TÜBİTAK

Original Article

Turk J Med Sci
2012; 42 (5): 823-829
© TÜBİTAK
E-mail: medsci@tubitak.gov.tr
doi:10.3906/sag-1102-1389

Endovascular treatment of abdominal aortic aneurysms with Endologix® stent graft: single-site experiences and short-term follow-up outcomes

Mustafa KAYAN[1], Turhan YAVUZ[2], Mustafa ETLİ[2], Şeyma BENZİN[1], Seda İBİŞOĞLU[1], Esma Dilek ÜSTÜN[1], Mert KÖROĞLU[1], Ergün CEYLAN[1], Ulaş SAĞLAM[2]

Aim: The aim of this study was to investigate the short-term results of endovascular repair of abdominal aortic aneurysms with the Endologix IntuiTrak Powerlink XL® (Endologix) stent graft and to share our clinical experiences in our center.

Materials and methods: Endovascular stent graft treatment was applied in 16 cases with infrarenal abdominal aortic aneurysm (13 men and 3 women; mean age: 70.2 years) in 2009 and 2010. Before treatment, all of the patients were examined with 128-slice computed tomography (CT) angiography for the assessment of abdominal aortic aneurysms. The Endologix stent graft (bifurcated system) was used for all of the patients.

Results: The aneurysms of the 16 patients were located at the infrarenal level. They were treated with aortobiiliac stent grafts. The technical success rate was 100%. No mortality, major complications, or need of urgent conversion to open surgery occurred in any of the patients. Only 1 patient died due to acute coronary syndrome in the early follow-up period and 1 patient was lost in the follow-up period. There were no aneurysm ruptures, graft migrations, or graft fractures in any of the patients.

Conclusion: Endovascular treatment of infrarenal aortic aneurysms with the Endologix stent graft has a high degree of technical success and is a useful alternative to surgery.

Key words: Infrarenal abdominal aortic aneurysm, endovascular aortic repair, computed tomography

Introduction

Endovascular aortic aneurysm repair (EVAR) was first defined in 1989, and wide use of this method has recently begun (1). Abdominal aortic aneurysms (AAAs) are the most commonly observed among all aneurysms, especially in patients over the age of 55 years. A substantial part of AAAs occurs distal to the renal arteries. Reasons for increase in the incidence of AAAs may include prolonged lifetime and important advances in diagnostic methods (2,3). When endovascular treatment is compared with surgery, a remarkable decrease is found in complication and mortality rates. The rate of perioperative mortality is 4.6% following open surgery, whereas it is 1.2%-1.6% following EVAR (3-6). Unless they rupture, many AAAs may be asymptomatic, but abdominal pain, back pain, and pulsatile abdominal mass findings can be present in symptomatic AAAs. The risk of rupture is related to aneurysm size. It increases significantly with sizes over 5.5 cm. Elective repair is required due to risk of rupture. The most important disadvantage of EVAR is the inadequacy of late period data (7-9). In our study, we aimed to review 16 infrarenal AAAs treated with a new device that is known as the bifurcated system. We also aimed to review our clinical experiences as well as short-term follow-up outcomes.

Received: 18.02.2011 – Accepted: 28.10.2011

[1] Department of Radiology, Faculty of Medicine, Süleyman Demirel University, Isparta - TURKEY
[2] Department of Cardiovascular Surgery, Faculty of Medicine, Süleyman Demirel University, Isparta - TURKEY
Correspondence: *Mustafa KAYAN, Department of Radiology, Faculty of Medicine, Süleyman Demirel University, Isparta - TURKEY*
E-mail: drkayan32@hotmail.com

