The Association between Iliac Fixation and Proximal Stent-graft Migration during EVAR Follow-up: Mid-term Results of 154 Talent Devices


Abstract

Objective: This study investigated the importance of iliac fixation to secure endograft fixation.

Materials and methods: Computed tomography (CT) scans of patients who underwent endovascular aneurysm repair with an endoprosthesis of great columnar strength (Talent™ stent graft) were analysed retrospectively. Patients were enrolled consecutively between June 2000 and January 2007 and prospectively followed up with serial CT imaging. The superior mesenteric artery was used as a reference point to determine endograft migration (centerline endograft displacement of ≥10 mm). Proximal and distal fixation lengths were defined as the length of the endograft that was in full apposition to the aortic neck or common iliac arteries, respectively.

Results: Proximal endograft migration occurred in 32 of 154 patients (21%) at a follow-up duration of 32 ± 14 months; 13 migrations required treatment (8%). Migration was more frequent in patients treated with aorto-uniliac devices than bifurcation devices (p < 0.008). The migrator and non-migrator groups had similar demographic and abdominal aortic aneurysm (AAA) characteristics. The migrator group had significantly shorter proximal (30 ± 12 mm vs. 41 ± 13 mm, P < 0.001) and distal endograft fixation lengths (31 ± 18 mm vs. 47 ± 15 mm, P < 0.001). By multivariate regression analysis, proximal and distal endograft fixations were significant predictors for endograft migration at follow-up (P < 0.001).

Conclusion: Iliac endograft fixation, along with proximal fixation, is a significant predictor for endograft migration.

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Migration is an issue for all types of endograft. This unique phenomenon after endovascular aneurysm repair (EVAR) has been extensively described in many reports, with a prevalence ranging from less than 3% up to 28%, depending upon which stent graft was used, the morphological abdominal aortic aneurysm (AAA) characteristics and the length of study follow-up time. The proximal aortic neck length, diameter and angle seem to have great influence on the risk of proximal endograft migration after EVAR. The other risk factors that have been studied are maximum aneurysm diameter, endograft configuration (aortic tubes vs. bifurcation grafts), the type of proximal endografts fixation (hooks and barbs) and the extent of endograft oversizing.

Thus far, most attention has been paid to optimise proximal endograft fixation in reducing endograft migration. Currently, there is a wide range of different concepts of endograft design, with shock-absorbing non-columnar stent grafts vs. more rigid grafts at both ends of the spectrum. It might be assumed that the more rigid grafts experience high forces on the graft material in case of changes in AAA and iliac configuration during follow-up, especially in tortuous anatomies. Kinking or even breakdown of the stent grafts might occur then. The importance of distal endograft fixation has received little attention. Especially in endografts with a high columnar or axial strength, similar to the Talent columnar support. In addition, closer placement of the distal end of the endograft to the iliac bifurcation seems to be protective against migration. These results were shown by Benharash and co-workers, who investigated trans-renal endografts with longitudinal support. The follow-up time in both studies were relatively short. As endograft migration is time dependent and might even occur many years after the index procedure, the aim of this study is to analyse the long-term association between iliac fixation and proximal endograft migration.

Materials and Methods

The patients analysed in this study were selected from a cohort of 290 patients with infrarenal abdominal aortic aneurysms (AAAs) who received primary treatment with a Talent bifurcated or aorto-uni-iliac endograft. Patients were enrolled consecutively between July 2000 and August 2007 at the Stanford University Medical Center and the St. Antonius Hospital, Nieuwegein, and prospectively monitored with serial imaging and clinical follow-up. Although patients were prospectively monitored initially, the data for this study were collected in a retrospective manner. Patients were included if they had preoperative and early postprocedural (<4 weeks after the index procedure) digital computed tomography (CT) scans and a second postprocedural follow-up CT scan with a minimum interval of 1 year post-EVAR. The second postprocedural CT scan analysed was the latest available CT scan at follow-up, or the latest CT scan before a secondary procedure had been performed to resolve complications related to the endograft or the AAA.

