sealing is too close to the left subclavian artery, we perform, before the procedure, an MRI to study the cerebral circulation, and only if we recognize a problem on the cerebral circulation, we perform a bypass from the carotid artery to the left subclavian artery.

Dr Turina: And the last question. How do you determine the place, where you put in your endovascular prosthesis in patients with an intramural hematoma? In my opinion, it is very difficult, almost impossible, to determine the place of the rupture from the CT alone, and probably intravascular ultrasound is the only solution to precisely delineate the place, where you should be putting your endovascular prosthesis.

Dr Dialetto: In our experience, we put the endovascular stent graft in intramural hematomas antegrade. In our patients it was possible to see at TEE the level of the rupture, and we implanted the endovascular stent graft at that level.

Dr A. Wahba (Trondheim, Norway): You are comparing two different groups: one is uncomplicated and the other one is complicated Type B dissection. Could you elaborate a little bit on the early mortality in stent-grafted patients? That was a worrying point. What did the patients die of, and were they at risk of death anyway?

Dr Dialetto: The deaths in the endovascular stent graft group are all periprocedural results. In those patients we had a rupture or dissection of the aorta.