Eur J Vasc Endovasc Surg (2016) 52, 56—63

Risk Factor Analysis for the Mal-Positioning of Thoracic Aortic Stent Grafts

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WHAT THIS PAPER ADDS

The association between anatomy and complications after TEVAR seems evident. However, objective data defining anatomical criteria that influence outcomes are lacking in the literature. This study focuses on mal-positioning after TEVAR, which is one of the early failure modes. The results reveal that global aortic anatomy characterized by tortuosity index was more critical than local anatomy. Adequate pre-operative planning through tortuosity index (TI) calculation to detect patients with a TI >1.68 can be useful to anticipate difficulties during stent graft deployment and thus reduce mal-positioning risk.

Objective: The present study aimed at quantifying mal-positioning during thoracic endovascular aortic repair and analysing the extent to which anatomical factors influence the exact stent graft positioning.
Methods: A retrospective review was conducted of patients treated between 2007 and 2014 with a stent graft for whom proximal landing zones (LZ) could be precisely located by anatomical fixed landmarks, that is LZ 1, 2, or 3. The study included 66 patients (54 men; mean age 51 years, range 17—83 years) treated for traumatic aortic rupture ($n = 27$), type B aortic dissection ($n = 21$), thoracic aortic aneurysm ($n = 8$), penetrating aortic ulcer ($n = 5$), intramural hematoma ($n = 1$), and floating aortic thrombus ($n = 4$). Pharmacologic hemodynamic control was systematically obtained during stent graft deployment. Pre- and post-operative computed tomographic angiography was reviewed to quantify the distance between planned and achieved LZ and to analyze different anatomical factors: iliac diameter, calcification degree, aortic angulation at the proximal deployment zone, and tortuosity index (TI).
Results: Primary endoleak was noted in seven cases (10%): five type I (7%) and two type II (3%). Over a mean 35 month follow up (range 3—95 months), secondary endoleak was detected in two patients (3%), both type I, and stent graft migration was seen in three patients. Mal-positioning varied from 2 to 15 mm. A cutoff value of 11 mm was identified as an adverse event risk. Univariate analysis showed that TI and LZ were significantly associated with mal-positioning ($p = .01$, $p = .04$ respectively), and that aortic angulation tends to reach significance ($p = .08$). No influence of deployment mechanism ($p = .50$) or stent graft generation ($p = .71$) or access-related factors was observed. Multivariate analysis identified TI as the unique independent risk factor of mal-positioning (OR 241, 95% CI 1—6,149, $p = .05$). A TI >1.68 was optimal for inaccurate deployment prediction.
Conclusion: TI calculation can be useful to anticipate difficulties during stent graft deployment and to reduce mal-positioning.

Article history: Received 28 December 2015, Accepted 19 March 2016, Available online 16 April 2016
Keywords: Stent graft, Mal-positioning, Thoracic aorta, Anatomy

INTRODUCTION

Exact stent graft positioning is one of the criteria that predicts the technical success of thoracic endovascular aortic repair (TEVAR), as it has been defined in the reporting standards.[1] Indeed, mal-positioning can be responsible for failure in the early peri-operative period,[2] because of inadvertent coverage of one of the arch branches in the case of proximal movement, or conversely, to a lack of thoracic aorta lesion exclusion in the case of caudal movement.

Mal-positioning can be defined as any discrepancy between the planned and achieved landing zones, occurring either during or, more rarely, after stent graft deployment, in which case it can be contemporaneous to the

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http://dx.doi.org/10.1016/j.ejvs.2016.03.025

advancement of a second stent graft or tip recapture. Mal-positioning, also known as inaccurate stent graft deployment, must not be confused with mis-deployment. The latter is totally different in that it implies incorrect alignment of the stent graft, an eversion of the proximal bare stent, or failure to fully deploy the device.[3]

Even though its existence is well known, inaccurate stent graft deployment has not been exhaustively studied,[4–6] and to the authors' knowledge no work has objectively quantified the problem's importance or assessed its causes. Concurrently, the more TEVAR indications are extended to hemodynamic and anatomically challenging landing zones, the more inaccurate stent graft deployment becomes an issue. For this reason some authors recommend better hemodynamic control or asystole to optimize positioning, particularly during TEVAR in aortic arch.[4,5,7–9] In point of fact, the main aim of this strategy is to counter the classic windsock effect, itself related to proximal hypertension after partial stent graft deployment. Although low cardiac output is indeed a requirement, it is in itself not sufficient to completely prevent mal-positioning.

