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OUR EXPERIENCE WITH ENDOVASCULAR TREATMENT OF ABDOMINAL AORTA ANEURYSM WITH TALENT STENT GRAFTING

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SUMMARY – The aim of the study was to evaluate the safety and efficacy of endovascular treatment of abdominal aorta aneurysm (AAA) with Talent stent-graft (TSG). From October 1999 to February 2002, 18 patients (17 male and one female) aged 65-77, with AAA >5 cm in diameter, were treated by bifurcated Talent stent grafting. In all patients, postinterventional CT was performed 24 hours after stent grafting. The sutures were removed on the seventh to ninth day after the procedure, and the patients were released for home care. Regular spiral CT control evaluation was scheduled at 1, 3, 6, 9, 12 and 24 months after stent grafting. The mean follow up time was 11 months. Talent stent grafting procedure was initially successful in all patients. During regular controls, the TSGs were not occluded. In two (11%) patients, Talent stent grafting was preceded by preinterventional embolization. In five (27%) patients, control spiral CT after stent grafting showed a small endoleak. In these patients, systemic heparinization was interrupted and spiral CT was repeated after seven days. Repeat spiral CT after seven days showed absence of endoleak in four of five (80%) patients. A small endoleak in one patient disappeared spontaneously a month after TSG placement. The mean annual reduction in aneurysmal sac diameter was 7.3 (0 to 28) mm. TSG placement is a safe and efficient method of AAA treatment. In patients with accurately determined indication for the procedure, it is today considered a justified alternative to surgery.

Introduction

The incidence of abdominal aorta aneurysm (AAA) generally ranges from 1.3% to 6.6%, and in high-risk population from over 5% to 20%[1-3]. Since 1950, elective surgery has been a common treatment method. This procedure, however, has a high mortality of 4% to 5% even in the centers with great experience[4]. The morbidity and mortality of the surgery increases with patient age. This, and the fact that elderly patients often suffer from comorbidity, has encouraged a search for less invasive endovascular methods for the treatment of AAA. The studies conducted during the last years have confirmed the endovascular stent grafting to be a safe and efficient method for AAA exclusion from circulation, particularly in patients who are for some reason not eligible for surgery[5-9]. Blum *et al.*[8] report that endovascular stent-graft placement is accompanied by numerous complications. The most frequent complication is endoleak, i.e. flow from the stent-graft lumen into the aneurysmal sac. Permanent filling of the aneurysmal sac can cause aneurysm growth, and increase in pressure could result in rupture and death[7]. However, the perigraft flow could cease spontaneously. A

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persisting endoleak demands an additional intervention in an attempt to reduce the blood inflow into the aneurysm. A routine postinterventional CT is exceptionally important for early endoleak detection and timely intervention.

Talent stent graft (TSG; Medtronic World Medical Manufacturing Corporation, Sunrise, Florida, USA) is an endoprosthesis used in endovascular AAA treatment in numerous centers worldwide[10-12].

This article reports on our results with TSG in AAA treatment.

Material and Methods

During a 29-month period (October 1999 - February 2002), 18 patients (17 male and one female), mean age 72 (55-77), with average AAA diameter of 6.9 (5.5-10.4) cm, were treated with endovascular TSG. All patients were informed on the possible advantages and disadvantages of the endovascular treatment of aneurysm and were offered to chose between surgery and endoluminal Talent stent grafting. According to the classification proposed by Blum *et al.*[13], there were ten patients with type B (proximal neck >15 mm, no distal neck but rather involvement of the aortal bifurcation), six with type C (proximal neck >15 mm and involvement of one iliac artery) and two with type D aneurysm (proximal neck >15 mm and involvement of both iliac arteries). Nine risk factors were determined: nicotine consumption, arterial hypertension, diabetes mellitus, hyperlipidemia, coronary disease, chronic obstructive pulmonary disease, renal insufficiency and presence of another aneurysm. The mean number of risk factors was 3.1 (0-6). The iliac artery diameter was 8-24 mm (mean diameter 12.4 mm). Unilateral iliac artery aneurysm was found in six, and bilateral in two patients. In both patients, it was possible to place stent graft so as to exclude the aneurysm from the circulation and one of the internal iliac arteries being left open. Bifurcated TSG was placed in all patients. In three (17%) patients (two with type C aneurysm and one with type D aneurysm), additional iliac extensions were needed besides the basic bifurcated stent graft. To prevent the occurrence of type II endoleak, in two (11%) patients TSG placement was preceded by embolization. In one patient, short occlusion of the left outer iliac artery was recanalized before stent grafting. After TSG placement, the recanalized site was bypassed with dia. 10 mm SMART stent (Cordis, Johnson & Johnson Medical NV/SA).