Baseline patient characteristics, including cardiopulmonary co-morbidity, the American Society of Anesthesiologists (ASA) score and aneurysm morphology are summarised in Table 1. Preoperative morphologic aneurysm measurements are depicted in Fig. 1. Maximum AAA diameter was measured on the preoperative CT scan. Aortic neck diameter was the maximum aneurysm neck diameter on the preoperative CT scan between the caudal portion of the lowest renal artery and the beginning of the AAA. Aortic neck length was the distance from the caudal portion of the lowest renal artery to the beginning of the AAA. When the aortic neck was not a straight tube, the distance between the lowest renal artery and the aneurysm neck portion that reached 85% of the proximal endograft diameter was used because endografts were 15% oversized compared with the aortic neck diameter.

The CT scans were performed with intravenous non-ionic contrast on a multi-detector-row CT scanner. The slice thickness was 1.5 mm, with delayed imaging to detect endoleaks.

Three-dimensional (3D) image analyses were performed on a TeraRecon (TeraRecon Inc., San Mateo, CA, USA) or digital computed tomography (CT) scans and a second postprocedural follow-up CT scan with a minimum interval of 1 year post-EVAR. The second postprocedural CT scan analysed was the latest available CT scan at follow-up, or the latest CT scan before a secondary procedure had been performed to resolve complications related to the endograft or the AAA.

Baseline patient characteristics and endograft fixation in migrator vs. non-migrator group

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>Migrator group (n = 32)</th>
<th>Non-migrator group (n = 122)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>71</td>
<td>73</td>
<td>NS</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>93</td>
<td>92</td>
<td>NS</td>
</tr>
<tr>
<td>ASA ≥ III (%)</td>
<td>58</td>
<td>56</td>
<td>NS</td>
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<tr>
<td>Co-morbidities</td>
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<tr>
<td>Cardiac (%)</td>
<td>29</td>
<td>34</td>
<td>NS</td>
</tr>
<tr>
<td>Pulmonary (%)</td>
<td>33</td>
<td>27</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>6</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>28</td>
<td>27</td>
<td>NS</td>
</tr>
<tr>
<td>Aneurysm characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max AAA (mm)</td>
<td>62 ± 9</td>
<td>61 ± 13</td>
<td>NS</td>
</tr>
<tr>
<td>Aneurysm neck diameter (mm)</td>
<td>27 ± 4</td>
<td>27 ± 3</td>
<td>NS</td>
</tr>
<tr>
<td>Aneurysm neck length (mm)</td>
<td>17 ± 11</td>
<td>26 ± 15</td>
<td>0.001</td>
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<tr>
<td>Aneurysms neck angle (°)</td>
<td>30 ± 16</td>
<td>30 ± 17</td>
<td>NS</td>
</tr>
<tr>
<td>Iliac aneurysm (n)</td>
<td>0</td>
<td>12a</td>
<td>NS</td>
</tr>
<tr>
<td>Endograft fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prox fixation length (mm)</td>
<td>30 ± 12</td>
<td>41 ± 13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dist fixation length (mm)</td>
<td>31 ± 18</td>
<td>47 ± 15</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 1

*a Hypogastric artery overstented in eight patients.
3Mensio workstation (3Mensio Medical Imaging, Bilthoven, The Netherlands) with maximum-intensity projection, centre line and orthonormal views, thus allowing for measurement of angles and curvilinear distances. All reported diameters were measured perpendicular to the centre line axis, and the reported lengths were curvilinear distances measured along the centre line of vessels.

Postoperative endograft fixation characteristics are illustrated in Fig. 2. The inferior border of the superior mesenteric artery (SMA) was used as a reference point to determine endograft migration when the early post-procedural and the latest follow-up CT scans were compared. The distance from the distal border of the SMA to the uncovered portion of the Talent endograft (e.g., the circumferential top of the bare stent) was used to measure endograft migration (distance H3 in Fig. 2). Endograft migration was defined as a distal migration of 10 mm or more during follow-up. Patients were placed in the migrator group if migration was 10 mm or more and in the non-migrator group if migration was less than 10 mm during follow-up. Proximal and distal endograft fixation and the distance from the distal part of the endograft to the iliac bifurcation were measured on the postprocedural CT angiograms (CTAs).

Factors considered as potentially influencing proximal migration included infrarenal aortic angulation, graft oversizing and amount of thrombus of the proximal aortic neck.

Proximal and distal endograft fixation was defined as the part of the proximal and distal portion of the endograft that was in full apposition with the aortic neck or iliac arteries — that is, for the proximal part of the Talent device, it is the uncovered bare stent (15 mm) plus the first proximal part of the covered stent graft. The endograft to iliac bifurcation distance was the distance from the distal circumferential portion of the stent graft to the cranial portion of the hypogastric artery origin. When the left and right distal endograft fixation or the distance to the hypogastric arteries differed, the mean distances were used.

