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THE APTUS™ HELI-FX™ ENDOANCHOR™ SYSTEM – THE INNOVATIVE ENDOVASCULAR REPAIR METHOD FOR THE PATIENT WITH POST- EVAR TYPE IA ENDOLEAK

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SUMMARY

Background:

The aim of our study was to present an innovative endovascular technique – the Aptus™ Heli-FX™ EndoAnchor™ system combined with the Endurant Stent Graft cuff used as a method of choice for the patient in a very poor general condition with symptomatic abdominal aneurysm and a post-EVAR type IA endoleak.

Case study:

An 85-year-old male patient, was operated on in March 2016 with endovascular aneurysm repair (EVAR) of a 9.3 cm in diameter ruptured abdominal aneurysm (RAA), accompanied by disturbance to the coagulation profile (prolonged INR of 3.3 because of anticoagulant treatment with Rivaroxaban due to atrial fibrillation). 9 months later, he developed a severe abdominal pain and was urgently referred to the Vascular Surgery Department, at the John Paul II Hospital, Kraków. The Angio-CT examination revealed the type IA and II endoleaks and a recurrence of the rupture symptoms. He was successfully operated on using an innovative endovascular repair system, the Aptus™ Heli-FX™ EndoAnchor™ system with a combination of other endovascular procedures, such as Endurant Stent Graft cuff implantation.

Conclusions:

The innovative endovascular repair system, Aptus™ Heli-FX™ EndoAnchor™ together with the Endurant Stent Graft cuff was successfully used in the treatment of the patient. This technique prevented him from developing serious complications or even death and gave him a much better quality of life in comparison with open surgery repair.

Key words: ruptured abdominal aneurysm, post-EVAR complications, type Ia endoleak, type II endoleak, quality of life

BACKGROUND

Although the endovascular method of repairing abdominal aortic aneurysm (AAA) with the use of Stent Graft has been used since 1991 (Parodi et al. 1991), there is a need for post-procedural frequent imaging during the follow-up of patients, since this method still bears a significant risk of serious complications including: endoleaks (Torsello et al. 1998; Veith et al. 1992), aneurysm expansion, rupture (Harris et al. 2000) and graft migration (Vourliotakis et al. 2016).

Endoleak, which is the flow of blood inside the aneurysm sac between the implanted Stent Graft and the wall of the vessel (Stavropoulos & Charagundla 2007), occurs in about 28% of patients (Baum et al 2000). The classification includes five types of endoleaks (see: Fig. 1).

Type I occurs at the proximal or distal end of the Stent Graft, when the graft wall is not properly expanded and tightly pressed to the aortic aneurysm neck wall, resulting in leakage of the blood to the aneurysmal sac. It causes a recurrence of the blood flow into the aneurysmal sac (Beebe et al. 1996) and the blood pressure as well, which increasing the risk of aneurysm growth and rupture (Lumsden 1995). The subtypes of the type I endoleaks includes: proximal – IA, distal – IB and in patients with aorto-uniiliac Stent Graft with an incomplete common iliac artery occlusion resulting in backflow to the aneurysm – IC (Veith et al. 2002). Type II is connected with the retrograde blood flow from the branch aortic vessels, e.g., an inferior mesenteric artery, lumbar arteries or internal iliac artery into the aneurysm sac. Type III is the result of endograft structural failure which may be the consequence of either a junctional separation of the modular components, holes and fractures or continuous arterial pulsation stress. The type IV endoleak is connected with the Stent Graft porosity. The diagnosis of this endoleak type might be made after normalization of the coagulation profile and exclusion of other causes (Baum 2000; Stavropoulos & Charagundla 2007).

