INFLUENCE OF ATHEROMATOUS LESIONS IN THE ILIO-FEMORAL SEGMENT ON THE OCCURRENCE OF STENTGRAFT THROMBOSIS AFTER ENDOVASCULAR TREATMENT OF AN ABDOMINAL AORTIC ANEURYSM

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Limb graft thrombosis (LGT) is one of the most frequent severe complications after endovascular repair of abdominal aortic aneurysms.

The aim of the study was to assess the influence of atherosclerosis in ilio-femoral segment on the incidence of LGT as well as to analyze the methods of treatment of LGT.

Material and methods. The medical records of 564 consecutive patients operated endovascularly for abdominal aortic aneurysm by means of bifurcated stentgrafts in the Department of General, Vascular and Transplantat Surgery of Medical University of Warsaw were analyzed. The minimal observation time after surgery was one year. Patients with inflammatory, ruptured and falls aneurysms as well as those with the observation period below 12 months were excluded from the study.

Patients were divided into two groups: test (B) and control (K) depending on the progression of atherosclerosis in the iliac arteries. Group B included 184 patients (13 women and 171 men), with advanced atherosclerotic lesions of ilio-femoral segment, corresponding to the A – C class in the TASC classification. The remaining 380 patients (25 women and 355 men) without significant blood flow disorders in the iliac arteries, constituted the group K. The computed tomography was done in all patients with acute limb ischemia.

Results. During the observation time up to 114 month, the LGT occurred in 43 (7.6%) cases: [group B – 34/184 (18.5%), group K – 9/380 (2.4%)]. The treatment of LGT included an attempt of patency restoring of the prosthesis by means of thrombolysis or thrombectomy combined with stenting. In case of failure the cross-over femoro-femoral bypass was implanted. Thrombectomy was successful in 21 of 40 cases (52.5%), the local thrombolysis was done in 5 patients and it was successful in three cases and in the remaining two patients the thrombectomy was done. In 16 of 24 patients after patency restoring of the prosthesis the angioplastics and stenting was done. In 17 cases the femoro-femoral bypass was implanted.

Conclusions. The atherosclerosis in ilio-femoral segment significantly increases the risk of LGT. An attempt of patency restoring (thrombectomy or thrombolysis) combined with stenting and cross-over femoro-femoral bypass implantation in case of failure seems to be the successful method of LGT treatment.

Key words: abdominal aortic aneurysm, atherosclerosis, ischaemia, stentgraft, endovascular repair, vascular graft, endarterectomy, thrombectomy, thrombolysis

The introduction of endovascular treatment in the early nineties of the past century considering patients with abdominal aortic aneurysms has proved to be an effective and safe method, especially in high-operative risk patients. Amongst operated patients one may find subjects with advanced atherosclerosis of the ilio-femoral segment, which is a significant risk factor considering endovascular treatment complications. Its importance has been widely analysed, especially in case of blood leakage into the aneurysmal sac (1-5).
Stentgraft thrombosis is one of the most frequent and life-threatening complications after endovascular treatment of abdominal aortic aneurysms. Literature data concerning its incidence ranged between 2.7 and 23.8% (6-12). Based on the presented publications the incidence of endoprosthesis thrombosis was 5.8%.

Most authors draw attention to the higher incidence of the above-mentioned complication during the postoperative period (13-24).

The basic aim of stentgraft thrombosis treatment consists in the restoration of proper blood flow to the lower extremity. The most common methods include thrombectomy, local thrombolysis, and cross-femoral bypass grafting reinforced with polytetrafluoroethylene (7, 13, 16, 18, 21, 25). In some centers, bypass grafts are used in each case of endoprosthesis thrombosis (21,25). According to the EUROSTAR registry, in case of secondary procedures after endovascular abdominal aortic aneurysm interventions, 11% of patients required femoro-femoral bypass grafting (26).