Bare-spring TSG was used in all patients. This endoprosthesis has 15 mm of proximal stent end not covered with Dacron. Suprarenal fixing of TSG was used in five (27.7%) patients.

The TSG body diameter varied from 24 to 32 mm, and the iliac extension was between 10 and 16 mm in diameter. The prosthesis length was between 160 and 170 mm. When using TSG body £28 mm, a 22F introducer was used, and when the TSG body diameter was >28 mm, the introducer was 24F. An 18F introducer was used for contralateral iliac extension.

In 17 patients, TSG was done under epidural anesthesia, and in only one patient under general anesthesia. The interventions were performed in an angiosurgery theater with Multistar TOP (Siemens).

Infrarenal localization, size of aneurysmal sac, and involvement of iliac arteries were shown on preoperative angiography which was as a rule performed with a 5F Pigtail Altaflow measuring catheter (Ettlingen, Germany).

Spiral CT was done prior to the intervention and 24 hours after TSG placement, and on controls performed at 1, 3, 6, 9, 12 and 24 months after stent grafting. The evaluation was performed on a spiral CT Somatom Emotion (Siemens). Each evaluation included contrast enhanced and noncontrast scans. In patients with AAA, the CT finding is the basis for decision-making on TSG placement. At the same time, one of CT scans was used for measurements to choose appropriate prosthesis size.

On contrast-free scanning, we used 8 mm collimation, 8 pitch, 130 kV, 120 mAs, and on contrast enhanced scanning 3 mm collimation, 1.5 pitch, 130 kV, 96 mAs. In both cases, the region from the celiac trunk to femoral arteries was scanned. On contrast enhanced scanning, an automatic syringe was used to administer 120 ml of Omipaque 300 at a rate of 4 ml/s. The scanning started 28 seconds after the beginning of contrast administration. In postprocessing, 3D reconstructions of contrast-enhanced examination were performed.

We retrospectively analyzed all CT scans of our 18 patients. Maximal aneurysm diameter, changes in aneurysm diameter during follow-up, and existence, size and localization of endoleak were analyzed. The endoleak was categorized as small (£25% of AAA circumference filled with contrast medium), moderate (>25% but £50%), or large (>50%)[14]. The contrast-free scans were used to analyze aortal calcifications that sometimes mimic perigraft flow.

In all patients, heparinization started already during the intervention. After TSG had been placed, 10,000 IU of heparin were administered intra-aortally. Systemic heparinization, which is usually achieved with 100 IU of heparin *per* kilogram of body weight, was continued for 48 hours. After that the patient was given Aspirin in a dose of 100 mg/day. In five patients in whom control CT performed 24 hours after the intervention indicated type I endoleak, heparin administration was stopped and Aspirin treatment started. Antibiotic therapy with Ceftiaxone in a dose of 1x2 g/day was started a day before the intervention, and continued until the third postinterventional day. The first four patients spent 24 days in intensive care, and were then moved to the Department of Vascular Surgery. The sutures were removed seven to nine days after the intervention, and the patients were released for home care.

Results

Eighteen patients with infrarenal AAA were treated by endovascular stent grafting. Placing of TSG was successful in all patients (Fig. 1 a, b, c). In five (27.7%) patients, postinterventional CT performed 24 hours after the intervention revealed perigraft flow. According to the classification proposed by Franco *et al.*[14], three patients had small perigraft flow (60%) and two patients had modest perigraft flow (40%). In three (60%) patients, endoleak was associated with type B aneurysm, and in two (40%) patients with type C aneurysm. In four (80%) patients, endoleak was detected at the junction of the stent graft body sleeve and iliac extension, and in one (20%) patient in proximal neck in contact between the stent graft body and aortal wall. Systemic heparinization was stopped in all patients with endoleak. Control CT was done prior to release from the hospital. In four patients, endoleak ceased spontaneously (Fig. 2a, b), and in one patient it was considerably reduced. In the latter patient, the perigraft flow was not visible on control CT done a month after TSG placement. In patients with internal iliac artery and lumbar arterial embolization done prior to TSG placement, no endoleak was detected.

