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Hellenic Society of Vascular and Endovascular Surgery

Hellenic Journal of Vascular and Endovascular Surgery

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Barcelona, Spain

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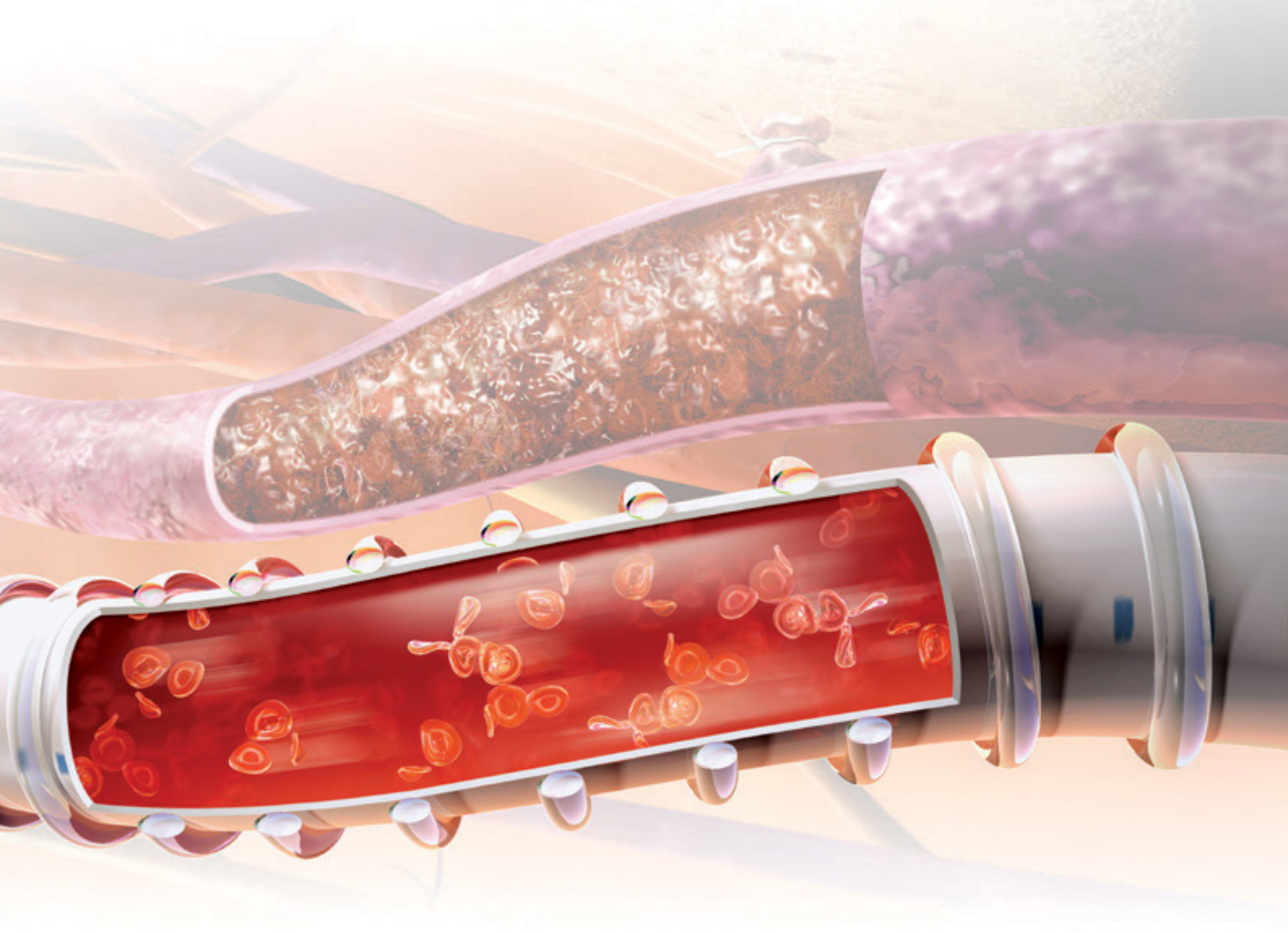

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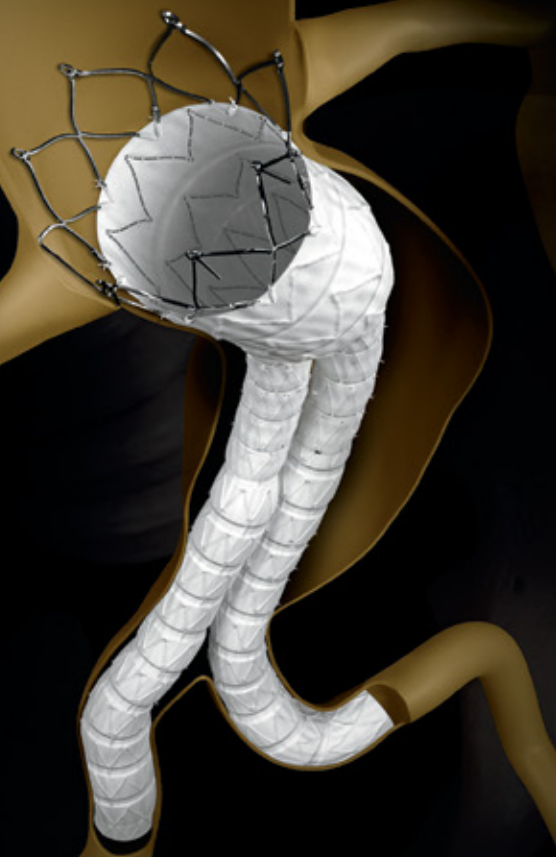

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[1] Torsello et al. Safety and effectiveness of the INCRAFT® AAA Stent Graft for endovascular repair of Abdominal aortic aneurysms. JOURNAL OF VASCULAR SURGERY; January 2015, Volume 61, Number 1. Pages 1-8.

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EDITORIAL

EVAR after NICE guidelines: what should we do and what should we not do?

Vincent Riambau

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Probably, when reading this editorial, if the forecasts do not confuse us again, the expected and feared guidelines of the NICE (National Institute for Health and Care Excellence) for abdominal aortic aneurysm (AAA) management[1] will have already been published, or maybe not yet. In any case, I think it is a good time for a reflection on the subject.

In an earlier editorial published in Angiologia[2], just a few days before the first draft of the aforementioned NICE guidelines came to light, we are already referring to the "immaturity" of the EVAR technique (endovascular treatment of abdominal aortic aneurysms). Moreover, we show our fear that "someone from outside our profession will call us to stop because of the accumulation of bad results." And so it has happened, or at least this threat exists from the NICE. As most of our readers know, NICE supports its guidelines in evidence-based medicine, especially that emanating from the United Kingdom in conjunction to a serious health economic analysis. It is fair to recognize that all randomized studies and their meta-analysis, no matter how obsolete they are, coincide in the early benefit of EVAR over open surgery. However, it also highlights the higher mortality and higher rate of re-interventions associated with EVAR in the long term[3-6].

The recommendations contained in the NICE draft are summarized in a harsh conclusion: not to offer EVAR whether open surgery is viable or not. Just leave the EVAR option in the case of the treatment of rupture AAA. This last point is a contradiction, because if the training that elective EVAR supposes is eliminated, how would the emergency EVAR be effectively addressed? We know that these recommendations are derived from the economic analysis of the EVAR under the British National Health System (NHS). But, we cannot ignore that the clinical evidence published by way of prospective and randomized studies does not clearly support EVAR. There are therefore two areas for improvement on which, who believe in EVAR, we must focus our attention. On the one hand, the cost and on the other, the clinical efficacy. That is, we must offer new and better evidence in terms of cost / effectiveness of the technique to convince, about the benefits of EVAR, to our patients, to the regulation agencies and to the health authorities, the payers.

It is no less true that randomized studies have great limitations. We will cite the most important. The first refers to the inclusion periods dating back to the year 1999, where most of the stent models applied were already removed from the market and therefore technologically overcome in subsequent years with other, theoretically better models. The EVAR-1[3] and DREAM[4] studies did not include as reinterventions those related to the events of laparotomies of the group of patients operated with open surgery. However, the OVER[5] does contemplate them, and thus substantially reduces the differences between the two treatment groups. Finally, it should be noted that these studies include the learning curve stages of the groups that started in EVAR, which implies a clear bias against this treatment group.

Beyond medical evidence there are other arguments, not negligible, in favor of EVAR. These are what keep EVAR as the technique of choice for the treatment of AAA in the developed world. We refer to the degree of satisfaction for patients. Published surveys show that the majority of patients undergoing EVAR continue to prefer this technique over the open option despite high rates of reoperation and the need for lifelong follow-up. What worries patients the most is mortality and the risks of perioperative organic failure[7]. At this point we could include the least interference of EVAR in sexual function when compared to that derived from open surgery[8].

In addition, it should be noted that EVAR offers greater satisfaction also for surgeons. The low morbidity, the almost zero mortality and the short hospital stay are clear reasons for professional satisfaction to be able to repair important injuries with minimal or percutaneous surgical procedures. This is especially true for those surgeons who had an exclusive training in open surgery and were able to star in the shift towards EVAR.

The third group that sees their expectations met is that of the medical device manufacturing industry. Obviously, the inclusion of EVAR and other endovascular techniques in the therapeutic arsenal of our specialty has represented an excellent business opportunity for those companies that bet in this direction. Although for some of them, the growth of the turnover is never enough.

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The fourth protagonist is undoubtedly the health authority or those who financially support the new technology. The most defensible argument is the reduction of hospital stays related to EVAR and other surgical techniques of other disciplines that have turned towards less invasive surgery. This has allowed, in many centers, to reduce hospitalization beds in favor of major outpatient surgery, day hospital or short stay, all without reducing surgical activity. The correct management of this change has meant and continues to mean a reduction in hospital costs that allow investments in other health plans. However, if the cost of the devices were more adjusted, our administrators would see their degree of satisfaction increased while improving the cost / effectiveness ratio and contributing to the sustainability of the health system. Precisely, one of the greatest difficulties that the NICE guidelines must overcome is to justify the change of hospital organization; if EVAR disappears, it would be necessary to increase the number of ICU beds, conventional ward, surgeons or simply increase the waiting list. The economic and social consequences of adopting these guidelines do not seem so innocuous. Therefore, the publication of the final document is delayed almost indefinitely.

Fortunately for EVAR advocates, the recent clinical practice guidelines of ESVS (European Society for Vascular Surgery)[9] are more permissive with EVAR. However, they restrict its use in complex anatomy cases with less conventional and few proven techniques.

At this point, it is mandatory to ask what we can do from now on to continue defending EVAR. In my modest opinion and following common sense as possible, in the absence of more clinical evidence, there are five premises to be considered immediately.

The first, the defenders of EVAR, must recognize its limitations. On the one hand the adverse anatomical conditions do not make it advisable to apply EVAR and therefore, not all AAA must be resolved with EVAR. However, even following a scrupulous patient selection, the most important limitation of EVAR focuses on its durability.

The second premise is to overcome, if possible, these limitations. Some are of a technological nature due to material failure. Other technical-anatomical, which forces us to innovate and develop some solutions and / or adjuvants that must be tested extensively in preclinical and followed and reported their results in well-designed clinical Registries or Registry-based randomized Clinical Trials.

The third being faithful to the instructions for use of the different devices. It is not advisable to forge an experience based on cases that have not followed the instructions for use. The failure is served and this would have harmful consequences for the EVAR technique, without forgetting aspects associated with medical malpractice.

The fourth is to continue to meet the expectations of the different actors: patients, surgeons, industry and administrators. For this, the treatments must be applied in the best conditions to obtain the best results in terms of reduction of reinterventions and mid-long-term mortality. With the latter, surgeons will also feel more satisfied. The industry must accompany doctors and patients as a collaborator in technological development to continue obtaining business opportunities. Companies must promote "postmarket" registries to know the behavior and results of their products in the real world and be able to compare with those provided by randomized studies and by other companies. There is general conviction that it will not be possible to conduct another randomized prospective study for economic reasons. Therefore, well-designed observational studies and Registry-based randomized Clinical Trials must be enhanced. If, in addition the industry adjusts its market prices, the fourth actor, the administration, would be satisfied. In order for EVAR to remain alive, the expectations of the four actors must be met. If one of them does not feel satisfied, the technique will be abandoned with the potential harm to all of them.

The fifth and final premise is to maintain the training of young vascular surgeons in the open repair of aorta to be able to treat with guarantees those AAA not candidates for EVAR. Failure to master the open technique implies a selection bias that would force indications outside the instructions for use or therapeutic abstention, both dangerously inappropriate.

So far we have wanted to transcribe a series of reflections on what the publication of the dreaded NICE guides may entail. Before knowing their latest version, they have already served as a touch of attention to make a point and followed in the history of EVAR, in my opinion absolutely necessary.

No conflict of interest.

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EDITORIAL

Current and future perspectives on endovascular treatment of para and juxtarenal AAA

Gaspar Mestres, Vincent Riambau

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In spite of the differences in definition of para- and juxta-renal abdominal aortic aneurysms (p-/j- AAA), the recent ESVS guidelines equate both concepts*: an aneurysm extending up to but not involving the renal arteries, necessitating suprarenal aortic clamping for open surgical repair (i.e. a short neck <10 mm)*[1]. There is a prolific literature concerning the treatment of jAAA, because it is one of the most challenging situations in vascular surgery commitment: exclusion of the aortic aneurysm avoiding impairment of visceral function[2,3].

Open surgery has traditionally been the standard treatment, via transabdominal or retroperitoneal approach, and necessitating suprarenal clamping and eventual transection of the left renal vein. Despite good mortality rates (as down as 4.1% 30-day or in-hospital mortality, following some systematic reviews)[1,2], these good results have only been achieved in fit patients, at high volume and dedicated centers, and tolerating a considerably high morbidity. Open repair is not possibility for all vascular surgery departments. Therefore, endovascular treatment (EVAR) of jAAA rose not only in order to improve these considerably good mortality rates, but to decrease morbidity and to extend the treatment of jAAA to unfit patients for open surgery and to centers with lower volume and expertise in open surgical repair of complex aneurysms.

There are no randomized trials comparing open and endovascular treatment of jAAA (and probably there will not be), so direct comparisons are not possible. And in spite of treating more comorbid and unfit patients with endovascular techniques, a recently published meta-analysis[2] comparing open and endovascular repairs and analyzing almost three thousand treated cases, concluded that there were no significant differences in 30-day mortality (3.3% for fenestrated EVAR [fEVAR] vs 4.2% for open repair), with lower morbidity (renal insufficiency, major early complication) but higher late re-intervention rate (11.1% vs 2.0%) for fEVAR. It has to be read as a success: endovascular surgery is able to obtain comparable, if not better, short-term results in worse condition patients.

Concerning endovascular treatment options, fEVAR should be considered as the first option, due to their reported safety and efficacy, and plentiful published evidence[1,2]. However, there are severe anatomical requirements: endograft availability and manufacturing can be delayed up to 8 weeks (except for the uncommon off-the-shelf devices), iliac access limitations, patent aortic lumen diameter and angulation, number of fenestrations and visceral vessels anatomy and orientation. Some of these limitations can be overtaken with bEVAR (branched EVAR), with internal or external branches, or in combination with fenestrations, which can allow deployment of the bridge stents through brachial access after endograft deployment, avoiding some fEVAR limitations like stenotic iliac access, wide aortic lumen, downward pointing of the visceral vessels, or more off-the-shelf available devices for emergency cases. However, it is more commonly used for thoracoabdominal aneuryms (TAAA) and there is less strong published evidence and a tendency towards worst results than conventional fEVAR, probably due to failing longer bridge stents, with a higher rate of thrombosis and type III endoleaks. Moreover, bEVAR is still subjected to important common limitations like availability, one wide iliac access is required with additional subclavian access, visceral vessels without prompt bifurcations and downward orientated[4].

When these alternatives are not feasible for any reason, parallel graft or chimney technique (chEVAR) appears as a very valuable alternative. In spite of some anatomical limitations (preferably not more than 2 downward pointing visceral vessels) and some concerns related to gutters, it can be used in narrow iliac accesses and in emergency setting[5].

In the near future, we will probably see a simplification of jAAA endovascular planning, increasing the number and competence of the off-the-shelf devices and decreasing or eliminating the manufacturing delays. Smaller profiles, pre-cannulated devices and multiple branch designs can help to advance in this endovascular era. But, beyond endograft perfection, an improvement in bridge stents design is mandatory because it is one of the main causes of bEVAR and fEVAR failure. Actually, some companies launched im-

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provements in their bridge stents shapes and radial forces (BeGraft+ platform [Bentley InnoMed, Hechingen, Germany], Gore Viabahn VBX [GORE Flagstaff, AZ]), but their superiority or mid-term durability has not been demonstrated. Bridging stents are the Achilles heel of endovascular treatment of juxtarenal and thoracoabdominal AAA, and until dedicated stentgrafts are designed, it won't be possible to give fEVAR the definitive strike against jAAA.

No conflict of interest.

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Endovascular repair of juxta- and para-renal abdominal aortic aneurysms

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Abstract:

Introduction: During the last two decades endovascular approach has been extensively adopted for the treatment of juxta-renal abdominal aortic aneurysm (jAAA) and para-renal aneurysms (pAAA). The aim of the current study was to evaluate the early and mid-term outcomes of endovascular treatment of jAAA and pAAA in a tertiary vascular center.

Methods: A retrospective study was undertaken of consecutive high-risk patients presenting with complex aortic aneurysm (jAAA or pAAA) and treated electively with either chimney endovascular aneurysm repair (ChEVAR), fenestrated (FEVAR) or branched (BEVAR) technique between 2016 and 2019. The primary end point was technical success rate, survival and target vessel patency during 30 post-operative days. Secondary outcomes were survival, target vessel patency and re-intervention rate during the study period.

Results: A total of 41 patients with presentation of complex aortic aneurysm were treated electively; 36 ChEVAR, 4 FEVAR and 1 BEVAR. The mean age of the patients was 71.2±6.7 years (95% male [39/41]), with mean aneurysm diameter of 64±14mm. Ninety-eight splanchnic arteries were targeted; 76 renal arteries, 19 superior mesenteric arteries and 3 coeliac trunk arteries. The technical success rate was 95% (39/41; 2 patients had a gutter endoleak intra-operatively). The overall 30-day mortality was 10% (4/41); only one aneurysm related. No patient presented spinal cord ischemia. The median follow-up was 6 months (1-36 months). Survival was 85% (SE 6%) and 80% (SE 7%) at 6 and 12 months, respectively. The freedom from re-intervention was 98% (SE 2.4%) and 89% (SE 5%) at 1 and 12 months, respectively. The freedom from target vessel occlusion was 98% (SE 2.4%) at 6 and 12 months. At 1st month computed tomography, 4 patients had gutter endoleak, which disappeared at the 6-month follow up.

Conclusion: Endovascular approach of pAAA and jAAA is an effective treatment option with high technical success rate. Early and mid-term outcomes are good in terms of mortality, target vessel patency and re-intervention rate.

INTRODUCTION

Juxta-renal abdominal aortic aneurysm (jAAA) is defined as an AAA with an infra-renal short proximal neck of <10 mm that may require suprarenal cross-clamping during open repair,[1] while para-renal AAA (pAAA) involves the renal arteries and always require a supra-renal cross-clamping.[2] JAAA and pAAA pathology are diagnosed in up to 15% of all AAA.[3,4] Traditionally, during the past decades open repair was the treatment of choice of such AAAs. Open repair is technically challenging due to the involvement of reno-visceral vessels, the potential renal or even visceral ischemia due to the proximal clamping, the advanced age of the patients, and the commonly coexisting severe comorbidities. Additionally, similar pathology represents the para-anastomotic aneurysms (PAA) after open repair, that may present in 0.5% to 15% in various reports.[5] Open repair of jAAA and pAAA has showed quite low perioperative mortality rates, however the morbidity rates are not insignificant.[6-8] In particular, the open repair of PAAs has demonstrated even higher morbidity (70% to 83%) and mortality rates (8% to 70%).[5,9,10]

On the other hand, during the last two decades endovascular approach has been extensively adopted for the treatment of jAAA and pAAA.[5,11] Fenestrated stent-grafts (FEVAR; fenes-

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trated endovascular aneurysm repair) incorporates the renal or all of the visceral branches in order to expand the proximal sealing zone.[3] Custom made branched devices or standardized off-the-shelf multibranched devices, such as the t-Branch (Cook Medical, Bloomington, IN, USA), has also been used in order to expand the proximal sealing zone to a healthy aorta.[12] Another endovascular technique that has been broadly used is the chimney technique (ChEVAR) that has also showed good aneurysm exclusion and patency rates.[13]

The aim of the current study was to evaluate the early and mid-term outcomes of endovascular treatment of jAAA and pAAA in a tertiary vascular center.

METHODS

Patients selection

A retrospective study was undertaken of consecutive high-risk patients presenting with complex aortic aneurysm (jAAA or pAAA) and treated electively with either ChEVAR, FEVAR or BEVAR (Branched EVAR) technique between 2016 and 2019. Proximal landing zone precluded any standard EVAR. Patients were classified as high risk for open aortic surgery. This was a single-center retrospective study, with all data being acquired prospectively. According to the local authorities, Institutional Review Board approval for informed consent of the patient was not deemed necessary for this retrospective study.

End points- Definition

The primary end point was technical success rate (absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction), survival and target vessel patency during 30 post-operative days. Secondary outcomes were survival, target vessel patency and re-intervention rate during the study period. Endoleak type Ia and gutter's endoleak were defined and reported separately as has been described previously.[14]

Peri-procedural characteristics

Demographic data, pre-operative comorbidities such as hypertension (HT), hyperlipidemia (HL), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), cerebrovascular disease (CVD), coronary artery disease (CAD), smoking, intraoperative and perioperative details were recorded. Blood test results, such as hemoglobin (Hb) level, white blood cell count and creatinine levels were also recorded.

Sizing and planning were performed based on the pre-operative computed tomography angiography (CTA) using a 3Mensio workstation (Medical Imaging B.V., Bilthoven, the Netherlands) with dedicated reconstruction software. All but 4 ChEVAR procedures were performed in an adequately equipped operating room, using a moveable radiolucent surgical table and a mobile digital angiographic system (Philips BV Endura, Philips Medical Systems, the Netherlands). The last 4 ChEVAR patients were treated with the new mobile digital angiographic system (Ziehm Vision RFD 3D, Ziehm Imaging GmbH, Nuremberg, Germany). The FEVAR and BEVAR cases were undergone in the angio-suite of the radiology department (Allura Xper FD 20, Philips, USA).

Standard Intra-operative management

All operations were undergone under general anesthesia. After the insertion of the sheaths, 50-100IU/kg of unfractionated heparin was administrated to the patient. After the first operative hour, activated clotting time (ACT) was calculated and repeated every 30 minutes. In the case that ACT target (200-300 sec) was not achieved, a further bolus administration of heparin was administered (50IU/kg). Cerebral oximetry (INVOS™ 5100C Cerebral/Somatic Oximeter, Medtronic, Minneapolis, MN, USA) was also applied in all cases as a standard of care.

Access

In all ChEVAR cases, bi-femoral access was used for the insertion of the main endograft. Concerning the parallel grafts, in cases of one chimney a left brachial access was preferred with percutaneous puncture under ultrasound guidance. Left axillary artery was dissected and two parallel sheaths were inserted when two chimneys were applied. Right axillary artery was additionally used in cases of three chimneys. In the B/FEVAR cases bi-femoral access was used for the insertion of the main endograft. The branches (t-Branch) were cathererized by right axillary artery because of the setup of the angio-suite, while in FEVAR cases, the splanchnic vessels were catheterized by the femoral access, except one case that upper extremity access was needed for the catheterization of coeliac trunk (CT) and superior mesenteric artery (SMA).

