Two Years Experience and Short-term Results of EVAR in Patients with Infra-renal Abdominal Aortic Aneurysm

MoatasemBellah Abdel HameedErfan [**], ***Mahmoud FouadReda*** [**],
Ahmad Gamal El Din Fouad [*], ***Mohammed Ali Hassan*** [*], ***Mohamed Hossny El Dessoki*** [*]
[*] Department of Vascular Surgery, Cairo University
[**] Department of General Surgery, Misr University for Science & Technology (MUST)

ABSTRACT

Background: *Abdominal Aortic Aneurysm (AAA) is the most common type of true aneurysm with high incidence of rupture. The introduction of endovascular grafting was a milestone in the treatment of patients with AAA as it provides a treatment option for those patients with large aneurysms with unfavorable conditions as the presence of significant medical comorbidities. By this innovation, an early benefit in quality of life can be achieved, as it relates to reducing hospital stay and recovery period in comparison to open surgery.* ***Aim of the work:****To highlight the advantages and disadvantages of EVAR in patients with infra-renal AAA and to select patients suitable for EVAR according to the patient selection criteria and to assess the possible complications of endovascular procedures and how to avoid it*. ***Patients & Methods:****A retrospective study was conducted at KasrAlainy Hospital from September 2012 to August 2014, involving 20 patients with favorable anatomy for endovascular repair of infra-renal abdominal aortic aneurysm. The findings of initial and short-term follow-up results were analyzed.* ***Results:*** *All patients were followed at one and six months post implantation with few aneurysm related complications. Two patients had type Iaendoleak (10%) & was managed by proximal ballooning and aortic cuff extension. One patient had Type Ibendoleak (5%) & was treated by iliac extension. Graft limb occlusion occurred in one patient (5%) during follow up and needed a femrofemoral bypass. Superficial wound infection occurred in one patient (5%) and responded to conservative treatment in the form of repeated dressing and systemic antibiotics. Two patients developed groin hematoma (10%) and also responded to conservative treatment. Absent pulse was detected at the end of the procedure in a single patient (5%), embolectomy was done & distal pulse was restored.* ***Conclusion:*** *Despite the small number of patients, the results seem to justify the performance of endovascular therapy in patients with favorable anatomy.*

Keywords: *Abdominal aortic aneurysms (AAA) , Endovascular techniques, EVAR*

INTRODUCTION

Abdominal Aortic Aneurysm (AAA) is the most common type of true aneurysm and has a high capability to rupture, which makes it a significant health care problem [(1)]. The prevalence of abdominal aortic aneurysms (AAAs) has been increasing rapidly during the past decade as aneurysmal rupture had been estimated as the 13th most common cause of death in the Western world [(2)].

The two primary methods for infra-renal AAA repair are open and endovascular repair which has proven to be safe and effective treatment [(3)]. Over the last decade, the management of aortic aneurysms has changed dramatically because of the progress of the technique of endovascular aneurysm repair. Patients and physicians have embraced endovascular aneurysm repair as a method of choice to treat high risk patients with aortic aneurysms [(4)].

PATIENTS AND METHODS

From September 2012 to August 2014, 20 patients were subjected to endovascular repair of infra-renal AAA. The most common comorbidities observed were systemic hypertension and smoking, followed by dyslipidemia, diabetes mellitus, renal and cardiac problems. The frequency of comorbidities is shown in Table 1. This study was approved by the Ethics Committee of *KasrAlaini Hospital, Cairo University*

Table 1 – Patients' comorbidities

Co-morbidities	No. of patients	%
Smoking	16	80%
Hypertension	15	75%
Hyperlipedemia	12	60%
Dm	6	30%
Renal problems	2	10%
Cardiac problems	1	5%

Patient Selection:

The procedure was planned based on CT angiography with contrast and three-dimension reconstruction, according to the following criteria:

- **Inclusion Criteria:**
  - Aneurysm diameter of > 5.0 cm documented by CT angiography
  - Aneurysm diameter with a documented expansion of > 0.5 cm in six months or > 1.0 cm in 12 months documented by CT angiography
  - Symptomatic AAA with impending rupture, regardless of its size
  - Proximal neck diameter of 32 mm or less.
  - Infrarenal non-aneurysmal neck length of ≥ 1 cm at the proximal and distal ends of the aneurysm
  - An aortic neck angle < 60 degrees.
- **Exclusion Criteria:**
  - Aortic neck with significant thrombus or circular calcification.
  - Severe Iliac artery tortuosity, calcification.
  - Ruptured or dissecting AAAs
  - Distal embolization or inflammatory aneurysms
  - Juxtarenal, Pararenal, Suprarenal or thoracoabdominal aneurysms
  - An aortic neck angle > 60 degrees
  - Morbidly obese patients whose weight exceeds 150 kg.
  - Mesenteric Vascular Occlusive Disease
  - Preexisting renal insufficiency
  - Terminal malignancy & poor life expectancy.
  - Refusal of the patient.