Postinterventional temperature, never in excess of 38.5 °C, was noticed in 15 (83.3%) patients. No special therapy was needed and the temperature spontaneously normalized during their stay at the hospital. Only one patient was subfebrile for 15 days. It was the patient with endoleak persisting on CT performed seven days after the intervention. The local finding at access points was good, and control CT showed regular position of TSG with no signs of any surrounding reaction.

The first four patients were placed in Intensive Care during the first postinterventional day. The mean resi-

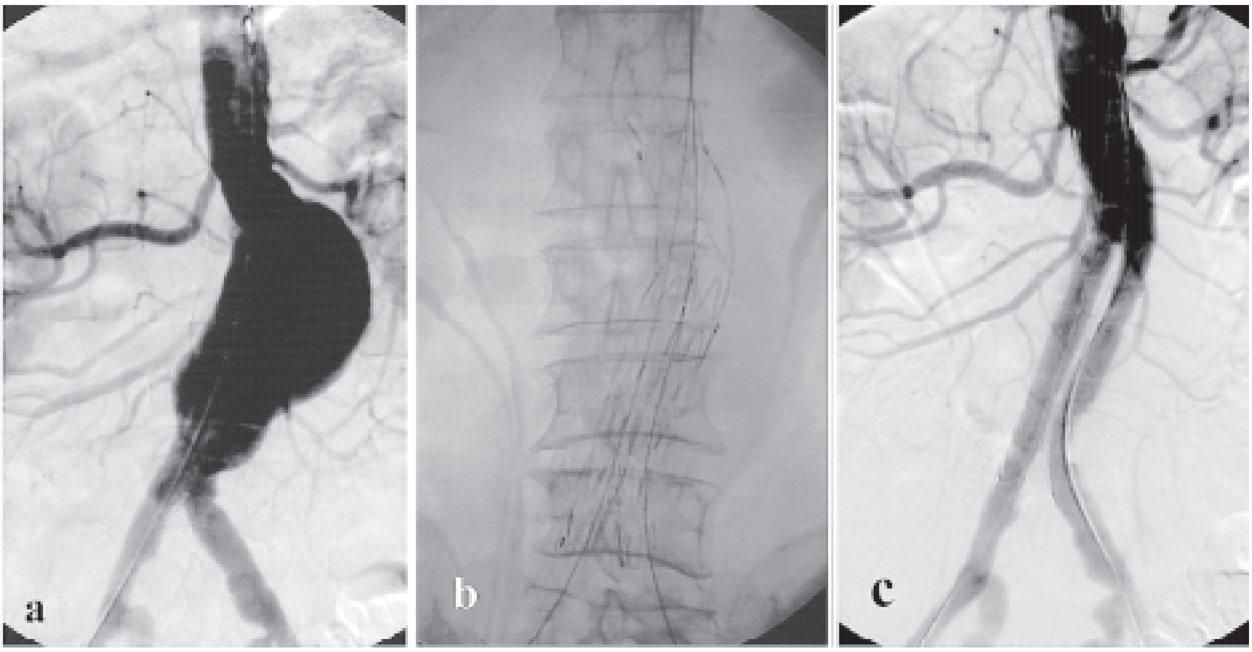

*Fig. 1. AAA, maximum diameter 74 mm, 71-year-old male: **a)** preinterventional angiography: infrarenal AAA with proximal neck 15 mm long and prominent angulation; **b)** bifurcated bare spring TSG placed; **c)** postinterventional angiography: aneurysm excluded from circulation. No signs of perigraft flow.*