The efficacy of thrombectomy depending on different centers, ranged between 25 and 85% (7, 13, 14, 18, 21, 22, 25, 27). Limitations of the above-mentioned method are mainly connected with technical difficulties in the introduction of the catheter into the lumen of the stentgraft, and the possibility to move and disconnect its elements leading towards type I or III leakage (25, 28). Thrombolytic therapy consisting in the local administration of drugs that cause the dissolution of the thrombus is recommended in the late postoperative period, because it allows to avoid surgical intervention (7, 18, 28). The limitation of the above-mentioned method is associated with the numerous contraindications, resulting from the general activity of thrombolytic drugs, and associated risk of hemorrhagic complications (25). It should be emphasized that in some patients after successful blood flow restoration, additional angioplasty or stentgraft implantation at the site of the stenosed prosthesis is necessary (13).

The aim of the study was to determine the influence of atherosclerotic lesions in the ilio-femoral segment on the incidence of stentgraft thrombosis, and analysis of the effectiveness of treating the above-mentioned complication.

**MATERIAL AND METHODS**

Abdominal aortic aneurysm endovascular operations are performed at the Department of General, Vascular and Transplantation Surgery, Medical University of Warsaw, since April, 1998. Until the end of June, 2012, 1109 patients with abdominal aortic aneurysms were subject to treatment by means of the above-mentioned method. 564 consecutive patients (526 men and 38 women) after endovascular abdominal aortic aneurysm procedures with the use of bifurcated, aorto-iliac stentgrafts were subject to analysis. Exclusion criteria included inflammatory, ruptured abdominal aortic aneurysms, and pseudoaneurysms, as well as those with unilateral stentgrafts. The minimum follow-up period was 12 months.

The general condition of patients before the operation was evaluated, according to criteria of the American Society of Anesthesiologists (ASA). The high risk of classical surgery was considered when the patient was in class III or IV, according to ASA, or in the presence of local operative risk factors, such as obesity, history of laparotomy, post-kidney transplantation, history of abdominal cavity and pelvis radiotherapy, and presence of stomy. Based on the above-mentioned criteria, 453 (80.3%) of the 564 patients with abdominal aortic aneurysms were diagnosed with high surgical risk, according to ASA, and in the remaining patients, endovascular procedures were performed because of local factors.

Prior to planned endovascular procedures all patients with abdominal aortic aneurysms were subject to angioCT, which evaluated the presence of atherosclerotic lesions in the ilio-femoral segment. Thus, the 564 patients with abdominal aortic aneurysms were divided into two groups: the study (B) and control (K) groups.

Group B comprised 184 (32.6%) patients with hemodynamically significant atherosclerotic lesions in the ilio-femoral segment. The location and severity of the lesions was evaluated, according to the Trans-Atlantic Intersociety Consensus TASC II international classification (29). The remaining 380 (67.4%) patients without significant atherosclerotic iliac artery lesions constituted group K.

All the surgical procedures were performed in the operating room, equipped with a digital,
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Mobile subtraction angiography device (OEC Vascular 9800) holding arm C. Conduction anesthesia was used in 487 (86.3%) patients. 58 (10.3%) patients were subject to general anesthesia, while 19 (3.4%) – local anesthesia. Table 1 presented the types and number of stentgrafts used.

In case of patients with significant stenosis of the external iliac artery preventing the introduction of the stentgraft, high-pressure balloon angioplasty was performed. In case we were unable to obtain an adequate diameter of the lumen of the vessel for endoprosthesis introduction, the following technique was used: preparation from the retroperitoneal approach above the external iliac artery stenosis, followed by vascular graft end-to-side anastomosis. The stentgraft was then introduced and the peripheral end of the prosthesis was anastomosed to the common femoral artery. In the presence of numerous atherosclerotic lesions in the common or deep femoral arteries, thrombendarterectomy or profundoplasty were additionally performed (fig. 1A).

Patients with advanced atherosclerotic lesions located in the common or deep femoral arteries, thrombendarterectomy or profundoplasty were additionally performed (fig. 1A).

In case the atherosclerotic lesions located in the common or external iliac arteries were responsible for the flexure or incomplete stent-graft expansion, high-pressure balloon angioplasty was performed, and if necessary, additional stents were implanted, in order to maintain the dilation effect.

After surgery prophylactic anti-thrombotic therapy was routinely used, low molecular weight heparin (LMWH) was replaced with aspirin (75 mg daily) on the day of discharge from the hospital. After 3, 6, and 12 months, and every year thereafter, patients were subject to angioCT, in order to control aneurysmal blood flow and determine the patency of the endoprosthesis.

