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Hellenic Journal of Vascular and Endovascular Surgery

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Outpatient treatment of truncal veins insufficiency

Athens, Greece

Perioperative Management of Antiplatelet and Anticoagulation Therapy in Vascular Surgery

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Covered Endovascular Reconstruction of Internal Iliac Bifurcation (CERIIB)

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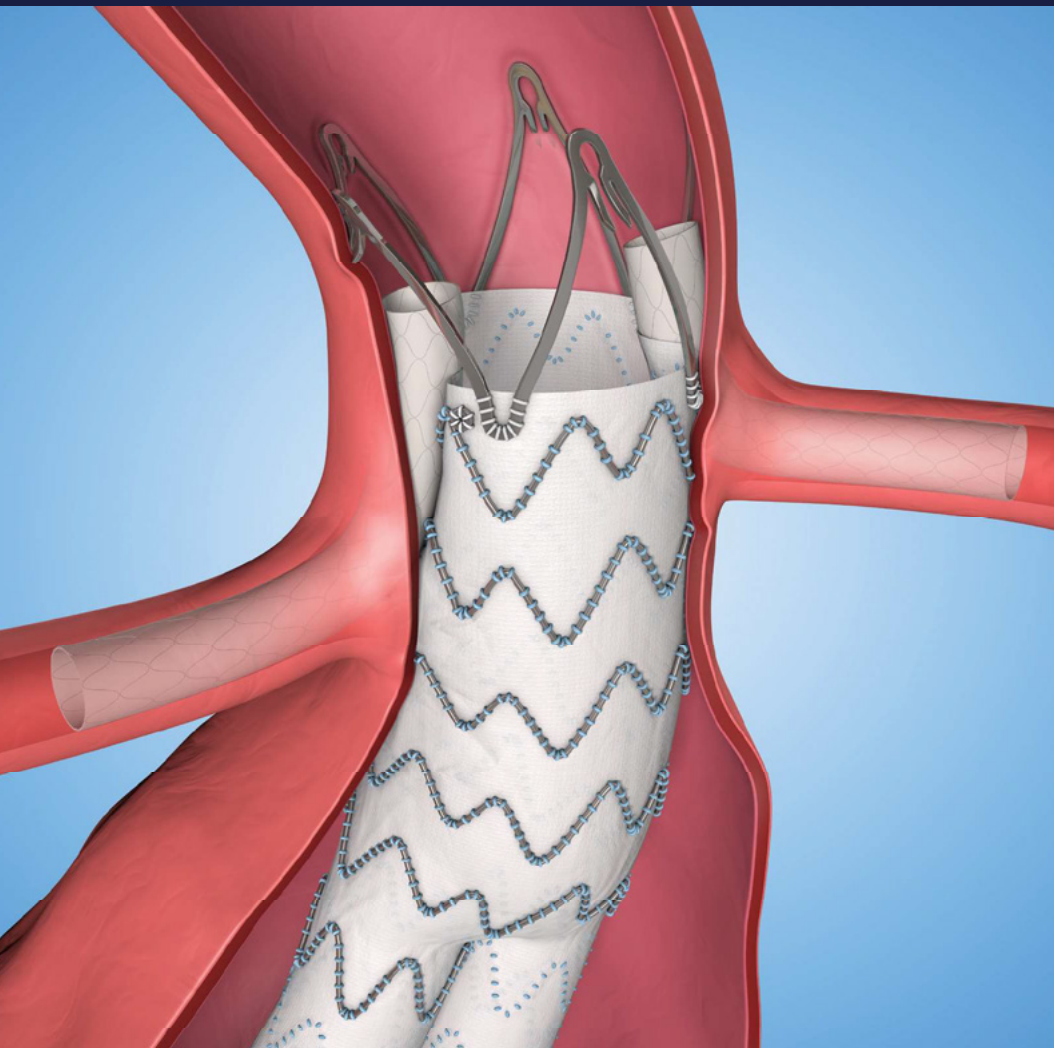
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EDITORIAL

The ESVS 2023 guidelines on the management of atherosclerotic carotid and vertebral artery disease. What is new and what remains to be answered