Those who fulfilled these criteria were classified as having favorable anatomy and referred to endovascular repair **(Fig. 1).**

Technique of EVAR

Most procedures were performed under combined general and epidural anesthesia. After Urinary catheter insertion, Patient draping from nipple down to the feet surgical femoral arteriotomy was done by groin incision. Broad spectrum antibiotics were administered before insertion of the stent-graft.

Procedure

- **Before Stent-Graft Deployment** ·
- The contralateral femoral artery was catheterized and a 6F sheath was inserted.
- A diagnostic pigtail catheter was inserted via this access into the aorta to the level of T12/L1.
- The ipsilateral femoral artery was catheterized. A standard guidewire and selective catheter (e.g., cobra) were advanced into the ascending thoracic aorta.
- The standard guidewire was exchanged for a very stiff guidewire (260-cm long Lunderquist), which was placed with the tip in the ascending aorta.
- The stent-graft was inserted under fluoroscopic guidance.
- Care should be taken if there is resistance during passage of the stent-graft through the iliac arteries to avoid dissections or rupture.
- The stent-graft should be advanced to the level of L1.

(B) Deployment of the Stent-Graft·

- Catheter angiography was performed to define the level of the renal arteries.
- The stent-graft was deployed so that the covered part of the graft material was located immediately below the renal arteries.
- After deployment of the main body of the device, the pigtail catheter was withdrawn over a standard guidewire.
- The contralateral limb was cannulated from the contralateral groin with a selective catheter and a hydrophilic guidewire.
- After cannulation of the contralateral limb gate, the position of the guidewire within, rather than without, the body of the graft should be confirmed either by the injection of contrast through a catheter, or by the rotation of a pigtail catheter.
- If retrograde cannulation of the limb was difficult, contralateral limb cannulation was achieved using a cross-over technique:
- A sidewinder (Simmons 1) or Sos Omni catheter was placed across the flow divider of the stent-graft main body.

- A hydrophilic guidewire (curved, 260 cm) was advanced to the contralateral iliac artery and snared.
- After inserting a second guidewire through the contralateral limb opening into the aorta above the stent-graft, the contralateral limb was inserted.
- Balloon angioplasty should be performed at the proximal, distal landing zone and at the device connections to enhance the seal.
- If there was an aneurysmal common iliac artery (>23 mm diameter) as well as an aortic aneurysm, it would be necessary to land the endograft limb in the external iliac artery.
- Before this was performed, it was necessary to embolize the internal iliac artery before insertion of the stent-graft to prevent retrograde flow into the aneurysmal common iliac artery and aortic aneurysm sac.
- This was achieved by coils or plugs usually before the procedure.

(C) Endpoint

- This was decided by good quality catheter angiography.
- The procedure was completed when angiography shows a patent stent-graft, patent endograft limbs, and absence of flow into the aneurysm sac (endoleak).

Postoperative follow-up: Patients were followed at 1 and 6 months after the procedure. Ultrasound and/or CT angiography were performed for follow up to exclude possible complications.

RESULTS

Twenty patients with AAA, 19 male and 1 female. The age rangedbetween 34 to 80 years with mean age of 68.25. Fifteen patients (75%) of the patients were symptomatic while five patients(25%) were asymptomatic and were accidentally discovered.

General anesthesia alone was done in **6/20** cases of the study, while combined general with epidural anesthesia was used in **14** patients. The mean (±SD) duration of the procedure in the EVAR was **2±0.6** hours. The estimated blood loss was **100-250** ml with **10/20 (50%)** patients requiring post-operative blood transfusion.

All cases of the study ended in a bifurcated graft except for one case for whom aortouni-iliac graft was used due to narrow aortic carina and completed the procedure with a femorofemoralbypass.

