Short-Term Outcome of Endovascular Repair of Aortic Aneurysms with Stent Grafts: Initial Results of the First Consecutive Series of Endovascular Aortic Repair in Iran

Ali Mohammad Haji Zeinali MD,* Mehrab Marzban MD, Mohammad Reza Zafarghandi MD, Mahmood Shirzad MD, Shapoor Shirani MD, Mohamad Alidoosty MD, Mojtaba Salarifar MD, Ebrahim Nematipour MD, Hamidreza Poorhoseini MD, Ebrahim Kasaian MD, Davood Kazemi Saleh MD, Babak Haghighat MD, and Mansour Arafat MD

Abstract

Background- Endovascular aortic repair (EVAR), as a new and less invasive method for treatment of aortic aneurysms, has shown lower short term complications than routine open surgical repairs. In this report we present our results with the first consecutive series of this technique in our patients.

Methods- From Dec. 2006, we began a prospective case series of EVAR patients for the first time in Iran, and so far, 15 consecutive patients (1 female, 14 male) with the mean age of 66 years (range 36 to 89 years old) underwent endovascular aortic aneurysm repair (3 thoracic, 11 abdominal, 1 combined thoracic and abdominal) with Medtronic "Talent" or "Valiant" stent grafts. In-hospital and one month follow up results are reported as short-term outcome.

Results- All 12 abdominal aorta aneurysms (AAA) were infrarenal with an acceptable proximal neck. In eight patients, associated iliac aneurysms were seen. For 11 AAA patients, routine modular stent grafts were used and in one case, unilateral stent graft was implanted because of difficulty of controlateral stent graft implantation. Four thoracic aorta aneurysms (TAA) were repaired with Valiant stent grafts. One of them was a Marfan patient with recent Bentall surgery and two were post-surgery saccular aneurysms. In all 15 cases, stent graft implantation was done successfully. In five cases, mild type II endoleak was seen at the end of the procedure, which was no longer present on one month follow up. One patient had post- procedure cerebral stroke with delayed mortality. No other major complications were seen in 1 month follow up in the other 14 cases. Minor complications like vascular access hematoma, anemia and increased creatinine were controlled on hospital stay period in some cases. Control CT angiography in some patients revealed no endoleak or aneurysm enlargement and 6 and 12-month follow up assessment will be done for mid-term results.

Conclusion- Endovascular repair of aortic aneurysm is feasible and safe for suitable cases based on both clinical and radiologic findings. Good case selection, good device selection and suitable follow up are the keys for success of EVAR ***(Iranian Heart Journal 2008; 9 (1): 6-13).***

Key words: aortic aneurysm ■ endovascular repair■ stent-graft ■ EVA

From 1991 when Parodi et al. successfully treated an abdominal aortic aneurysm (AAA) with a stent graft for the first time,[1] endovascular repair of aneurysm (EVAR) has rapidly developed.

The incidence of AAA is 21 per 100,000 and

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Corresponding Author: Ali Mohammad Haji Zeinali, Assistant professor of interventional cardiology, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran, 1411713138.
Tel: +9821-88029620 Fax: +9821-88029637 Email: Ali_zeinali_cardio@ yahoo.com.

TAA is 6 per 100,000 persons year.[2] About 15% of AAA patients die from rupture. Open surgery is the conventional method for treatment of aortic aneurysm but in the last decade EVAR has emerged as an alternative to surgery, especially in patients with serious comorbidities. This paper presents the short term outcome of the first series of patients that underwent EVAR for aortic aneurysms in our center. We began EVAR from one year ago as a prospective case series study for the first time in Iran, and the mid and long-term results will published in the future.

Methods

From Dec. 2006 to Sept. 2007, we treated 15 patients with Medtronic stent grafts for their aortic aneurysms. In-hospital results and one month follow up were reported as the short term outcome, and it has been decided to report all cases with their follow-up annually. The characteristics of these 15 patients are presented in Table I.