The primary outcome measure of the study was proximal migration of the stent graft. For comparison, patients were placed in non-migrator or migrator groups, which have been previously defined.
Statistical Analysis

Continuous data are presented as the mean ± standard deviation (SD) and range. Discrete variables are given as counts and percentages. For comparison of values between groups, the Student’s t-test was used for continuous variables and the chi-square test for binary variables. Multivariate logistic regression was done to test for predictors of migration. The five most significant parameters analysed between the two groups with the Student’s t-test or the chi-square test were then analysed in a multivariate model. The risk of migration for different proximal and iliac fixation lengths was calculated from the results of the multivariate model. On the basis of multivariate outcome, the risk of migration for six different proximal endograft fixation groups as a function of iliac fixation lengths was calculated. Statistical significance was considered at P < 0.05. All statistical analyses were performed with SPSS 15.0 software (SPSS Inc., Chicago, IL, USA).

Results

Of the 290 patients treated by Talent EVAR, 136 patients (47%) did not meet the inclusion criteria and were not eligible for analyses. The excluded patients had no follow-up period that met the criteria of inclusion (n = 17) or missed one of the necessary CT scans (n = 52). Moreover, CT scans could not be collected in 22, CT scans were not digitally recorded in 32 and the inferior quality of the CT scans precluded 3D reconstructions in 13. Nine of 154 patients (6%) received an aorto-monoiliac endograft, and the other 145 patients (94%) received a bifurcated endograft. The mean follow-up period was 32 ± 14 months, (range, 12–58 months).

Migration

Among the 154 included patients, proximal migration (>10 mm endograft displacement) of the endograft occurred in 32 (21%) during follow-up. The mean length of migration was 22 ± 16 mm (range, 10–71 mm) in the migrator groups vs. 2 ± 2 mm (range, 0–9 mm) in the non-migrator group (P < 0.001). Migration was significantly more frequent in patients with longer follow-up (mean follow-up was 28 ± 13 months in the non-migrator group and 36 ± 13 months in the migrator group, P = .006). In the migrator group, 25 of 32 patients (78%) were followed up for more than 2 years.

A subgroup analysis revealed a significant difference in occurrence of migration between the patients treated with a bifurcated endograft and patients treated with a uni-iliac endograft (P = 0.008). Migration occurred during follow-up in five of nine patients (56%) treated by means of an aorto-uni-iliac endograft vs. 19% in the bifurcation group.

Baseline patient and AAA characteristics

No significant differences in age, sex distribution, ASA score, co-morbidities, maximum AAA diameter, aneurysm neck diameter and neck angle were revealed between the migrator and non-migrator groups (Table 1). However, aortic neck length was significantly shorter in the migrator group (17 ± 11 mm vs. 26 ± 15 mm, P = 0.001).

Endograft fixation characteristics

The proximal length of endograft fixation (uncovered bare stent plus first part of the covered stent graft) was significantly different among the migrator and non-migrator groups (30 ± 12 vs. 41 ± 13 mm, P < 0.001). Distal endograft fixation was significantly longer in the non-migrator group compared with the migrator group (47 ± 15 mm vs. 31 ± 18 mm, P < 0.001) and did not change significantly during follow-up (non-migrator group 47 ± 15 mm vs. 45 ± 16 mm, migrator group 31 ± 18 mm vs. 28 ± 14 mm). In eight patients (5%) the iliac fixation length was less than 20 mm and all of them had migration of the stent graft. Distance from the circumferentially distal end of the endograft to the hypogastric artery was not significantly different between the two groups (non-migrator group, 11 ± 10 mm vs. migrator group, 15 ± 15, P = 0.08). In 88 patients (57%) one or both legs of the stent graft were not extended up to the hypogastric arteries.