Emergency angioCT was performed in all patients with clinical symptoms of acute limb ischemia after stentgraft implantation. In case stentgraft thrombosis was diagnosed leading towards acute limb ischemia endoprosthesis patency restoration was attempted. Thrombectomy or arterial thrombolysis were performed. Thrombectomy was performed by means of Fogarty’s catheter or high-pressure balloon angioplasty under fluoroscopy control. The recombined plasminogen activator (rTPA) was used in case of thrombolytic therapy, being administered by means of a percutaneous, perforated catheter introduced from the opposite side, its tip placed inside the thrombus. Initially, 5 mg of rTPA was administered during a period of 15 minutes, followed by continuous infusion 1 mg/hour under fibrinogen control. The effectiveness of thrombolysis was controlled by means of arteriography, and depending on the progress of recanalization the catheter was relocated. The decision concerning the termination of thrombolysis was undertaken after restoration of blood flow through the stentgraft or when the maximum dose of 100 mg was attained. In case of unsuccessful thrombolysis, thrombectomy was performed. In cases where the endarterectomy identified stenosis or stentgraft bending, we routinely implanted a balloon expandable

<table>
<thead>
<tr>
<th>Type of stentgraft</th>
<th>Group B number</th>
<th>%</th>
<th>Group K number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith</td>
<td>136</td>
<td>73.9</td>
<td>255</td>
<td>67.1</td>
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<tr>
<td>Excluder</td>
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<td>13</td>
<td>57</td>
<td>15</td>
</tr>
<tr>
<td>PowerLink</td>
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<td>8.7</td>
<td>56</td>
<td>14.7</td>
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<tr>
<td>Talent</td>
<td>7</td>
<td>3.8</td>
<td>6</td>
<td>1.6</td>
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<tr>
<td>Aorfix</td>
<td>1</td>
<td>0.5</td>
<td>6</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Fig. 1. Additional intraoperative procedures in patients with advanced atherosclerosis

A – ilio-femoral graft, B – endarterectomy of the deep femoral artery with patch implantation
stent. In case of patency restoration failure we performed a crossover femoro-femoral graft.

For the reliable assessment of study results we calculated the following: percentages, average values, standard deviations, standard errors, medians, and used statistical analysis tests (chi², Fisher’s, Log-rank), and Kaplan-Meier’s analysis. The STATISTICA for Windows (StatSoft, Inc) program was used. p=0.05 was considered as statistically significant.

RESULTS

Statistical analysis showed no differences between both groups, considering patient gender (chi²: p>0.83), maximum diameter of the abdominal aortic aneurysm (chi²: p>0.92), and different stentgrafts used (chi²: p>0.05). The observation period after endovascular procedures in case of abdominal aortic aneurysms ranged between 13 and 114 months (mean group B – 55.5; SD=25.1, SE=1.7; mean group K – 54.8; SD=24.9, SE=1.3). No statistically significant differences in the observation period were observed between both groups (chi² p=0.74). Figure 2 presented data.

The degree of surgical risk, according to the ASA scale was significantly higher in group B patients (p=0.001).

Forty patients required additional intraoperative procedures [group B– 33/184 (17.9%), group K – 7/380 (1.8%)]. Statistical analysis by means of Fisher’s test showed that additional procedures were performed significantly more often in case of group B patients (p=0.001). Table 2 presented the above-mentioned.

During the 114 months observation period stentgraft thrombosis was observed in 43 (7.6%) of the 564 patients [group B – 34/184 (18.5%), group K – 9/380 (2.4%)] after endovascular treatment of abdominal aortic aneurysms, being significantly more common in group B. The log-rank test showed statistically significant differences between both groups, considering stentgraft patency, in favor of group K (p=0.0001). Figure 3 presented these characteristics.

Impatency of the endoprosthesis branch was observed during the initial 30 days after surgery in 27 of 43 cases (62.8%). In the remaining 16 (37.2%) patients the above-mentioned complication was observed between the first and 78-th month of observation.

During the initial 30 days after surgery, stentgraft thrombosis was observed in 27/564 (4.8%) patients [group B – 22/184 (12%), group K – 5/380 (1.3%)]. In 6 cases (group B – 4, group K – 2) this was observed during the initial three days, and in the remaining 21 (group B – 18, group K – 3) – between the fourth and 30-th postoperative day.