Table I: Patients and procedure characteristics

No	Sex	Age	Co-morbidities	Aneurysm site	Stent-graft (Medtronic)	Hospital Stay	30-day morbidity or mortality	30-day Device complication
1	M	77	Hypothyroidism CAD	AAA + iliac aneurysm	AF3618C155AX IXW1818C80AX IW1816C80AX IW1410C90AX	5 days	-	Controlled endoleak Type II
2	M	68	CAD (CABG) DM, HTN	AAA + iliac aneurysm	AF3620C170AX IW1424C105AX IXW2222C79AX	8 days	-	Controlled endoleak type II
3	M	51	Previous coarctoplasty surgery	TAA	TF3838C150X	8 days	Transient hoarseness	-
4	F	36	Marfan, Ascending Aorta Dissection (Previous Bentall)	TAA	TF3434C200X	6 days	-	-
5	M	85	CAD, COPD CRF, DM, HTN	AAA	AF3416C155AX IW1416C90AX	9 days	Elevated serum Cr	-
6	M	62	CAD (CABG)	AAA + uniliac stenosis	AF2616C140AX AXF3434W28AX	10 days	Reversible limb ischemia	Unsuccessful contralateral device implantation
7	M	75	CAD (CABG) HTN	AAA + iliac aneurysm	AF3016C170AX IW1416C105AX	5 days	-	Controlled endoleak Type II
8	M	68	CAD	AAA + iliac aneurysm	AF2816C155AX IW1416C75AX	5 days	-	Controlled endoleak type II
9	M	70	CAD (CABG) Hyperthyroidism DM, CRF, HTN	AAA + iliac aneurysm	AF2820C170AX IW1424C1.5AX	4 days	-	-
10	M	77	CAD, HTN	AAA + TAA + iliac aneurysm	AF3220C170AX IW1418C90AX TF4242C150X	11 days	-	Controlled endoleak type II
11	M	71	CAD, COPD	AAA	AF2818C155AX IW1418C90AX	5 days	-	-
12	M	66	CAD, CMP	AAA + iliac aneurysm	AF2818C155AX IW1422C90AX IW1814C75AX	30 days	CVA, death	-
13	M	65	CAD	AAA	AF2616C140AX IW1416C75AX	6 days	-	-
14	M	78	CAD, Renal stenosis, CRF	AAA	AF3020C155AX IW1418C90AX	8 days	Elevated serum Cr	-
15	M	44	Previous aortic surgery	TAA	TC2424B100X	5 days	-	-

CAD = coronary artery disease, HTN = hypertension, DM = Diabetes mellitus, CMP = cardiomyopathy, COPD = chronic obstructive pulmonary disease, CRF = chronic renal failure, CABG = coronary artery bypass graft, AAA = abdominal aorta aneurysm, TAA = thoracic aorta aneurysm, CVA = cerebrovascular accident, Cr = creatinine

There was one female and 14 male patients and the mean age was 66 (34 to 89) years old.

Three thoracic, 11 abdominal and one thoracic and abdominal aortic aneurysms were treated. Most of the patients had co-morbidities as mentioned in Table 1 and because of these co-morbidities, referring surgeons had suggested EVAR for them. Some patients were symptomatic with abdominal pain or pulsation from AAA, and hemoptysis or hoarseness for TAA.

Morphology of the aneurysms

Four patients had TAA that began after the origin of the left subclavian artery and ended before celiac artery. Two were post-surgery aneurysms, one was atherosclerotic and one was a Marfan woman that had undergone earlier Bentall surgery with reimplantation of the carotid arteries because of ascending aorta dissection.

Twelve patients had AAAs that were infrarenal with a good proximal neck. In four patients, AAAs were terminated before the iliac bifurcation and in eight patients, there were iliac aneurysms. One patient had both AAA and TAA as mentioned above.

Imaging

Case selection for endovascular intervention was based on non-invasive imaging methods like computed tomography (CT), magnetic resonance imaging (MRI), transesophageal echocardiography (TEE), and intravascular ultrasound (IVUS). Pre-intervention CT angiography or MR angiography are replacing contrast angiography as the primary imaging studies. Angiography can show landing zone length and the distribution of thrombus at the fixation sites. Spiral CT remains the gold standard for preoperative assessment. In our study we selected patients based on the CT angiography with 3mm sections. In CT scan we evaluated the length and diameter of the aneurysm and proximal and distal landing zones, great arteries and iliofemoral arteries as the access site (Fig. 1).