Materials and methods

Endovascular abdominal stent graft treatment was applied in a total of 16 cases of nonruptured infrarenal abdominal aortic aneurysms (13 men and 3 women; mean age: 70.2 years, range: 58-87 years) in 2009 and 2010. Patients with open aneurysms, inflammatory aneurysms and suprarenal extension, presence of underlying connective tissue disease, underlying cancer or previous stroke, ineligibility for follow-up, and serious distal arterial circulation problems were not included. Symptomatic or asymptomatic infrarenal AAA cases with the following criteria were included: the widest diameter was over 5 cm, the femoral or iliac arteries were suitable for endovascular intervention, there was presence of recoverable peripheral arterial disease, the nonaneurysmatic diameter of the proximal aneurysm neck was between 18 and 26 mm, and the aneurysm neck length was adequate for attachment of the graft at the most inferior level of the renal ostia (10,11). Consent was obtained from all of the patients before the procedure. The procedure was performed under the supervision of a team of specialists comprising a radiologist, cardiovascular surgeon, and anesthesiologist in an angiography laboratory with a fully equipped intensive care unit after necessary sterilization and a sterile operating environment were ensured. All of the patients were examined with a 128-slice computed tomography (CT) angiography device in terms of eligibility for EVAR. Mean blood loss was estimated at 200 cc. During the procedures, a mean of 180 cc of contrast medium was used. Using 3-dimensional CT angiography images, the diameters of the infrarenal abdominal aorta and iliac and femoral arteries, the presence of intraluminal thrombus, wall calcification, intraluminal flow, length of the aneurysm in which the stent would be placed, and type and size of the graft to be used were examined (Table 1). Moreover, the angle between the aneurysm and the iliac artery was examined in detail.

Table 1. Before the procedure, infrarenal level measurements by multidetector CT. **P:** patients, **L1:** infrarenal aneurysm neck length, **L2:** infrarenal aneurysm neck diameter of transfers, **L3:** infrarenal aneurysm diameter of the widest transfers, **L4:** open lumen diameter of the widest transfers of infrarenal aneurysms, **L5:** distance of renal artery-iliac bifurcation, **A°:** angulation of the aneurysm neck, **B°:** angulation of the iliac arteries, **C:** iliac artery diameters.

P	L1 (cm)	L2 (cm)	A°	L3 (cm)	L4 (cm)	L5 (cm)	B°		C (cm)	
							Right	Left	Right	Left
1	2.5	2.5	126	6.5	4.3	15.0	124	130	0.6	1.2
2	3.0	2.3	147	5.9	4.2	14.2	120	128	0.7	0.9
3	2.0	1.8	99	8.0	5.9	10.6	163	147	1.4	1.7
4	5.1	2.2	98	5.7	5.7	11.5	145	178	1.3	1.1
5	1.0	1.8	116	6.8	5.7	11.3	160	137	0.7	0.9
6	2.8	2.1	163	5.4	4.0	10.6	133	153	0.8	0.7
7	2.3	1.9	138	5.3	4.3	11.3	130	145	1.2	0.9
8	2.4	2.4	142	5.4	5.4	12.7	136	142	1.1	1.3
9	1.8	2.3	155	6.2	5.2	11.2	144	139	1.4	1.3
10	1.6	2.1	128	5.2	3.4	10.5	134	138	1.5	1.3
11	2.2	2.1	104	5.3	2.8	12.4	121	123	1.8	1.7
12	2.3	2.1	110	6.4	3.2	13.7	140	120	1.5	1.2
13	2.4	2.2	120	5.1	3.7	11.6	115	140	2.0	1.5
14	2.5	2.4	102	7.2	5.6	14.5	120	114	1.8	1.5
15	2.7	2.2	120	6.0	2.8	15.0	112	116	1.9	1.1
16	2.5	2.1	119	6.7	2.6	14.0	118	125	2.1	1.5