The following therapeutic scheme was recommended in case of stentgraft thrombosis (fig. 4):

- In each of the 27 patients (group B – 22, group K – 5) thrombectomy was performed using Fogarty’s catheter or high-pressure balloon arteriography. In 15 patients the
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Table 2. Comparison of additional intraoperative procedures in group B and K patients

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>Group B</th>
<th>Group K</th>
<th>p</th>
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<tbody>
<tr>
<td></td>
<td>Nb. of procedures</td>
<td>% of procedures</td>
<td>Nb. of procedures</td>
</tr>
<tr>
<td>Ilio-femoral graft</td>
<td>5</td>
<td>2,7</td>
<td>0</td>
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<tr>
<td>Unilateral femoro-femoral graft</td>
<td>2</td>
<td>1,1</td>
<td>2</td>
</tr>
<tr>
<td>Thrombendarterectomy of the common femoral artery and profundoplasty</td>
<td>9</td>
<td>4,9</td>
<td>0</td>
</tr>
<tr>
<td>Balloon angioplasty of the stentgraft</td>
<td>17</td>
<td>9,2</td>
<td>9</td>
</tr>
<tr>
<td>Implantation of an extending stent into the stentgraft</td>
<td>7</td>
<td>3,8</td>
<td>1</td>
</tr>
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attempt proved to be successful (group B – 12, group K – 3).

– Additionally, in 11 of the 15 patients (group B – 9, group K – 2) we implanted an extending stent into the stenosed stentgraft.

– In the remaining 12 patients (group B – 10, group K – 2) after an unsuccessful thrombectomy attempt cross-femoral grafting was performed.

– One patient after the cross-femoral graft (group B – 1, group K – 0) developed thrombosis of the vascular prosthesis and five years previously implanted femoro-popliteal graft. Despite four attempts to restore patency the above-mentioned proved unsuccessful. Due to the development of necrotic lesions lower leg amputation was required.

During the observation period ranging between 1 and 114 months after endovascular surgery of abdominal aortic aneurysms, stentgraft thrombosis was observed in 16/564 (2.8%) patients [group B – 12/184 (6.5%), group K – 4/380 (1.1%)]. In 12 cases (group B – 9, group K – 3) this was observed during the first year after surgery, and in the remaining 4 cases (group B – 3, group K – 1), 26, 35, 44 and 78 months after surgery, respectively (fig. 5).

Fig. 4. Therapeutic management in patients with stentgraft thrombosis in the early postoperative period
Stentgraft patency restoration was attempted in all the 16 patients (group B – 12, group K – 4). The following therapeutic management was recommended in case of stentgraft thrombosis:

- Five patients (group B – 4, group K – 1) were subject to local thrombolysis by means of rTPA administration, which proved successful in three cases (group B – 2, group K – 1).
- Thirteen patients (group B – 10, group K – 3), including two (group B – 2, group K – 0) after unsuccessful thrombolysis were subject to thrombectomy, which proved successful in 6 cases (group B – 5, group K – 1).
- Three patients after successful thrombectomy and two after local thrombolysis underwent additional stent implantation to the stenotic stentgraft.
- After unsuccessful thrombectomy, cross-femoral grafting was performed in five of the seven cases (group B – 3, group K – 2).
- The remaining two patients (group B – 2, group K – 0) after unsuccessful thrombectomy were subject to lower leg amputation, due to necrosis.

During the 114 month observation period, four patients that were treated for stentgraft thrombosis developed acute lower limb ischemia.

In one case, after 11 months, we observed recurrent thrombosis of the previously patent stentgraft following extending stent implantation. Consecutive thrombectomy proved unsuccessful, requiring cross-femoral bypass graft surgery.

In the remaining three patients, after 14, 15 and 23 months following cross-femoral bypass grafting we observed prosthesis thrombosis. In two cases patency restoration was possible by means of Fogarty’s catheter, while in one re-transplantation was required, due to numerous stenoses.