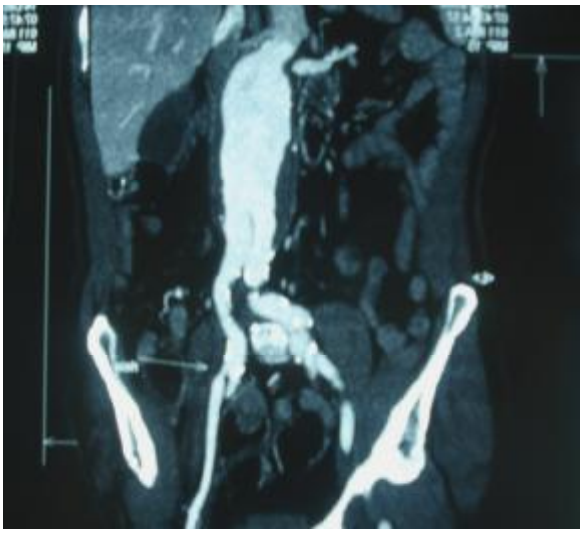


Fig. 1. CT angiography of abdominal aorta aneurysm.

Routine chest X-ray, KUB and cardiac echocardiography was done for evaluation of cardiopulmonary co-morbidities and device position. Control CT angiography was done for some patients as a short-term imaging follow up study modality.

Technical aspects

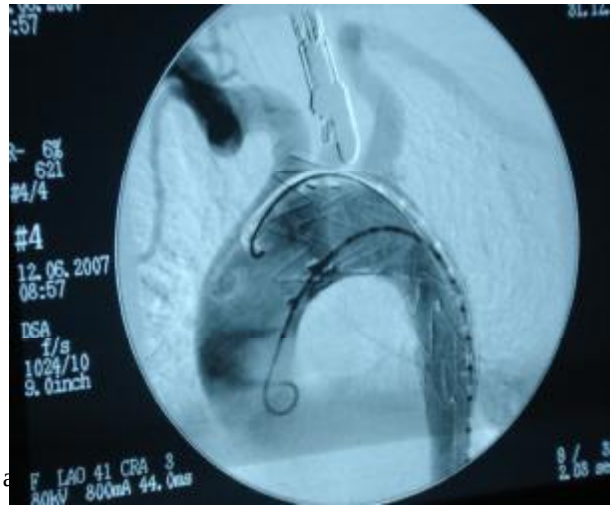
All procedures were done in cardiac catheterization room with digital subtraction modalities. (Fig. 2).

The patients were admitted one day earlier and routine radiologic, laboratory tests, PFT and anesthesiologist consultations were done. No special premedications were used. The

informed note of consent was obtained from patients and their families. All EVAR procedures were done under general anesthesia. Firstly the cardiac or vascular surgeon performed bilateral femoral arteriotomy for AAA and unilateral for TAA. After administration of 5000 IU heparin, the interventionalist inserted the 7 Fr arterial sheath and aortography was done with a marker pigtail catheter under digital subtraction guidance. After reevaluation of the aneurysm sac, proximal and distal neck, great arteries and iliofemoral access, the best site for the main body and contralateral stent-graft device insertion was selected. Then the Backup-Meier 0.035 guide wire was passed from the aneurysm and placed in the ascending aorta and after removal of the 7 Fr sheath, the main body of the stent-graft device was placed in the suitable position. Aortography was done with fixed table for choosing the best position for final device deployment. After selection of the best position, the device was unloaded carefully. In the TAA group, there was a one-piece tubular stent graft device and the procedure ended with one device implantation, but in the AAA group, contralateral limb stent-graft must be implanted. After removal of the pigtail catheter from the contralateral arterial sheath, an A_1 catheter with hydrophilic 0.035 guide wire was passed from the short limb of the main body stent-graft. Then another Backup-Meier 0.035 guide wire was inserted and the contralateral stent-graft was implanted with 4-5 cm stent overlap in a suitable position. After removal of the main body delivery system and insertion of a 12 Fr arterial sheath, final aortography with digital subtraction was done for evaluation of success of aneurysm exclusion and absence of endoleak. Finally surgeons removed both sheath and contralateral delivery system and repaired the arteriotomy sites.