All patients were routinely admitted to the ICU postoperatively. The mean duration of ICU stay was 24 hours The mean (±SD) change in hemoglobin level was a decrease by 1.2±0.7 g/dL.

Anatomical features for aneurysm morphology in the studied patients were as follows:

Table 2 – Proximal landing zone

	Measurement	**Mean diameter**
Proximal neck	15.2 - 30.5 MM	22.47 MM
Proximal neck length	11 - 41 MM	22.57 MM
Proximal neck angulation	< 60º	
Max. Transverse aneurysm diameter	47.7 - 83.5 MM	*66.39* MM

Table 3 - Distal landing zone:

	Measurement	**Mean diameter**
RT CIA diameter	9 - 18.2 MM	*13.5 MM*
LT CIA diameter	8.8 - 17.5 MM	*13.25 MM*
RT EIA diameter	6.8 - 11.8 MM	*9.29 MM*
LT EIA diameter	6.5 - 11.8 MM	*8.71 MM*

The Zenith Flex (Cook) was used in **4/20 (20%)** of the cases, while Endurant II (Medtronic) was used in **16/20 (80%)**.

Procedure related complications:

Table 4 – Morbidity& Mortality:

Complication	*No*	*Incidence*	*Management*
Endoleak Ia Ib	 2 1	 10% 5%	Ballooning Aortic cuff Iliac extension
Wound infection	1	5%	Superficial wound infection respond to conservative ttt
Groin hematoma	2	10%	Conservative ttt
Other complications	Distal lower limb occlusion	5%	Embolectomy by fogarty's catheter
30 days mortality	0	0%	

Follow up:

Duplex or CT angiography were done 1 & 6 month post implantation for all patients and revealed 100% patency rate of the main graft and both iliac limbs**(Fig. 2)**, No further increase in aneurysm diameter, absence of detectable flow in aneurysm sac and absence of device migration..

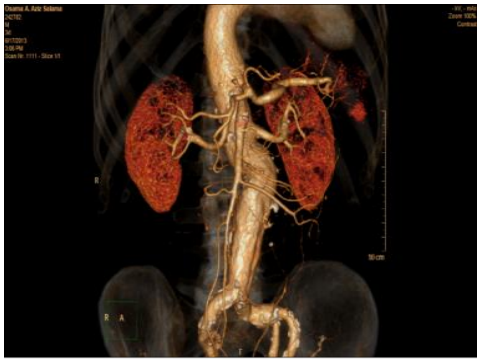

Figure 1: Patient showing infra-renal abdominal aortic aneurysm with a diameter of 70.8 mm treated by amedtronic (Endurant II) graft

Figure 2: Completion angiogram with patent graft and no endoleaks.

DISCUSSION

AAA is a localized dilatation of the abdominal aorta that measures greater than 3.0 cm in diameter.The main risk of an untreated AAA is progressive expansion, rupture and death. AAA rupture risk increases with increasing aortic diameter and this catastrophic event is associated with a mortality of 50% to 80%. Since Parodi demonstrated the feasibility of endovascular repair, endovascular aneurysm repair (EVAR) has emerged as the gold standard for aneurysm repair[(5)].

Not all patients with AAAs with indications for intervention are candidates for endovascular procedures and, in reality the adequate selection of patients is the most important factor for success in treatment. The main criterion of selection

relates to the anatomy of the aortic, iliac and femoral system [6].

Computed tomography is currently considered the cornerstone for the evaluation of patients with AAAs in order to study the possibility of endovascular repair [7].

In our study group, 19 males and one female were included aged between 34-80 years with 75% (15 patients) aged above 66 years, this reflect that the AAA is a disease of aging male. Smoking, hypertension, dyslipidemia and ischemic heart disease were the main risk factor in our patients with smoking present in 16 patients (80%), hypertensionin 15 patients (75%) and dyslipidemia in12 patients (60%).

Kent et al, assured that these are well-defined clinical risk factors associated with the pathogenesis of AAA except for diabetes [8].

In this study, 5 patients (25%) were asymptomatic and 15 patients (75%) were symptomatic with either abdominal pain that was present in 9 patients(60%) or abdominal mass which was present in 6patients (40%).

The symptoms are directly related to the size of the aneurysm and 20% of infra renal AAA associated with unilateral Common iliac artery aneurysm. Medium size aneurysm(4-<5.5cm) was found in 5 patients (25%),large aneurysm (5.5-<6cm) present in 3 patients(15%) and very large aneurysm > 6 cm was in 11 patients (55%) of patients.