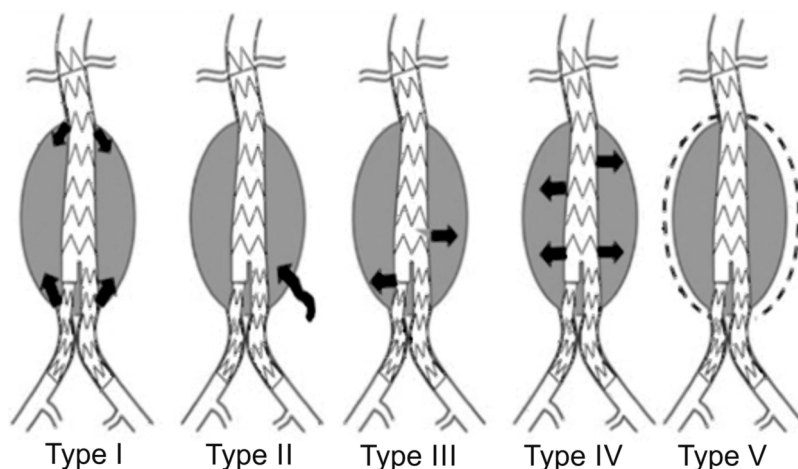


Fig. 1. Types of endoleaks

Recently, researchers have also enumerated type V – called “endotension” – which is connected with the expansion of the aneurysm sac more than 5 mm in diameter without any radiographic evidence of a leak site (Rosen & Green 2008; Bashir et al. 2009).

The European Society of Cardiology (ESC) guidelines on the diagnosis and treatment of aortic diseases recommended:

1. After TEVAR or EVAR surveillance - 1 month, 6 months, 12 months and then yearly (Class I C).
2. Angio-CT is recommended as the first choice imaging technique for follow-up after TEVAR or EVAR (Class I C).
3. In abdominal aneurysm, the Doppler ultrasound examination with or without contrast agents, which should be considered for annual postoperative surveillance, with non-contrast CT imaging over 5 years (Class IIa C).
4. For follow-up in young patients, MRI should be preferred to CT for imaging magnetic resonance-compatible stent grafts (Class IIa C) (Erbel et al. 2014).

This surveillance procedure helps to prevent the uncontrolled growing and rupture of aneurysm when the previously mentioned complications occur.

In a case of an endoleak we have to consider a treatment which is directed to the type of endoleak. To treat the type I endoleak we have to create a tighter attachment at the violated ends of the endograft. Usually, this should be undertaken immediately after diagnosis, because of the gradual increase in the risk of the rupture. This may be achieved by open surgical, endovascular or hybrid methods. Endovascular techniques such as supplementary stents, endograft extension, embolisation and sometimes balloon angioplasty might be used (Baum 2000; Stavropoulos & Charagundla 2007; Dominique et al. 2014). Recently, innovative endovascular methods, such as implanting fenestrated Stent Grafts, chimney grafts, sandwich implanting technique and endostapling are also available (Dominique et al. 2014), however they should be carefully chosen according to the ESC Guidelines (Erbel et al. 2014).

The aim of our study was to present an innovative endovascular technique – the Aptus™ Heli-FX™ EndoAnchor™ system combined with the Endurant Stent Graft cuff and used as a method of choice for the patient in a very poor general condition with symptomatic abdominal aneurysm and a post-EVAR type IA endoleak.

CASE REPORT

An 85-year-old male patient, with a past medical history of ischemic heart disease, atrial fibrillation, hypertension and obesity, developed a 9.3 cm in diameter ruptured abdominal aneurysm (RAA), accompanied by a disturbed coagulation profile (prolonged INR of 3.3 because of anticoagulant treatment with Rivaroxaban due to atrial fibrillation). He was operated on in March 2016 using endovascular aneurysm repair (EVAR) (see Fig 2 a,b).