Type of stent-graft and stents

Stent grafts with either supra-renal fixation system (Endurant; Medtronic Ave, Inc, Santa Rosa, Calif or Incraft, Cordis, Cardinal Health, Santa Clara, California, US) or Nellix system, Endologix, Irwin, California, US) were used in ChEVAR procedures; in one patient a thoracic endograft from Bolton (Medical, Sunrise Florida, U.S) was also used. The oversizing of the main aortic graft was varied between 23% and 30%. The choice type of endografts were selected according to personal preferences of each surgeon taking into consideration the anatomical characteristics of the aneurysm. In the BEVAR case the t-Branch (Cook Medical, Bloomington, IN, USA) was used, and in the FEVAR cases a custom made device also from Cook was used.

In all cases a balloon expandable covered stent was preferred where patient's anatomy permitted a successful stenting. When longer stents were demanded, either a self-expanding covered stent was used or in the recent cases the VBX (W.L. Gore & Associates, Flagstaff, AZ, USA) that can be up to 79mm. Relining with self-expanding bare metal stents was applied according to surgeon's preference or in cases where an inadequate angulation of the inserted stent was detected in the intra-operative angiography.

Dual antiplatelet therapy with clopidogrel 75 mg and aspirin 100 mg, was administered in all patients for at least the first post-operative month. Patients that were under antico-

agulation with DOACs or VKA antagonist, received single antiplatelet treatment additionally.

Follow-up

All patients have been under follow up protocol including CTA before discharge, duplex ultrasonography with plain x-rays was used as standard follow-up method at 6-month follow-up, CTA at 12 months and yearly thereafter. All data derived from CTAs were analyzed and registered in a xl file.

Statistical Analysis

Continuous data were reported as a mean ± standard deviation. Categorical data were expressed as absolute numbers and percentage of prevalence (%) in the study cohort. Survival times were initially compared among groups with the log-rank test and Kaplan- Meier curves were generated. P value was considered significant when it was <0.05. Statistical analysis was performed by SPSS 22. 0 for Windows software (IBM Corp, Armonk, NY).

RESULTS

Patients characteristics

Between 2016 and 2019, a total of 41 patients with presentation of complex aortic aneurysm were treated electively in our department. The mean age of the patients was 71.2±6.7 years (95% male [39/41]), with mean aneurysm diameter of 64±14mm. The mean length of AAA neck was 4±2mm in jAAA patients (28/41) and 0mm in 13 patients who had pAAA. Table 1 shows the most common co-morbidities of the patients; all patients were classified as ASA 3 or 4.

Co-morbidities	
HT	61% (25/41)
HL	34% (14/41)
CAD	46% (19/41)
Smoking	46% (19/41)
COPD	42% (17/41)
CRD	5% (2/41)
CVD	2.5% (1/41)
ASA classification	
ASA 3	90% (37/41)
ASA	10% (4/41)

Table 1. This table demonstrates the co-morbidities. HT: hypertension; HL: hyperlipidemia; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; CRD: chronic renal disease; CVD: cerebrovascular disease; ASA: American Society of Anesthesiologists.

Intra-operative details

All patients were treated under general anesthesia. Table 2 shows the devices that have been used for ChEVAR (Figure 1), FEVAR (Figure 2) and BEVAR (Figure 3). Seven patients (17%; 7/41) were a secondary procedure after previous aortic repair (6 after EVAR and 1 for para-anastomotic aneurysm after open repair); for the 6 redos after EVAR, 2 patients have been treated with ChEVAR using an Endurant Cuff, 3 with ChEVAR using Nellix and 1 with FEVAR, while the one patient with the para-anastomotic AAA was also treated with ChEVAR using the Nellix device. Ninety-eight splanchnic arteries were targeted; 76 renal arteries, 19 superior mesenteric arteries and 3 coeliac trunk arteries. In terms of type of stents for target vessels (TVs) 74 balloon expandable covered stents were used for the renal arteries (35 BeGraft, Bentley Innomed, GE, 7 Atrium V12, Maquet SAS, FR, 28 LifeStream, C. R. Bard, USA, 4 VBX, W. L. Gore, USA) and 2 self-expanding covered stents (Viahban, W. L. Gore, USA). Additionally, 19 balloon expandable covered stents were also used in SMA (18 BeGraft, Bentley Innomed, GE and 1 VBX) and 3 in CT (2 BeGraft, Bentley Innomed, GE and 1 VBX). Additionally, we used for relining self-expanding stents, 6 for the SMA and 15 for the RA (E-luminex, C. R. Bard, USA).

	Number of target vessels	1	2	3	4	Total
Type of endograft in ChEVAR	Nellix*	4	3	3	0	10
	Endurant**	4	6	12	0	22
	Incraft	0	3	0	0	3
	Relay	0	0	1	0	1
	FEVAR***	0	0	2	2	4
	BEVAR	0	0	0	1	1
	Total	8	12	18	3	41

*3 cases after previous EVAR, 1 case for para-anastomotic aneurysm

**2 cases with Cuff after previous EVAR

***1 case after previous EVAR

Table 2. This table shows the devices that have been used. ChEVAR: chimney endovascular aneurysm repair; FEVAR: fenestrated EVAR; BEVAR: branched EVAR.

Median perioperative time was recorded at 235 minutes (range 180-360 minutes) while the median radiation exposure time was 49 minutes (range 30-102 minutes). The median contrast volume used was 194ml (range 72-400ml). Blood loss was within acceptable limits as median transfusion volume was 1.6 RBC/patient (0-3). The technical success rate was 95% (39/41; 2 patients had a gutter endoleak intra-operatively). After the procedure, patients were usually transferred directly to the ward. However, some patients had to be admitted to the ICU, usually due to pre-existing comorbidities. For these patients, median stay at the Intensive Care Unit (ICU) was 1day (range 0-10 days).

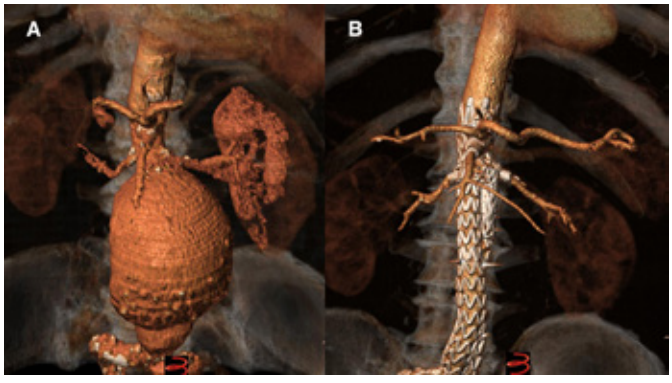

Figure 1. A pre-op and post-op computed tomography angiography of a chimney endovascular aneurysm repair case.

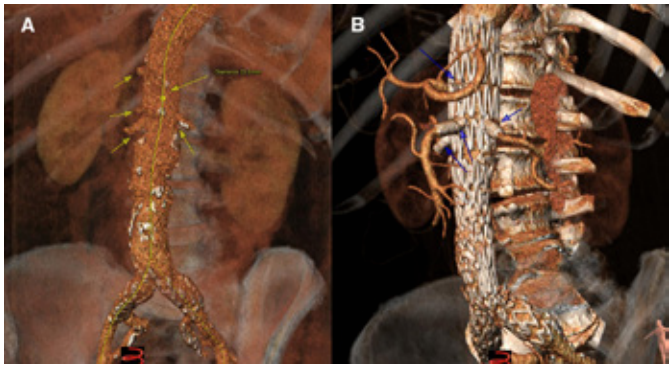

Figure 2. A pre-op and post-op computed tomography angiography of a fenestrated endovascular aneurysm repair case.

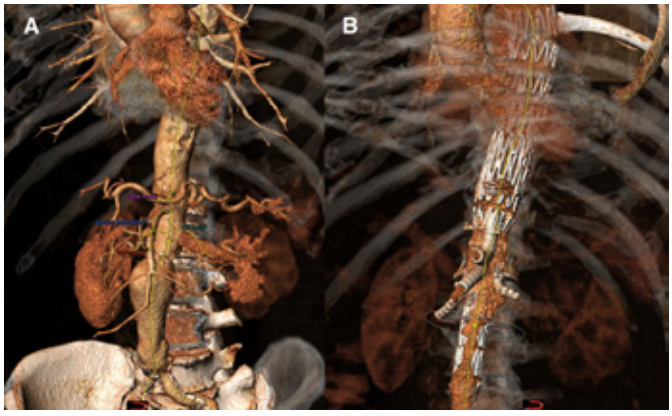

Figure 3. A pre-op and post-op computed tomography angiography of a branched endovascular aneurysm repair case.

Early outcomes

The overall 30-day mortality was 10% (4/41); all patients after ChEVAR. A patient died after severe systemic inflammatory response syndrome and multi-organ failure in the 10th post-operative day (without Endoleak and with patent splanchnic vessels in post-op CTA). Two patients died due to myocardial infarction on the 2nd and the 9th post-operative day. One aneurysm related death was attributed to an injury of a renal artery branch probably due to the stiff wire needed in this particular anatomy (severe aortic atherosclerosis and angulation of the aorta and the renal artery) that caused severe hemorrhage and retroperitoneal hematoma, despite the immediate re-intervention with subsequent embolization of the branch the same day. During hospitalization, 1 more patient had a non-fatal myocardial infarction and 2 patients had a non-disabling stroke (1 hemorrhagic and 1 ischemic). Two patients had a respiratory infection (pneumonia), 3 had a paralytic ileus and 1 patient presented with a transient upper limb paralysis due to brachial plexus injury. No patient presented spinal cord ischemia. All patients were discharged in good condition. One patient after the discharge presented gastro-intestinal bleeding the 20th post-operative day that was successfully treated conservatively.

Follow up outcomes

The median follow-up was 6 months (1-36 months). Two patients died during follow up. One patient at 6 months due to chest infection and one patient at 2 years because of liver cirrhosis. No patient presented a renal insufficiency. The KM analysis showed that survival was 85% (SE 6%) and 80% (SE 7%) at 6 and 12 months, respectively (Figure 4). Additionally, 3 patients needed a re-intervention, one patient had a type III endoleak at 1st month and a new stent graft was inserted, one patient had a limb occlusion at 6 months and underwent a fem-fem bypass, and one patient had a in-stent stenosis of the SMA at 6 months of follow up, and a re-intervention was undertaken with a covered balloon expandable stent. The patient with the t-Branch treatment had a small endoleak type III between the branch device and the distal graft and he is still under surveillance (Figure 3). KM analysis showed that freedom from re-intervention was 98% (SE 2.4%) and 89% (SE 5%) at 1 and 12 months, respectively (Figure 5). During follow up, only one right renal artery stent was thrombosed during the 6th follow-up month after ChEVAR. KM analysis showed that freedom from target vessel occlusion was 98% (SE 2.4%) at 6 and 12 months (Figure 6). An in-stent stenosis was noted in 3 patients (all ChEVAR patients; 2 RRA and 1 SMA; that was treated as mentioned above) during the 1st month CTA without any clinical presentation, and patients with the RRA in-stent stenosis were treated conservatively. At 1st month CTA, 4 patients had an endoleak type Ia (all defined as gutter endoleaks), one patient type III (that was treated with a limb extension) and the patient with the t-Branch mentioned above had also type III endoleak between the main graft and the distal one. In all 4 patients the gutter endoleak disappeared at the 6-month follow up.

DISCUSSION

During the last decades, endovascular interventions have been constantly increasing for the treatment of complex aortic aneurysms.[15] The recent ESVS (European Society for Vascular Surgery) guidelines,[16] highlighted that in complex endovascular repair of jAAA, FEVAR should be considered the preferred treatment option when feasible (IIa, C), while the use of parallel graft techniques may be considered as an alternative in the emergency setting or when fenestrated stent grafts are not indicated, not available, and as a bailout (IIb, C). This is more pronounce for patients that have severe comorbidities, that usually are turned down for open repair. However, with the relatively novel endovascular techniques, the treatment of those patients is now feasible. In this study, the technical success rate was 95%, with no intra-operative death. Although, those were patients with ASA 3 and 4, most of them were treated without any severe peri-operative complication. Along this line, a recent systematic review showed that endovascular treatment of pAAA and jAAA was a safe and efficient treatment with high technical success rate and low mortality.[17] Li et al.[18] presented another systematic review and pooled analysis comparing FEVAR with ChEVAR techniques, showing that both fenestrated and chimney techniques are attractive options for jAAA treatment with encouraging early and mid-term outcomes.

The mortality rate of this study's cohort was 10%. Howev-

er, only one death was absolutely aneurysm-related, after an injury of a renal artery branch probably due to the stiff wire needed in this particular anatomy, while other causes were mainly myocardial infraction and chest infection. A recent study analyzed custom made devices and physician modified devices for the treatment of complex aneurysms also showed an early mortality rate of 4% and 14%, respectively.[19] In another large systematic review on FEVAR and ChEVAR, it was highlighted that no statistically significant differences were found between the two endovascular approaches for pararenal aortic pathologies in terms of 30-day mortality, renal impairment, or endoleak.[20] Thus, different endovascular approaches present similar results in terms of mortality. In this study, most of the patients were treated with ChEVAR technique, because of logistic and economical reason that exist in our country. Another important reason was that some patients had a large aneurysm and could not wait for a custom-made device that could be available up to 12 weeks; although this situation is changing. Although, those are complex aneurysm requiring complex endovascular approach, it is apparent that the main cause of mortality is the frailty of those patients. Most of them, they are not candidates of open repair, thus endovascular treatment for them might be the only option. In this study, the outcome during follow up is encouraging, with the survival rate at 12 months period was 80%. Literature evidence has shown that survival during follow up can be 90% at 12 months to 73% at 48 months of follow up.[3]

A recent propensity score analysis in patients with pAAA undergoing F/BEVAR or open surgical repair suggested that although no difference was noted in terms of 30-day mortality, dialysis, or organ-specific postoperative complications, the incidence of acute kidney injury was higher after open repair.[21] In our study, no patient presented either early or late renal insufficiency, even the patients with the renal stent occlusion or the renal stent stenosis. Another study highlighted, that postoperative acute kidney injury might be more common after BEVAR and its prevention was based on staged procedures, early interventions for renal side branch complications, and regular surveillance.[22]

Seventeen percent of our patients were treated as a redo procedure after EVAR or open repair with good technical success rate and good clinical outcome. Previous studies have also showed that fenestrated and branched stent-grafting represents a feasible option for the repair of jAAA after prior endovascular or open aortic surgery. Despite increased technical difficulties it was associated with high technical success rate and was advantageous in terms of mortality and morbidity compared to redo open aortic surgery.[23] Reyes et al.[24] reported a study on the use of FEVAR, BEVAR, and ChEVAR on postsurgical pararenal aneurysms showing that those less invasive endovascular approaches allow effective treatment approaches. Additionally, the treatment of patients with Endoleak type I repair after previous EVAR appeared generally feasible, with good early to midterm outcomes. Different endovascular treatments options are available, and the choice should be based on endoleak characteristics, aortic anatomy, and the patient's surgical risk.[25]

Two points of consideration in patients with complex endovascular treatment, are the incidence of endoleak, mainly type Ia in ChEVAR and type III in FEVAR and BEVAR, along with the stent patency of the splanchnic vessels. Recently Donas et al.[19] have reported that there was no significant differences recorded in the endoleak Ia rate: 1.93% of the chimney patients vs. 2.06% for the FEVAR group (p=0.939). In another study, Lachat et al.[26] also highlighted nearly all of the aneurysms showed no increase in diameter over a >2-year mean follow-up with few endoleaks or branch occlusions. Generally, a low rate of chimney graft occlusions has been noted, which appeared to occur generally a few months after placement. Involvement of the renal artery had no severe clinical consequences[13]; along this line, in our study we have identified one early stent occlusion and two renal stent stenosis but without any clinical implication. Similar good results have been demonstrated in FEVAR patients even during long term period. The pooled TV patency rates during 12, 24, 36, 48 and 60 months were 95.4, 92, 91, 88 and 87%, respectively.[3]

Recently, devices with visceral inner branches might represent another feasible option to address selected target vessels in F/BEVAR. Stent grafts with inner branch(es) in combination with fenestrations seem to be a better configuration than stent grafts with inner branches alone. Estimated survival at 1 year was 80.0%, while the estimated inner branch target vessel stent patency at 1 year was 91.9%. % ± 8.9%.[27] Additionally, percutaneous upper extremities access has been used for F/BEVAR procedures showing low incidence rate stroke (2%). However, there is still some doubt on higher access-related complication rate compared with open access.[28]

The main limitation of this study was its retrospective nature. The number of patients is relatively small, however these cases concerned endovascular treatment of complex abdominal aortic aneurysms. Additionally, there was a heterogeneity in terms of treatment methods, although the indication was similar in all patients (pAAA or jAAA). Longer follow up and larger equal number for each approach might demonstrate clearer and more solid evidence for the endovascular approach of pAAA and jAAA.

CONCLUSION

Endovascular approach of pAAA and jAAA is an effective treatment option with high technical success rate. Early and midterm outcomes are good in terms of mortality, target vessel patency and re-intervention rate taking into consideration that many of those patients are unfit for open repair with severe co-morbidities.

No conflict of interest.

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INVITED COMMENTARY

Complex endovascular aortic repair in Greece: first steps towards centralization

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In the current issue Matsagkas et al.[1] present their experience on 41 consecutive patients with complex aortic aneurysms (juxtarenal & pararenal) that were treated with advanced endovascular techniques [Chimney EVAR (ChEVAR), Fenestrated/branched EVAR (F/BEVAR)] during the period 2016 and 2019. This is probably the largest documented experience with complex aortic endovascular repair in Greece and the authors should be congratulated and thanked for sharing these data.

Technical success rates were very good (95%) and in line with other published experience. This is notable considering that this series had also a learning curve effect at least for the first cases. Moreover, 17% of the patients were previously operated in the aorta, and it is a well known factor that redo complex endovascular aortic procedures have an increased risk for technical difficulties and problems both with regard to planning and execution.[2]

Despite that most of the procedures were performed with a mobile C-arm, operation duration, and fluoroscopy times remained within normal values. One could therefore argue that although a hybrid room is the ideal environment to perform complex aortic endovascular procedures, a standard OR with a mobile C-Arm should not be considered prohibitive at least for pararenal pathologies.

Thirty-day mortality was 10%. Although most patients did not die due to "absolutely aneurysm related" causes, as the authors stated, these data show that complex endovascular aortic procedures have a significantly higher impact on patient outcome compared to standard EVAR, which means that patient selection should be also more critical. Particularly for the management of most complex thoracoabdominal aortic aneurysms, our experience in Nuremberg has shown that one "should think twice" before offering such complex procedures in very high-risk patients (ASA IV). Obviously sometimes it is indeed very difficult to deny treatment particularly when patients are referred to a large volume center as a last resort option.

One patient suffered a renal bleeding probably due to perforation of a small renal branch during wire manipulations. Such complications are fortunately relatively rare, but upon occurrence most of the time have devastating clinical outcomes unless treated immediately. Centers aiming to perform complex aortic endovascular procedures should therefore be prepared to handle such complications urgently as this was done in authors' center. This includes, appropriate material availability (different types of coils etc.) and personnel with respective expertise always available. This is also an additional reason why these procedures should be preferentially centralized.

Stroke is a potential complication during complex endovascular procedures as noted in two patients in this series.[1] Upper access required for ChEVAR and BEVAR carries certainly a risk of debris dislodgement in the aortic arch and therefore stroke. ChEVAR in particular may require more than one upper accesses with multiple passages of the sheaths through the aortic arch increasing potentially the risk of stroke compared to FEVAR (performed via femoral access only) or BEVAR (only one upper access with one sheath passage for all target vessels).[3] Lately new generation steerable sheaths enable catheterization of downward branches via femoral access, providing thus an option to avoid upper access and this could potentially reduce the risk of stroke in these procedures.

Long waiting times may be indeed a problem for customized fenestrated-branched stent-grafts as highlighted by the authors. Our experience showed that real-life waiting times are about 12 weeks. During this waiting period there is an ongoing risk of aneurysm rupture, which approached 2% in 1000 patients that were planned to undergo a F/BEVAR procedure in Nürnberg within the period 2010-2019. This shows that there is need for improvement in order to reduce the waiting time and rupture related mortality before F/BEVAR. Patients at higher risk for rupture (e.g. those with very large aneurysms) should be identified and probably treated with off-the shelf devices, even if that means dealing with some anatomical imperfections. Prompt graft measurement and order to avoid the physician-related delay is also mandatory. Quicker

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graft construction and delivery is obviously desirable, but resources are limited. Logistical efforts to mate the delivery date with an OR date are also justified, but often face both hospital organization and patient willingness problems. Finally, waiting for cost authorization may also contribute to the problem in some hospitals.

Where do all the above leave us? Complex endovascular aortic repair requires high-level of logistical organization, technical expertise, and ability to handle complications of the procedure in due time. These prerequisites can be better fulfilled in higher volume centers. Every effort for centralization of these procedures in Greece would be therefore beneficial both for the patients and the further development of the technique. Furthermore, creation of a few aortic centers in Greece could be also financially beneficial for the country given that many patients with complex aortic pathologies seek treatment abroad with much higher hospitalization expenses.

No conflict of interest.

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Endovascular treatment of ruptured pararenal abdominal aortic aneurysm using the Chimney technique

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Abstract:

Aim: To demonstrate the feasibility of emergent endovascular repair of a ruptured pararenal aneurysm using chimney grafts.

Case Report: We report the treatment of 3 patients with rupture of a pararenal abdominal aortic aneurysm by using the chimney technique to extent the proximal landing zone above the renal arteries. All patients were operated under local anesthesia. Target vessels included 5 renal and 1 superior mesenteric artery. Technical success was achieved in all patients, with no 30-day complications. During follow-up all target vessels were patent with no sign of endoleak.

Conclusion: The use of chimney technique in a ruptured pararenal aneurysm is feasible. More robust data on chimney EVAR in ruptured cases are, however, required. The technique described here could reduce the number of patients with ruptured AAAs who are deemed unsuitable for EVAR based on anatomical criteria.

INTRODUCTION

Abdominal aortic rupture (rAAA) comprises a potentially fatal situation needing immediate treatment. Although for decades open repair has been considered the treatment of choice nowadays endovascular repair (EVAR) is becoming increasingly popular in rAAA treatment.[1] Both the Society of Vascular Surgery (SVS) and the European Society of Vascular Surgery guidelines recommend endovascular repair (EVAR) over open repair for a rAAA if anatomically suitable,.[2, 3] The presence of an adequate proximal landing zone has been contemplated mandatory to achieve a sufficient seal. Aortic rupture in patients with pararenal aneurysm has been considered a challenge as open repair require in most cases supraceliac clamping associated with high mortality and morbidity rates.[4] The use of parallel grafts for the splanchnic vessels to extent the proximal landing zone above the renal arteries (chimney EVAR/chEVAR) has been reported as a less invasive therapeutic solution for such patients, though not adequately studied so far.[4] We report 3 cases of pararenal AAA rupture (rAAA) treated with the chimney technique.