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The European Society for Vascular Surgery (ESVS) has recently published updated guidelines on the management of atherosclerotic carotid and vertebral artery disease,¹ revising the previously published 2017² and 2009³ guidelines. The rationale for writing the ESVS 2023 carotid guidelines is that several studies have been published since 2017, including 39 primary or secondary analyses from randomised controlled trials (RCTs), 71 systematic reviews and/or meta-analyses, and data from 50 vascular registries or quality initiative programmes.¹ Consequently, 133 recommendations were issued, of which 84 were unchanged, 11 were "regraded" since 2017 and 38 are new. Five new sections were added, including the management of free floating thrombus (FFT), the management of carotid webs (CaW), the management of symptomatic patients with an ipsilateral 50-99% carotid stenosis and atrial fibrillation, the planning of carotid interventions in anticoagulated patients, and the timing of carotid interventions in patients with acute ischaemic stroke undergoing thrombolysis.

For patients presenting with recent carotid territory symptoms and evidence of FFT within the carotid artery, therapeutic anticoagulation is recommended (Class I, Level C). For patients who develop recurrent symptoms whilst receiving anticoagulation therapy, surgical or endovascular removal of the thrombus may be considered (IIb, C). Intravenous thrombolysis is not recommended (III, C), since it is associated with a 15-fold increased risk of silent ischaemia, TIA, or stroke/death.⁴ In any case, factors that should be taken into account in the decision making include the presumed aetiology, the recurrence of symptoms during anticoagulation, the interval since TIA/stroke onset, the size of infarct and the accessibility of the FFT.¹

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A CaW is a ridge like filling defect, possibly a variant of fibromuscular dysplasia, that may act as a pocket for thrombus accumulation and cerebral embolisation.¹ According to the ESVS 2023 carotid guidelines, for symptomatic patients with a carotid web in whom no other cause for stroke can be identified after detailed neurovascular work up, carotid endarterectomy (CEA) or carotid artery stenting (CAS) may be considered to prevent recurrent stroke (IIb, C).

For patients with a transient ischaemic attack or minor ischaemic stroke in the presence of atrial fibrillation and an ipsilateral 50-99% carotid stenosis, multidisciplinary team review is recommended to determine whether urgent carotid revascularisation or anticoagulation alone is indicated (I, C). For patients who report recurrent event(s) in the territory ipsilateral to a 50-99% carotid stenosis whilst on therapeutic levels of anticoagulation, CEA or CAS is recommended (I, C). Factors that should be taken into account in the decision making include the presence of infarctions in other vascular territories, the evidence of emboli on transcranial doppler and the presence of left atrial appendage thrombus.

The optimal timing of carotid interventions after thrombolytic therapy (TT) remains controversial. A recent systematic review and meta-analysis has shown an inverse relationship between timing to CEA and peri-procedural stroke/death: peri-operative stroke/death rate was 13% when CEA was performed three days after TT completion and 10.6% after four days.⁵ The risk was predicted to reduce to below the 6% threshold after six days. Consequently, the ESVS 2023 carotid guidelines recommend that, for patients with acute ischaemic stroke due to a symptomatic 50-99% carotid stenosis who have received intravenous thrombolysis, delaying CEA or CAS by six days following completion of thrombolysis should be considered (IIa, B).

Another interesting, new recommendation is that, for patients undergoing CEA, intra-operative completion imaging with angiography, duplex ultrasound or angioscopy should be considered in order to reduce the risk of peri-operative stroke (IIa, B). The recommendation is based on a meta-analysis of 34 observational studies, which showed that perioperative stroke is reduced by 17% when completion angiography is performed, whereas completion angioscopy is associated with a 52% reduction.⁶

Although these guidelines cover some gaps in our everyday practice, several questions remain to be answered. One of these questions is whether the 3% (asymptomatic) and 6% (symptomatic) 30-day risk thresholds for performing CEA or CAS should be reduced, since many vascular surgeons would claim that we can do better than that. A meta-analysis, however, of four large RCTs comparing CEA with CAS in patients with asymptomatic carotid stenosis (n=6,659) showed that the 30-day death/stroke rate was 2.2% (CEA) vs. 3.1% (CAS). In a meta-analysis of 10 RCTs comparing CEA with CAS in patients with symptomatic carotid stenosis (n=5,797), the respective rates were 5.1% and 9.3%. Therefore, it seems that the 3% and 6% thresholds should not be reduced at present.