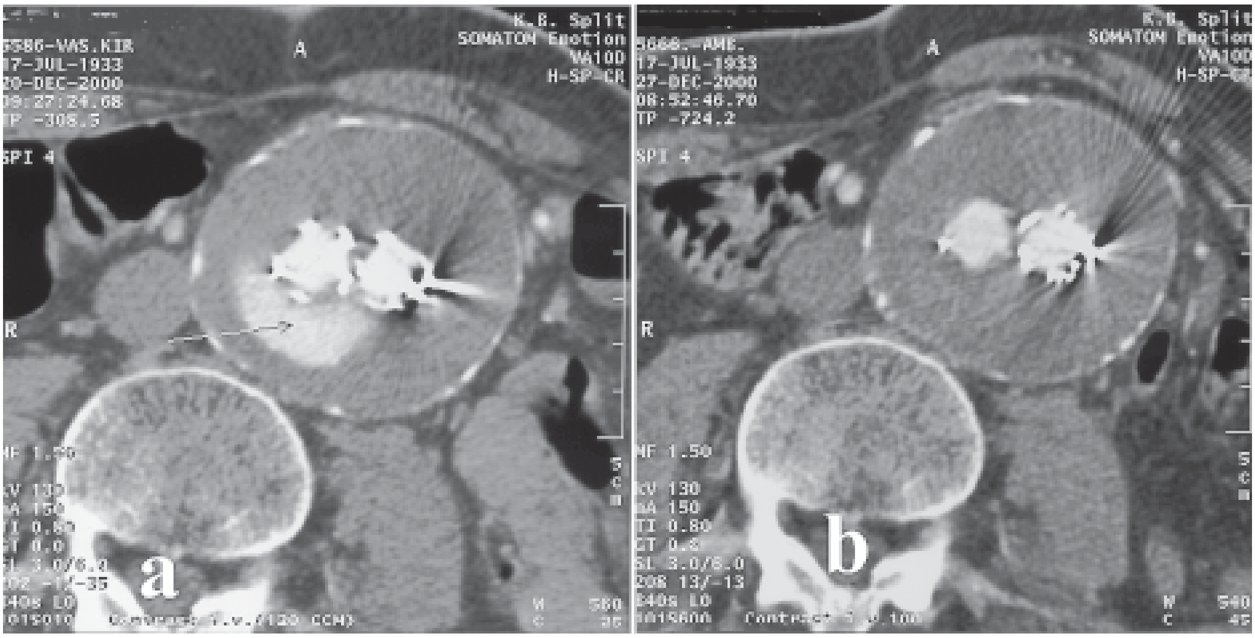

*Fig. 2. **a)** Postinterventional contrast enhanced CT in a patient with AAA 24 hours after TSG placement: visible endoleak at the junction of the stent-graft body sleeve and opposite iliac extension. Contrast colors <25% of the cross-section surface (arrow), which is an indication of small perigraft flow; **b)** control contrast enhanced CT done after seven days. No signs of endoleak.*

dence time was 21 hours. None of the patients required any additional therapy, so we believe that their stay in Intensive Care was not necessary.

Sutures at the sites of inguinal incisions were removed on the seventh to ninth postinterventional day, and the patients were released home. The mean hospitalization time was 9.1 (7-14) days.

The mean follow-up time was 11 (3-25) months. During the follow-up period, no TSG migration or late endoleaks were noticed. Maximal AAA diameter ranged between 5.5 and 10.4 cm. No increase in the aneurysmal sac was noticed in any patient during the follow-up. As expected, comparison of preinterventional and immediate postinterventional measurements showed no change in AAA diameter. However, subsequent control evaluations obtained between the third and twelfth postinterventional month showed a considerable AAA diameter reduction. Only one patient showed no reduction in the aneurysmal sac diameter. It should be noted that this patient did not belong to the group of patients with early endoleak. The mean aneurysmal sac reduction was 7.3 (0-28) mm (Fig. 3 a, b).

On control scans of the patients in whom the bare spring TSG wires were placed across the renal artery origin, no renal stenosis was noticed, and the kidney size remained unchanged.

Discussion

Earlier trials and numerous clinical studies point to the success of AAA treatment with endovascular stent grafting[5-16]. In the literature, treatment success of as much as 90%-96% of patients is quoted[17]. In a series of 121 patients, using different types of endoprosthesis, May *et al.*[9] achieved a primary success rate of 88%. It was confirmed by the studies of Blum *et al.*[13] in a series of 154 patients, with successfully placed bifurcated stent graft in 87% of patients. In this series, surgical conversion was done in three patients only, whereas serious complications including one death occurred in 2%, and minor complications in 8% of patients. Ivancev *et al.*[18], and Moore *et al.*[19] report on similar results. We report on our own results with TSG use in endovascular treatment of AAA. Our series included 18 patients, all with successfully placed bifurcated TSG.