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CASE 1

A 68-year-old patient was referred to the emergency department because of acute back pain and loss of consciousness. He had a history of an AAA treated by endovascular means 10 years previously. The patient had underwent coronary angioplasty earlier that year, was a heavy smoker and therefore conventional aneurysm repair was regarded as highly unfavorable. The patient was hemodynamically stable. The department's protocol followed in each rAAA case has been described.[5] Computed tomography angiography revealed an abdominal aortic rupture with a large hematoma and active bleeding in the psoas major muscle. The previous aortic endograft was migrated due to significant aortic neck dilatation. Because of the absence of an adequate infrarenal neck, the deployment of a conventional stent-graft was infeasible without extending the proximal landing zone above the renal arteries. Based on preoperative imaging, the distance between the distal renal artery and the superior mesenteric artery was 22 mm, which would be sufficient to provide adequate proximal seal when using an endograft in conjunction with two chimneys to the renal arteries. The aortic diameter at the suprarenal level was 29 mm, which would allow deployment of a 36mm endograft and two chimneys for the renal arteries. For parallel running chimney-grafts a significant degree of oversizing is necessary to allow the main aortic body to surround the chimney and to prevent the occurrence of gutters, that may

predispode for type I endoleak. We usually prefer an oversize of at least 20% for the main endograft, trying not to exceed 30% to avoid the risk of endograft folding.

The patient was operated under local anesthesia and antibiotic prophylaxis. Access was acquired to both common femoral arteries and the left axillary artery. Two long 7-F sheaths were advanced through the subclavian artery and positioned in the descending aorta. Both renal arteries were cannulated and Be-graft balloon-expandable covered stents (Bentley, Hechingen, Germany; 6×38-mm and 6×58-mm for the right and left renal artery, respectively) were positioned using both 7-F sheaths from the axillary approach. Subsequently, an 8F long sheath was positioned through the femoral artery, and angiography in lateral position was performed to determine the position of the superior mesenteric artery.

An Endurant endograft (Medtronic, Santa Rosa, CA, USA) was deployed just distal to the superior mesenteric artery, followed by placement of both chimney grafts. After chimney deployment, kissing balloon of the chimney grafts and the aortic endograft was accomplished. After positioning of both iliac limbs, final angiography showed complete exclusion of the aneurysm without endoleak and patent renal arteries and superior mesenteric artery. The procedure duration was 110 minutes, with 18 minutes of fluoroscopy time and an estimated blood loss of 150 mL. The patient was admitted to the intensive care unit for 24 hours. Three days after the procedure, CTA showed a small endoleak type I probably gutter-related. At 6 months follow-up the patient was well without any complications, while CTA showed patent stents and no evidence of endoleak any more (Figure 1).

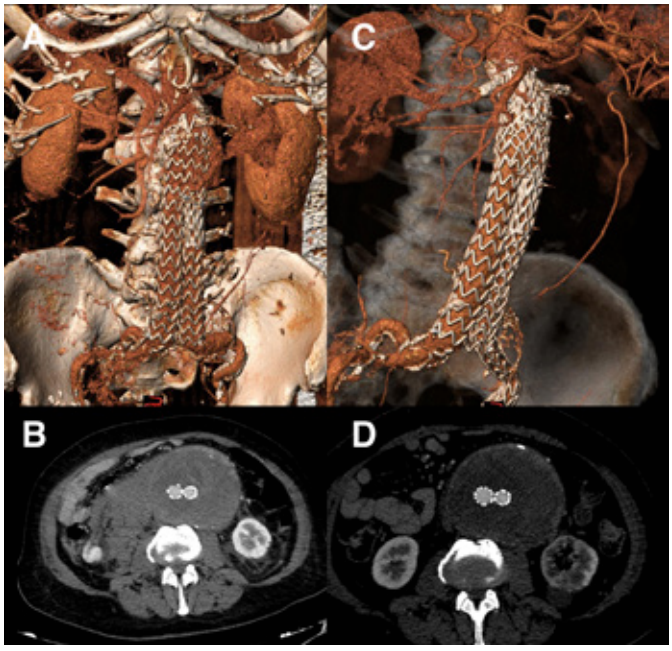

Figure 1. 3D reconstruction (A) and axial (B) computed tomography angiography showing the ruptured pararenal abdominal aortic aneurysm. 3D reconstruction (C) and axial (D) computed tomography angiography 6 months after double chimney showing patent renal arteries with no sign of endoleak.

CASE 2

A 77-year-old man with a 6 cm diameter pararenal rAAA was referred from a district Hospital. Patient's history included severe comorbidities, including chronic obstructive pulmonary disease, hypertension and a previous myocardial infarction. Computed tomography angiography (CTA) showed a rAAA starting 3 mm distally from the lowest renal artery. The distance between the two renal arteries was 4 mm and in case of a double chimney the sealing zone obtained was inadequate reaching 14 mm. When choosing 3 chimneys, two for the renal arteries and one for the superior mesenteric artery, proximal landing zone was 24 mm in length (Figure 2). The aortic diameter in the visceral segment was 27 mm.

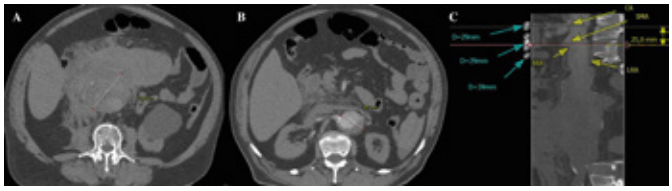

Figure 2. A,B. Computed tomography angiography depicting a ruptured pararenal aneurysm with a 72mm maximum diameter and an infrarenal neck 40mm in diameter C. Center lumen line showing the distances between the three target vessels for planning a 3x chEVAR.

After cutdown of the left axillary artery, two 7 Fr Shuttle (Cook, Bloomington, IN, USA) sheaths were advanced into the renal arteries, while with an additional cutdown of the right axillary artery a 7 Fr sheath was advanced for the catheterization of the SMA. After bilateral femoral cutdown, a 36mm diameter Endurant II bifurcated endograft (Medtronic, Santa Rosa, CA, USA) was advanced and deployed at the orifice of the coeliac trunk. Two balloon expandable covered stents (Bentley, Hechingen, Germany) 6 mm in diameter and 57 mm in length were deployed in each renal artery, and one 7 mm diameter and 38 mm in length stent in the SMA. Finally, a prolonged kissing balloon of chimney stents and the Endurant stent graft was performed to minimize the risk of gutters and improve the conformability of the devices. Completion angiography showed complete exclusion of the aneurysm without endoleak and patent splanchnic vessels (Figure 3).

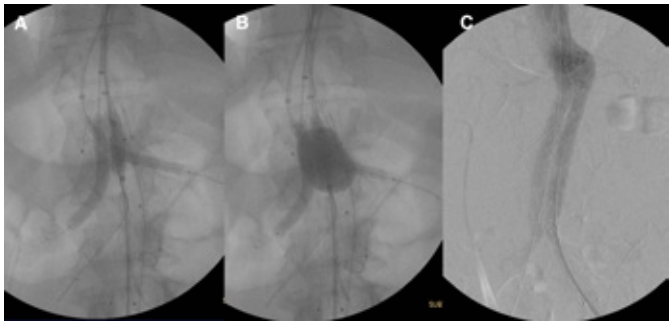

Figure 3. A,B. Intraoperative images showing the inflation of the balloons inside the target vessels and the aortic endograft after chimney deployment. C. Final angiogram showing patent splachnic veessels with no sign of rupture or endoleak.

The patient was admitted to the intensive care unit for one day. He passed gas and mobilized from the first postoperative day. Three days after the procedure, CTA confirmed the adequate endograft position and the exclusion of the aneurysm sac. The patient was discharged on the fifth post-operative day. At 1st month follow-up the patient was well without any complications, while CTA showed patent stents and no evidence of endoleak (Figure 4).

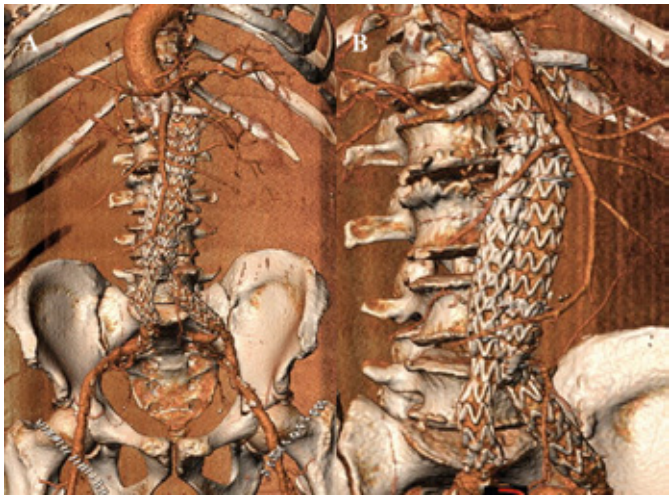

Figure 4. A,B. 3D reconstruction computed tomography angiography 1 month after triple ch-EVAR showing the patent target vessels with no sign of endoleak.

CASE 3

A 70-year-old patient was referred to the emergency department from another district hospital with the diagnosis of a rAAA. The patient was hemodynamically stable. He had a history of abdominal aortic aneurysm treated by endovascular means 8 years previously. The previous aortic endograft was migrated due to significant aortic neck dilatation (Figure 5). The infrarenal aortic neck proximally from the migrated endograft was 6mm in length, while the distance between the lowest renal artery and the highest was 19 mm. An endograft in conjunction with one chimney to the left renal artery was considered sufficient to provide adequate proximal seal.

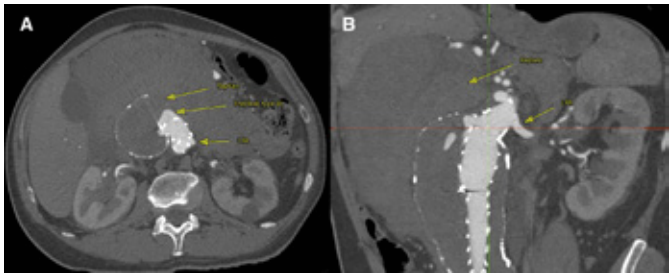

Figure 5. A. Axial computed tomography angiography showing the ruptured pararenal abdominal aortic aneurysm B. 2D reconstruction computed tomography angiography depicting the rupture and the presence of an endoleak type I.

The procedure was performed the same manner as mentioned above. Under local anesthesia and access to both common femoral arteries and the left axillary artery, an Endurant (Medtronic, Santa Rosa, CA, USA) endograft was deployed just distal to the right renal artery, followed by deployment of a chimney graft. After chimney deployment, kissing balloon of the chimney grafts and the aortic endograft was accomplished. After deployment of both iliac limbs, final angiography showed complete exclusion of the aneurysm without endoleak and patent renals and superior mesenteric artery (Figure 6).

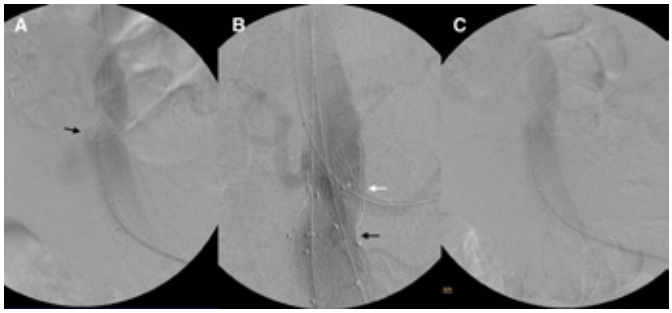

Figure 6. A. Intraoperative image showing the AAA rupture (black arrow) and the distal migration of the previous endograft. B. The deployment of one chimney into the left renal artery. Note the proximal markers of the previous (black arrow) and the current (white arrow) aortic endograft. C. Final angiogram showing patent renal artery with no sign of rupture or endoleak.

Three days after the procedure, CTA showed patent chimneys and no evidence of endoleak. At 1 month follow-up the patient remains well without any complications (Figure 7).

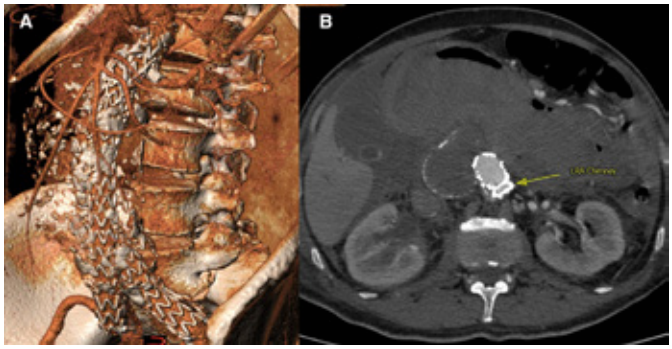

Figure 7. 3D reconstruction (A) and axial (B) computed tomography angiography showing 1 month after single ch-EVAR showing the patent renal artery with no sign of endoleak

DISCUSSION

This case series demonstrates the feasibility of using the chimney technique to treat ruptured juxtarenal aneurysms, providing a theoretically valuable alternative to patients deemed unfit for emergency open aortic aneurysm repair. Based on our limited experience with these 3 patients and considering their favorable outcome we now prefer to treat patients with ruptured pararenal aneurysm with the chimney technique given also the immediate availability and the minimal invasiveness of the procedure. Certainly technical issues as the need of local anesthesia combined with the need of upper auxiliary approach in a prolonged procedure and the device/material availability should be considered in the set up although as it

shown from our series can be successfully accomplished.

In most cases pararenal rAAAs are anatomically challenging and time is needed preoperatively for adequate planning and sizing. We always measure the aneurysm using a dedicated three-dimension programme (3Mensio, Pie Medical Imaging B.V., Maastricht, Netherlands), creating a center lumen line for the aorta and each target vessel separately. In this way we can easily and reliable measure the diameters and the lengths and chose the right endografts.

Although the instructions of use of the endograft deployed in this case series recommend a minimum landing zone of at least 15mm, we usually intend for a sealing zone of at least 20mm when treating pararenal patients with the chimney technique. The suprarenal part of the aorta does not seem to dilate significantly over time.[6] Recent studies showed that using a longer proximal suprarenal landing zone was not associated with an increase in perioperative mortality and morbidity, though required longer procedure and fluoroscopy duration.[7] By using an extended proximal sealing zone we may have a better long-term durability of the procedure, as we rely on the theoretically healthier part of the diseased aorta.

Several aortic endografts have been used for treating patients with chimney EVAR. Due to logistic reasons, in our department we use the Endurant endograft when treating aortic ruptures as it is available in a large variety of sizes in our hospital stock. Nevertheless, this endograft constitutes the sole endograft with a CE mark for the chimney EVAR technique. The choice of the optimal chimney graft is also a matter of debate. In the Pericles registry, balloon-expandable stents were deployed in nearly half of the target vessels, while almost 40% were self-expanding stents.[8] There was a trend toward balloon-expandable covered stents having improved patency and fewer type Ia endoleak; however self expanding stent were deployed in more tortuous and challenging anatomies.[8] We usually choose a balloon-expandable covered stent, but self-expanding covered stents could also be used. Having the target vessel sheaths inside and after marking the edge of the proximal sealing zone we deploy the main endograft at first and then deploy the balloon expandable stents accurately just in the middle portion of the bare suprarenal stent of the main endograft. In a second step and by leaving the balloons inside the target vessel grafts, simultaneous kissing balloon inflation is easy without the need of material exchange. Self-expandable stents can be used instead especially in cases when longer lengths are needed, although the need for additional balloons deployment should be acknowledged.

The presence of a type I endoleak remains the main problem of the chimney technique. Although the majority of those endoleaks detected intraoperatively diminish or even resolve with prolonged balloon inflation, still a few patients will have a type I endoleak, propably gutter related, in the final angiogram. Our strategy is to wait for the postoperative CTA, as most of these endoleaks spontaneously disappear given the absence of heparinization after the first postoperative day. Embolization possibilities (coils or Onyx) for the remaining endoleaks that persist and may lead to sac expansion have been used with encouraging results.[9,10]

CONCLUSION

The use of chimney technique in a ruptured pararenal aneurysm is feasible. More robust data on chimney EVAR in ruptured cases are, however, required. The technique described here could reduce the number of patients with ruptured AAAs who are deemed unsuitable for EVAR based on anatomical criteria.

No conflict of interest.

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INVITED COMMENTARY

Chimney technique: pushing the envelope of the endovascular treatment of ruptured pararenal abdominal aortic aneurysms

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According to the European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms, the treatment of choice for intact abdominal aortic aneurysms (AAAs) depends on the life expectancy of the patients: open AAA repair should be considered in patients with long life expectancy, endovascular AAA repair (EVAR) in patients with reasonable life expectancy and suitable anatomy, whereas elective AAA repair is not recommended in patients with limited life expectancy.[1] Contrary to these stratified, based on the life-expectancy of the patients, guidelines on the management of intact AAAs, the recommendation for ruptured AAAs (rAAAs) is clearly and without restrictions in favor of EVAR, with the only prerequisite being anatomic suitability: "in patients with ruptured abdominal aortic aneurysm and suitable anatomy, endovascular repair is recommended as a first option".[1]

It is most unfortunate, however, the fact that the stronger the indication, the lower the suitability. A recent systematic review and meta-analysis on the morphological suitability for endovascular repair of intact AAAs showed that the proportion of men eligible (within manufacturers' instructions for use) for standard EVAR was 54%, with the respective proportion of women being 34%.[2] On the other hand, a recent study on the suitability of rAAAs for standard EVAR was only 40% despite the fact that 97% of the patients included in this study were men.[3] Thus, patients with rAAAs seem to benefit more from EVAR but are less likely to be suitable for that compared to patients with intact AAAs.

It has also been proven that the outcome of open repair of rAAAs unsuitable for EVAR is significantly worse than the results of open repair of morphologically suitable AAAs, with the odds of perioperative death increasing by 9-fold for "unsuitable" rAAAs and 7-fold for "borderline" rAAAs, compared with "suitable" rAAAs.[4] In this context, unsuitable anatomy not only excludes patients from EVAR but also compels to an open repair with unfavorable prognosis.

The paper by Kouvelos et al, published in the current issue of the Hellenic J Vasc Endovasc Surg, demonstrates the feasibility of the chimney graft technique in the treatment of ruptured pararenal AAAs, thus expanding the suitability of endovascular repair of rAAAs. The paper focuses on patients in whom open repair is more difficult and, consequently, associated with the worst outcome: those with pararenal AAAs and those in need of open conversion because of a previous EVAR. Indeed, suprarenal clamping, which is mandatory in cases of pararenal aneurysms, has been associated with an almost 5-fold increased risk of in-hospital mortality,[6,7] whereas open conversion has been associated with a mortality rate of up to 22% even in elective cases.[8] The chimney graft technique obviates the need of laparotomy and suprarenal or supraceliac clamping, thus avoiding splanchnic ischemia or, at least, restricting it to that already caused by hypovolemic shock. The obviation of general anesthesia is equally important, since it has been well-established that locoregional anesthesia is associated with lower 30-day mortality than general anesthesia in patients undergoing endovascular repair of rAAAs.[9]

Apart from these general points, the paper by Kouvelos et al.[5] addresses a variety of technical issues which are encountered at each step of rEVAR using the chimney technique. Adequate oversizing and the choice of the combination of endografts are the most important decisions that have to be made during preoperative planning. Moreover, when an aortic endograft has already been placed, the distance between the superior mesenteric artery and the bifurcation of the previous aortic endograft is crucial since it may not be enough to allow the deployment of the contralateral limb of a new aortic endograft. Alternative solutions in such cases include aortic cuffs and aortouniiliac endografts. Intraoperatively, implantation of the endografts under the pressure of a ruptured AAA requires considerable experience acquired in elective cases. The vascular surgeon should also be able to treat potential intraoperative or postoperative complications including, but not limited to, chimney graft patency and endoleak type Ia. The anesthesiologist may also have some objections to the bilateral upper limb arterial access in a patient with a rAAA, in whom continuous invasive blood pressure monitoring would

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be desirable. The presence, however, of at least three sheaths, two in the upper limbs and another one in the femoral artery may help in the overcoming of these objections, since one of these sheaths will always be available for blood pressure monitoring.

There is no doubt that the endovascular treatment of ruptured pararenal AAAs using the chimney technique is a complex procedure, requiring a lot of experience if the excellent results, presented by Kouvelos et al[5], are to be reproduced. The vascular surgeon should feel quite comfortable with the technique before attempting to do it under pressure and be ready to treat potential adverse events. In any case, the Larissa team is to be commended both for their clinical work as well as the academic paper which broadens the horizons of rEVAR by introducing a technique which increases the number of patients in whom this life-saving procedure may be applicable.

No conflict of interest.