Another debatable issue is whether the time threshold for a patient being defined as recently symptomatic (currently six months) should be reduced. Since 2004, when an analysis of pooled data from ECST and NASCET was published, it is known that the highest-risk period for stroke recurrence is the first 2 weeks and that the benefit of carotid endarterectomy is maximal in the first 2 weeks, whereas, after 3 months there is no statistically significant benefit.⁷ Consequently, the 6-month threshold, apart from arbitrary, is probably obsolete and should be reduced to 3 months.⁸

Are 80-99% asymptomatic carotid stenoses (ACS) associated with higher rates of late ipsilateral stroke compared with 60-79% stenoses? A linear association between stroke risk and the degree of carotid stenosis was found in the ACSRS study⁹ as well as in a meta-analysis of 12 cohort studies.¹⁰ Nevertheless, this association was not reproduced in a meta-analysis of the medical treatment group of three RCTs.¹⁰

Does severe ACS cause cognitive impairment and can carotid interventions either reverse or prevent cognitive decline? It seems that whether ACS causes cognitive impairment depends on whether it causes impairment of the cerebrovascular reserve (CVR), since it has been shown that an abnormal breath holding index, which is a measure of CVR, is a statistically significant predictor of a decrease in the Mini-Mental State Examination score. Whether this cognitive decline can be reversed or prevented by carotid interventions remains questionable, with mixed results in the literature. Patients with ACS and objective ipsilateral ischemia would be the best candidates for neurocognitive function improvement after carotid revascularization.

What is the effectiveness of low dose rivaroxaban plus aspirin (vs. aspirin alone) in ACS patients? The COPMASS trial enrolled 7,470 patients, 1,919 of whom had carotid disease.¹¹ In this particular group of patients, after a mean follow-up of 21 months, there was a non-statistically significant reduction in the endpoints of efficacy and a non-significant increase in major bleeding with low dose rivaroxaban plus aspirin vs. aspirin alone. The subgroup analysis was underpowered, so further trials are required and there is no guideline from any scientific society currently recommending low dose rivaroxaban plus aspirin in ACS patients.

Is carotid artery near occlusion as benign as previously thought in patients presenting with stroke/TIA? A pooled

analysis of ECST and NASCET concluded that CEA conferred no notable reduction in stroke at five and eight years in patients with symptomatic carotid near occlusion (CNO), largely because of low rates of ipsilateral stroke in patients who were treated medically.¹² A meta-analysis, however, of 32 observational studies including 703 patients with CNO showed that the 1-year stroke/death rate was 4% following CEA, 6% after CAS, and 19% with BMT.¹³ Similarly, a subsequent meta-analysis of 26 studies including 1,506 patients reported that the late risk of ipsilateral stroke, neurological/cardiac death, or MI was 4.26/100 patient years in CNO patients treated by CEA or CAS, and 13.3/100 patient years (95% CI 5.54 e 31.95) in patients treated medically. The guideline that CEA and CAS are not recommended in patients with CNO (III, B) was not changed, but the debate has grown.¹⁴

In conclusion, the ESVS 2023 guidelines on the management of atherosclerotic carotid and vertebral artery disease have addressed some questions but, due to the lack of available data, have left several others unanswered. These unanswered questions highlight the existing gaps in the literature and offer opportunities for future research. One of the problems faced by research on carotid stenosis is that, fortunately for the patients - unfortunately for the studies, the outcomes, such as strokes and deaths, are relatively rare, so large number of patients are required to draw firm conclusions. This problem calls for multicenter studies and research coordination among vascular centers dealing with carotid disease and, fortunately enough, there are several of those in Greece.

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Single stem visceral debranching for complex aortic disease

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What this paper adds

Treatment of complex aortic diseases including thoracoabdominal aortic aneurysms and aortic dissection is highly challenging. Hybrid repair may be useful in some situations wherein anatomy, the need of emergent repair or patient comorbidities preclude the use of total endovascular or direct open reconstruction. This paper details an original hybrid repair in which a single branch is used to reroute all visceral vessels.