The proximal end of TSG is designed in three shapes. In the bare spring design, 15 mm of the proximal end of the prosthesis body, which equals the length of a segmental stent, is not covered with Dacron. The beginning of the covered part is marked with platinum markers. To prevent curling of the graft material, the upper edge of Dacron is fixed with an additional wire loop. This TSG type is also known as "free flow" because it enables unobstructed flow

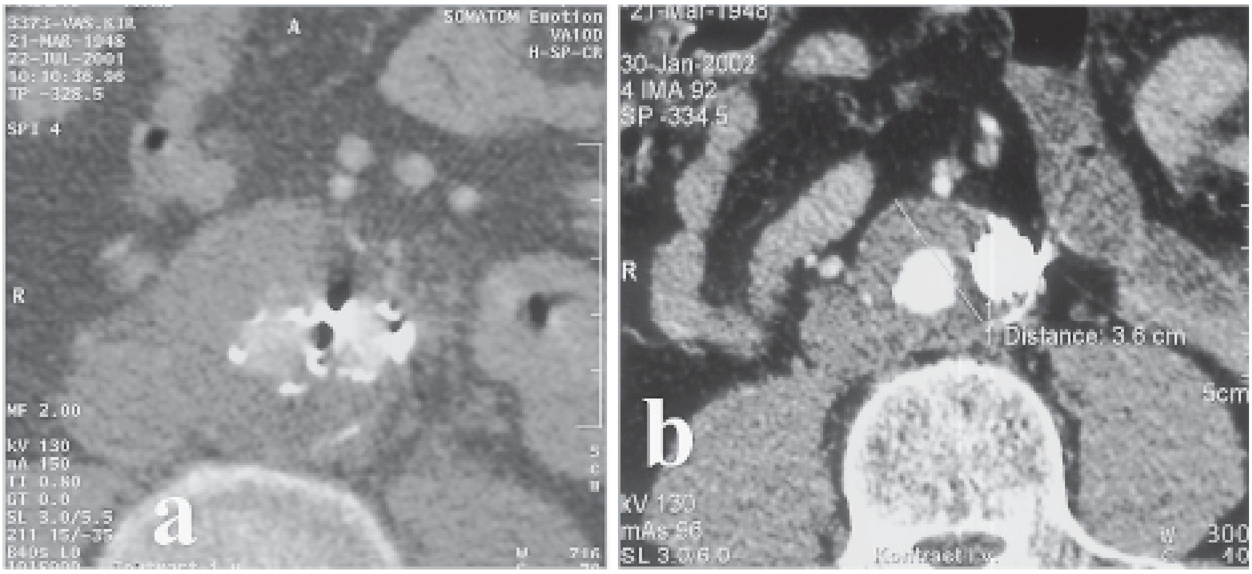

*Fig. 3. A 54-year-old male with infrarenal aneurysm, maximum diameter 64 mm: **a)** postinterventional contrast enhanced CT done 24 hours after bifurcated TSG placement; no change in aneurysm diameter; **b)** control contrast enhanced CT done six months after TSG placement. A significant reduction in the aneurysm sac diameter visible.*