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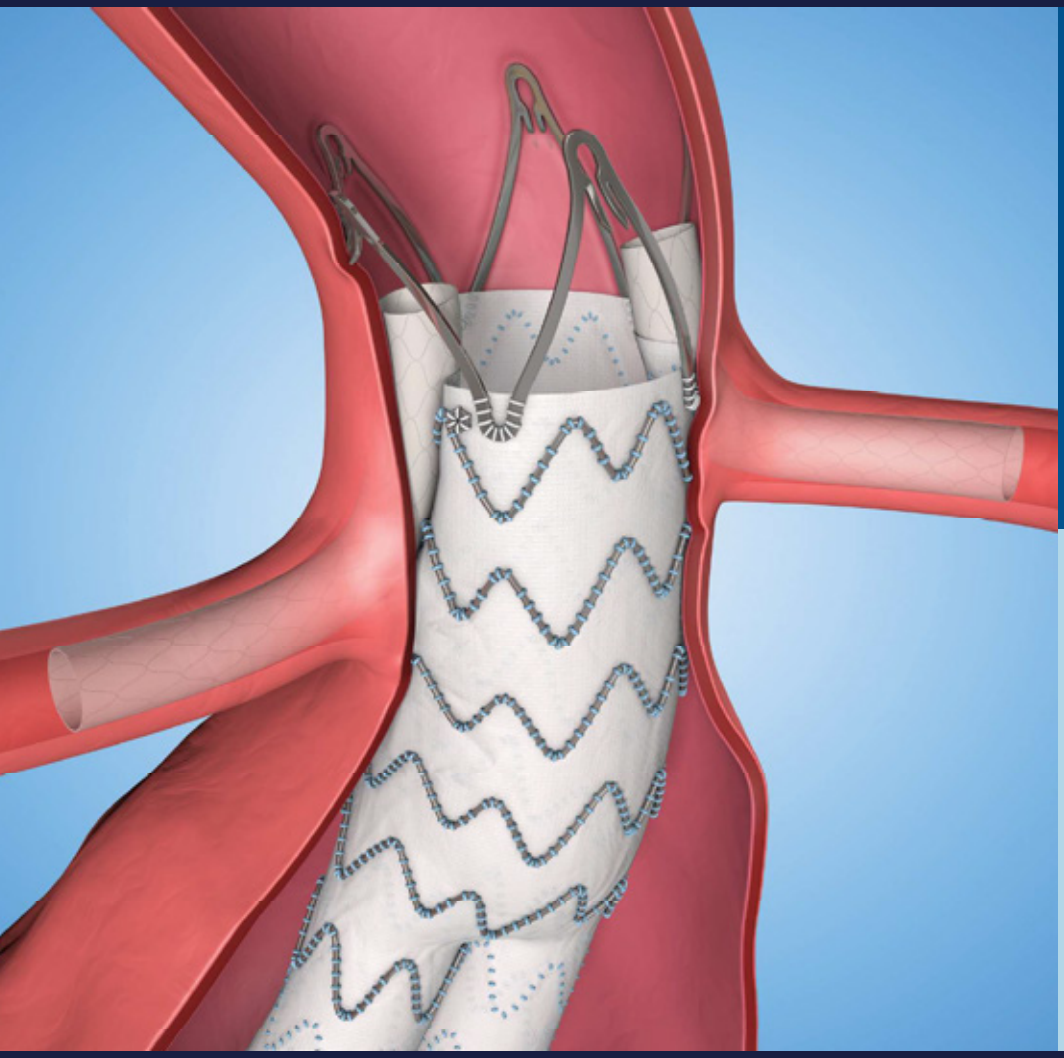

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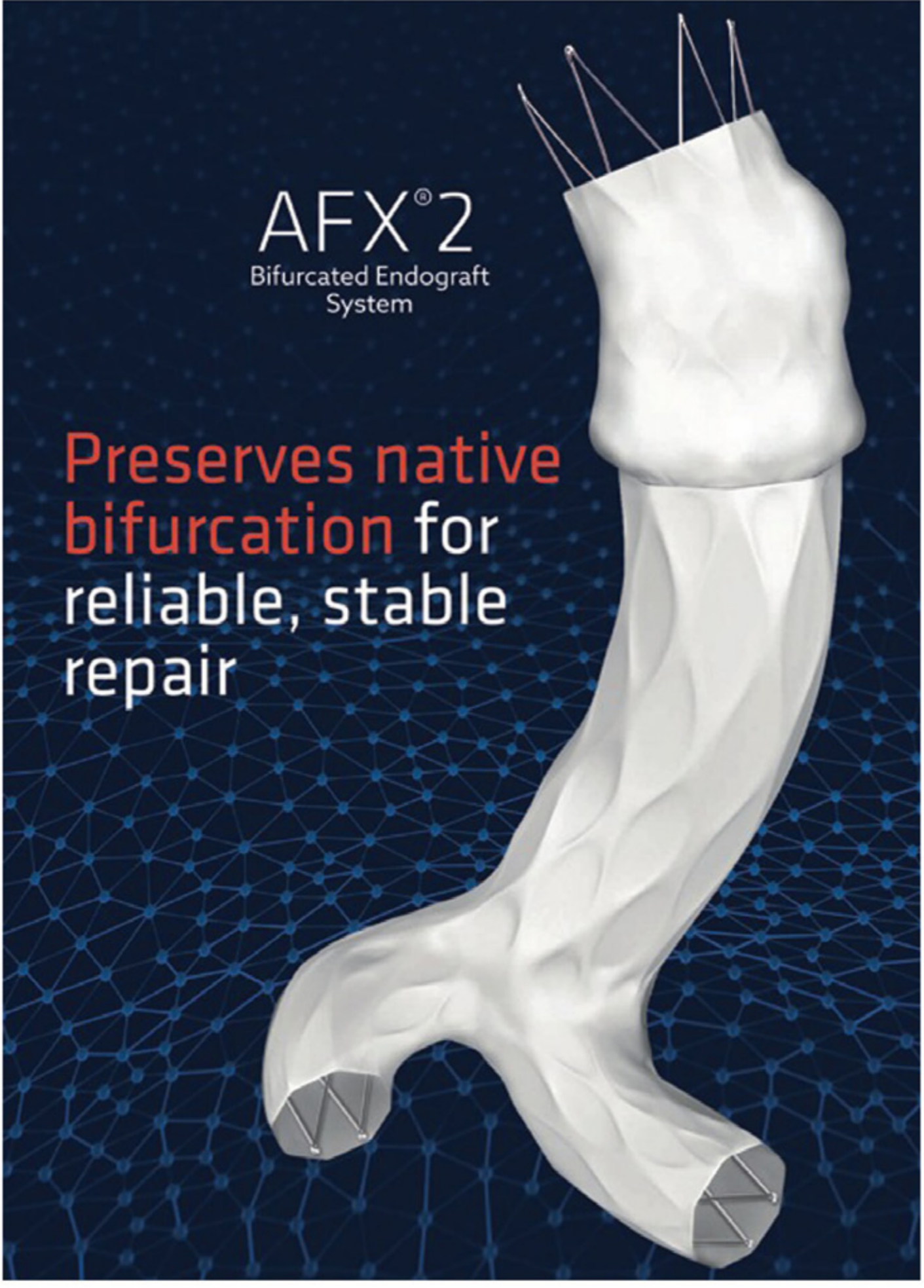

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Management of splanchnic arterial aneurysms - a case series

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Abstract:

Splanchnic arterial aneurysms remain an infrequent clinical entity although the increased utilization of different imaging modalities has raised their detection rate within the last decades. In this study, we describe a small case series including two hepatic artery aneurysms, two splenic artery aneurysms and one gastric artery aneurysm that were treated at a Hellenic University Department. They are associated with a high rupture risk and a high mortality when ruptured. It is very important to promptly treat these aneurysms when symptomatic. There is no high-level recommendation for their treatment when they are still asymptomatic. Open surgery is usually selected for ruptured or unstable cases. However, endovascular repair may be preferred for stable cases when the anatomy of the arterial tree is favorable or for patients of increased surgical risk.

***Keywords**: splanchnic aneurysms, visceral aneurysms, arterial aneurysms, treatment*

INTRODUCTION

Visceral or splanchnic arterial aneurysms are quite rare, with an estimated incidence of 0.1%-2% in the general population.[1] However, the increased utilization of ultrasound or cross-sectional body scanning for the diagnosis of intra-abdominal pathologies has raised their incidence within the last decades. The most commonly affected arteries include the splenic (60%), hepatic (20%), superior mesenteric (5%), celiac (4%), gastric and gastroepiploic (3%), intestinal (2%), pancreaticoduodenal (1%), and others (5%).[2] The most frequently reported causes include atherosclerosis, fibromuscular dysplasia, or hereditary diseases such as Marfan-or Ehlers-Danlos syndrome.[3,4] However, abdominal trauma and the increasing use of laparoscopic or endovascular techniques recently have raised the incidence of visceral arterial pseudoaneurysms.[5] It has been suggested that approximately 20% of visceral aneurysms rupture with a mortality rate of 20%-100%.[6] However, the rupture risk for pseudoaneurysms rises up to 70% due to the lack of arterial wall.[4,6]

Traditionally, small asymptomatic splanchnic aneurysms (<2cm) that were incidentally detected were managed with close surveillance and early elective repair in certain subgroups of higher rupture risk such as females of reproductive age.[1,7,8] Symptomatic or ruptured aneurysms led to an emergency open procedure in the past although endovascular repair has gained popularity within the last decades with satisfying results.[9] The recent ESVS (European Society of Vascular Surgery) Guidelines on the management of mesenteric vascular diseases recommend prompt treatment of symptomatic aneurysms although the recommendations on the treatment of asymptomatic aneurysms or the type of repair are of lower strength.[10] Furthermore, the natural history of these aneurysms is difficult to be established due to the limited number of case series, and there is still no clear consensus regarding precise indications for repair or the proper type of treatment.

Therefore, our aim is to report a small case series of visceral arterial aneurysms treated at a Hellenic University Department and to discuss on proper management.

METHODS

We retrospectively collected data referring to patients treated in our Department for splanchnic arterial aneurysms within the last 5 years. Splanchnic artery aneurysms are defined as aneurysms involving branches of the celiac, superior or inferior mesenteric artery.[9] Baseline characteristics of patients, location of the aneurysm, clinical presentation, treatment, outcome and follow-up are reported. Patients with mesenteric venous aneurysms or renal arterial aneurysms were excluded. Only patients presenting with symptoms or asymptomatic patients with aneurysms eligible for treatment were included. As a rule, aneurysms over 2cm in diameter or pseudoaneurysms of any size were eligible for treatment. Follow-up included clinical examination at regular intervals as well as a computed tomography angiography (CTA) at one month after treatment.

A written informed consent was obtained from all patients

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included in this retrospective study. A written approval was obtained from the Ethical Committee of our institution as well.

CASE SERIES

Within a period of 5 years, we have treated 5 cases of splanchnic arterial aneurysms. Overall there were 4 male patients (80%) and one female patient (20%). Mean age of patients was 49.4±10.1 years. The following locations of the aneurysms were recorded: hepatic artery (40%), splenic artery (40%) and gastric artery (20%). Two cases were asymptomatic, one case presented with a symptomatic pseudoaneurysm and two cases with rupture. Except for one patient, the rest of the aneurysms were true (80%). Mean diameter of the aneurysms was 3.3±0.6 cm. All basic characteristics of the cases including comorbidities and treatment are presented in Table 1.

One case with a ruptured aneurysm of the right gastric artery was treated endovascularly with embolization using cyanoacrylate glue. One case with an asymptomatic aneurysm of the splenic artery was treated with laparoscopic ligation of the artery and removal of the spleen as it was too close to the splenic hilum. The rest of the patients (60%) were treated with an open procedure. (Table 1) One patient with a ruptured aneurysm of the right hepatic artery was treated with aneurysmorraphy plus partial enterectomy as signs of peritonaism and instability were present. One patient with a symptomatic pseudoaneurysm of the splenic artery underwent ligation of the artery proximally and removal of the spleen after proximal clamping of the aorta under the diaphragm as the aneurysm extended also up to the splenic hilum. Finally, the last patient with an asymptomatic aneurysm of the left hepatic artery near the hepatic hilum underwent resection of the aneurysm and interposition of a short PTFE graft to preserve distal perfusion. 30-day complications, length of hospital stay and ICU (intensive care unit) stay are reported in Table 2. After a mean follow-up of 2.4± 1.3 years, all patients remain asymptomatic. All imaging was uneventful at one month.

DISCUSSION

This case series shows that both open and endovascular treatment could yield satisfying results in patients with symptomatic or asymptomatic splanchnic arterial aneurysms when selected properly.

Splenic artery aneurysms (SAAs) account for almost 50% to 75% of all visceral arterial aneurysms.[11] They may be associated with other intra-abdominal aneurysms involving visceral (3%) and renal (14%) arteries, such as in one of our cases.[9,12] Although they present with a female to male predominance of 3-4:1 and they are associated with multiparity, our two cases were equally distributed among the two genders.[9] The most common causes are arteriosclerosis and portal hypertension although our two cases included a patient with polyarteritis nodosa and a case with a pseudoaneurysm.[9,13] Pseudoaneurysms at this location are usually caused by chronic pancreatitis or by trauma although the cause in our patient was not clear.[4] With more than 95% of aneurysms in pregnant females being diagnosed after rupture, rupture rates range around 10% in most of the observational studies.[4,11,14] Hence, none of the two cases presented with rupture in our series.

Number of case	Gender	Age	Location of aneurysm	Symptoms	Type/Size of aneurysm	Comorbidities	Anticoagulant treatment	Treatment	Follow-up
1.	Male	34	Right hepatic artery	Rupture, renal infarcts	True/ 3.5 cm	Polyarteritis nodosa, Smoking Other aneurysms: splenic, both renal arteries	-	Aneurysmorraphy plus partial enterectomy	1 year
2.	Male	76	Right gastric artery	Rupture	True/ 3 cm	Hypertension	-	Endovascular embolization with glue	5 years
3.	Male	45	Splenic artery	Abdominal pain	Pseudoaneurysm/ 4.5cm		-	Open ligation of the splenic artery and splenectomy	2 years
4.	Male	58	Left hepatic artery	Asymptomatic	True/2.5cm	-	-	Aneurysm resection and PTFE graft interposition	3 years
5.	Female	60	Splenic artery	Asymptomatic	True/ 3cm	Hypertension	-	Laparoscopic ligation of the splenic artery and splenectomy	1 year

Table 1

Number of case	Gender	Location of aneurysm	30-day complications	ICU stay (days)	Hospital stay (days)
1.	Male	Right artery	Temporal renal dysfunction and rise of hepatic enzymes	4	10
2.	Male	Right gastric artery	None	0	5
3.	Male	Splenic artery	Respiratory infection in the ICU	4	8
4.	Male	Left hepatic artery	Temporal rise of hepatic enzymes	3	10
5.	Female	Splenic artery	Left Pleural effusion that needed evacuation	3	9

ICU, intensive care unit

Table 2

Regarding treatment, ruptured SAAs should be promptly treated.[10,14] Most of the authors suggest that an asymptomatic aneurysm of 1 to 2 cm in diameter should be closely monitored with imaging studies every 6 months.[11,14,15] However, elective repair is recommended when the aneurysm grows fast or exceeds 2 cm[10]. Especially in pregnant women or women of childbearing age, the indication may include aneurysms of any size due to the high risk for rupture.[10,11] Mortality remains high in cases with rupture and reaches 40% although elective cases are associated with low mortality and morbidity.[16]

The location of the SAA as well as its presentation dictates the type of procedure that is performed. Surgical repair is preferred for all symptomatic aneurysms because of the greater likelihood of success.[14,16] Resection with end to end anastomosis can be performed in many cases, due to the predominantly proximal location of SAAs and to the redundancy and tortuosity of the artery.[11,17] This usually allows for splenic preservation, which is important for the immune system. However, aneurysms involving the splenic hilum usually require splenectomy such as in our two cases, although this is performed more commonly when the aneurysm is ruptured.[11,14] Transcatheter embolization with either coils or glue (N-butyl cyanoacrylate) is particularly appropriate for saccular aneurysms or fusiform aneurysms with good collateral flow to the end organ, except those located at the splenic hilum.[18,19] In cases of portal hypertension, transcatheter embolization or stent-graft placement may be preferred because the extensive collateral circulation complicates surgery.[20] In case of pseudoaneurysms, splenectomy still remains the standard of treatment although endovascular repair is gaining popularity.[21] Finally, we preferred a laparoscopic approach in one of our cases as it avoids large incisions in younger patients and the morphology of the aneurysm prohibited an endovascular repair.[22]

Hepatic arterial aneurysms (HAAs) are the second most frequent visceral arterial aneurysms, with almost half of them being pseudoaneurysms.[1,14] The increasing performance of percutaneous biliary procedures, non-operative management of trauma, and liver transplantations has led to an increasing incidence of hepatic artery pseudoaneurysms.[23] However, both our HAA cases were true aneurysms. True aneurysms occur 4 times more frequently in the extrahepatic arteries, concurring with our cases. Regarding pathogenesis, they are associated mainly with arteriosclerosis and acquired medial degeneration.[14] Most of the HAAs are identified incidentally while performing CT scanning or ultrasound examination although one of our cases presented with rupture.[24] When ruptured, clinical presentation more frequently includes jaundice, biliary colic, and gastrointestinal hemorrhage rather than a free, intraperitoneal rupture.[14,24] According to centers with large experience, indications for treatment of HAAs include symptomatic aneurysms, non-atherosclerotic aneurysms, multiple aneurysms, and aneurysms >2 cm in good-risk patients with a life expectancy of at least 2 years, concurring with our strategy.[23]

Surgical treatment of HAAs depends on the location of the aneurysm, presence of collateral flow, and health status of the patient. Vascular reconstruction is usually needed for aneurysms involving the proper hepatic artery although asymptomatic HAAs located at the common hepatic artery may be managed without reconstruction if collateral flow through the gastroduodenal artery or right gastric arteries is adequate.[9,23] However, to prevent hepatic infarction, ligation or embolization of the aneurysm is best performed only if the portal vein is patent.[9,25] Additionally, endovascular repair including embolization or stent-graft placement may be used in patients of higher surgical risk with satisfying results.[6,26] In a systematic review by Kok et al., technical success was 100% and visceral preservation 94.7% for patients treated endovascularly for splanchnic aneurysms.[6] Especially for intrahepatic aneurysms, percutaneous embolization is considered a first-line treatment due to the complicated nature of open repair.[9] Finally, percutaneous approaches appear to be particularly useful in the treatment of hepatic artery pseudoaneurysms, where there is a history of previous abdominal surgery and severe comorbidities.[27]

Finally, gastric artery aneurysms are less frequent with an estimated incidence of 3-4%.[9] Specifically, the incidence of right gastric artery aneurysms is estimated to be 0.001%.[28] They are usually detected in male patients in the 6th or 7th decade of their lives, concurring with our case.[28] Although the asymptomatic aneurysms remain undetected in their majority, symptomatic aneurysms present with rupture in almost 90% of the cases.[29] Treatment depends on the condition and clinical presentation of the patient. In cases of rupture and hemodynamic instability, a laparotomy followed by ligation of the artery is indicated.[30] Endovascular treatment including embolization or stent-grafting remains an option for stable or asymptomatic patients and cases of high risk for open surgery.[28,31] However, stent-grafting is often difficult due to tortuosity of the vessel or due to small diameter.[28] Recently, the use of multilayer flow modulator (MFM) stent has also been described for visceral aneurysms with narrow necks.[32] However, their use in patients with rupture or bleeding should be avoided as they convert the blood stream into the sac from turbulent to laminar, without fully occluding it.

In conclusion, splanchnic artery aneurysms although infrequent are associated with a high rupture and mortality rate. Therefore, they should be promptly treated when they fulfill the aforementioned indications. Open surgery is usually selected for ruptured or unstable cases. However, endovascular repair may be preferred for stable cases when the anatomy of the arterial tree is favorable or for patients of increased surgical risk.

No conflict of interest.

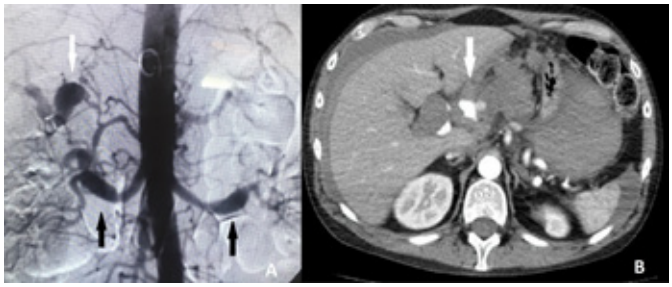

Fig 1. (A) Digital subtraction angiography (DSA) of case 1 showing the aneurysm of the right hepatic artery (white arrow) as well as aneurysm of both renal arteries (black arrows). (B) Computed tomography angiography (CTA) of the same patient showing the ruptured aneurysm with the perianeurismal hematoma. (arrow)

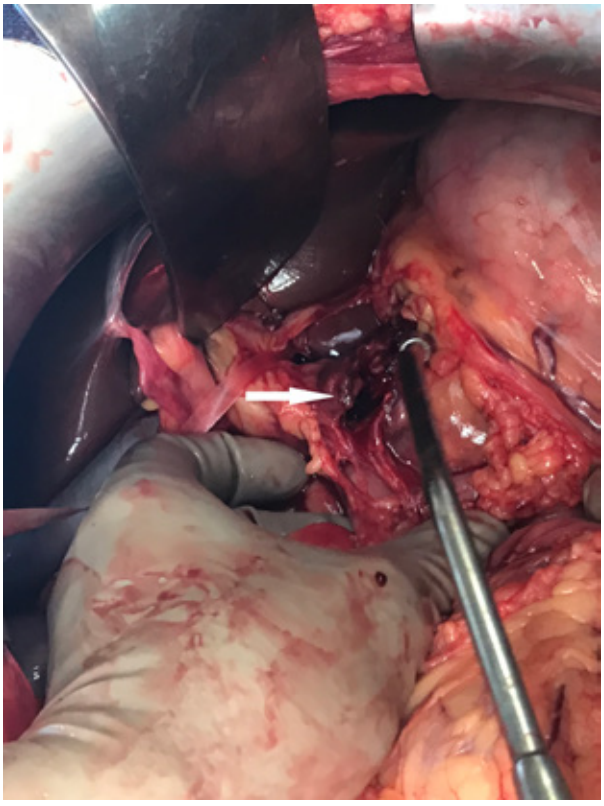

Fig 2. Intraoperative image of case 1 showing the location of the rupture (arrow).

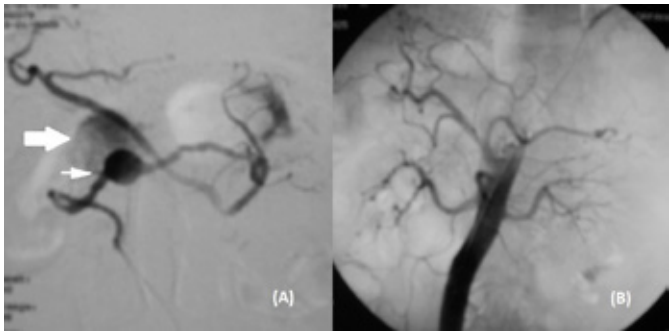

Fig 3. (A) Digital subtraction angiography (DSA) of case 2 showing a ruptured aneurysm of the right gastric artery (thin arrow) with extravasation (thick arrow). (B) DSA from the same patients after the endovascular embolization. There is no sign of the aneurysm or any bleeding.

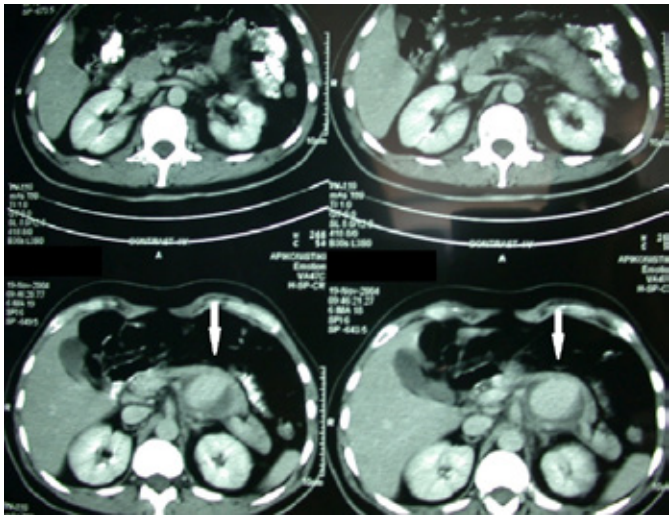

Fig 4. Computed tomography angiography (CTA) of case 3 showing a large pseudoaneurysm of the splenic artery (arrows).

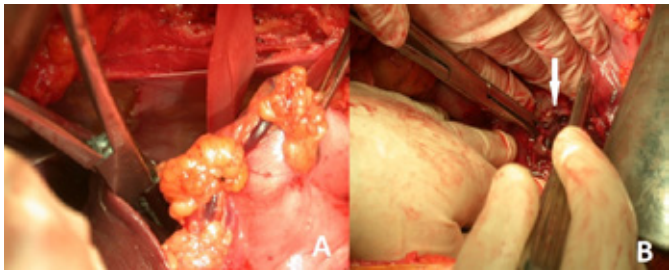

Fig 5. (A) Intraoperative image of case 3 showing the vascular clamp located just under the diaphragm. (B) Intraoperative image of the same patient showing the ruptured artery (arrow).

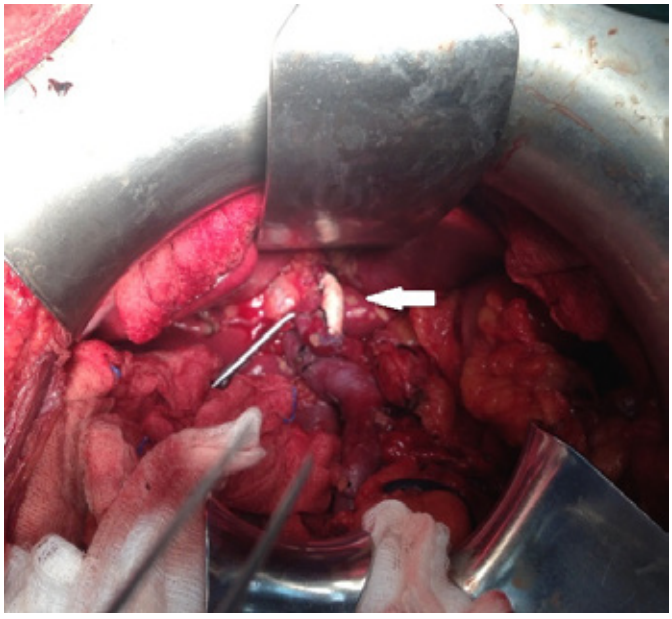

Fig 6. Intraoperative image of case 4 showing the interposition of a synthetic PTFE graft (arrow) after resection of a left hepatic artery aneurysm.