Procedure

Patients were evaluated hematologically and systemically. All of the patients were monitored and the procedures were performed by administering local anesthesia and sedation. Cefazolin (1 g) was used prophylactically before the procedure. An injection of heparin (1 cc = 5000 units) was administered during the procedure and it was repeated depending on the duration of the procedure if required. In all of the cases, the Endologix IntuiTrak Powerlink XL® (Endologix) stent graft (bifurcated system), which is a new device in this type of treatment, was used. The right iliac artery was surgically prepared in order to advance a 21F graft, and a 12.5F peel away introducer (vascular sheath) was placed. In order to place the leg of the stent graft on the contralateral side and to obtain control angiography, a 9F vascular sheath of 11-12 cm in length was placed. When the size of the stent graft was selected, sizes of 5 mm more than the diameter of the aortic neck as measured in CT were preferred. Values measured by angiography, performed by imaging the vascular sheath placed into the left iliac artery and by CT angiography, were confirmed before the procedure. Later, a passage was formed between the bilateral iliac arteries with a guide wire, using a snare catheter. A double-lumen catheter was placed over the guide wire. The rigid guide wire advanced from the right iliac artery and was fixed to a point in close proximity to the aortic arch. Physiological serum was prepared by priming from all spaces of the graft taken to the table. The graft was loaded onto the rigid guide wire in the right iliac artery, and the contralateral leg was released when the bifurcation level was reached. The graft was seated on the bifurcation by withdrawing towards the iliac arteries and, thus, first the main body and later the contralateral and ipsilateral legs were opened. An aortic extension on the main body was used in all of the patients. Meanwhile, after performing the aortography, localization of the renal arteries was determined and marked. Later, some technical adjustments were made: a 2-cm uncovered section of the graft at 2 cm above the renal arteries was slowly withdrawn under fluoroscopy and fixed at the renal level. In the repeated aortography, dilatation was provided with an aortic occlusion balloon under necessary conditions. After the procedure, patients were monitored in the intensive care unit, vital findings were followed closely, and, later, the patients were transferred to the cardiovascular surgery service for follow-up. Patients were discharged following a 2-day hospitalization period. Patients with no postprocedure complaints were instructed to attend a check-up visit with Doppler ultrasonography after 3 months. Graft migration, intraluminal flow, and endoleakage were evaluated with contrasted thoracic and abdominal multislice CT (MSCT) performed after 6 months.

Results

The risk factors associated with the patients are given in Table 2. Of the patients with pretreatment American Society of Anesthesiologists (ASA) scores of III and IV, 4 were in the high-risk group. The common symptoms were abdominal pain and reflective back pain. Not included was one patient who was ineligible for follow-up due to serious distal arterial circulation problems. There was a complaint of claudication occurring when walking a distance of 100-150 m in one case, but there were no secondary skin findings associated with an arterial disease. In all of the cases, there was at least one additional pathology related to infrarenal aortic aneurysms. In all of the cases, femoral arteries were selected as the insertion site and an aortobiiliac stent graft was placed. When necessary, the system was extended to the level of the renal artery by placing an aortic extension on the main body. Early patient follow-up outcomes were evaluated at 1, 3, and 6 months.

Table 2. The patients' risk factors and accompanying diseases.

Parameters	Number	Percent (%)
Age > 70 years	8	50
Hypertension	7	44
Cardiac disorder	6	38
Peripheral arterial occlusive disorder	4	25
Smoking	9	56
Type II diabetes mellitus	1	6
Renal function impairment	1	6
Symptomatically	16	100
ASA class I	6	38
ASA class II	6	38
ASA class III-IV	4	25

A primary leak occurred in 1 patient during the procedure, which was observed at the 1-, 3-, and 6-month follow-up evaluations. It was completely thrombosed and had completely disappeared. In one case, the localized stenosis found in the external iliac artery was treated using the balloon angioplasty method in order to facilitate interventions. We were informed that a female patient in the high-risk group (ASA IV) died due to acute coronary syndrome. One patient was lost in the follow-up period. Rupture, graft migration, and stent breakage were not found in any of the patients (Figure 1). In all of the patients, preoperative aneurysm diameters and diameter measurements were evaluated at month 6 (Table 3). MSCT abdominal angiography was performed in month 6 following the procedure in all of the cases under follow-up. If the open lumen diameter of the aorta was reduced to below 3 cm, the outcome was regarded as successful (Figure 2). Migration, recurrence of the aneurysm, and occlusion were not found.