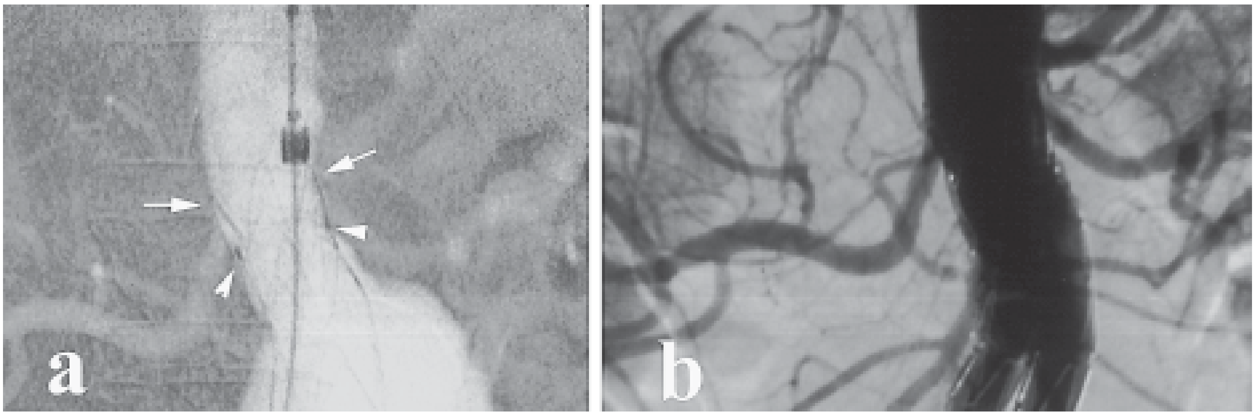

*Fig 4. a) **Deployment of bare spring TSG body with road map control. Wires of bare proximal part of the stent-graft across the renal artery origin (arrows). Platinum marker at the beginning of Dacron cover placed downstream the renal artery origin (arrow top); b) postinterventional angiography: aneurysm excluded from circulation. Flow through renal arteries not compromised.***

through the lateral wall of the proximal part of the stent graft. In experiments with animals, Whitbread *et al.*[20] placed Wallstent graft across the renal artery origin and no change in the renal flow was noticed in any animal. Contrary to these findings, Sapoval *et al.*[21] describe stenoses or occlusions of the internal iliac artery in as many as 41% of patients whose origins were crossed over with Wallstent. In the open web design, 15 mm of the proximal end of the TSG body are covered with Dacron in a zigzag technique, so that part of the stent-graft resembles a crown. The third design is the one with the proximal end of TSG completely covered with Dacron. The advantage of the bare spring design is that it can be used in an aneurysm with short proximal neck. In such patients, the Nitinol bare springs of the stent-graft can be placed across the renal artery origin without causing any obstruction to the blood flow. The other two designs ensure better adhesion of endoprosthesis to the aortal wall, but they are not to be placed across the renal artery origins, so they can only be used in patients with proximal neck longer than 15 mm. Armon *et al.*[22] believe that, because of the short AAA proximal neck, the open web design of TSG can only be used in a smaller number of patients. In patients with short aneurysm neck, the proximal part of TSG must be anchored above the renal artery origin, thus they are only suitable for use of the bare spring design. In our patients, we used only the bare spring TSG. In five (27.7%) patients, its bare proximal end passed across the renal artery origin (Fig. 4 a, b). In patients with only one kidney, or those with intensive atherosclerotic changes of renal arteries, TSG was always deployed downstream the renal artery origin site.

Endoluminal placement of stent-graft was performed by a multidisciplinary team including an interventional radiologist, a vascular surgeon and an anesthesiologist. There is a disagreement between different authors on where the intervention should be performed. Some authors prefer operating rooms (OR) because of the sterile conditions, while others perform the interventions in semisterile angiosurgery theaters because of much better fluoroscopic images and better quality of road mapping. In our hospital, the OR and angiosurgery theater are located on the same floor, so endovascular stent-grafting was performed in the angiosurgery theater. The patient was washed and prepared for the intervention as if it were a major surgery. TSG was as a rule placed under epidural anesthesia. General anesthesia was used in only one patient with extensive degenerative changes of lumbar vertebrae.