Abstract:

Objective: Hybrid treatment of complex aortic disease has been described with various techniques of retrograde visceral bypass. The use of a single branch to revascularize all renal and visceral vessels may be less cumbersome than multiple synthetic branches and may seem to be efficient in terms of patency.

Methods: We retrospectively included 15 patients between 2013 and 2021. Indication was aortic dissection (AD) (type A, acute or chronic type B), thoracoabdominal aortic aneurysms (TAA), visceral occlusive disease. Surgery consisted in median laparotomy, visceral vessel debranching from native aorta or from an aortic graft. In case of AD, surgical fenestration was performed. Additional TEVAR completed the treatment when indicated, during the same procedure or later on.

Results: Mean age was 60 years. 9 (60%) patients were treated for AD, 3 (20%) for TAA, 3 (20%) for occlusive disease. A total of 65 target vessels were debranched through the single stem retrograde vascular graft (SSRVG) technique. Aortic surgical fenestrations were performed in 8 cases and TEVAR in 4 cases. In the postoperative course, 3 TAA patients died, 7 patients developed renal insufficiency (47%), 4 patients presented pneumonia (27%) and 3 colonic ischemia (20%). After a mean follow up of 21 months, all vessels (but 2 IMAs) were patent and no endoleak was noted.

Conclusion: SSRVG technique offers a feasible and safe solution in various complex aortic diseases. The use of a single graft makes the technique straightforward by reducing the volume of multiple branch assembly in the retroperitoneal space with satisfying patency rates. Further studies with larger patient sample size and longer follow up are needed to elucidate the efficacy and durability of the technique.

Keywords: Hybrid surgery, visceral vessel debranching, TEVAR, aortic dissection, thoracoabdominal aortic aneurysm

INTRODUCTION

Treatment of complex aortic disease such as thoracoabdominal aortic aneurysm (TAA) or aortic dissection (AD) is a challenge for both patients and surgeons and the best therapeutic option is still subject to controversies. Open repair remains a challenge and even with improvements like distal perfusion and spinal protection, only fit patients with limited comorbid-

ities can undergo such invasive procedure. More and more TAA and AD cases become amenable to a totally endovascular repair due to constant progress of devices and skills^{1,2}. Nonetheless, uncertainty of long-term results, limits in technical feasibility and availability of devices still restrict its wide applicability. As a result, there are situations wherein total open surgery is considered a great surgical "insult" and total endovascular repair is not an option. For those patients can hybrid repair, combining both open and endovascular techniques, offer an appealing alternative. Several reports have been published since the nineties underlining the role of debranching of the supra aortic trunks and a tubular stent-graft on the treatment of lesions of the aortic arch using^{3,4}. The same strategy may be used for the treatment of abdominal or thoracoabdominal lesions. Visceral vessels are bypassed first, paving the way for a synchronous or metachronous exclusion of the aortic lesion by a stent-graft^{5,6}. The stemming of visceral debranching from the infrarenal aorta avoids the need for proximal aortic

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clamping, thoracotomy, and limits the duration of and end-organ ischemia. However various techniques of debranching stemming either from the infrarenal aorta or the iliac arteries have been described, they did not reach the same level of popularity as that of arch debranching⁵. This lack of success may be due to several reasons for technical failure including a poor donor artery, the use of multiple grafts in an “octopus” configuration and suboptimal choice of the best tunnels for retrograde visceral grafts. With the disappearing of the skills in open abdominal vascular surgery among (young) vascular surgeons we have found useful to herein report our original technique of abdominal visceral debranching using a single stem retrograde visceral graft (SSRVG). Indications, principles, technical details and outcomes of patients are provided.

METHODS

Patients et indication

This is a single center retrospective study. Between 2013 and 2019, 168 patients who were treated for a visceral artery surgery were identified. Patients selection used the French common classification of medical procedure (CCAM) with a specific code, namely EDKA003: «remplacement d’une artère digestive par laparotomie». Decision to perform a hybrid visceral debranching rather than a total open or endovascular treatment resulted from a multidisciplinary consensus. All medical records were reviewed and patients treated with this particular single branch retrograde bypass technique were identified. A total of 15 patients were identified. Data were collected on an Excel spread-sheet on a password-protected computer, including demographics and clinical characteristics, type of the disease (TAA, AD, occlusive disease), emergency or elective cases, symptoms at presentation, preoperative workup, intraoperative data and postoperative course. Target vessel patency was evaluated on most recent postoperative CT scan. Given the nature of the study, a waiver was given by the Sorbonne University review board regarding informed consent of patients.