Discussion

Most aortic aneurysms are nonspecific with no particular reason, whereas there is an underlying pathology, such as congenital connective tissue diseases (Marfan syndrome, Ehlers-Danlos syndrome, etc.), vascular malformations, infections, noninfectious inflammations, vasculitis (Takayasu disease, temporal arteritis, etc.), in less than 5% of cases (12,13). None of our patients were connected to specific pathologies as mentioned above, probably for many reasons. AAAs are the most commonly seen aneurysms. It is believed that 1 out of every 200 deaths in the world is related to AAAs. It is most

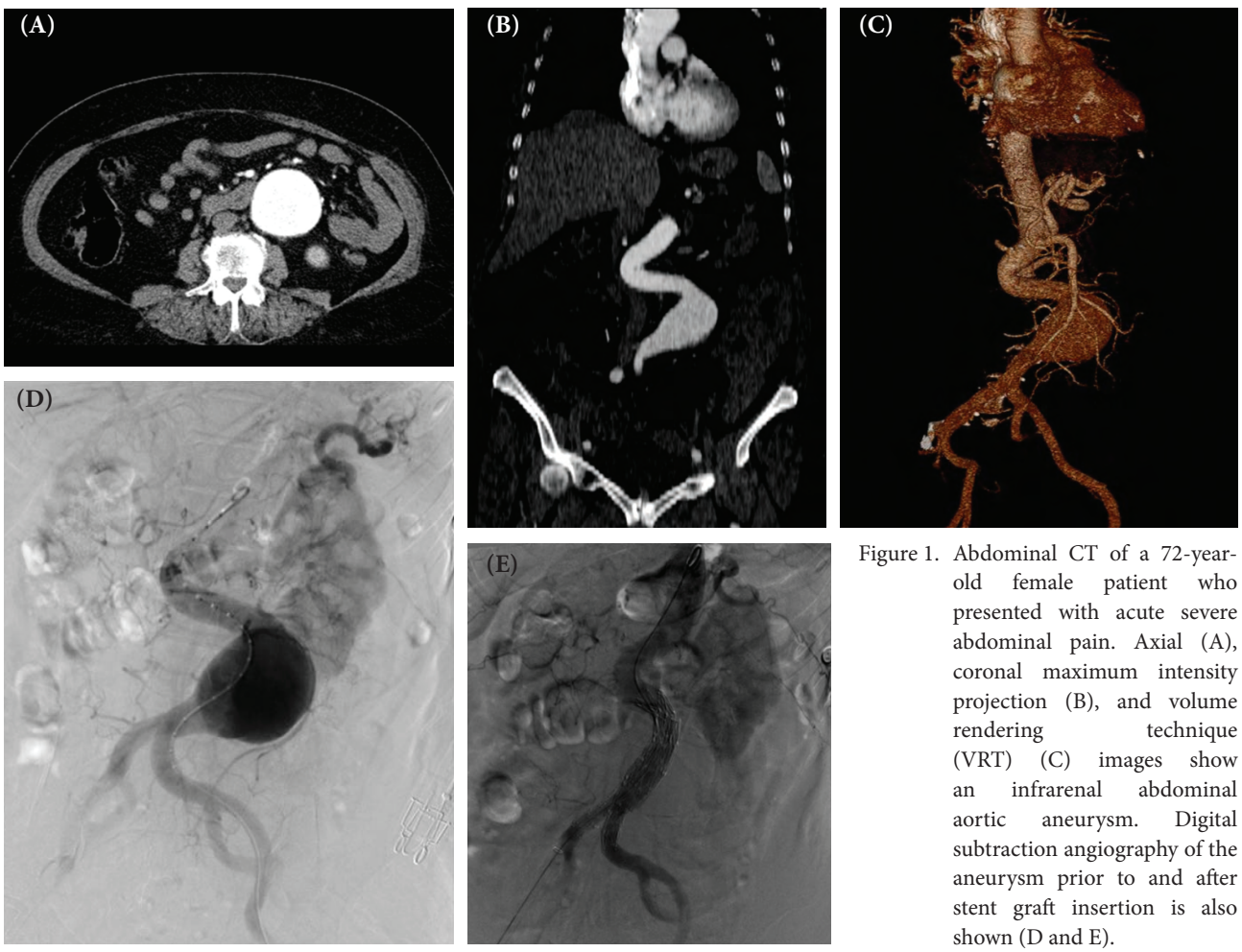

Figure 1. Abdominal CT of a 72-year-old female patient who presented with acute severe abdominal pain. Axial (A), coronal maximum intensity projection (B), and volume rendering technique (VRT) (C) images show an infrarenal abdominal aortic aneurysm. Digital subtraction angiography of the aneurysm prior to and after stent graft insertion is also shown (D and E).