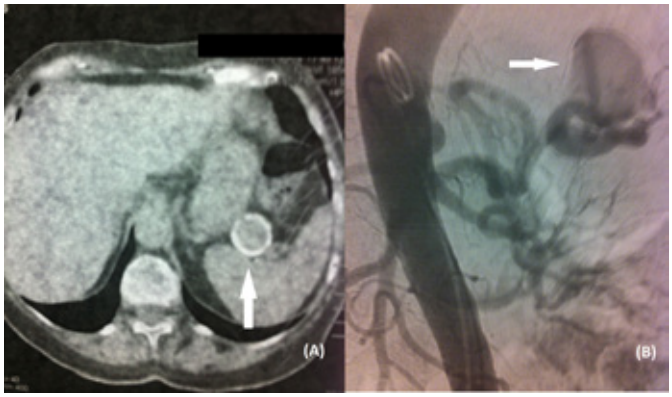

Fig 7. (A) Computed tomography angiography (CTA) of case 5 showing an atherosclerotic aneurysm of the splenic artery. (B) Digital subtraction angiography (DSA) of the same patient showing the aneyrysm (arrow) at the splenic hilum as well as the tortuosity of the splenic artery.

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Assessment of Voice, Eating, Reflux and Swallowing Impairment in Carotid Endarterectomy patients using Scores questionnaires

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Abstract:

Objective: The purpose of this prospective study was to identify and quantify Voice, Eating, Reflux and Swallowing Impairment using self-reporting questionnaires in patients after Carotid Endarterectomy (CEA).

Material-Methods: A prospective case cohort study was undertaken including patients that underwent CEA for asymptomatic carotid disease. The patients filled in the Voice Handicap Index (VHI), Eating Assessment Tool 10 (EAT-10), Reflux Symptom Index (RSI) and Swallowing Impairment Scores (SIS-6) questionnaires pre -, 48h-post- and one-month post-surgery. Under direct visualization, nerve injury was recorded during the steps of operation.

Results: Thirty patients were treated with CEA. Intra-operatively, hypoglossal ansa cervicalis was dissected in one patient (3.4%), while rami was dissected in 7 patients (24.1%). Regarding swallowing and voice questionnaires scores, at the preset time points, the peak was observed 48h after surgery [(pre-op vs 48h; VHI: 0.57 vs 9.1; p=0.027; EAT: 0.73 vs 4.94; p=0.037; RSI: 0.91 vs 7.73, p=0.007; SIS-6: 1.12 vs 5.47, p=0.0012], while values almost returned to baseline one month later [(pre-op vs 1 month; VHI: 0.57 vs 0.74; p=0,345/ns; EAT: 0.73 vs 1.14; p=0,496/ns; RSI: 0.91 vs 1.52, p=0.506/ns; SIS-6: 1.12 vs 1.07, p=0.906/ns].

Conclusion: Self-reported questionnaires can identify voice, eating, reflux and swallowing impairment that may be associated with cranial nerve injury. This impairment seems to be transient during the first post-operative month.

Keywords: *Carotid endarterectomy, Assessment of voice quality, Assessment of swallowing, Cranial nerve injury*

INTRODUCTION

Carotid endarterectomy (CEA) is considered as the standard treatment of choice for stroke prevention in patients with severe carotid stenosis in an average risk population[1]. However, CEA may cause early complications such as cranial nerve injuries (CNI) that may be particularly troublesome for certain patients (e.g. patients who sing or speak publicly for a living). CNI may potentially result in significant prolonged disability and may even require further surgery for palliation of symptoms and improvement of function. Postoperative CNI rates vary between 3% and 27%, depending on the observer, definition of CNI, and study design.[3] Prior studies mainly focused on anatomically proven lesions and surgeons' estimations, while the clinical relevance of CNI has not yet been thoroughly examined, in terms of patient's actual functionality after surgery. The most examined clinical consequence refers to the voice alteration.[4,5] Other potentially severe complications, such as swallowing/eating disturbances are far less studied and their true incidence and impact on patients' everyday life remains largely unknown.[6,7] The aim of this study was to identify and quantify Voice, Eating, Reflux and Swallowing Impairment using self-reporting questionnaires in patients after Carotid Endarterectomy (CEA).

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MATERIAL AND METHODS

A prospective case cohort study was undertaken including patients that were treated with traditional CEA and patch plasty for asymptomatic carotid disease.

Exclusion criteria were: 1) Any kind of previous operation in the neck, 2) proved voice or swallowing disorder preoperatively, 3) tumor of the neck, 4) history of radiation of the neck, 5) history of thyroidectomy

All patients underwent a CEA under general anaesthesia with an oblique (skin crease) cervical incision. Careful dissection was mandatory to avoid iatrogenic lesions of the hypoglossal, vagus and recurrent laryngeal nerve, causing dysphonia and hoarseness; unnecessary manipulation of the arteries should be avoided to prevent cerebral embolization. Heparin (5000 IU) was routinely administered before clamping and a longitudinal arteriotomy was performed from the distal common carotid to the internal carotid as far as the end of the plaque.

Patients were asked to fill in the following questionnaires assessing swallowing and voice function:

a) Eating Assessment Tool (EAT) -10 questionnaire: The EAT-10 may be utilized as a clinical instrument to document the initial dysphagia severity and monitor the treatment response in persons with a wide array of swallowing disorders. The normative data suggest that an EAT-10 score of 3 or higher (mean + 2 SD) is abnormal.[8]

b) Voice Handicap Index (VHI) questionnaire: The VHI has three content domains representing functional, physical, and emotional aspects of voice disorders. There are 10 items corresponding to each domain, each item being measured on a five-point Likert-type scale (from 0 - never to 4 - always). A high score is expected to correspond to a more severe voice disorder. The VHI is usually completed within 5 minutes. The overall median VHI score in the group of 67 Greek subjects with voice disorders was 32 (mean 37, SD 21.3), the range being from 4 to 97 out of a maximum possible score of 120.[9]

c) Reflux Symptom Index (RSI): Patients were instructed to fill out the 9-item RSI on a rating scale ranging from 0 to 5, where 0 means no problems and 5 means a severe problem. Patients were given clear instructions about how they will fill out the 2 questionnaires according to the above-mentioned rating scales.[10]

d) Swallowing Impairment Index (SIS-6) is one of the most commonly used questionnaires in the related literature that has been validated for diagnosis of swallowing impairment. It is a self-administered, 6-item assessment of symptoms related to dysphagia, which provides an analysis of the spectrum of symptoms reported by patients. SIS-6 scoring ranges from 0 (no swallowing alterations) to 24 (highest swallowing impairment).[11]

The clinical functional status was assessed at three set time points (pre-surgery, 48 h post -surgery and at one month after surgery). An ENT doctor performed the indirect laryngoscopy, while patients were further assessed with validated questionnaires for two major functions: voice and swallowing. We aimed at the detailed recording of the surgery steps and for that purpose patients were categorized according to diathermy use (monopolar or dipolar), nerve exposure (identification/dissection) or the overt nerve damage/dissection under direct visualization. Injury to the following cranial nerves were distinguished: facial nerve (VII), facial droop; glossopharyngeal nerve (IX), swallowing difficulty unless other diagnosis confirmed; vagus nerve (X), hoarseness unless laryngoscopy normal; hypoglossal nerve (XII), any tongue deviation or discoordination.

STATISTICS

Continuous data were reported as a mean ± standard deviation. Categorical data were expressed as absolute numbers and percent prevalence (%) in the study cohort. Statistical significance between the groups for continuous variables used the independent t-test for normally distributed data or the Mann-Whitney U test for nonparametric data. The Fisher exact test was used for categorical variables, as appropriate. Descriptive and inferential statistics was performed. Non parametric Spearmans Rho was used to assess correlation among ansa dissection and questionnaires scores; Repeated measures analysis was applied to study questionnaires score variation at various time points. Statistical significance was set at p=0.05. SPSS 22.0 and Sigma plot 12.5 were used.

RESULTS

In terms of intra-operative manipulations, carotid artery exposure below hypoglossal nerve was undertaken in 22 patients (73%), while above hypoglossal nerve exposure was undertaken in 8 cases (27%). Hypoglossal loop was performed in 12 patients (41.3%), while vagus exposure took place in one patient (3.3%). In terms of intra-operative muscle injuries, digastric muscle dissection was required in 6 cases (20.0%). In terms of nerve dissection identification, hypoglossal ansa cervicalis was divided in one patient (3.3%), while rami was dissected in 7 patients (23.3%) (Table 1). No intermediate or severe wound haematoma was identified post-operatively.

Techniques	N (%)	Total
Preparation below hypoglossal nerve	22 (73.0%)	30
Preparation below and above hypoglossal nerve	8 (27%)	30
Hypoglossal loop	12 (40.0%)	30
Vagus preparation	1 (3.3%)	30
Muscle injuries		
Partial digastric divided	6 (20.0%)	30
Nerve injuries		
Hypoglossal ansa cervicalis division	1 (3.3%)	30
Hypoglossal rami divided	7 (23.3%)	30

Table 1. Techniques and CNIs

Regarding swallowing and voice questionnaires scores, at the pre-set time points, the peak was observed 48h after surgery, while values improved and in some cases almost returned to baseline one month later. All scores returned to baseline one month after surgery, while 48h post-op score was 5-20 times higher than baseline. All four assessment tools scores had a similar pattern through time and differences between baseline values and peak values were statistically significant. Mean (except VHI) values at 48h time point were indicative of severe problem, according to suggested cut-of scores.[8,12,13] (Table 2 & Fig.1)

	Pre-op	48h post-op	P Pre-op vs. 48h post-op	1month post-op	P Pre-op vs. 1month post-op
EAT	0.73±2.91	4.94±9.07	0.037	1.14±1.80	0.496
SIS-6	1.12±3.00	5.47±6.25	0.001	1.07±2.36	0.906
RSI	0.91±1.91	7.73±10.22	0.007	1.52±3.1	0.506
VHI	0.57±1.23	9.10±9.47	0.027	0.74±2.35	0.345

Table 2. Prospective questionnaire scoring

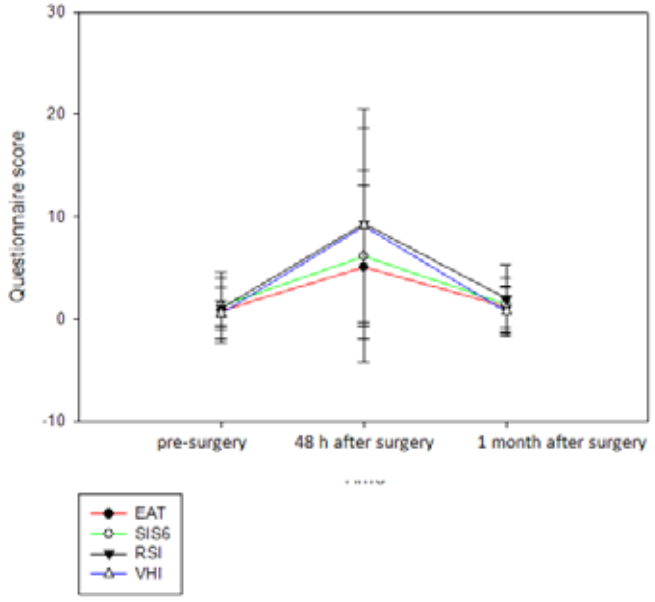

Figure 1. Prospective CN functionality (clinical assessment)

In those 8 patients with the dissection of the rami or the ansa cervicalis no significant associations were found between questionnaires scores, either regarding voice or swallowing. (Spearman's Corelation Rho for ansa dissection and 48 post-op: VHI: rho=0.065, p=0.768; EAT-10: rho = -0.256, p=0.561; SIS-6: rho=-0.166, p=0.449; RSI: rho=0.49, p=0.826).

DISCUSSION

The findings of the present study indicate self-reported questionnaires may identify transient functional impairment that may be associated to cranial nerves injury after CEA affecting voice, swallowing, reflux and eating. A transient voice and swallowing alteration might be indeed underestimated, since patients are often able to compensate deficits resulting in a "normal" voice and questionnaire scoring might be within normal range. Currently, there are no formal protocols including objective functional impairment measurement at set time points that may be associated to CNI, thus, it is possible that subtle nerve lesions may have been missed. According to literature, most postoperative nerve lesions seem transient, although permeant damage and consequent serious impact on patient's life cannot be excluded[12]. This study demonstrated that cranial nerves are vulnerable to injury in almost 43% of the cases (cumulative muscle and nerve injuries), however, the true post-operative impact on nerve functionality is non-significant, since all parameters return to baseline values at the end of the first post-operative month. Along these lines, previous epidemiological studies reporting low incidence of CNI, such as the VSGNE study (5.6%) such as the New York Carotid Artery Surgery study (NYCAS, 5.5%),[14] the European Carotid Surgery Trial (ECST, 5.1%),[5] and the North American Symptomatic Carotid Endarterectomy Trial (8.6%).[15] Recurrent laryngeal nerve dysfunction causing vocal fold paralysis is a well-recognised cause of voice disturbance. The discordance of voice dysfunction and nerve injury might imply that disturbance of the extralaryngeal skeleton is partially responsible: the digastric muscle's division itself might cause a change in vocal fold motility, and thus postoperative hoarseness.[4]

It has been well documented that cranial and cervical nerve damage are related to local trauma to the nerve by means of retraction, stretching, clamping and transection. However, most of the clinical injuries occur from nerve damage during retraction.[16]

Hypoglossal nerve dysfunction can present with subclinical symptoms manifested only by deviation of the tongue to the ipsilateral side of injury. Severe injury can result in profound tongue clumsiness, tongue biting, dysarthria, and symptomatic mastication and deglutition.[14] Injury to this nerve can result in symptoms ranging from mild dysphagia to severe recurrent aspiration, respiratory failure, and malnutrition. Injury results in uncoordinated swallowing and ablation of the gag reflex. Clinical manifestations of vagal injury range from mild symptoms of hoarseness and loss of effective cough mechanism, to upper pharyngeal dysphagia with aspiration, to life-threatening airway obstruction from bilateral recurrent laryngeal nerve injury. Injuries can involve the recurrent laryngeal nerve, superior laryngeal nerve, and the vagus trunk. Damage to the glossopharyngeal nerve can result in uvula deviation and dysphagia with a potential risk of aspiration.[16]

Clinical assessment is of great importance as sometimes functional impairment that may be associated CN dysfunction (eg in the case of superior laryngeal nerve; SLN dysfunction) is hard to accurately establish, because the diagnosis can be hard to make, even when direct laryngoscopy examination is used .[17] Thus, CNIs may be underdiagnosed in many cases. The worst score on the questionnaires was observed 48 hours after the surgery. Patients might be in stress if they are not reassured that this is a rather transient functional impairment condition and that recovery is expected within 1 month.

In the present study, voice and swallowing were assessed with various tools and by different experts to avoid assessment bias, while nerve injure severity and the applied techniques were not associated with outcome. The above along with the fact that almost (but RSI score) variables, regardless of the magnitude of their peak, returned to baseline values 1 month after the surgery.

Apparent limitation of this study was the small sample. Another potential limitation was that we did not include patients that were treated under local anesthesia as a comparable group in order to minimize the possibility that the results of the tests were not been affected by other conditions such

endotracheal intubation of the general anaesthesia. Larger samples in future studies might allow significant associations between questionnaire scores and techniques/kind of injuries to emerge. Longer follow up may also be of interest to evaluate if there is any impact on these patients during the long term period.

CONCLUSION

Self-reported questionnaires can identify voice, eating, reflux and swallowing impairment that may be associated with cranial nerve injury. This impairment seems to be transient during the first post-operative month.

No conflict of interest.

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Modular e-learning for a practical skill in vascular surgery

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Abstract:

Introduction: Working Time Regulations in Europe allied with the endovascular revolution require vascular surgeons to be innovative in achieving competence during their training period. We evaluated the feasibility of eLearning to teach the use of OsiriX for sizing and planning endovascular aortic aneurysm repairs.

Materials and Methods: Eight blended learning modules were constructed, consisting of instructional PDFs, demonstration videos, CT angiogram downloads for individual practice and online support forums. These were delivered online over a nine-week period. The learning material encompassed an introduction to the OsiriX interface, the basic skills to use OsiriX for sizing and planning of aneurysm repairs and advanced techniques for reconstruction and online communication relating to imaging.

Results: The course was successfully delivered and produced positive feedback from registered users. A high rate of dropouts occurred during the early phase. The design and implementation of a fully web-based course by full time clinicians utilising multimedia and user forums to teach vascular surgeons the performance of a practical skill is feasible.

Conclusions: A modular instructional course offered online by vascular surgeons is feasible in teaching clinicians the use of OsiriX for 3D reconstructions of CT angiograms of aortic aneurysms. Shortening course duration may improve compliance. The instructional model is effective and well received by compliant learners.

Keywords: *online training, education, e-learning, distance learning, vascular surgery*

INTRODUCTION

Since 2009, the European Working Time Directive (EWTD) limits doctors working within the European Union to a 48-hour working week[1]. The implementation of this regulation has coincided with both the endovascular revolution and an exponential increase in the skills and knowledge that vascular surgical trainees must acquire during their training period. Ingenuity and the application of new methods of learning are necessary to achieve competence and maintain clinical standards.

e-learning (eL) is being increasingly applied for educational purposes in medical and surgical specialties[2,3]. The formal definition of eL is very broad; its most familiar representation is in the form of delivery of educational content using the electronic medium of the Internet[4]. eL eliminates the need for travel and all related expenses; provides the user with more time and flexibility for the planning of individual learning[5]; minimizes the running costs of the instructional course[6,7]; facilitates the receipt and recording of feedback and suggestions[8] and enhances the ergonomy of repeating the teaching course. Appropriate instructional design is an essential requirement to successfully deliver these significant benefits to the user. In the case of practical skills relating to a surgical specialty, such design and delivery require significant input from practising clinicians.

The eL team of the European Society for Vascular Surgery (ESVS) researched the feasibility of eL provided by clinicians to target a specific learning need inherent to the endovascular revolution. Our study describes the development and implementation of a fully online instructional model to teach vascular surgeons how to interpret and utilise cross-sectional imaging to size and plan aortic aneurysm repair using the OsiriX 3D reconstruction platform.

OsiriX (Pixmeo SARL, Switzerland) is a Picture Archiving and Communications System (PACS) and 3D reconstruction platform that processes Digital Imaging and Communications in Medicine (DICOM) data produced by imaging equipment. It

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enables instantaneous conversion of 2-dimensionally stored axial imaging into 3-dimensional representations that facilitate planning and implementation of surgical interventions. OsiriX is available online for download and allows surgeons to readily and independently plan and size endovascular aneurysm repairs from their personal Apple Mac desktop or laptop computers running MacOS X.[9]

There is not an official electronic instructional manual for OsiriX, although some free training materials are available online through the official website.[10] A free Portable Document Format (PDF) electronic textbook has been published in 2008.[11] The "OsiriX: The pocket guide (2nd edition)" published in 2009 by the developers of the OsiriX software is in classic textbook format with no interactive elements.[12] There are two wiki sites for online OsiriX support and documentation, but one has not been updated for a long period of time.[13] A textbook on an older version of OsiriX has been published in 2011 by Maki Sugimoto; it is in Japanese and therefore inaccessible to international readers[14]; the same applies to a similar publication in Italian. One of the primary authors of our eL course has been tutoring OsiriX courses in the past at the national level and has published a descriptive paper on his experience[15].

MATERIALS AND METHODS

Initially, a task-related eL course on the use of OsiriX was authorized by the Education & Training Committee of the European Society for Vascular Surgery (ESVS). At a later moment, the eL was designed and finally consisted of eight modules prepared by the eL team of the ESVS. The eL course was implemented over two nine-week periods over a couple of years. The ESVS eL OsiriX team consisted of two primary authors, five assisting tutors, three ESVS e-Learning researchers and two medical educationalists. All members of the team were employed primarily either as vascular surgeons or as vascular surgery trainees.

A total of 288 hours was invested in writing the PDF textbook (which was later divided into eight modules) and 13 hours in creating and editing the eight video presentations. The group of seven tutors spent a total of 73.8 hours in 1288 online sessions, lasting a mean of 3 minutes 26 seconds per online session. This time was allocated to editing uploaded course material, responding to forum questions, updating content, evaluating students' performance and providing feedback. These estimates do not include the time spent in data upload, particularly for the larger sized files, as that was an automated process not requiring the presence of a dedicated operator. The time durations involved in PDF and video construction are approximations by the authors and not a logged record of working hours. All other times relating to course delivery and online interactions have been calculated based on computer generated server logs.

The project was titled "Planning And Sizing With Osirix For Vascular Surgery" and was primarily aimed at vascular surgeons and trainees. The course was devised utilising readily available software programmes, with an emphasis on intuitive instructional design. The planning, delivery and evaluation of this course have been guided by two vascular surgeons; a Professor and a PhD researcher in medical education. The course fee was €120 per participant, payment of which generated individual login details to access the online resources.

Each module consisted of three components; a Portable Document Format (PDF) text covering conceptual theory; explanatory videos created with Screenflow™ (Telestream, USA), introducing main concepts and demonstrating all practical steps involved in the module; and appropriate DICOM CT angiography files to download and practice upon while using OsiriX. Discussions and comments on each module were supported on an online forum. Six expert instructors took turns to monitor online traffic and manage the helpdesk inbox. Each week's curriculum concluded with a mandatory online self-assessment multiple choice question quiz and an optional, anonymised feedback page hosted at SurveyMonkey (surveymonkey.com; USA).

The topics incorporated into the eight modules ranged from basic technical issues (installing OsiriX, importing DICOM files, organising an image library, etc.) to advanced Abdominal Aortic Aneurysm (AAA) measurement and 3D reconstruction techniques. The course design was intended to help users gain familiarity with the OsiriX interface, understand the use of routine OsiriX commands, record exact AAA measurements in orthogonal planes, create volume and surface rendering and produce, present and interrogate orthogonal, multiplanar and curvilinear reconstructions. An online assessment at the conclusion of the course tested participants' ability to size and plan repair of an authentic AAA case. Successful candidates would receive a certification of completion with the seal of approval of the ESVS.

RESULTS

117 individuals registered for the course. 52 (44.4%) participated in all eight modules, completed the final assessment quiz and provided feedback using the online survey form.

A mean of 6 participants (range 2-10) per module utilised the online forum provided and posted a mean of 4.5 (range 1-9) questions in individual forum threads. The discussion forums were utilised by participants for clarifications relating to course requirements (e.g. deadlines for submitting an assessment quiz) or additional OsiriX features not included in the course syllabus (e.g. importing/exporting password protected DICOM series).

The participant feedback obtained at weekly intervals for each module was consistently positive with modules scoring higher than 4/5 (1 - detrimental, 5 - excellent) in all fields apart from one; details are provided in the next section. The final assessment quiz was successfully completed by 98% of participants who attended the entire course, with a mean grade of 7.98/10. Twelve out of these 52 learners scored the highest possible mark; 10/10. There was a high rate of withdrawals (55%) from the course; this is analysed in further detail below. (Fig.1)

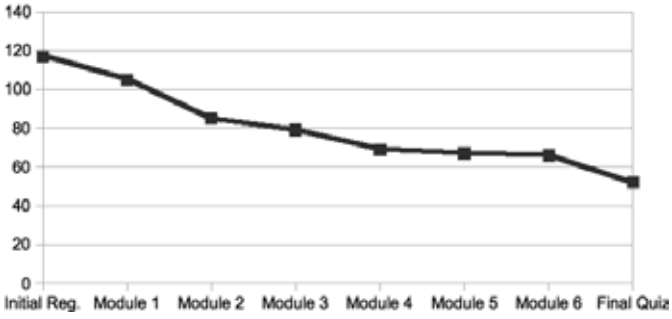

Figure 1.