The patients stayed in the ICU usually for one or two days after the procedure. No routine maintenance anticoagulation was given. In the next days, anesthesiologists and surgeons visited the patients for evaluation of cardiopulmonary function and arteriotomy site healing and transfer to general ward. Most patients were discharged 5 to 8 days after admission. All stent-grafts were Medtronic Talent or Valiant stent-grafts (Fig. 3).

(A)



The implanted Talent endoprosthesis is composed of a polyester graft fabric sewn to a self-expanding nitinol wire frame. The design concept is modular. Proximal and distal stent-graft diameters range from 22 mm to 46 mm, and the total covered length of the device ranges from 112 to 116 mm. Neck anatomy is very important in EVAR procedures. When diseased implantation sites are selected for

device fixation, complications were increased.[3] Almost all infrarenal devices require 1.5 cm aortic neck length to provide an adequate fixation site for aneurysmal exclusion.

Results

EVAR for TAA was done in four patients and it seems this is technically the simplest with shorter operation times than AAA exclusion. No paraplegia was seen in these four patients. One patient with post-coarctoplasty aneurysm who had previous hoarseness as a symptom had a recurrence of hoarseness 3 weeks after EVAR, which was relieved spontaneously. However EVAR was contraindicated in Marfan patients but a Marfan woman who had ascending aorta dissection was scheduled for a hybrid procedure. Bentall surgery with carotid artery reimplantation was done earlier and then EVAR was performed for arch and descending aorta aneurysm exclusion. One patient had both TAA and AAA that were excluded with EVAR in the same setting.

From 12 AAA that were treated with EVAR, eight had iliac aneurysms. In 11 cases, there were no device-related complications but in one patient, contralateral limb device could not be implanted because of severe tortuosity and stenosis of the left iliac artery. We changed our plan and with one stent-graft extension, the main body became unilateral and the left iliac artery was occluded and femoro-femoral bypass with occlusion of the left iliac artery was done by the surgeon for salvage of the left limb and prevention of endoleak. In 10 patients, there was very good final aortography in digital subtraction view at the end of the procedure, but in five there were type II endoleaks that were observed and in one-month follow up, they had no problems. The mean hospital stay was 7 days (range 5 to 11) and only in one complicated patient with post-procedural cerebral stroke and death, it was one month.

Discussion

Ruptured abdominal aortic aneurysms with an incidence of 9.2 cases per 100,000 per year is the 13th cause of death in the USA.[4,5] The mean age is 59 to 69 years with a male to female ratio of 3:1. The life-time probability of rupture in untreated thoracic aneurysms is between 75 and 80%.[6]

Between 1991 and 2005, Safi et al. performed 1887 operations for ascending arch or descending thoracic aorta aneurysms.[7] They performed 1106 operations for repair of the distal aorta (descending thoracic 305, and thoracoabdominal, 801). The 30-day mortality rate was 14.5% with an immediate neurological deficit rate of 3.2%.

The gold standard treatment for aortic aneurysm has been surgery, with short-term mortality incidence of 10-20%. In recent years, endovascular aortic repair (EVAR) of descending aneurysms has shown great promise. Volodos published the first report on endovascular stent grafting for a thoracic aortic lesion in 1991,[8] while the first clinical series was published by the Stanford group in 1994.[9]

From 1991 since EVAR began by Parodi et al, several studies have been conducted. Pei Ho et al.[10] in 2006 published a systemic review of clinical trials comparing open and endovascular treatment of abdominal aortic aneurysms published from 1991 to 2004. This review showed that there were 96 studies on EVAR of aortic anurysms, 41 of which compared clinical outcomes and physiological changes of EVAR and open repair. This review concluded that endovascular repair offers significant benefits to aneurysm patients in the early post-operative period. However, it does not show an advantage over open rapair in mid- and long-term outcome. Furthermore, EVAR carries more morbidity and higher cost in the long term.[10] The EVAR 1 trial compared endovascular repair with conventional open surgery in patients judged fit for open AAA repair between 1999 to 2003. EVAR was done in 543 and open surgery in 539 patients in a randomized trial

in 41 British hospitals. The primary outcome measured was all-cause 30 day mortality, which was 1.7% in EVAR group vs. 4.7% in the open-repair group. Secondary interventions were more common in patients allocated to EVAR (9.8% vs. 5.8%). The researchers concluded that in patients with large AAA, treatment by endovascular repair reduced the 30-day operative mortality by two –thirds compared with open repair.[11]