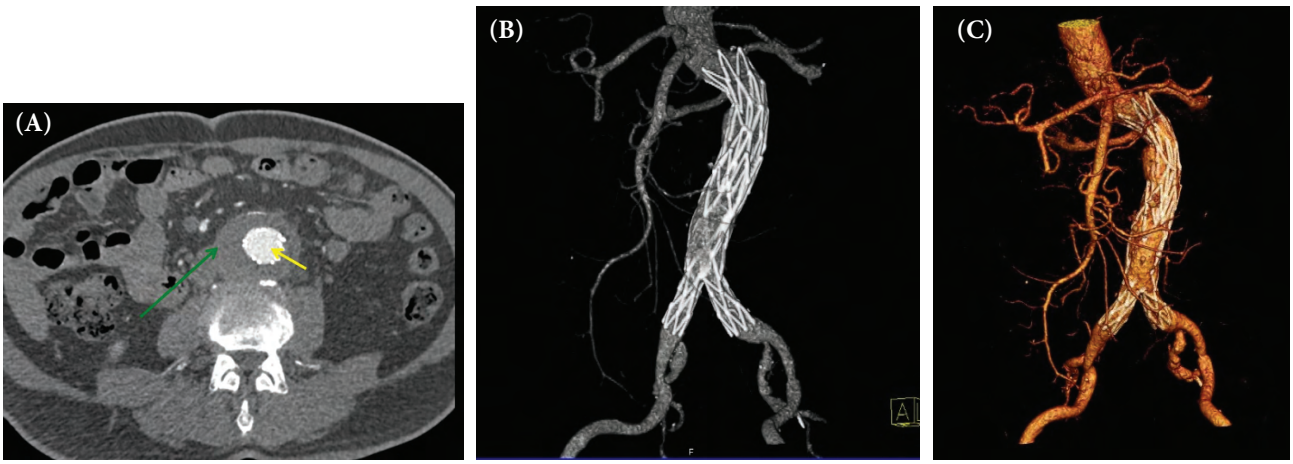

Figure 2. CT images of the same patient 6 months postoperatively: contrast-filled lumen (yellow arrow) and the thrombosed aneurysm (green arrow) on an axial CT image (A); bifurcated stent graft VRT image (B and C).

Table 3. Comparison of aortic diameters preoperatively and at month 6. **L3:** Infrarenal aneurysm diameter of the widest transfers, **L4:** open lumen diameter of the widest transfers of infrarenal aneurysms, **L6:** infrarenal aneurysm diameter of the widest transfers, **L7:** open lumen diameter of the widest transfers of infrarenal aneurysms, **A:** decrease in the widest diameter, **B:** decrease in the open lumen diameter of the widest transfers of infrarenal aneurysms.