PARTICIPANT FEEDBACK

Anonymised voluntary feedback was obtained during all modules. Direct feedback was obtained from the participants through an online questionnaire comprising structured responses and free text replies to questions. Feedback was also obtained from the online forum set up for each module, although its main role was to complement tutor-student communication.

We standardised responses to enable comparative scoring between modules on a modified Likert scale. Scores of 4, 3, 2, 1, and 0 were allocated for *excellent, good, satisfactory, unsatisfactory* and *detrimental* effects for each item respectively. The aggregate score attained by all respondents for each scoring item in a module was divided by the maximum achievable score for that item; this value was then expressed as a fraction of 5. Text analysis was performed upon free form responses and summarised as outcome points. The standardised scores allocated for each evaluated outcome measure are indicated in Table 1.

Evaluated outcome		Standardized score (out of 5.0)
Ease of access	PDF Textbooks	4.4
	Videos	3.9
	CT DICOM Files	4
Language & Content Difficulty	PDF Textbooks	4.1
	Audio content	3.5
Learning Value	PDF Textbooks	4.1
	Videos	3.8
	Module score	3.8
	Overall	3.9

Table 1. Standardised scores allocated for each evaluated outcome measure

Accessibility

All users reported ease of accessing the modules and interacting with adaptive elements, with mean scores of 9.5/10 and 9/10 respectively. The ease of accessing the three different kinds of resources (PDF textbooks, videos and CTA DICOM files) was reported to be high (4.4/5, 3.9/5, 4/5 respectively) with a mean effect of 4.1/5.

Language and Content difficulty

None of the online instructors was a native English speaker; this aspect was commented negatively upon in the feedback of five of the participants. Out of the 117 participants, 27 (23%) were either native English speakers or living in an English-speaking country (mainly UK); the majority of the remainder were from Southern Europe. The clarity and language of the PDF textbook scored 4.1/5 and audio quality of the educational videos scored 3.5/5.

Learning value

Participants rated the overall learning value at 3.9/5, giving scores of 4.1/5 to the PDF textbooks, 3.8/5 to the videos and 3.8/5 to the individual modules.

Analysis of withdrawals

52 (44.4%) of the 117 registered participants completed all eight weeks of training and the final assessment quiz. The highest and lowest dropouts occurred between initial registration and first module (12 participants; 10.2%) and between modules 5 and 6, where only 1 participant dropped out (1.49%), respectively (Fig.1.). Following feedback analysis, participants who did not complete the course were contacted via email and asked three questions regarding the reasons for withdrawal; the questionnaire returned a 26% (17/65) response rate. The primary reason identified for withdrawal was that users lacked in personal time for the lessons and / or assessment (>60%). None of the respondents indicated an inappropriate level of difficulty of content or language as a cause for withdrawal. The strongest variable identified by respondents, which might improve compliance with course completion, was truncation of the course to a 4-week syllabus. Details of dropout analysis are summarised in Tables 2 and 3.

Answer	Participants	%
I did not have enough time for the lessons	11	64.7
I did not have enough time for the assessment questions	9	52.9
Problems with my internet access	3	17.7
The content was not useful to me	1	5.9
Problems with the online format in the course	1	5.9
Problems with the English language in the course	0	0
The content was too difficult for me	0	0
I left the course when I had learned enough	0	0
I lost interest so I left	0	0
Other (participant has provided a detailed explanation)	8	52%

Table 2. Answers to "What was the main reason that you did not continue / complete the 2011-12 online OsiriX course from ESVS eL?"

Answer	Participants	%
Shorter course over 4 weeks rather than 8	10	71.4
Restrict course to OsiriX advanced techniques, avoid basic skills	2	14.3
Restrict course to OsiriX basic skills, avoid advanced techniques	1	7.1
Pairing up with another online participant during the course	1	7.1
More one-on-one instruction from online tutors	0	0

Table 3. Answers to "Which of the following would make you more likely to complete an online OsiriX course in 2013?"

DISCUSSION

The ESVS eL OsiriX team successfully devised and implemented a fully online instructional method for 3D sizing and planning of aneurysm repairs, to achieve learning goals for a technical skill in the setting of restricted EWTD for vascular surgeons and vascular surgery surgical trainees. The OsiriX online course was designed and delivered by full time clinicians with a declared interest in medical education. No significant technical problems were encountered during the nine-week courses.

The comprehensive inclusion of OsiriX functions within the syllabus, the modular online instructional design, and the implementation of an evaluation quiz at the end of each module enabled participants who completed the course to achieve and demonstrate competence in sizing and planning for aneurysm repair. Nearly all of the learners who completed the course passed the final assessment and were certified.

There was a high drop out rate from registered participants to the course. The most common reason identified was lack of time to invest. The most common suggestion for improved compliance was to reduce the duration of the course.

Providers of the OsiriX eL course invested a total of 374.8 hours in devising and delivering the instructional material. A team approach and the expert input from vascular surgeons with an interest in medical education enabled a set of full-time clinicians to successfully implement this novel teaching method. The positive outcome from this feasibility study enables subsequent iterations of this online course to evaluate objective learning gains and to make a comparative analysis of its ergonomy and efficiency. Feedback was consistently positive in the course feedback forms and online discussion forums. The online instructors received positive comments, suggestions for future course improvement and inquiries about future course dates. The initial course material has been incorporated into an interactive iBook™ that has been available online.[16]

CONCLUSION

A fully online instructional course with modular weekly design can be successfully implemented by full-time clinicians to teach vascular surgeons and trainees the use of OsiriX for 3D reconstructions of CTA of aortic aneurysms. Users who did not complete the course suggest that shortening its duration may improve compliance. The instructional model is effective and well received by the cohort of learners who comply with the course requirements.

Disclosure of interests: At the time of the eL course, all authors were members of ESVS. NP, SJM and JDB held different positions within the ESVS eL team.

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Applied statistics in vascular surgery Part V: The use of Kaplan-Meier and Cox proportional hazard regression model

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Abstract:

Survival data analysis is used when the time until the event is of interest. The significance of survival analysis is that it takes into consideration that the event will probably not have occurred for all patients at the end of the follow-up period. One of the most commonly used approaches in survival analysis is the Kaplan-Meier estimator, which splits the estimation of survival probability into a series of intervals and calculates the probability of surviving until the end of each interval. However, it cannot control for multiple covariates. Multivariate analysis, using the Cox proportional hazard regression model, is applied when there are multiple, potentially interacting covariates and provides an estimate of the Hazard Ratio and its Confidence Intervals. A brief description of these basic survival data analyses is presented.

INTRODUCTION

Survival or time-to-event analysis is the process of analyzing data measuring the time until a specific event occurs in the population under investigation[1-5]. Such event may be adverse, (e.g. death), positive, (e.g. discharge from hospital) or neutral (e.g. walking a distance). The unique characteristic of this type of analysis is that the event will probably not have occurred for all patients at the end of the follow-up period, or patients may have been lost to follow-up, or they may have experienced another event, which will make further follow-up impossible[1-5]. In this case, we only know the time period (eg. the total number of days) within which the event did not occur; these observations (subjects who did not experience the event) are called “censored” as they drop off the analysis of the subsequent follow up. It is evident that survival time has two components which must be clearly defined; a beginning point and an endpoint that is reached either when the event occurs or when the follow-up time has ended. A basic assumption of the survival analysis is that censored individuals have the same probability to experience a subsequent event as individuals that remain in the study and there is sufficient follow-up time and number of events for adequate statistical power[1-5].

TYPES OF APPROACHES FOR SURVIVAL ANALYSIS

Based on the research hypothesis, three main types of time-to-event analysis can be used, either alone or in conjunction; non-parametric, parametric and semi-parametric. Parametric implies that the model comes from a known distribution (e.g. normal distribution), non-parametric makes no assumptions about the distribution, while in semi-parametric some components, even from unknown distributions, can be added to a parametric model. The most common non-parametric approaches are the Kaplan-Meier (or product limit) estimator and the life table estimator of the survival function[2, 5-8]. In a non-parametric approach, a univariable analysis for categorical factors of interest is conducted. Semi- and fully-parametric models are used when we want to investigate the relationship between several covariates and the time-to-event. For that reason, we usually use non-parametric approaches as the first step in our analysis to generate the descriptive statistics and we thereafter continue with semi-parametric or parametric approaches in case of multivariate models[2, 5-8].

COMMON APPROACHES FOR SURVIVAL ANALYSIS: THE KAPLAN-MEIER ANALYSIS

Kaplan-Meier analysis was first introduced in 1958 by Edward L. Kaplan and Paul Meier[9] who collaborated to publish a study on how to deal with incomplete observations. The Kaplan-Meier method is used to estimate the probability of survival past given time points and it calculates a survival distribution. Furthermore, the survival distributions of two or more groups can be compared for equality[1-6, 8-11]. When preparing a Kaplan-Meier analysis the researcher needs to construct a raw dataset table, in which each subject is characterized by three variables: 1) **time (t)**, which is the survival or censoring time 2) **status** of the event at time t (1=event or 0=no event/censored), and 3) the study **group** in which the participant belongs (eg. 1=treatment group or 2=control group). The table is then sorted by ascending serial time beginning with the shortest time for each group. The technique is to divide the follow-up period into a number of small-time

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intervals, determining for each interval the number of cases followed up over that interval and the number of events of interest (e.g. deaths) during each period. The **survival probability** (which is also called the survivor function) S(t) is the probability that an individual survives (in case of death) from the start time to a specified time (t), which means that the event of interest has not yet occurred by time (t), or in other words, the probability that the time of the event (eg. death) is later than some specified time (t). The **hazard function** h(t) or λ(t), which is also named as "*force of mortality*" [μ (t)], is the probability that a subject experienced the event of interest (death, relapse, etc.) during a small-time interval, given that the individual had survived up to the beginning of that interval. The survival probability can be plotted against time, using the **Kaplan-Meier curve**[1-6, 8-11]. In a Kaplan-Meier plot (Figure 1), the *x axis* represents time, from start to the last observed time point, while the *y axis* is the proportion of subjects surviving, in a way that all subjects are alive without an event at time zero. The Kaplan-Meier curve is usually drawn as a solid line (similar to a staircase), which shows the progression of event occurrences. In such a curve, a vertical drop indicates an event, while a vertical line indicates that a patient was censored at this time. Kaplan-Meier analysis can estimate median time, which is the time at which, in 50% of cases, an event of interest has occurred and mean time, which is the average time for the event.

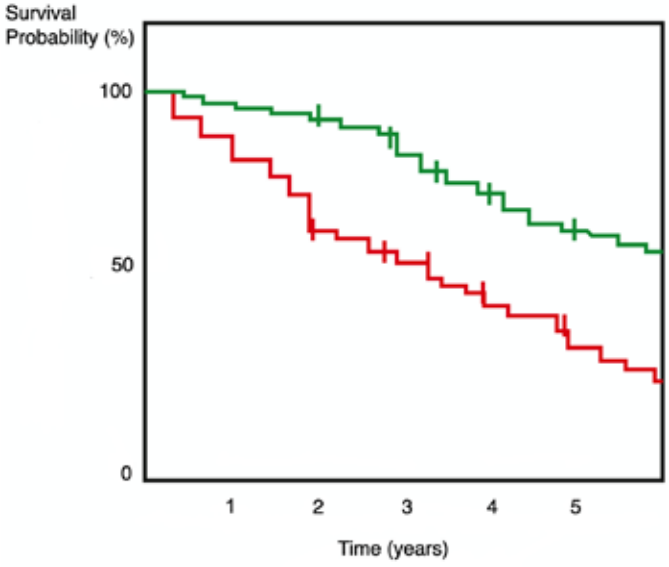

Figure 1. A Kaplan-Meier plot: The *x axis* represents time in years, from start to the last observed time point, while the *y axis* is the (%) proportion of subjects surviving. Two Kaplan-Meier curves are drawn as solid lines (similar to a staircase) with green (treatment A) and red (treatment B) color. The vertical drops indicate events, while the vertical lines indicate that a patient was censored at this time

After plotting of survival data, a **life table** is usually used to depict the number of events and the proportion surviving at each event time point. In a life table, the reader usually finds data concerning the time at which an events occurs, the number of subjects who experience an event at that time, the number of subjects who did not have an event or who were not censored before that time (*patients at risk*), the proportion of surviving at that time and its standard error with lower and upper 95% Confidence Intervals (CIs). In case we want to compare the survival times of two or more groups, the **log-rank test** is used, which is based on chi-square statistic and checks if the observed number of events in each group is significantly different from the expected number. In log-rank test all time points are weighted equally. Other tests include the **weighted log-rank test** in case we want to compare groups, but with more importance ("weight") to certain events, the **Breslow test**, in which the time points are weighted by the number of cases at risk at each time point, the **Tarone-Ware test**, in which the time points are weighted by the square root of the number of cases at risk at each time point and others.[1, 3, 7].

THE COX PROPORTIONAL HAZARD REGRESSION MODEL

The Kaplan-Meier estimator is one of the most commonly used methods to illustrate survival curves. However, the disadvantage of Kaplan-Meier estimator is the lack of controlling for other covariates. In that case, a **Cox proportional hazard regression model** should be used. The latter is a semi-parametric model, which can act as a multiple regression model investigating the association between the survival time with one or more predictor variables and provides an estimate of the hazard ratio (HR) and its CIs[1, 4, 8, 12] . It is similar to multiple regression analysis, except that the dependent variable is the hazard function at a given time. Furthermore, while Kaplan-Meier analysis requires categorical variables, Cox regression can also work with continuous variables. In Cox models, the baseline or underlying hazard function corresponds to the probability of dying (or reaching an event) when all the explanatory variables are zero. A basic assumption in Cox models is the "*proportional hazards*" assumption[11, 13], which means that the hazard functions for any two individuals at any point in time are proportional. So, if the risk of death at some initial point in time in an individual is twice as high as that of another individual, then at all later times the risk of death should remain twice as high.

CONCLUSION

As scientific literature frequently deals with survival time data, censorings cannot be overlooked, as they carry important information. Survival analysis and comparisons using the log-rank test are important in that case. However, when multiple confounders should be taken into consideration, multivariable analyses can be performed using Cox proportional hazard regression model and the results can be interpreted using hazard ratios. Understanding of survival analysis is of paramount importance for both researchers and clinicians.

No conflict of interest.

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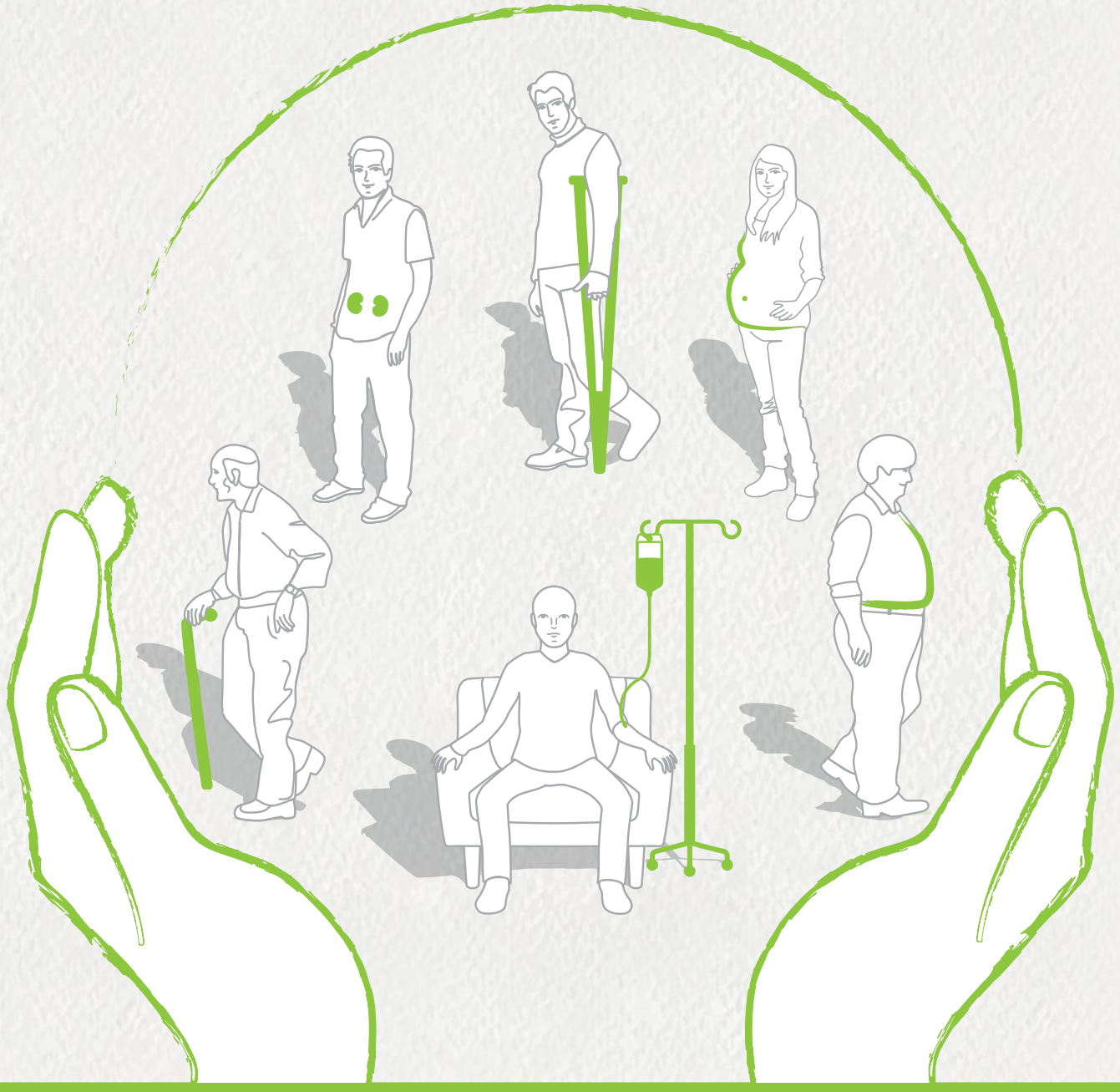

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Post-EVAR aneurysm sac enlargement: When conventional screening tests fail, laparotomy remains the key to findings

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Abstract:

A 69-year-old man underwent standard EVAR for a symptomatic abdominal aortic aneurysm (maximum diameter 10.5cm). The patient presented four years later with an enormous abdominal mass and back pain. Computed tomography angiography (CTA) revealed an abdominal aortic aneurysm (max diam. 15cm) with no signs of endoleak or rupture. We decided to proceed to urgent laparotomy. Intraoperative findings were two sites of active bleeding (endoleak type IIIb) and absence of type I/II endoleak. We sutured the graft defect and enhance it with Dacron patch. Postoperative course was uneventful, and the patient remains in good health six months postoperatively.

CASE

A 69-year-old man underwent EVAR using endograft with suprarenal fixation (Endurant, Medtronic) for a symptomatic abdominal aortic aneurysm (maximum diameter 10.5cm). Four years later, the patient presented with an enormous abdominal mass and back pain. Duplex scan revealed an AAA of ~15cm and no signs of endoleak or rupture. Computed tomography angiography (CTA) revealed the AAA (max diam. 15cm) with no component disconnection or endoleak/rupture. (fig.1) Owing to the enormous dimensions of the aneurysm and its symptomatic character, we decided to proceed to urgent laparotomy. (fig.2) After the incision of aneurysm sac and the removal of excessive amount of thrombus, two sites of active bleeding were identified (one in the internal surface of right iliac limb and one in the anterior surface of left iliac limb).(fig.3) No type I/II endoleak was identified intraoperatively. We decided to suture the graft defect and enhance it with Dacron patch. (Fig.3) Postoperative course was uneventful, and the patient remains in good health three months postoperatively.

TECHNICAL NOTES - DISCUSSION

In this case, bleeding may be attributed to manufacturer fault, to tearing of the fabric due to stent graft fatigue or to porosity. According recent recommendations, identification of fabric hole after the first 30 days post-operation should be considered as type IIIb endoleak and be treated promptly. Type III endoleak expose the aneurysm to direct aortic pressure with a subsequent risk of rupture. Moreover, some suggest that type IIIb endoleak can be misdiagnosed with type IV or type II endoleaks. Long-term follow-up after EVAR is mandatory and in cases where there is a significant aneurysm sac expansion or the patient becomes symptomatic intervention is indicated.

From our experience, it seems that conventional screening tests (CTA and duplex scan) may fail to diagnose the endoleak. Type IIIb endoleak should be highly suspected in cases with continuous growth of an excluded aneurysm sac without direct radiologic evidence of endoleak. Other diagnostic methods such as contrast enhanced ultrasound or digital subtraction angiography may be utilized but it is uncertain whether their findings are definitive for the diagnosis. In case of aortography one should try to do bilateral balloon occlusion of the proximal limbs. The reason we didn't perform DSA or intraoperative angiography was because we were determined to evacuate that 15cm mass.

Management options at the time of the presentation included endovascular procedure with relining of the endograft or conversion to open procedure with possible explantation of the endograft. In case of conversion, the vascular surgeon should always ensure proximal control of the aorta so in case of endograft dislocation he will be able to clamp the aorta immediately and avoid hemorrhage.

According type IIIb endoleaks, there are two recent systematic reviews available in the literature with comparable results. [1,2] In one third of the cases the definite therapy was performed by conversion. Moreover, the main body seems to be the most common location for the holes and the in majority of cases, endograft's fabric was polyester.

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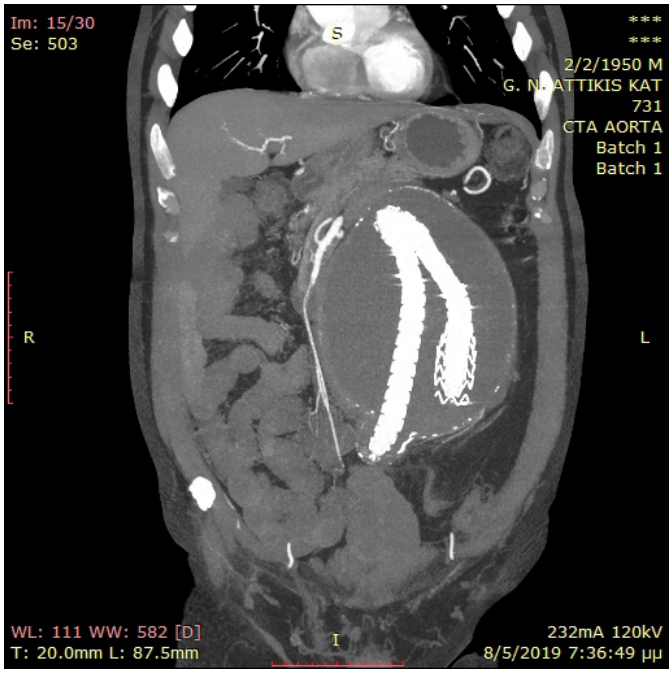

Figure 1

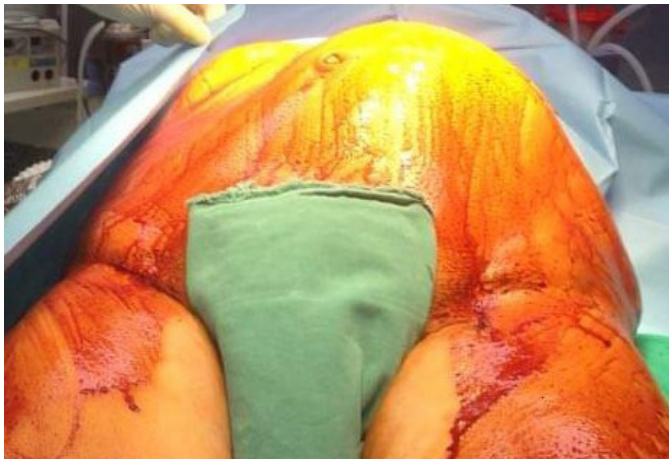

Figure 2

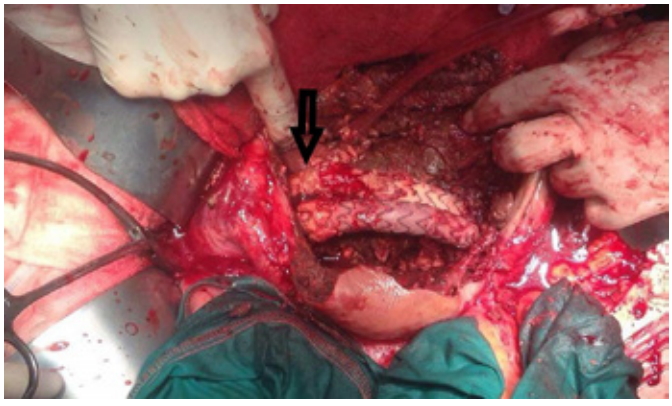

Figure 3

CTA revealed an expansion of the abdominal aortic aneurysm without recognizing any endoleak. No limb disconnection and no signs of rupture were noted either.