The present study aimed at quantifying the issue of mal-positioning and analyzing the influence of different anatomical factors on exact stent graft positioning.

MATERIALS AND METHODS

Design

Between January 2007 and November 2014 all patients admitted to the study institution for thoracic aorta pathology and treated by stent graft were retrospectively reviewed. Of these, only patients for whom proximal landing zones (LZ) could be precisely located by anatomical fixed landmarks, that is LZ 1, 2, or 3, were included.

Patient demographics, procedural reports, and short and mid-term outcomes were recorded. Pre- and post-operative computed tomographic angiography (CTA) was analyzed according to a standardized protocol.

Exclusion criteria comprised patients treated in zones 0 or 4, as mentioned above, and those with unavailable or unsuitable CTA because of inadequate arterial opacification or imaging protocol.

Technical success was defined as the successful deployment of the stent graft with no surgical conversion, mortality, or angiographically detected type I or III endoleaks at the end of the procedure.[1]

Adverse events included, in relation to mal-positioning were endoleak, migration, and unintentional coverage of supra-aortic branches. Endoleak types were classified according to reporting standards for TEVAR.[1] Only migrations associated with symptoms and/or requiring re-intervention were considered.

All data and CT imaging used was anonymized. Because of the retrospective design and according to French law it is neither necessary nor possible to obtain approval from an ethical committee (in French CPP, for Comité de Protection des Personnes) for this type of non-interventional study. Moreover CPPs are not entitled to issue waivers of approval for this type of study.

Imaging analysis protocol

All patients underwent triple phase CTA with a multidetector CT scanner (Siemens Sensation 64 cardioscanner, Erlangen, Germany). Slice reconstruction thickness was 0.75–3 mm. Imaging data were collected as axial images and transferred to a workstation for processing using dedicated vascular software (Endosize, Therenva, Rennes-France).

The first step of imaging analysis comprised extraction of a three dimensional (3D) arterial lumen centerline (CL) from the ascending aorta to the femoral artery. Secondly, Matlab scripts were developed to extract 3D coordinates (x,y,z) of each point generated at 1 mm increments along the CL. The aorta was then divided into four anatomical zones according to the Ishimaru classification,[10] where the position of the different anatomical landmarks, brachiocephalic trunk, left common carotid artery, and left subclavian artery (LSA), were mapped to the CL. Finally, morphological parameters were analytically computed, using specifically developed Matlab functions.

The first of these parameters was aortic angulation around the proximal deployment zone. To calculate this aortic angle, designated as θ, three reference planes (A, B, C) were previously defined. All were perpendicular to the CL at different levels: plane B to the cross section view showing the stent totally apposed to the wall, and planes A and C to the cross section views located 15 mm along CL above and below plane B, respectively. The choice of 15 mm distance between the planes is based on the usual length of the proximal stent. The aortic angle θ corresponds to the angle between planes A and C within a 30 mm range (Fig. 1).

Given the potential discrepancies between the planned and the achieved proximal LZ on the one hand and the potential effect on aortic angle of stent deployment on the other, aortic angulation was calculated on the pre-operative CTA. Nevertheless, this was only done after having located the tip of the stent in relation to a fixed anatomical landmark on the post-operative CTA.

The second morphological parameter quantified was tortuosity index (TI) of the thoracic aorta. This index was defined as the ratio of the incremental true length of the aorta along the CL ($L_{CL\ A-B}$) to the linear distance between its endpoints (d_{A-B}) (Fig. 2).

The concept of conflict between stent graft and iliac artery was introduced as a further parameter and determined by comparing the minimal diameter of the external iliac artery to the stent graft sheath diameter. Conflict was considered to exist whenever the external iliac artery was smaller than the delivery catheter caliber.

To further and better assess the difficulty of advancing the delivery catheter, the degree of calcification of the arterial access was analyzed. Grading was as follows: 0 = absent (absence of calcification); 1 = mild (<25% of the vessel length calcified); 2 = moderate (25–50% of the vessel length