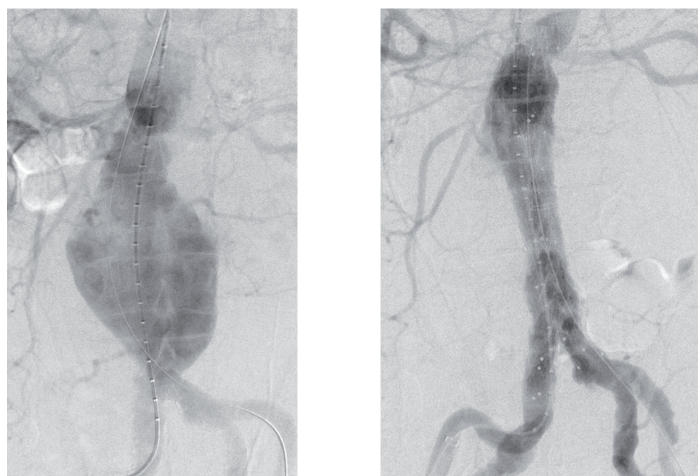
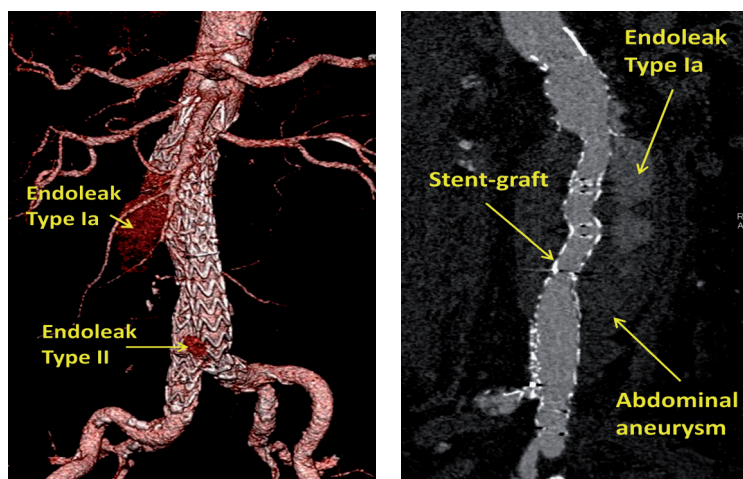


Fig. 2. Angiograms of the patient's abdominal aorta: a) before the Stent Graft implantation; b) after the Stent Graft implantation

The procedure was conducted without any complications. The angio-CT of the abdominal aorta performed on the 4th postoperative day showed a type IA endoleak with the suspicion of a type III endoleak, which were treated with a temporary discontinuation of the anticoagulation treatment. The next angio-CT performed later on the 11th postoperative days, did not reveal a type I and III endoleak, however it did reveal a small type II endoleak, with no need of treatment.

After a successful Stent Graft implantation, despite an initial serious condition (systolic blood pressure 80 mmHg with constant infusion of pressor amines), the patient improved very fast and was discharged from the hospital in a good condition, with the diameter of the aneurysm sac reduced from 9.3 to 8.8 cm.



Ryc. 3. The views of endoleaks a) in Angio-CT; b) intraoperative angiography

9 months later, (December 2016), he developed a severe abdominal pain and was urgently referred to the Vascular Surgery Department, at the John Paul II Hospital, Kraków. The Angio-CT examination revealed a fresh onset of the type IA and type II endoleak with an enlargement of the aneurysm sac (see Fig. 3 a, b).

The patient was in a very bad general condition, so an innovative endovascular repair system – the Aptus™ Heli-FX™ EndoAnchor™ system combined with the Endurant Stent Graft cuff – was the method of choice for the operation (see Fig. 4 a, b).

Catheterization was performed through his left radial (5-F port) and right femoral (7-F port) artery under local anesthesia. An angiographic control was performed via a pig-tailed catheter introduced through the radial artery port and confirmed a type IA endoleak. The 7-F femoral port was exchanged to 20-F and the controllable Aptus™ catheter was used (Parodi et al. 1999). 6 endoanchors of EndoAnchor™ system were employed to seal up the collar and stop the leak from the proximal portion of the stent-graft (see Fig. 4 b). On the second step, the Endurant Stent Graft (cuff) was implanted. The graft material was expanded by Reliant Stent Graft Balloon Catheter (Parodi et al. 1991). Intraoperative control angiography showed a significant reduction in the endoleak in the region of the lumbar artery. The whole procedure lasted 3.5 hours (see Fig. 5 a, b).

Post-procedural angio-CT showed no sign of a type IA endoleak but confirmed a small type II endoleak from the lumbar artery only (see Fig. 6). There were no postoperative complications and the patient was discharged from the hospital on 7-th post-procedural day in a good general condition

The 6-month follow-up has not revealed any complications. The patient is in a good condition. It should be stressed, that the Aptus™ Heli-FX™ EndoAnchor™ system combined with the Endurant Stent Graft cuff is effective in the elimination of endoleaks, allowing one to use a minimally invasive procedure, which finally prevents the patient from serious complications or even death and gives the patient a much better quality of life in comparison with open surgery repair.