Note the enormous abdominal mass.

Intraoperative findings included two sides of bleeding. We suture the holes and enhanced it with Dacron patch.

CONCLUSION

It is - once more - proved that long-term follow-up is mandatory in patients treated with EVAR. Diagnosis of type IIIb is a difficult task and misdiagnose is possible. We need further studies to identify if there is difference in the incidence of type IIIb endoleak among dacron and ePTFE endografts. Surgeons should remember that when there is a mysterious post-EVAR aneurysm sac enlargement, exploratory laparotomy remains the key to findings.

Acknowledgment:

1. Informed consent has been obtained from the patient before publishing.
2. This case report was also presented at 2nd Athens Cardiovascular & Thoracic Symposium which was held in Athens (Greece) 7-9 November 2019.3

No conflict of interest.

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Total endovascular repair of aortic arch dissection using parallel graft technique

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Abstract:

Purpose: To present the successful repair of aortic arch dissection using parallel graft technique.

Technique: A 62 years old man with history of arterial hypertension experienced retrosternal pain radiating to the back and nausea. An emergent CT depicted a non A- non B dissection of aortic arch. Endovascular repair was suggested to the patient. A total endovascular reconstruction with exclusion of primary entry tear using thoracic stent graft followed by chimney technique to the innominate and left common carotid artery and periscope graft of left subclavian artery were successfully performed.

Conclusion: Total endovascular repair of aortic arch dissection using parallel graft technique is an effective minimal invasive treatment especially in emergent situations. More studies are required to assess its future efficacy.

Keywords: *Aortic arch Dissection, Chimney technique, total endovascular repair*

INTRODUCTION

Conventional open repair of aortic arch dissection with cardiopulmonary bypass and deep hypothermic arrest is a highly demanding procedure with significant morbidity and mortality despite improvements in cardiothoracic surgery[1]. Thoracic endovascular aortic repair (TEVAR) was principally designed for pathologies of the descending thoracic aorta[2]. However aortic lesions proximal to the left subclavian artery (aneurysm, dissection, penetrating ulcer, intramural hematoma) which are highly challenging due to their anatomical configuration and hemodynamics of the aortic arch can also be treated endovascularly using off-the-self devices minimizing unfavorable outcome in high risk patients, providing less perioperative morbidity and mortality[3]. Total endovascular aortic arch repair using parallel graft technique is a minimal invasive technique which allows exclusion of the aortic arch lesions preserving concurrently inflow to the supra aortic branches avoiding median sternotomy and aortic clamping even in emergent situations. We describe a case of a patient with acute aortic arch dissection successfully treated by parallel graft technique.

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CASE REPORT

A 63 years old man was presented to the emergency department due to retrosternal pain radiating to the back and nausea the last 2 hours. His medical history was remarkable for arterial hypertension without taking appropriate antihypertensive regimen and smoking. His blood pressure was 250/120 mmHg during examination, ECG showed sinus tachycardia and chest X-ray was normal. D-dimers were 2600 μu/dl, troponin levels were negative for myocardial ischemia. Biochemical tests were within normal range apart from kidney function tests where creatinine and urea were 2.6mg/dl and 130 mg/dl accordingly. A provisional diagnosis of acute dissection was made and an emergent computed tomography aortography (CTA) was performed. CTA depicted a non A- non B aortic dissection initiating between left common carotid and left subclavian artery at Ishimaru zone 2 extending up to common iliac arteries (Figure 1). The patient was hospitalized to the coronary unit for hemodynamic monitoring and control of blood pressure and rhythm with antihypertensive and anti-impulse therapy. The patient experienced recurrent episodes of retrosternal pain during his hospitalization so emergent intervention was scheduled. We decided to use the technique of total endovascular repair using TEVAR plus parallel graft technique for perfusion of supra aortic branches as the patient refused hybrid or open repair due to the necessity for sternotomy. Informed consent was obtained from the patient to proceed with TEVAR.

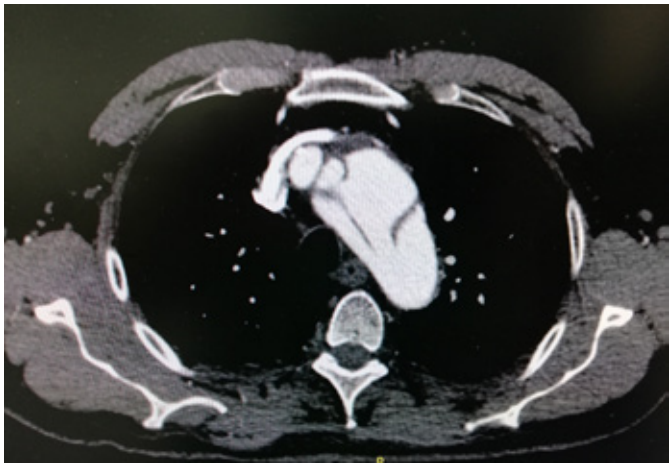


Figure 1. CTA depicted an aortic arch dissection at Ishimaru zone 2.

TECHNIQUE

Under general anesthesia exposure of the right common femoral, right axillary, left common carotid artery (LCCA) and left branchial artery was gained under surgical cutdown. A guidewire (Terumo Corporation, Tokyo, Japan) was advanced from right axillary artery to the right common femoral artery to avoid inadvertent entry to the false lumen through retrograde approach. It was then exchanged with an extra-stiff double curved exchange guidewire (Lunderquist, Cook Medical, Bloomington, USA) through a Vertebral catheter (Boston Scientific, MN, USA) 100cm long. A 7F-90cm (Arrow International, Inc, Reading, USA) was advanced through the right common femoral artery to the ascending aorta. An aortography was performed which revealed the supra aortic branches and the dissection. A 45mm-150mm thoracic endograft (GORE TAG, W.L, Flagstaff, AZ) was firstly introduced and positioned under fluoroscopy in the proximal part of descending aorta. Two Viabahn stent-grafts (GORE, W.L, Flagstaff, AZ) 11x39mm and 11x59mm deployed proximal to the origin of left vertebral artery to the endograft in the descending thoracic aorta after cannulation of the left subclavian artery (LSA). A second Gore Tag 45-100mm thoracic endograft was deployed in such a way that the proximal part of the endograft was across the origin of LCCA. The innominate artery was cannulated, and an "internal iliac side branch" 16-14.5 x70mm was temporarily placed in the ascending aorta through a 12Fr GORE sheath using an extrastiff double curved guidewire. The LCCA was subsequently cannulated and an 8x79mm Viabahn graft was placed in the ascending aorta using a PTFE covered guidewire (Rosenwire, Cook Medical, Bloomington, USA). A third Gore Tag 45mm-150mm thoracic endograft was deployed under fluoroscopy 3cm proximal to the origin of innominate in the ascending aorta. Overlap between thoracic endografts was 5cm.Then the chimney stent-grafts in the innominate and LCCA were deployed and postdilated. Final aortography confirmed exclusion of dissection and patency of the supra aortic branches (Figure 2). The patient was transferred to the intensive care unit and extubated the next day. He was discharged the 7th postoperative day under dual antiplatelet therapy for 3 months followed by lifelong single antiplatelet therapy and antihypertensive regimen. Post-operative CTA at 1 month depicted thrombosis of false lumen with patent supra-aortic branches and no endoleak (Figure 3,4).

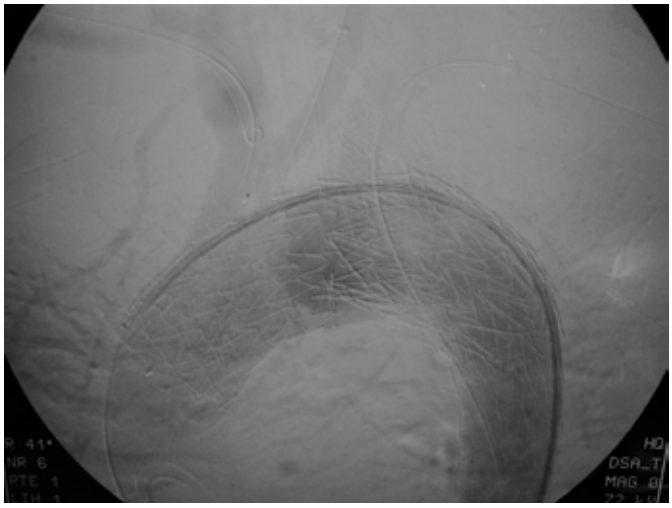
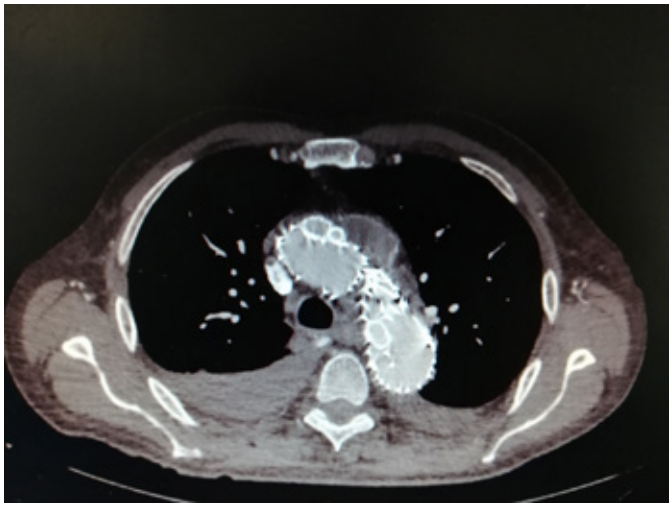


Figure 2. Final aortography confirmed exclusion of dissection and the patency of the supra aortic branches.



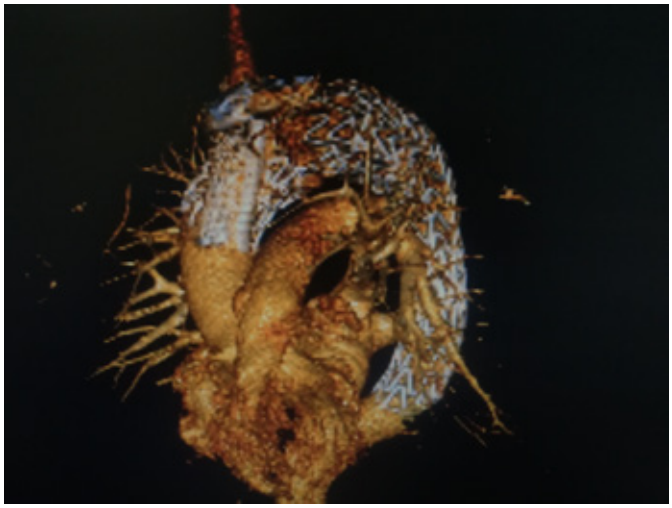


Figure 3,4. Follow up axial and 3D reconstruction images show exclusion of false lumen with patent parallel grafts.

DISCUSSION

The chimney technique was first described by Greenberg at 2003 used for the endovascular repair of juxtarenal/suprarenal abdominal aortic aneurysms[4]. It is a minimal invasive technique based on the implantation of parallel stent grafts. In the aortic arch, it was initiated as a bail out technique for preservation of left subclavian artery with proximal extension of the landing zone during TEVAR. Parallel graft technique in the aortic arch has been extended for preservation of all supra aortic branches especially in emergent situations[3,5]. In a recent meta-analysis of 379 patients Li Y et al showed that technical success rate of chimney technique was 91% the rate of 30-day mortality was 4%, the rate of patency was 93%, the rate of perioperative endoleak was 21%, and the rate of stroke was 5%[3]. Moulakakis et al published another meta-analysis reporting primary technical success was 99.2%. The perioperative mortality rate was 4.8% and the stroke rate was 4%, while the overall endoleak rate was 18.5%[6].

In our patient parallel graft technique was used as an emergent operation due to recurrent episodes of thoracic pain and refusal of patient for open or hybrid repair. Periscope grafting in left subclavian artery was used to preserve perfusion of arm and vertebrobasilar system to minimize the risk of proximal gutter and endoleak 1a as well as to preserve collateral circulation of the spinal cord.

CONCLUSION

Total endovascular repair using parallel graft technique is an effective treatment of aortic arch pathologies in emergency situations. Its long term efficacy needs to be defined due to anatomical and hemodynamic configurations of the aortic arch.

No conflict of interest.

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A single center early experience with the AnacondaTM Fenestrated device used for the treatment of a para-renal abdominal aortic aneurysm: A case report

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Abstract:

Endovascular abdominal aortic aneurysm repair (EVAR) is an alternative to open surgery for the treatment of infrarenal abdominal aortic aneurysms (AAAs) with exception in cases that involve visceral branches. In such cases preservation of visceral perfusion is of great importance. A wide range of custom-made devices have been used for this reason. The ANACONDA™ Fenestrated Endograft (Vascutek, Inchinnan, United Kingdom) has been used since 2011 for the repair of AAAs unsuitable for standard-EVAR. In this report we present our early experience with the Anaconda Fenestrated device implanted in a patient with a 63mm para-renal inflammatory AAA with successful result.

Keywords: *Anaconda Fenestrated Endograft, Juxtarenal AAA, Pararenal AAA, Thoracoabdominal aortic aneurysm*

INTRODUCTION

Endovascular abdominal aortic aneurysm repair (EVAR) is a well-established alternative to open surgery for the treatment of infrarenal abdominal aortic aneurysms (AAAs). Overall, the suitability of EVAR is primarily affected by anatomic criteria[1]. In these patients the Fenestrated Endovascular Aneurysm Repair (FEVAR) technique may be a valuable alternative[1,2]. The era of fenestrated/branched stent grafts (FBSGs) for the treatment of AAAs with short necks started in 1999[3,4].

The ANACONDA™ Fenestrated Endograft (Vascutek, Inchinnan, United Kingdom) has been used since 2011 for the repair of AAAs unsuitable for standard-EVAR[5]. The purpose of the current report is to present our initial experience with the ANACONDA™ fenestrated device implanted in a patient with a para-renal AAA.

CASE PRESENTATION

A 63 years old male presented in our institution with a 63mm asymptomatic inflammatory pararenal AAA diagnosed accidentally. His past medical history included hypertension, hyperlipidemia and coronary artery disease (ASA score II). The decision to treat the patient by endovascular surgical procedure was taken after an unsuccessful laparotomy due to excessive retroperitoneal fibrosis discovered intraoperatively. The aneurysm morphology was assessed by 3mm slices spiral computerized tomographic angiography (CTA) with axial and coronal reconstructions showing a left accessory renal artery perfusing the upper 2/3 part of the left kidney while the main renal artery raised from the sac and was almost fully thrombosed (Fig. 1a). A customized fenestrated device based on the Anaconda ™ system was designed according to the preoperative measurements. This included four fenestrations for the four main visceral arteries (celiac artery CA, superior mesenteric artery SMA'', and the two renal arteries RAs) (Fig. 1b).

Surgical Procedure

The procedure took place in the interventional radiology cathlab with the patient under general anesthesia. An arterial access and a urinary catheter were placed perioperatively for cardiovascular monitoring purposes. A bolus dose of 5000 IU of heparin was injected intravenously immediately before femoral artery cannulation, with additional boluses of heparin given as required by the duration of leg ischemia aiming at ACT of 250 seconds. Bilateral open femoral artery exposure was used as access points for the stent graft deployment system. The main body of the graft was inserted from the left iliac axis, oriented properly and partially deployed. The cannulation of the fenestrations made with a Vanshie-1 catheter through a long 45cm long arrow sheath and a 0,035" hydrophilic Terumo stiff guidewire.

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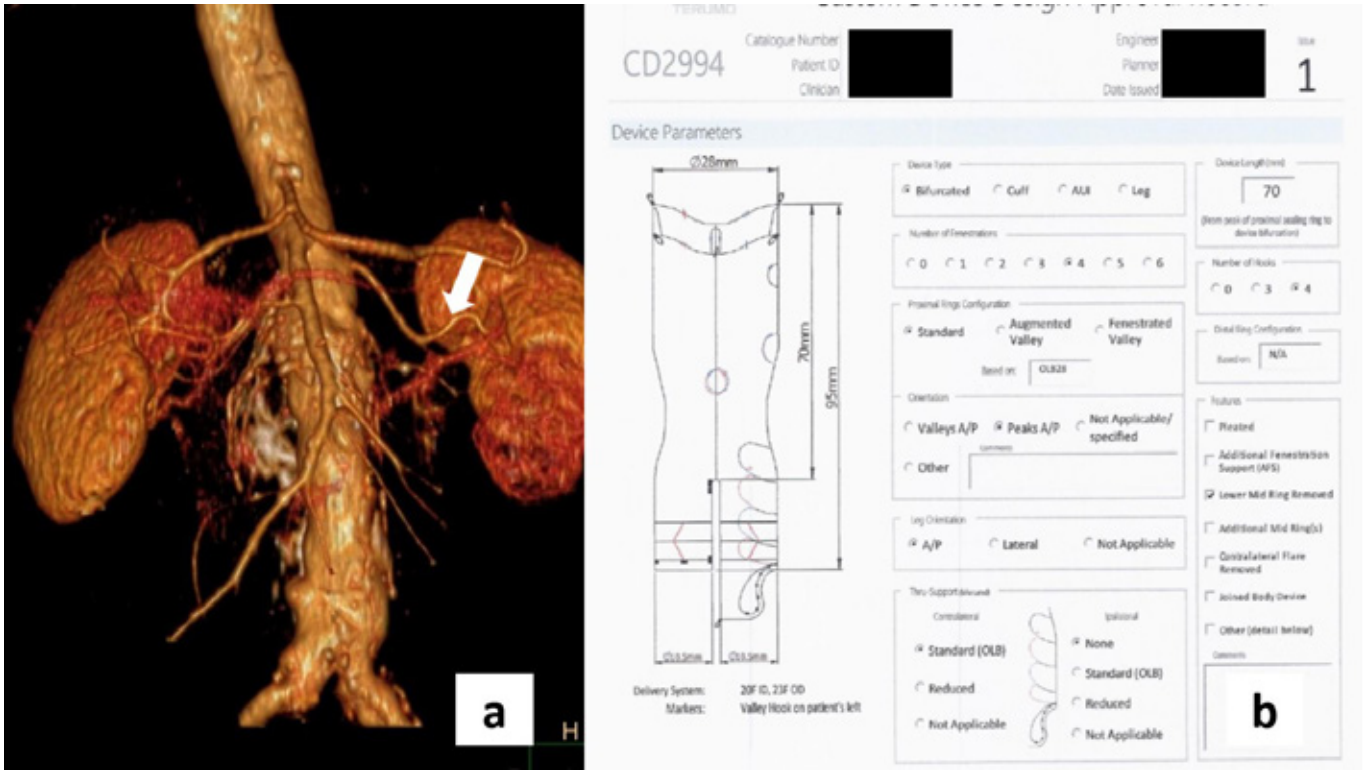

Figure 1. a. 3-D reconstruction of the pre-operative CTA* revealed the para-renal inflammatory abdominal aortic aneurysm with the accessory left RA** (white arrow) b. Preoperative drawing of the custom-made fenestrated stent-graft with tube configuration.

*CTA: Computerized Tomographic Angiography

**RA: Renal Artery

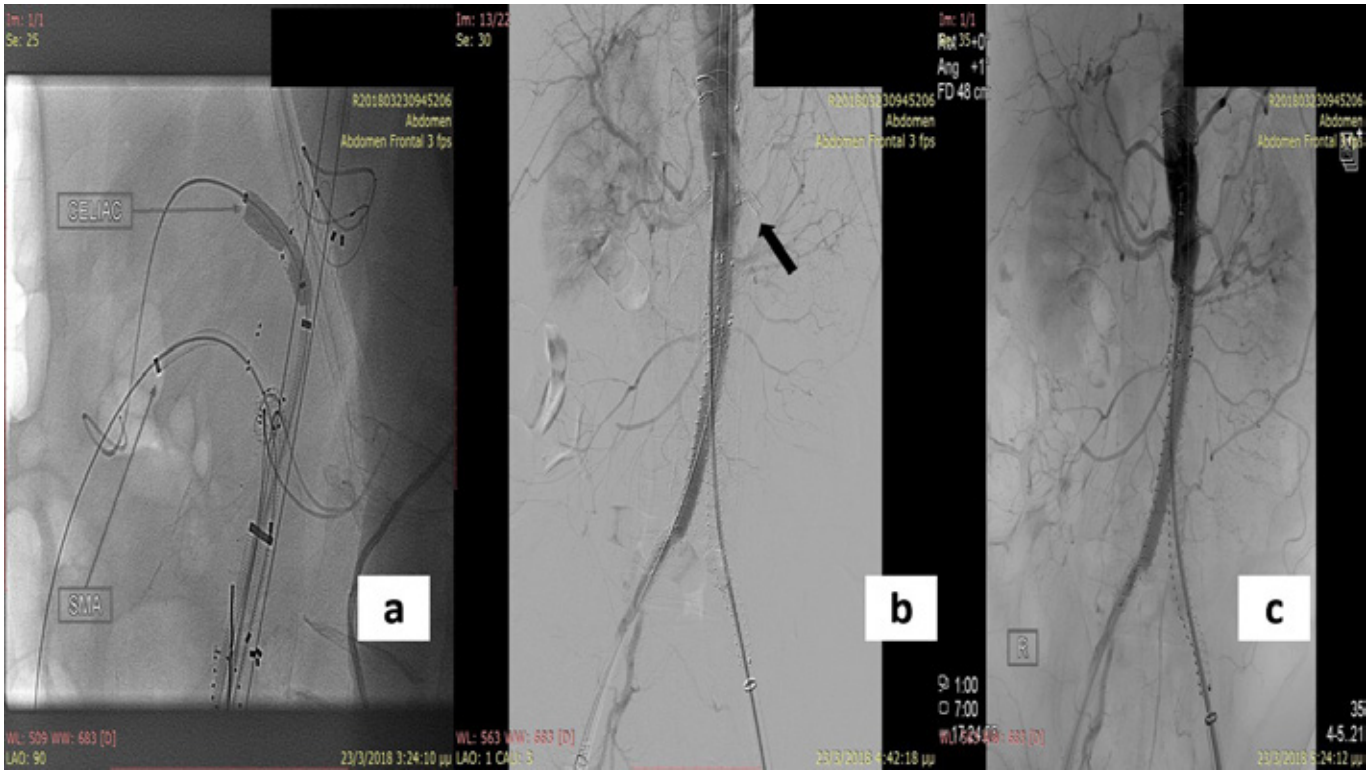

Figure 2. Intraoperative image; a. after insertion of the covered stents within the target arteries (celiac and superior mesenteric arteries) and partial deployment of the main body. b. occlusion of the left RA* covered stent due to transient vasoconstriction with absence of flow (black arrow). c. restoration of blood flow after balloon angioplasty and final angiography with satisfactory results.