Evidence suggests that patients with larger aneurysms are less suitable for EVAR. Larger aneurysms are often associated with arterial anatomy that is less favorable for EVAR. It has been shown that patients with AAA > 6 cm have worse clinical outcome after EVAR [8].

The stent grafts used were Medtronic (Endurant II) in 16 patients (80%) and cook (zenith) in 4 patients (20%).**Brown et al.,** found that there are no clear advantages of one stent-graft design over another. The overall performance among the available devices is similar and the available data confirm uniformly low complication rates. The choice of a particular device design is based upon multiple factors, including patient anatomy, operator preference, and cost. An endograft system that can handle all types of AAA, including those with angulated or tortuous anatomy, has yet to be achieved [9].

A complication that is not inherent to endovascular procedures, but that deserves attention is graft thrombosis. In our study no cases showed graft thrombosis. In a study done by **Silvestre et al.,** they have observed two cases (4.8%) between the second and third months of follow-up, which led to the deaths of both patients due to severe post-revascularization syndrome, despite attempts for surgical treatment [13].

In a systematic review, **Drury et al.,** evaluated three randomized controlled trials and observed a higher rate of this complication (6.4%) after endovascular repair in comparison to open repair (2.9%) [14].

This can be explained as the angulation of the endograft branch, that follows the often tortuous or kinking natural path of the arteries[15]. To reduce this type of complication, **Oshin et al.**, suggest the primary use of additional uncovered stents in cases of kinking or stenosis of the endograft or native artery. After adopting this strategy, they have not observed any branch occlusion. Stents were used in 11.2% of the operations[16].

Pelvic ischemia is another complication that may be observed after bilateral occlusion of the internal iliac arteries or occlusion of one single patent artery. Pelvic ischemia presents variable degrees of clinical manifestations, especially in the gluteal muscles and colon, besides male sexual dysfunction. In our series, bilateral occlusion didn't occur in any of the cases.

Cochennec et al. compared open repair and endovascular repair of AAA involving the iliac bifurcation and did not find differences in the postoperative mortality rates nor in the systemic complication rates between the two groups. The patients undergoing open repair had more abdominal wall complications and were more prone to colon ischemia. In the endovascular group, gluteal claudication was more common [17].

In this study, there were no secondary reinterventions required for any of the major complications. Major complications such as graft migration, structural failure, graft distortion, aortoenteric fistula, or aneurysm rupture were not encountered during the follow-up. This may be attributed to the advancements in graft design as well as operator-dependent insertion technique.

Endoleaks, characterized as an exclusive complication of endovascular repair, occurred in 3 patients (15%) of our cases, with reintervention in only two cases of: one type Ia and the others type Ibendoleak. In a systematic review, **Drury et al.**,

analyzed randomized controlled trials on the safety and effectiveness of endovascular repair and observed endoleaks in 17.5% of the cases in a period of less than 30 days (3.5% type I and 14% type II). When the follow-up period was longer than 12 months, the incidence was 21.3%; type II increased to 6.8%, with cases of type III endoleak (4.2%). In the same review, the authors observed a 16.2% rate of secondary intervention [(14)].

It is believed that favorable anatomy is a determinant factor for the success of the procedure. Data from the Eurostar study [(18)], show that the best results were obtained in patients with aneurysms measuring less than 6.5 cm and presenting anatomy favorable, regardless of surgical risk, which was also observed by **Mendonça et al.** [(19)]

On analyzing the importance of proximal neck length, a higher incidence of early and late endoleak type I was found; but not an increase in late reinterventions, and only an increase in the early use of proximal extension and expandable balloon stents. However, high rates of complications and perioperative mortality were observed in patients with proximal necks less than 15 mm. An increase in the mortality rate within 30 days after the procedure was also described in patients with proximal necks shorter than 15 mm in the Eurostar study [(20)].

On the other hand, a publication of a pilot study on the Talent® endograft with low profile system, aneurysms with necks as short as 3 mm were treated, with a 30-day mortality rate of 1.5%. In a five-year follow-up, the rate of aneurysm rupture was 3.5% and conversion to open surgery occurred in 0.9% of the cases (1/137) [(21)]

CONCLUSION

In view of its long-term durability and effectiveness, as well as the increased surveillance burden, EVAR is most appropriate for patients at increased risk for conventional open aneurysm repair. EVAR may be the preferred treatment method for older, high-risk patients or other clinical circumstances likely to increase the risk of conventional open repair, if their anatomy is appropriate.