Predictors of migration

Multivariate logistic regression analysis to test for predictors of proximal migration revealed proximal length of endograft fixation, preoperative aortic neck length and distal endograft fixation along with follow-up time as significant predictors (Table 2). Infrarenal aortic angulation, amount of graft oversizing and amount of thrombus in the proximal aortic neck were not significant predictors, but differences between the groups were small. Multivariate logistic regression analysis revealed no predictive value for endograft configuration (monoiliac vs. bifurcated endografts). Based on the results of multivariate logistic regression analysis, the risks of migration for six different proximal fixation groups were calculated for iliac fixation distances (Fig. 3). Group 1 had short proximal fixation lengths (30 mm) and group 6 had long proximal fixation lengths (55 mm). The iliac fixation length was especially important in the group with short proximal endograft fixation, as shown in Fig. 3. Of the treated patients, 63 out of 154 (41%) had a relatively short proximal fixation (that is <35 mm, uncovered bare stent plus covered proximal part of the stent graft) and 39 out of 154 patients (25%) had

<p>| Table 2 | Multivariate logistic regression for migration 10 mm or more |</p>
<table>
<thead>
<tr>
<th>Factor</th>
<th>Estimate</th>
<th>SE a</th>
<th>Odds ratio</th>
<th>P value</th>
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</thead>
<tbody>
<tr>
<td>Aortic neck length (mm)</td>
<td>0.028</td>
<td>0.29</td>
<td>1.029</td>
<td>0.324</td>
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<tr>
<td>Prox. Fixation length (mm)</td>
<td>−0.124</td>
<td>0.039</td>
<td>0.884</td>
<td>0.001</td>
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<tr>
<td>Dist. Fixation length (mm)</td>
<td>−0.086</td>
<td>0.023</td>
<td>0.918</td>
<td>0.000</td>
</tr>
<tr>
<td>FU period (months)</td>
<td>0.89</td>
<td>13.487</td>
<td>1.093</td>
<td>0.000</td>
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<tr>
<td>Monoiliac-bif endograft</td>
<td>1.087</td>
<td>1.278</td>
<td>2.966</td>
<td>0.258</td>
</tr>
</tbody>
</table>

a Standard error.
Association between Iliac Fixation and Proximal Stent-graft Migration during EVAR Follow-up

3 year migration rate

![Graph showing three-year migration rate](image)

a relatively long proximal fixation (>50 mm, again uncovered bare stent plus covered proximal part of the stent graft). When iliac fixation was relatively short, (mean iliac fixation <30 mm) migration rates of almost 60% at 3 years of follow-up were determined, indicating the importance of good iliac fixation in selected patients with short proximal fixation length.

During a mean clinical follow-up time of 41 ± 11 months there has been no AAA ruptures in the migrator group. In the migrator group 13 needed surgical revision; nine patients were treated with aorto-uni-iliac endografts and femoro-femoral crossover bypass, one patient was treated with aortic neck banding and three patients needed endograft explantation. Nineteen patients are under regular observation as proximal fixation is still >15 mm and no endoleaks (not even type II endoleaks) occur. In the non-migrator group only two patients have been diagnosed with complex type II endoleaks with growth of the native aneurysm; both patients have been successfully treated with intra-arterial embolisation.

Discussion

In the last decade of EVAR, numerous articles have been published concerning the importance of optimal proximal endograft fixation, but only a few studied the importance of distal iliac endograft fixation in preventing endoprosthesis migration. Only the reports of Heikkinen and Benharash et al. showed a highly important role for iliac fixation in preventing endograft migration; however, both had short-term follow-up. The proposed explanation for this phenomenon could be that the iliac limbs are the foundation of the endograft. The consequences of repeated downward pulsation of blood flow in the face of weakness of resistance forces can result in proximal migration of the endograft. The iliac limbs are the pilings or support structure of the endograft, which is less susceptible to migration when distal iliac fixation is good. We think that this phenomenon will be especially important in endografts with a high columnar strength, similar to the studied Talent endograft, as the continuous blood flow is transmitted throughout the whole stent-graft system. We believe it is important for new-generation stent grafts to have a more flexible configuration and thus a less rigid device. The decrease of columnar strength has to be compensated, for instance, by more secure proximal fixation such as anchoring pins or barbs, or maybe additional endoluminal stapling of the proximal part of the device.

The current study substantiated the importance of sufficient iliac fixation and showed that iliac fixation is of major importance in patients in whom the proximal fixation site is not optimal. Although not as important as proximal fixation, iliac fixation is of major importance in patients with short proximal aortic necks. The shorter the proximal fixation, the longer the iliac fixation has to be to prevent future endograft migration. As the renal arteries limit proximal endograft fixation length in endografts without fenestrations, the only way to achieve more fixation is to extend the endograft at the bottom of the common iliac arteries all the way to the hypogastric arteries. In Fig. 3 we have shown that even when the iliac fixation already exceeds 3 cm, it is still more beneficial to extending the iliac limbs further.