The EVAR 2 trial was a randomized, controlled trial that compared EVAR and outcome in patients unfit for open repair of AAA in British hospitals. The researchers concluded that EVAR had considerable 30-day operative mortality in patients believed to be unfit for open repair of their aneurysm. EVAR did not improve overall survival or aneurysm-related mortality compared to no-intervention and was associated with a need for continued surveillance and reinterventions, at substantially increased cost.[12] The durability of the stent-graft is still an issue that has an important role in long term safety. Endovascular aneurysm repair in some randomized studies seems to be superior to open repair, at least for the first postoperative month.[11,13] EUROSTAR thoracic registry is an observational study which was established in 2000.[14] In this registry up to July 2005, a total of 581 patients were recruited on to the EUROSTAR thoracic registry by a total of 54 different European institutions. The mean age of the patients was 63.4 years, with 77% male population. Complete technical success was achieved in 520 patients. 10% had arterial complications, rupture of the aorta, thrombo-emboli and ischemia related to exclusion of aortic side-branches. Device-related complications were reported in 51 (9%) patients.

Currently, follow up extends to a maximum of 5 years. A total of 108 patients have died, 67 within 30 days of their operation and 41 after this period. This registry had some points: a variety of thoracic aortic pathologies were treated by endovascular stent grafting and complete technical success was achieved in 90%. The total incidence of endoleak type 2 on completion of the procedure was 90%. The incidence of paraplegia was low (2.5%) and if three or more endografts were deployed within the aorta, a highly significant risk factor for paraplegia was observed. Sixty-seven percent of patients with paraplegia died and the incidence of intracranial stroke was 3%. These results are consistent with the expectation of superior outcome from endovascular repair in comparison to the known results of conventional open surgery, at least in the medium term.[14]

Some other trials were published about some specific devices too. For example, the VALOR trial is a prospective, multicenter, non-randomized evaluation of the safety rate of all-cause mortality and efficacy (successful aneurysm treatment at 1 year) of the Talent (Medtronic) thoracic stent-graft system when used in patients with thoracic aortic aneurysm.

In our study, we began EVAR treatment for both thoracic and abdominal aortic aneurysm patients who had some risks for open surgery. Because these are the first EVAR experiences in Iran, we have some limitations in patient and device selection, and we largely depended on referral surgeons who must suggest this new technique for patients. In the first year of the study, we had some referral patients, 15 of whom had our inclusion criteria and underwent EVAR with one month clinical follow up. We collected important data such as aneurysm size, device type and size, in-hospital to 30 day morbidity and mortality, hospital stay, cardiopulmonary and renal complications, limb ischemia, wound morbidity, stroke, endoleak, and intraoperative conversion. Short-term (30 day) outcome was the first end point and mid-term (30 day to 3 year) and long-term are the final goals of this prospective case series study. The majority of patients were male (14/15) with the mean age of 66 (36 to 89) years old and had some significant cardiopulmonary comorbidities and was

referred by surgeons as high-risk patients for open operation.

As mentioned, EVAR for TAA was simpler than AAA, with shorter operation times and less complications. Good proximal neck length and diameter is the most important point for implantation success and prevention of endoleak. Because of the probability of aortic arch atherosclerosis, catheterization and device manipulation must be done carefully for prevention of any stroke. For implantation of the device in TAA group, the systolic blood pressure must be dropped below 90mmHg. EVAR in AAA group needed more flouroscopic time and catheterization technical skills, especialy for contralateral limb device implantation. We had some problems for crossing the device from iliofemoral tortuosity, aneurysm and stenosis. Preoperation radiologic assessment of the access site is very important in this regard.

Conclusion

Endovascular treatment of aortic aneurysm is safe and feasible, especially for high-risk patients for open surgery. In some countries, like Iran, it began late because of some device preparing problems, but it will surely progress rapidly. Team work in EVAR is the key point. Good learning curves for all members of the team, careful case selection and understanding about possible complications and their management are the most important items for any center that to began EVAR. Our initial short-term results of EVAR for TAA and AAA showed good safety and feasibility. For evaluation of mid- and long-term results, close follow up must be continued.

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