REFERENCES

1. **Abu Rahma A.** Suggested standard for reporting on arterial aneurysm. J Vas Surg.; 2000; 31: 721.
2. **Thompson M and Bell P.** ABC of arterial and venous disease: arterial aneurysms. BMJ2000; 320:1193-1196.
3. **Rutherford R and Krupski W.** Current status of open versus endovascular stent graft repair of abdominal aortic aneurysm. J VascSurg2004; 39: 1129–1139.
4. **Greenberg R,Chuter T, Sternbergh W et al.** Zenith AAA endovascular graft: intermediate-term results of the US multicenter trial. J VascSurg2004; 39(6):1209–1218.
5. **Eckroth-Bernard K, Garvin R and Ryer E.** Current Status of Endovascular Devices to Treat Abdominal Aortic Aneurysms. Biomedical Engineering and Computational Biology2013; (5): 25-32.
6. **Stanley B, Semmens J, Mai Q et al.** Evaluation of patient selection guidelines for endoluminal AAA repair with Zenith stent-graft: the Australian experience. J EndovascTher 2001; 8(5):457-464.
7. **Palma J, de Souza J, Rodrigues Alves C, et al.** Self-expandable aortic stent-grafts for treatment of descending aortic dissections. Ann Thorac Surg.2002; 73(4):1138-1142.
8. **Kent K, Zwolak R, Egorova N et al.** Analysis of risk factors for abdominal aortic aneurysm in a cohort of more than 3 million individuals. J VascSurg2010; 52:539.
9. **Brown L, Greenhalgh R, Kwong G et al.** Secondary interventions and mortality following endovascular aortic aneurysm repair: device-specific results from the UK EVAR trials. Eur J VascEndovascSurg 2007; 34:281.
10. **Greenhalgh R, Brown L, Kwong G, et al.** 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; 364:843-848.
11. **Prinssen M, Verhoeven E, Buth J et al.** The DREAM participants. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med 2004; 351(16):1607-1618.

12. **Harris P and Buth J.** An update on the important findings from the EUROSTAR EVAR registry. Vascular2004; 12:33-38.
13. **Silvestre J, Motta F, Sardinha W et al.** Endovascular treatment of infrarenal abdominal aortic aneurysm in patients with favorable anatomy for the repair – initial experience in a university hospital. J. vasc. bras.2011; 10(1), 31-39.
14. **Drury D, Michaels J, Jones L, et al.** Systematic review of recent evidence for the safety and efficacy of elective endovascular repair in the management of infrarenal abdominal aortic aneurysm. Br J Surg2005; 92:937-946.
15. **Von Ristow A, Pedron C, Gress M et al.** Aneurisma da aorta abdominal - tratamentopelatécnica endovascular. In: Brito CJ. Cirurgia vascular - cirurgia endovascular - Angiologia. Rio de Janeiro: Revinter2008; 68:1225-1304.
16. **Oshin O, Fisher R, Williams L et al.** Adjunctive iliac stents reduce the risk of stent-graft limb occlusion following endovascular aneurysm repair with the Zenith stent-graft. J EndovascTher2010; 17:108-114.
17. **Cochennec F, Marzelle J, Alaire E, et al.**Open vs endovascular repair of abdominal aortic aneurysm involving the iliac bifurcation. J VascSurg2010; 51:1360-1366.
18. **Harris P, Vallabhaneni S, Desgranges P et al.** Incidence and risk factors of late rupture, conversion, and death after endovascular repair of infrarenal aortic aneurysms: the EUROSTAR experience. European Collaborators on Stent/graft techniques for aortic aneurysm repair. J VascSurg2000; 32:739-749.
19. **Mendonça C, Moreira R, Carvalho C et al.** Tratamento endovascular de aneurismas da aorta abdominal empacientes de alto riscocirúrgico. J VascBras 2009; 8:56-64.
20. **Leurs L, Kievit J, DagnieleP at al.** EUROSTAR collaborators. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. J EndovascTher2006; 13:640-648.
21. **Turnbull I, Criado F, Sanchez L et al.** Five-year results for the Talent enhanced low profile system abdominal stent graft pivotal trial including early and long-term safety and efficacy. J VascSurg2010;51:537-544.