From these findings, we can say that the iliac fixation is a determinant for proximal stent-graft stability. As the proximal fixation zone is also a major determinant of migration, we are not able to determine an ideal iliac fixation length. As recommended by the manufacturer, the minimum iliac fixation length is 20 mm. In the current study eight patients (5%) had an iliac fixation of less than 20 mm. All of them had migration of the stent graft. Although this finding suggests that we have to extend the limbs of the stent graft at least 20 mm into the iliac arteries, another 24 patients (16%) had migration of the stent graft although iliac fixation was more than 20 mm. In cases where the durability of the proximal attachment zone is in doubt, we think the best way to achieve the best fixation is to extend the iliac limbs all the way to the hypogastric arteries.

In the current study, five of nine aorto-monoiliac Talent endografts showed evidence of migration. Although the number of patients treated by means of a monoiliac endograft was not large enough to give definite conclusions about the durability of this endograft configuration, this trend towards higher migration rates in this selected patient group deserves attention. Studies have described good results using monoiliac endografts, but we think larger studies are needed that focus on this selected patient group to definitively prove the durability of this configuration. Contrary to our expectations, we did not find a significant role for aortic neck diameter and angle when the two studied groups were compared. Numerous reports have described an association between large aortic neck angle and diameter and risk of migration. A reasonable explanation for this is that the mean neck length of the studied patients was relatively long and the neck angles were small compared with other studies.

A limitation of this study is the fact that we did not determine the influence of proximal aortic neck elongation as a confounding factor for migration. Even in open AAA repair, suturing a prosthetic graft in the infrarenal aorta, the appearance of caudal graft displacement can occur due to continuing neck elongation. Litwinski et al. showed that postoperative elongation of the infrarenal aortic neck after EVAR may create the radiographic perception of...
migration without necessarily causing a loss of the proximal stent-graft fixation.20

A remarkable finding in this study was that more than 10 patients were found to have proximal migration that was not described in radiology computed tomography angiography (CTA) reports. All of these measurements were done on axial CTA views without 3D reconstructions with central lumen lumen measurements. Secure measurements regarding migration and distance measurements can only be performed accurately when the aorta is considered as a straight tube and thus with perpendicular views. Especially in cases where the abdominal aorta is tortuous or there is much angulation, precise morphological measurements can only be done accurately with 3D central lumen line reconstructions.

In the current study the proximal migration rate of 21% at a mean follow-up of 32 months is high comparable to other studies.3–5 One of the explanations could be that we measured all the variables on the CT scans, including migration rate, with 3D central lumen line reconstructions at the 3D workstation. Most of the referred studies, done in the past decade, did not use this type of exact measurements. The 3D reconstructions allow most accurate measurements, especially in patients in which the aortic neck is very tortuous. Secondly, >55% of the included patients were referred from other hospitals due to serious cardiopulmonary co-morbidity and hostile abdomens. Of the patients described in this study, 41% had a proximal fixation of less than 35 mm including the first 15 mm of uncovered part of the endograft and the mean aneurysm neck of the migrator group was only 17 mm. As has been known from other reports, the length of the aneurysm neck is a predictor for migration.5,6

The question that arises from this study is what should be the iliac fixation length in order to give the most optimal distal fixation. We showed that even in patients with a long proximal fixation, more distal iliac fixation offers some benefit. Patients with short aortic necks do have the most benefit. Furthermore, it is clear from this study that short proximal and distal fixation length is a major reason for graft migration during follow-up. Again, violating the instructions for use concerning minimal proximal and distal fixation length has been associated with worse outcome in the long run.

Conclusion

Our results confirm that the iliac fixation is a highly significant predictor of migration during follow-up after a successful EVAR procedure with an endoprosthesis with great columnar strength, similar to the studied Talent stent grafts. The optimum iliac fixation length cannot be determined from this retrospective study and is dependent on the proximal endograft fixation length. Although patients with short proximal endograft fixation benefit the most from a longer iliac fixation length, we showed that even when proximal fixation is long (>30 mm), extending the iliac limbs even further will be beneficial in preventing migration. We therefore think that the iliac limbs have to be extended up to the hypogastric arteries, irrespective of the achieved proximal fixation length.

Conflict of Interest/Funding

Christopher K. Zarins is a consultant to Medtronic.

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References