Franco *et al.*[14] report on the endoleak incidence on initial CT in 32% of patients. The importance of perigraft flow after endovascular stent grafting has not yet been determined. Matsumura *et al.*[23] indicate that permanent endoleak can cause an increase in aneurysm diameter and intra-aneurysm pressure. For this reason, Rozenblit et al.[24] underscore the value of arterial spiral CT in detecting and follow-up of endoleak. Franco *et al.*[14] write about a decrease in AAA diameter in six out of seven patients with persistent endoleak, and increase in aneurysm diameter in the patients in whom endoleak was not confirmed by CT. The spontaneous disappearance of endoleak is an indication that patients with initially confirmed endoleak are not necessarily candidates for surgery or interventional radiology. Franco *et al.*[14] find that any endoleak not larger than half of the AAA circumference can heal spontaneously. Moore and Rutherford[19] report on spontaneous cease of endoleak in 53% of patients from their series. Type I endoleak, which is also the most frequent perigraft flow in postinterventional CT, is a consequence of incomplete exclusion of the aneurysmal sac from the circulation and can occur at different locations[14]. The endoleak from the proximal part of the stent-graft could be caused by distal migration of the stent-graft, which is most frequently a consequence of short or wide proximal neck of AAA. A distal endoleak occurs when the iliac extension size is incorrectly selected or when the graft is short. Dorffner *et al.*[17] report that even microscopic sutures on the stent-graft coating and incomplete adhesion of the stent-graft to the blood vessel wall could also cause endoleaks. In all our patients, TSG placement was successful. Postinterventional CT showed the presence of endoleak in 27.7% of patients, and it spontaneously ceased in all of them. In four out of five patients, the endoleak occurred at the junction of the stent-graft body sleeve and iliac extension for contralateral iliac artery, and in one patient at the contact between the wall of the proximal neck of AAA and the stent-graft body. It should be noted that all patients underwent systemic heparinization. Postinterventional CT that detected endoleak was performed only 24 hours after TSG placement. Therefore, there are two possible causes of endoleaks in our patients. Firstly, 24 hours might be too short a period for a material with memory, such as Nitinol from which the TSG wires are made, to adopt its final shape and establish the desired contact. This could be supported by the fact that the most frequent endoleak location was the junction between the stent-graft body and iliac extension. The endoleak can also be caused by systemic heparinization. We stopped systemic heparinization in all patients with endoleak. This theory is supported by the fact that control CT performed seven days after TSG placement did not show endoleak in four patients, while in the fifth patient it considerably subsided. Control CT obtained in the fifth patient one month after the intervention indicated no presence of endoleak.

Some studies report on late endoleak as a consequence of caudal migration of the stent-graft, disconnecting of the stent graft body from the contralateral iliac extension, and graft rupture[13,20]. Similar to Uflacker *et al.10* and Hausegger *et al.*[12], we observed no TSG migrations. Hausegger *et al.*[12] find this to be attributable to the stent-graft construction. Longitudinally placed Nitinol wires support the entire construction and prevent knicking and longitudinal shrinking that could be caused by telescopic retraction of the stent-graft segment. Additionally, the iliac extensions are well fixed in iliac arteries and act as support poles.

Another frequently mentioned reason for late endoleak is disconnecting of the stent-graft parts. However, disconnecting is highly improbable in TSG. When TSG elements are correctly placed and well adhere to each other, they cannot be separated without use of intensive force.

Endoleak can be caused by flow through arteries originating from the vessels changed by aneurysm. These are most often lumbar arteries, lower mesenteric artery, and internal iliac artery[25,26]. Such endoleak often causes an increase in the intra-aneurysmal pressure, so its early detection is particularly important[14]. This endoleak type was not found in our patients. However, preinterventional examinations detected arteries that could cause endoleak in two patients. In one patient, two wide lumbar arteries originated from the AAA that sent collaterals to iliac arteries. Both arteries were detected on angiography and arterial CT. To prevent endoleak, both arteries were embolized with microcoils. In the other patient, the right hypogastric artery originated from aneurysmatic expansion of the common iliac artery. In this patient, to bypass AAA and right common iliac artery, an additional iliac extension had to include the beginning of the right external iliac artery. In order to prevent backflow and endoleak, we decided to perform preinterventional embolization. Metal coils were used to occlude the hypogastric artery origin. Cynamon *et al.*[27] report on 41% of complications after hypogastric artery embolization. We believe that embolization of one hypogastric artery at its origin does not cause complications because such high embolization prevents filling of aneurysm, and does not prevent backflow into the hypogastric artery branches located distally from the embolization site. After embolization, our patient showed neither signs of claudication nor ischemia of pelvic organs. Control examinations of both patients that underwent preinterventional embolization revealed no endoleak.

Mialhe *et al.*[28] noticed that in 20% of patients, a spontaneously closed perigraft flow could reopen at 12-14 months. Similar observations were recorded by Parodi[29], who reports on late endoleak in 10% of spontaneously healed perigraft flows. Our patients with endoleak were followed up for a mean of 10.9 months (3-18) months, and no secondary endoleaks were detected.