*RA: Renal Artery

The re-positioning system of the endograft was used to improve the apositioning. After that, the guidewire was exchanged with a 260 cm long J-tip stiff wire (Rosen wires for the renal arteries and Amplatz guidewires for the SMA and Celiac artery) and Advanta V12® covered stents (Atrium Medical, Hudson, NH) were delivered within the target arteries (Fig. 2a). These included one 7x32 for the CA, one 9x32 for the SMA and two 7x22 for the renal arteries. There were no major technical issues or intraoperative complications, apart from difficulty in advancing the covered stent in the SMA, where we used an extra micro-catheter to introduce the guidewire distally into the artery. The covered stent in the left renal artery occluded immediately after deployment due to the transient vasoconstriction with absence of flow in the left accessory RA (Fig. 2b). The left renal artery was catheterized again, and the vessel patency was restored after a balloon angioplasty. Thereafter, all stent grafts flared with a compliant aortic balloon. Final angiography demonstrated good apositioning of the device and patency of all the visceral vessels and both iliac arteries (Fig. 2c). Total operative time was 240 min, radioscopy time 169 min contrast used 270mL and blood loss was approximately 350mL. After the procedure, the patient was admitted to the ICU department for two days and discharged in the 8th post-operative day. The six-month follow-up was satisfactory with good device position and no endoleaks (Fig. 3).

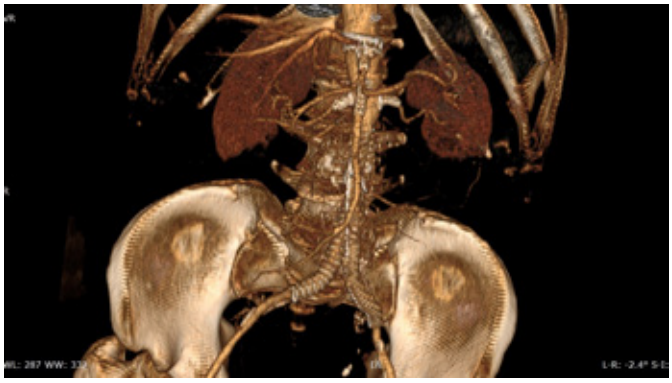

Figure 3. CTA* imaging six months after was satisfactory with good sealing of the device, patency in all visceral branches, the iliac arteries and no endoleak.

*CTA: Computerized Tomographic Angiography

DISCUSSION

EVAR has been established as an alternative to open surgery for the treatment of infrarenal AAAs, despite that EVAR is affected by the patients' anatomy. Current data regarding the use of EVAR for infra-renal AAAs have shown that using devices outside the instructions-for-use may result in significantly more late complications and graft-related adverse events[6]. However, the insertion of FBSGs for the treatment of AAAs with short proximal necks has been established as an alternative to open repair with a high degree of clinical, technical and satisfactory midterm outcomes according to data from the Global Star Registry[7]. Unfavorable anatomical criteria for the use of FEVAR were also identified including adequate landing zones, cannulation of visceral arteries and suitable diameter access vessels[8]. Nowadays, several fenestrated grafts are commercially available. Most of the currently available knowledge is based on the Zenith® custom-made fenestrated endograft device (Cook Medical, Brisbane, Australia). FSGs include devices with fenestrations (holes) or scallops (gaps or valleys in the upper margin of the graft) to access visceral arteries simply to allow extension of the sealing zone proximally, limited only by the desire to reduce the number of visceral vessels included into the repair[9]. Nowadays, the whole aorta, including the visceral vessels can be treated totally by endovascular means. If these devices are implanted successfully, they lead to complete exclusion of the aneurysm while maintaining sufficient perfusion to vital organs. The main disadvantage of the custom-made fenestrated devices is that they currently require a long period of time for the pre-procedural planning and manufacture of the stent graft. This limitation has led to the development of 'off-the-shelf' fenestrated and branched devices such as the Cook p-Branch and t-Branch as well as the Endologix Ventana[10]. On the other hand, open surgery for para-renal AAAs and type IV TAAA is technically challenging and linked to higher morbidity and mortality rates when compared to infrarenal aortic surgery, especially in patients who are frail for open repair. The suprarenal aortic clamping, by itself, has been variably associated with an increased morbidity and mortality, whilst the redo nature of the surgery after an open repair adds a degree of difficulty and prolongs recovery time.

The Anaconda fenestrated device (Vascutek, Inchinnan, United Kingdom) was designed for the treatment of patients with AAA unsuitable for standard-EVAR. The first four cases have been described by Bungay et al. in 2011, who concluded that Anaconda fenestrated stent graft device was suitable for AAAs repair in cases of hostile neck anatomy[5]. There are some technical issues that make the Anaconda device technology unique for complex cases such as the increased flexibility and fixability of the device.The main advantage of this stent graft is that it remains re-deployable. Hence, even after complete unsheathing of the device, the physician is still able to partially collapse and change the orientation or height of the stent graft. In our case, we did not face any major technical issues during device deployment. The results were satisfactory from both the technical success of the procedure and the six-month follow-up.

CONCLUSION

In this report we quote our initial experience with a new custom-made device for the treatment of a patient with complex aortic pathology unsuitable for standard-EVAR. The new Anaconda fenestrated device is a promising feasible option implanted without any major technical difficulties.

No conflict of interest.

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Endovascular Approach for the Treatment of a Distal Aortic Arch Aneurysm in a Nonagenarian Patient

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Abstract:

Elder patients with thoracic aortic aneurysms could safely be treated endovascularly, with a reasonable morbidity and mortality rate. Our aim is to present a patient with a large aortic arch aneurysm treated with endovascular means and a synchronous carotid-subclavian bypass. Due to his good condition, a 93-year old male with a 10cm aneurysm of the distal aortic arch underwent an endovascular repair, using a thoracic endograft and 1 parallel graft to the left common carotid artery, associated with a synchronous carotid-subclavian bypass and an occlusion of the subclavian artery with plug. The initial postoperative CTA presented a minor gutter endoleak, while the patient was discharged without any further complications. One year later, he is continuing a normal life.

INTRODUCTION

Endovascular management of descending thoracic aorta diseases (TEVAR) is recommended as the standard of treatment, irrespectively of patients' risk factors, as it is associated with lower mortality and morbidity rate, compared to conventional surgical repair.[1,2] However, complex endovascular repair may be associated with higher mortality in elder patients and age ≥80 years may be an independent predictor for higher early all-cause mortality.[3] Herein, we report a case of a 93-year-old male suffering from a large symptomatic thoracic aortic aneurysm treated using a parallel graft and simultaneous carotid-subclavian bypass. This report has been approved by the Ethics Committee of the Hospital.

CASE REPORT

A 93-year old male, with a history of a previous open surgical repair of a descending thoracic aortic aneurysm (15 years ago at the mid portion of the descending aorta) and a known 80mm aortic arch aneurysm suffered acute and recurrent episodes of intense thoracic pain. The patient had previously denied any surgical treatment. Furthermore, his medical history was significant for hypertension, dyslipidemia, mild chronic obstructive pulmonary disease (FEV1 84%) and atrial fibrillation (AF) under treatment with direct oral anti-coagulant. Cardiologist evaluation revealed no acute heart disease and the ejection fraction was preserved (50%). Computed tomography angiography (CTA) revealed a distal aortic arch aneurysm with a maximum diameter at 96mm, associated to a proximal para-anastomotic aneurysm and severe aortic tortuosity (Figure 1). Taking in account his age and co-morbidities, an endovascular approach was decided. The aneurysm included left subclavian artery (LSA) and the distance from left common carotid artery (CCA) was 9 mm. A parallel graft technique (chimney TEVAR) was decided for the preservation of the left CCA and a carotid-subclavian bypass with a plug deployment at the orifice of the LSA, thus the proximal landing zone was 18 mm up to innominate artery.

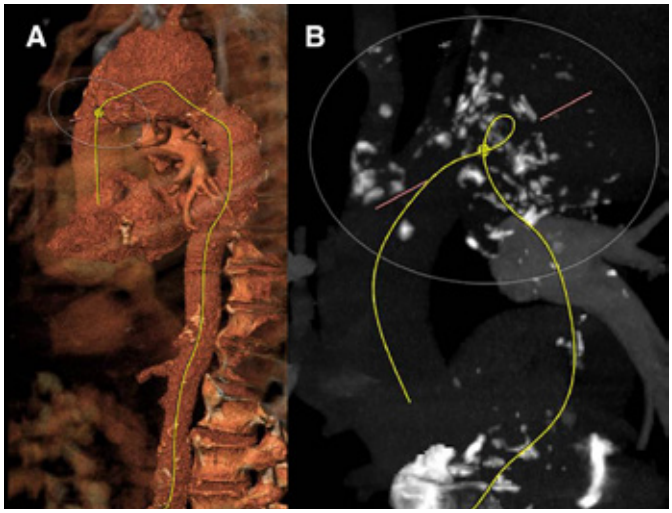

Figure 1. A large aortic arch aneurysm was detected in the pre-operative computed tomography angiography (Panel A). In antero-posterior view, an extreme tortuosity of the aorta was revealed, making the decision making and endovascular treatment more demanding (Panel B).

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Initially, a carotid-subclavian bypass was constructed through a transverse cervical access, using a 6mm polytetrafluoroethylene (PTFE) graft (Propaten, Gore, Delaware, USA). After the accomplishment of the bypass, two thoracic endografts and 1 stent graft were used for aneurysm exclusion and left CCA preservation in order to achieve adequate sealing. The extreme aortic tortuosity was confronted using a through and through guidewire from the right axillary to the left common femoral artery and mild tension was used to achieve adequate endograft deployment. Guidewire advancement was challenging and finally a snare from below up to the aortic arch was used to accomplish the through and though maneuver. (Figure 2) A thoracic endograft (Relay 44x44x200mm, Bolton Medical, Florida, USA) was inserted proximally while a covered balloon expandable stent graft (10x57mm, Be-Graft, Bentley, Innomed, Germany) was deployed into the left common carotid artery, through a direct carotid puncture. Relining using a self-expanding 12x60mm stent was applied to enforce the main stent graft (E-Luminexx, Bard, New Jersey, USA). A second thoracic graft (46x46x200mm, Valiant, Medtronic, USA) was deployed distally to achieve complete sealing. The procedure was completed through a percutaneous puncture of the left brachial artery and the insertion of a 14x10mm plug (Amplatzer, Abbott, Illinois, USA) at the orifice of the LSA.

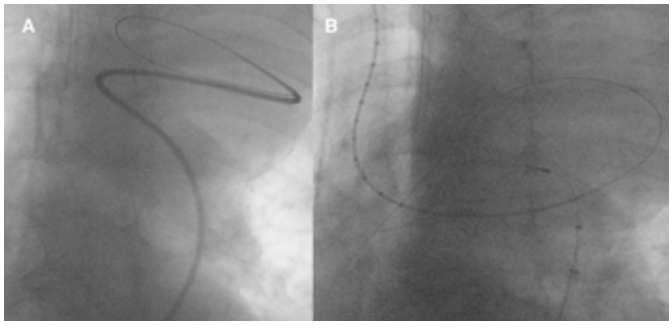

Figure 2. Guidewire advancement may be challenging in elder patients due to aortic anatomy (Panel A). In this case, the use of snare was inevitable to achieve the passage of the through and through guidewire (Panel B).

Completion angiography showed no endoleak while left CCA stent and left carotid-subclavian bypass were patent. Intra-operatively the patient was transfused using 1 red blood cell unit. Median contrast used was estimated at 100 ml and radiation exposure 289mGy. The total duration of the operation was 300min. The patient was transferred to the ward under close monitoring. The 4th post-operative day, a rapid AF, with cardiac decompensation and dyspnea, was detected and the patient was transferred to the cardiology department. Medical management was effective and pre-discharged CTA showed exclusion of the aneurysm sac, patent parallel graft and by-pass as well as a minimal gutter endoleak (Figure 3). Finally, the patient was discharged the 10th post-operative day in a good general condition. A close surveillance with clinical re-evaluations and laboratory exams confirmed the uneventful later post-operative period.

Figure 3. First-month follow-up with computed tomography angiography revealed aneurysm stabilization and endografts patency (Panel A). A carotid-subclavian bypass and a plug occlusion of the left subclavian artery were used to prevent spinal cord ischemia by preserving collaterals patency (Panel B).

After a 30-day rehabilitation program, the patient had completely recovered at his daily routine. A non-contrast CTA revealed the stabilization of the sac and the adequate graft deployment. No further complication was recorded during the 1st year of follow-up. The patient denied a CTA imaging surveillance. Clinical and laboratory evaluation were in order.

DISCUSSION

Current guidelines for the management of descending thoracic aorta disease have not specified a life-expectancy or age limit in order to provide endovascular treatment for TAA.[1] However TEVAR should be considered as the first line treatment option in cases of favorable anatomy even in patients unfit for open surgery.[1] TEVAR seems to be beneficial in terms of mortality in elective and urgent cases with a 5-year survival rate at 62.5% in intact aneurysms.[2] In urgent cases, one third of patients will survive after a treated ruptured thoracic aneurysm during the mid-term follow-up.[2] In this case, due to high comorbidity and the presence of a large symptomatic aneurysm, an endovascular approach was decided and accomplished after a detailed pre-operative risk assessment.

Spinal cord ischemia (SCI) affects 5-year survival and the mortality rate is estimated at 20% for patients that survived the early post-operative period.[4] The prevention of spinal cord ischemia is mandatory in patients undergoing a long coverage of the aorta and preventive measures are indicated in these cases.[1] Advanced age may be associated with aortic and spinal artery atheromatosis, which may affect neurological outcomes after thoracic aorta repair.[5] Along this line, elder patients may be considered as a high risk group of SCI. In this case, LSA preservation was decided using a carotid-subclavian bypass, as its initial coverage was inevitable in order to achieve a safe proximal sealing zone. Taking in account that (1) extra-thoracic bypass surgery is safe and effective in the form of debranching, (2) a carotid-carotid bypass has a primary patency at 88%, (3) further bypass to the LSA could affect patency and (4) the increased the risk of total occlusion of all supra-aortic vessels in case of bypass thrombosis, a hybrid procedure using a parallel graft for the preservation of the left CCA was decided.[6,7]

Current endovascular experience has shown that nona-

genarians with a good functional status may be successfully treated and benefit from a median survival of 56.2 months.[8] Patient selection is mandatory in this fragile group.[8] In this case, the patient was in a very good general status and had an active daily routine. Even in technical terms, an endovascular approach in elder patients may be challenging due to the special anatomic characteristics, as aortic tortuosity.[9] In this case, a through and through guidewire from the right axillary to the left femoral artery was needed to achieve the successful and safe deployment of the endograft. An individualized approach is mandatory in order to select these elder patients that may benefit of an endovascular repair as complications are acceptable but significantly greater than in younger patients.[10]

Untreated descending thoracic aortic aneurysms are related with high rupture rate and a low 5-year survival, while age and non-treatment approach are related to higher rupture risk.[11] Open surgical repair in patients elder than 70 years old is associated with higher morbidity in comparison to younger patients.[12] In cases with complex aortic anatomy and need for extended endovascular treatment, a high post-operative complication and mortality rate of more than 25% may be suspected.[13] In any case, endovascular repair is associated with significantly lower morbidity and mortality than surgery, reflecting that minimal approaches may be a safer option in high risk elder patients.[14] In this case, despite the technical success, the patient needed a long hospitalization of 10 days due to post-operative complications that were managed conservatively. After the initial period, the patient recovered completely and regained his initial daily routine.

CONCLUSION

Endovascular aortic aneurysm repair seemed safe and feasible in this case. Elder patients may be treated with minimally invasive techniques, achieving a reasonable morbidity and mortality rate.

No conflict of interest.

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Forthcoming Events

EVC 2020
March 8-10, 2020
Maastricht, Netherlands

19th Panhellenic Congress of Vascular and Endovascular Surgery
March 19-21, 2020
Athens, Greece

CX 2020
April 21-24, 2020
London, UK

LIVE 2020
May 14-16, 2020
Larissa, Greece

ESVCS 2020,
May 22-24, 2020
Padova, Italy

VAM 2020,
June 17-20, 2020
Toronto, Canada

CIRSE 2020,
September 12-16,
Munich, Germany

ESVS 2020,
September 29-October 02
Krakow, Poland

Welcome to the official webpage of the Hellenic Vascular Registry (HEVAR, VascularRegistry.gr). VascularRegistry.gr runs under the auspices of the Hellenic Society of Vascular and Endovascular Surgery (HSVES). HEVAR is a member of Vascunet. HSVES' goal is the systematic recording of the total vascular activity in Greece, as seen in the existing national vascular registries worldwide as the VSQIP, the VQI, the Swedvasc, the GermanVasc and others.

Have said about the "Registry"

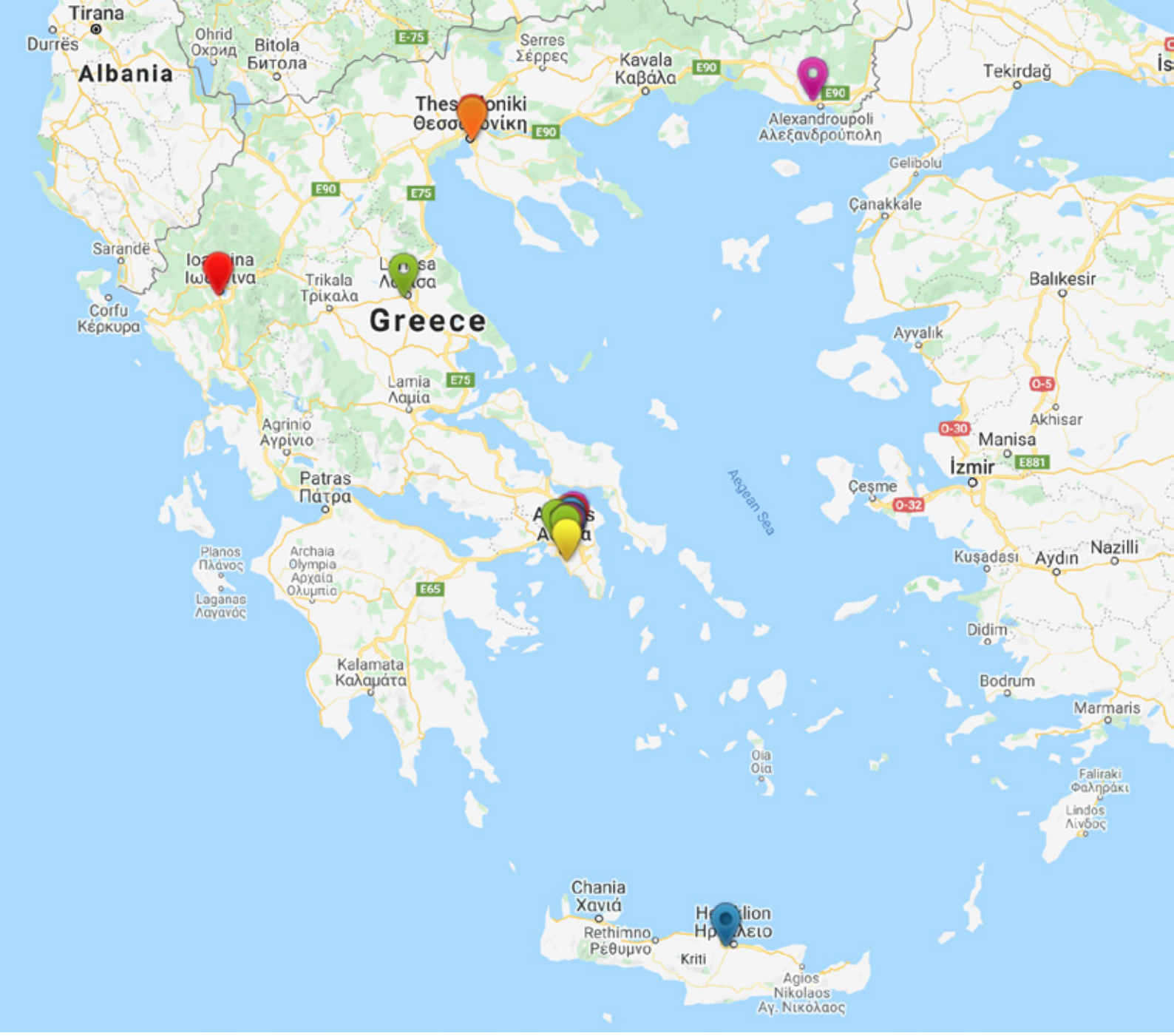
> "… I think it is necessary to step up the separation and entrenchment of the specialties. One measure in this direction would be to finally establish a Vascular Registry to get to know who is doing what, how it is done and what is the outcome."
>
> ***Sechas MN**. The Evolution of Vascular Surgery in Greece. Hellenic Vascular Surgery, Issue 21, 2010 (105-108).*

So far in HEVAR, more than...

15
Hospitals participating

50
Physicians registered

1,160
Patients included



A. Vascular Surgery Departments / Units

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  - 251 Air Force Hospital – Vascular Surgery Department
  - G. Gennimatas, Athens General Hospital – Vascular Surgery Department
  - Korgialenio-Benakio Greek Red Cross, Athens General Hospital – Vascular Surgery Department
  - KAT Attika General Hospital – Vascular Surgery Department
  - Konstantopoulio General Hospital of N. Ionia – Vascular Surgery Department
  - Laiko University Hospital – 1st Surgery Department
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  - Attikon University Hospital – Vascular Surgery Department
- Evros
  - University Hospital of Evros – Vascular Surgery Department
- Heraklion
  - University Hospital of Heraklion – Department of Thoracic – Heart and Vascular Diseases
- Thessaloniki
  - AHEPA General Hospital of Thessaloniki – Vascular Surgery Department
  - Hippokration General Hospital of Thessaloniki – 5th Surgery Department
- Ioannina
  - University Hospital of Ioannina – Surgery Department
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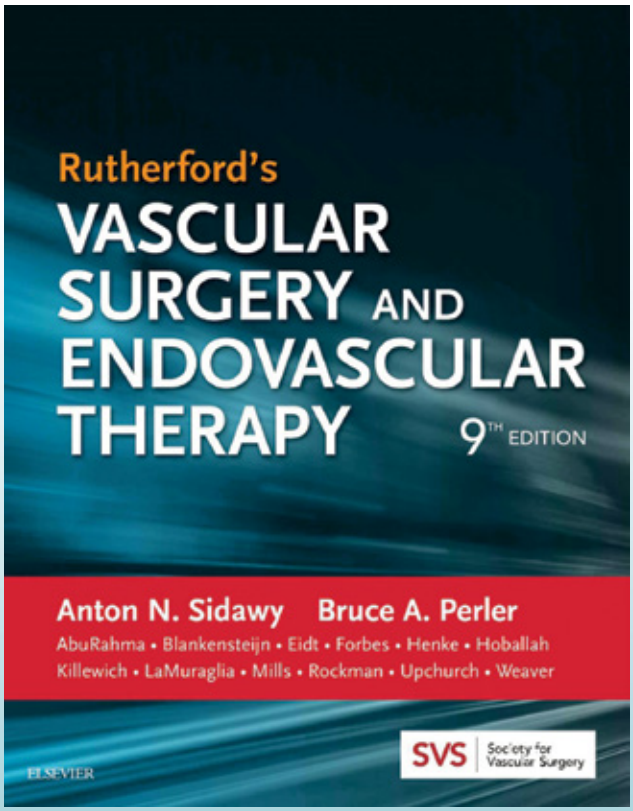

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