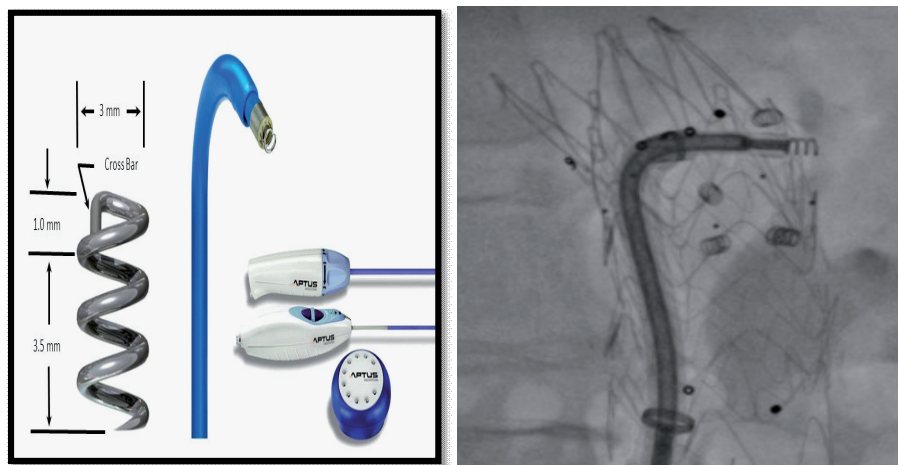


Fig. 4. a) the Aptus™ Heli-FX™ EndoAnchor™ system; b) intraoperative view

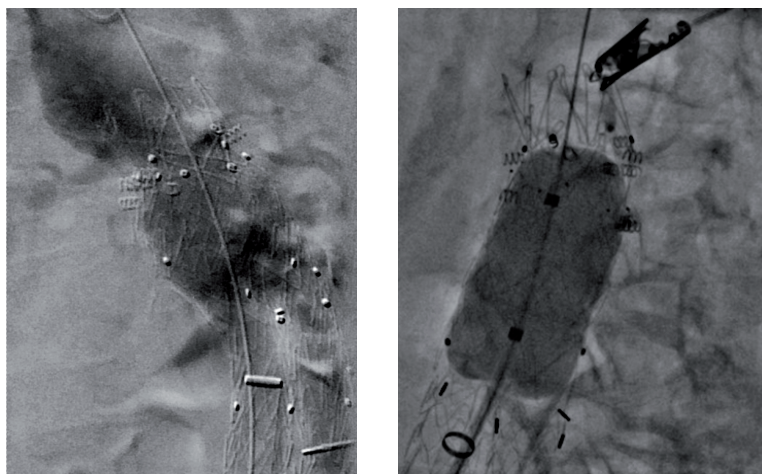


Fig. 5. Intraoperative views: a) after implantation Stent Graft cuff and endoanchors; b) during the graft material expanding by Reliant Stent Graft Balloon Catheter

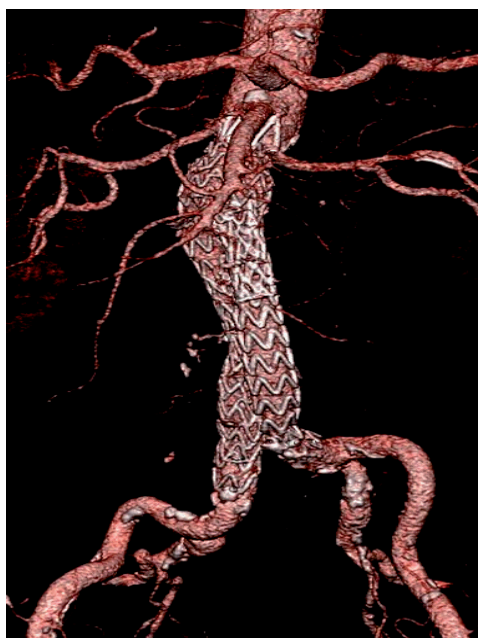


Fig. 6. Post-procedural Angio-CT of the Stent Graft with no visible type II endoleakage

CONCLUSION

The innovative endovascular repair system – the Aptus™ Heli-FX™ EndoAnchor™ combined with the Endurant Stent Graft cuff was successfully used as a method of choice for the patient in a very poor general condition with symptomatic abdominal aneurysm and a post-EVAR type IA endoleak. It prevented

the patient from serious complications or even death and provided him with a much better quality of life in comparison with open surgery repair.

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