Patients	Preoperative		Postoperative			
	L3 (cm)	**L4** (cm)	**L6** (cm)	**L7** (cm)	**A** (cm and %)	**B** (cm and %)
1	6.5	4.3	2.6	2.5	3.9 (60%)	1.8 (42%)
2	5.9	4.2	2.8	2.8	3.1 (53%)	1.4 (33%)
3	8.0	5.9	5.0	2.8	3.0 (38%)	3.1 (53%)
4	5.7	5.7	2.6	2.6	3.1 (54%)	3.1 (54%)
5	6.8	5.7	2.1	2.1	4.7 (69%)	3.6 (63%)
6	5.4	4.0	3.8	2.7	1.6 (30%)	1.3 (33%)
7	5.3	4.3	2.2	2.2	3.1 (59%)	2.1 (49%)
8	5.4	5.4	3.8	2.9	1.6 (30%)	2.5 (46%)
9	6.2	5.2	3.8	2.8	2.4 (39%)	2.4 (46%)
10	5.2	3.4	3.5	2.6	1.7 (33%)	0.8 (24%)
11	4.8	2.8	3.2	2.4	1.6 (33%)	0.4 (14%)
12	6.4	3.2	4.6	2.7	1.8 (28%)	0.5 (16%)
13	5.1	3.7	4.9	2.4	0.2 (4%)	1.3 (35%)
14	7.2	5.6	5.3	2.6	1.9 (26%)	3.0 (54%)
15	6.0	3.5	-	-	-	-
16	6.7	2.6	-	-	-	-

commonly observed at the infrarenal level (95%) because the elastin layer is weaker at this level (14).

EVAR is preferred over surgery for patients requiring treatment. This method is applied to approximately 50,000 subjects each year worldwide (15). The Endologix device used in this study is different from those previously used. In this system, the contralateral leg is on the main body and the procedure is performed with unilateral arteriotomy. Although bilateral arteriotomy is routinely used

in EVAR, unilateral arteriotomy is sufficient for endovascular treatment with bifurcated systems. Therefore, unilateral arteriotomy is a superior feature of this device. The system attaches to the healthy neck, beneath the iliac bifurcation and renal arteries, and migration is prevented by a double-sided safety mechanism. As the system is supported by iliac bifurcation, it may be used in aneurysms with a healthy neck of less than 1.5 cm. The 21F delivery system placed into the arteriotomy site can also be used as a hemostatic valve. The main body has an infrarenal design and this device prevents any lateral or downward extension. In 80% of Endologix cases, an aortic extension is required. In our study, the Endologix bifurcated system was used in all of the patients and an aortic extension was placed in all of the patients, and graft migration was not observed at follow-up. In 1 patient, the length of the neck to which the aneurysm was attached measured 1 cm in diameter. In a study group of 7 patients with advanced age and comorbidities, Rahman et al. (16) reported that aortic stent graft treatment was successfully performed instead of the surgical method in the treatment of infrarenal aneurysms in 6 patients and a thoracic aneurysm in 1 patient, using Medtronic Talent® (Medtronic Vascular, Santa Rosa, California, USA). A bilateral arteriotomy was performed in 6 patients with aortobiiliacs, for whom stent grafts were inserted. In our study, the EVAR method was performed instead of surgery by using the bifurcated system. Additionally, for all of the patients in our study, the stent graft was placed by unilateral arteriotomy. Similar to the present study, Tom et al. (17) used the bifurcated system in 7 patients, using a different device called the Prostar XL® system (Abbott Vascular, Abbott Park, Illinois, USA) with unilateral arteriotomy. Although the endovascular treatment method is used in some centers in Turkey, the bifurcated system is not widely used. Therefore, new studies are needed for technical optimization and long-term results with the Endologix stent graft.

The EVAR treatment method is performed all around the world under the cooperation of interventional radiologists, cardiovascular surgeons, and anesthesiologists. In the present study, all of the procedures took place in the interventional radiology unit and included the participation of the above-mentioned team. Conversion to open surgery may be performed during endovascular treatment or at a later period (18). The reason for the absence of conversion to surgery in our study may be the low number of patients and lack of long-term data.

The most commonly observed complication of endovascular treatment is leakage, the incidence of which varies between 10% and 50%. It is known that most primary leakages may be due to spontaneous thrombosis. If leakages do not result in thrombosis but persist, they are referred to as persistent leakages, and the approach in such cases depends on the type of leakage (16,19). In this study, primary leakage was found in one case, and it was observed that the leakage thrombosed and disappeared completely during follow-up.

Although EVAR is a method that is widely used, endovascular treatment with the Endologix stent graft (bifurcated system) is a new approach. Limitations of the present study were the low number of cases, the absence of long-term outcomes versus surgery, and the use of a new device. New studies that include no limitations are necessary.