The study also compared the incidence of acute lower limb ischemia in all 564 patients, in relation to the recurrence of acute ischemia after stentgraft thrombosis treatment in 43 patients throughout the observation period. The above-mentioned rates were 7.6% and
DISCUSSION

Although atherosclerosis is often cited as a risk factor of the possible complications following endovascular abdominal aortic aneurysm operations, its pathogenesis remains to be described (7, 26, 30, 31). In our material atherosclerotic lesions in the ilio-femoral segment were observed in 79.1% of patients with stentgraft thrombosis. The study showed statistically significant differences between groups B and K considering the number of additional procedures (p<0.05).

In our study, stentgraft stenosis was mainly observed in the early postoperative period (62.8%), mostly between the fourth and 30-th day after surgery. These data are consistent with the observations of most authors describing the above-mentioned complication (7, 14-18, 20-24, 27, 32-34). Fairman et al. noted that 82% of stentgraft impatency cases occurred during the initial six months after surgery (18).

Thrombectomy, thrombolysis and cross-femoral bypass grafting were used in case of stentgraft thrombosis treatment. Thrombectomy using Fogarty’s catheter or high-pressure balloon angioplasty was successful in 21 of the 40 patients (52.5%). In two cases the above-mentioned procedures were performed after unsuccessful thrombolytic therapy. In literature data there are studies describing the high efficacy of mechanical thrombectomy (21, 27), as well as opinions concerning the possibility of disconnecting graft elements during patency restoration (14, 28, 25). Such complications were not observed in our study. Similar results were obtained by Erzurum et al. They observed no blood flow outside the endoprosthesis lumen after surgical endarterectomy (21).

Local thrombolysis was used in five patients with endoprosthesis thrombosis in the distant observation period. In three patients such management proved successful, while the remaining two were qualified for mechanical thrombectomy. Becquemin et al. reported that using local thrombolysis, stentgraft patency restoration was possible in 50% of cases (36). The aforementioned authors and Fairman et al. reported that in the absence of the effect of the above-mentioned therapy cross-femoral bypass grafting was performed, without mechanical patency restoration attempts (18, 25). Bohannon et al. described the effectiveness of rheolytic thrombectomy using the Angiojet system (35).

Sixteen of the 24 patients after effective prosthesis endarterectomy were additionally subject to angioplasty with the implantation of extending stents, due to stentgraft flexure or stenosis. Only one of these patients was diagnosed with stent thrombosis, which developed 11 months after its implantation. Carpenter et al. proposed a similar management algorithm (13). Sivamurthy et al. recommended stenting of the iliac artery stenoses, before endoprosthesis implantation (23).

Seventeen patients after unsuccessful stentgraft endarterectomy were subject to cross-femoral bypass grafting, in order to restore blood flow to the limb. Three patients developed thrombosis, after 14, 15 and 23 months, respectively. Yilmaz et al. analysed data obtained from 148 patients after endovascular abdominal aortic aneurysm treatment. These patients were subject to unilateral endoprosthesis and suprapubic graft implantation, proving the high effectiveness of the method. Prosthesis patency after 12 months was observed in 96.3% of cases, and after four years in 94.1% (37). Erzurum et al. reported 46.8% of cases of recurrent lower limb ischemia in the first year of the observation period after cross-femoral bypass grafting, due to bifurcated stentgraft thrombosis (21). In our study the above-mentioned complications were not observed, and throughout the observation period, primary suprapubic graft patency amounted to 86.4%.

The comparison of distant treatment results in case of stentgraft thrombosis showed that recurrent lower limb ischemia was only observed in one of the 24 patients following prosthesis endarterectomy, and in three of 17 patients after cross-femoral bypass grafting. Differences in the recurrence rate of acute lower limb ischemia between patients who managed stentgraft patency restoration, and those after cross-femoral bypass grafting were statistically insignificant (p>0.05). These results might confirm the validity to perform endarterectomy in case of endoprosthesis thrombosis.
CONCLUSIONS

Atherosclerotic lesions in the ilio-femoral segment are a significant risk factor of stent-graft thrombosis incidence after endovascular abdominal aortic aneurysm treatment. In case of this complication an effective therapeutic method consists in an attempt to perform endarterectomy in combination with stenting, and if unsuccessful, cross-femoral bypass grafting.

REFERENCES


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