Small endoleaks are easily overseen on arterial CT scans. For this reason, Golzarian *et al.*[30] recommend that biphasic spiral CT be used for endoleak detection. This method detects by 11% more endoleaks than arterial CT alone. The protocol of such examination includes native scanning, which is very useful for differentiation of small endoleak from calcifications in aortal wall. We used the scanning protocol of Golzarian et al.3[0] in all our patients.

Parodi *et al.*[5] were the first to present their observations on reduced AAA diameter after endovascular stent grafting. The stent-graft occludes lateral aortal branches, and neointimal hyperplasia manifests on its surface. The neointima growing along the stent-graft, the same as adventitial reaction and mechanical effect of the stent-graft, prevents aneurysm expansion[32]. Reduction in the aneurysmal sac diameter is expected three months after the stent-graft placement. Blum *et al.*[13] noticed an insignificant reduction in the aneurysmal sac diameter during the first 12 months, and a significant reduction 24 months after the procedure. The filling of the aneurysm through lumbar arteries or lower mesenteric artery has a contrary effect that prevents reduction of aneurysm. Matsumura *et al.*[23] noticed that a persisting endoleak may cause an increase in the aneurysm diameter. Increase in AAA diameter was not recorded in any of our patients. In only one patient, the aneurysm diameter remained unchanged 12 months after TSG placement. In all other patients, the aneurysm diameter was reduced. The most significant reduction was noticed between the third and twelfth month. The mean reduction was 7.3 (0-28) mm. Comparison of the results of AAA diameter reduction in patients in whom endoleak was detected on the first postinterventional CT and those without endoleak showed no significant difference in aneurysmal sac diameter between them. On the contrary, the most significant reduction in diameter (28 mm) was noticed in a patient with early perigraft flow.

Conclusion

The results obtained in our series of patients show that TSG placing is a successful method of AAA treatment. The results obtained are consistent with those reported in the literature. Although endoleak was a common event, in most cases it ceased spontaneously. TSG resulted in reduction of AAA diameter in a large percentage of patients. The aneurysm diameter was reduced in patients with complete primary success as well as in those with primary endoleak that spontaneously ceased during the follow-up. Therefore, it is concluded that endoluminal placement of TSG is a safe and efficient method of AAA treatment. We believe that in patients with accurately determined indication for the procedure, it is a justified alternative to surgery.

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Sažetak

NAŠE ISKUSTVO U ENDOVASKULARNOM LIJEČENJU ANEURIZME ABDOMINALNE AORTE TALENT STENT-GRAFTOM

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Cilj rada bio je procijeniti sigurnost i učinkovitost endovaskularnog liječenja aneurizme abdominalne aorte (AAA) talent stent-graftom (TSG). Od listopada 1999. do veljače 2002. godine 18 bolesnika (17 muškaraca i jedna žena) životne dobi između 65 i 77 godina s AAA promjera >5 cm liječeno je postavljanjem bifurkacijskog TSG. U svih bolesnika poslijeintervencijski CT rađen je 24 sata nakon intervencije. Sedmog do devetog poslijeintervencijskog dana skinuti su šavi i bolesnici su otpušteni na kućnu njegu. Redoviti kontrolni pregledi provedeni se spiralnim CT-om, i to 1., 3., 6., 9., 12. i 24. mjeseca nakon postavljanja TSG. Srednje vrijeme praćenja iznosilo je 11 mjeseci. U svih bolesnika postignut je primarni uspjeh, a na kontrolnim pregledima TSG je bio prohodan. U dvoje (11%) bolesnika prije postavljanja TSG napravljene su prijeintervencijske embolizacije. U petoro (27%) bolesnika na poslijeintervencijskom CT-u bilo je vidljivo manje endopropuštanje. U tih bolesnika ukinuta je sistemska heparinizacija i na spiralnom CT-u ponovljenom nakon sedam dana u četvoro od pet (80%) bolesnika endopropuštanja više nije bilo. U jednog je bolesnika manje endopropuštanje spontano prestalo mjesec dana nakon postavljanja TSG. Srednje smanjenje promjera aneurizmatske vreće iznosilo je 7,3 mm (0-28 mm) na godinu. Postavljanje TSG predstavlja sigurnu i učinkovitu metodu liječenja AAA. U bolesnika s pravilno postavljenom indikacijom danas se opravdano smatra alternativnom metodom kirurškom liječenju.