In conclusion, the new bifurcated system (nonmigration system) has several advantages, such as having a very small insertion site at the femoral artery, low mortality and morbidity rates, a shorter hospitalization period, and lower blood loss and smaller transfusion requirements.

References

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991; 5: 491-9.
2. Samy AK, Whyte B, MacBain G. Abdominal aortic aneurysm in Scotland. Br J Surg 1994; 81: 1104-6.
3. Greenhalgh RM, Brown LC, Kwong GP, Powell JT, Thompson SG, EVAR trial participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet 2004; 364: 843-8.

4. Prinssen M, Verhoeven ELG, Buth J, Cuypers PWM, van Sambeek MRHM, Balm R et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med 2004; 351: 1607-18.

5. Mehta M, Taggert J, Darling RC 3rd, Chang BB, Kreienberg PB, Paty PSK et al. Establishing a protocol for endovascular treatment of ruptured abdominal aortic aneurysms: outcomes of a prospective analysis. J Vasc Surg 2006; 44: 1-8.

6. Sadat U, Boyle JR, Walsh SR, Tang T, Varty K, Hayes PD. Endovascular vs open repair of acute abdominal aortic aneurysms - a systematic review and meta-analysis. J Vasc Surg 2008; 48: 227-36.

7. Lederle FA, Wilson SE, Johnson GR, Reinke DB, Littooy FN, Acher CW et al. Immediate repair compared with surveillance of small abdominal aortic aneurysms. N Engl J Med 2002; 346: 1437-44.

8. Jordan WD, Alcocer F, Wirthlin DJ, Westfall AO, Whitley D. Abdominal aortic aneurysms in "high-risk" surgical patients. Comparison of open and endovascular repair. Ann Surg 2003; 237: 629-30.

9. Bley TA, Chase PJ, Reeder SB, François CJ, Shinki K, Tefera G et al. Endovascular abdominal aortic aneurysm repair: nonenhanced volumetric CT for follow-up. Radiology 2009; 253: 253-62.

10. Zarins CK, AneuRx Clinical Investigators. The US AneuRx Clinical Trial: 6-year clinical update 2002. J Vasc Surg 2003; 37: 904-8.

11. Du Toit DF, Saaiman JA, Carpenter JP, Geldenhuys KM. Endovascular aortic aneurysm repair by a multidisciplinary team: lessons learned and six-year clinical update. Cardiovasc J S Afr 2005; 16: 36-47.

12. Dereume JPE, Fereira J. The Corvita system. In: Hopkins B, Yusuf W, Whitaker S, Veith F, editors. Endovascular surgery for aortic aneurysms. London: WB Saunders; 1997. p.122-39.

13. Sanfelippo PM. Abdominal aortic aneurysm—2003: what we know, what we don't know—a review. Int J Angiol 2003; 12: 145-52.

14. Halloran BG, Davis VA, McManus BM, Lynch TG, Baxter BT. Localization of aortic disease is associated with intrinsic differences in aortic structure. J Surg Res 1995; 59: 17-22.

15. Stone DH, Brewster DC, Kwolek CJ, Lamuraglia GM, Conrad MF, Chung TK et al. Stent-graft versus open-surgical repair of the thoracic aorta: mid-term results. J Vasc Surg 2006; 44: 1188-97.

16. Rahman A, Çolak MC, Özdemir H, Özgüler M, Çil BE. Aortic aneurysms' treatment with endovascular stent-graft. Türk Göğüs Kalp Damar Cer Derg 2009; 17: 167-72 (in Turkish with English abstract).

17. Tom CW, Krajcer Z. Use of the IntuiTrak stent-graft delivery system for percutaneous abdominal aortic aneurysm exclusion: initial single-center experience. Tex Heart Inst J 2010; 37: 331-3.

18. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002; 35: 1048-60.

19. Golzarian J, Maes EB, Sun S. Endoleak: treatment options. Tech Vasc Interv Radiol 2005; 8: 41-9.