APPROACH

Patients are operated on under general anesthesia in a supine position with mild lordosis. A transperitoneal median laparotomy is performed in all cases. The retroperitoneum is firstly entered lateral to the duodenojejunal junction after section of the lesser mesenteric vein. The left renal vein (LRV) is mobilized using a large rubber tape, permitting exposure of the abdominal aorta proximal and distal from the renal ostia up to the iliac arteries. The right and left renal arteries (LRA and RRA) and inferior mesenteric artery (IMA) are then dissected distal to any ostial lesion and taped. The superior mesenteric artery (SMA) is exposed through a left lateral approach from its ostium to distal to any ostial lesion. Exposure of the SMA can be demanding while expose of its ostial segment deals with the felting of mesenteric plexus. Approach of the intramesenteric segment necessitates the section of the Treitz ligament. To get a full mobilization of the SMA one or both pancreaticoduodenal branches must be ligated. The

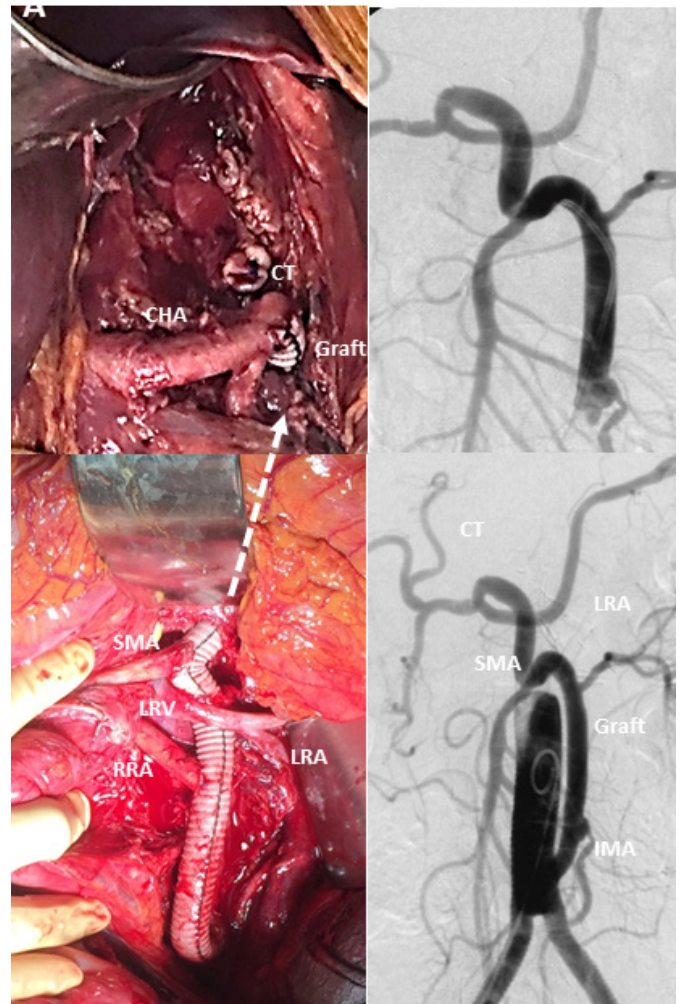


Figure 1: Intraoperative picture illustrating the single branch montage. On the left panel (A), the Dacron graft starts from the main graft (MG), receives the RRA via a small Hybrid Maquet Fusion 7mm diameter graft (so-called « cactus »), is routed behind the LRV and receives on its left the LRA and on its right the SMA. The graft is tunneled retropancreatic (white dotted arrow) up to the CT (middle panel) where an end-to-end anastomosis was performed (CT is ligated, CHA: common hepatic artery). The right panel (B) shows a post-operative arteriography of another patient. Image in the lower right corner is the overall aspect and image in the upper right corner is a magnification of RVG.

celiac trunk (CT) is approached through a section of the lesser omentum. After the taping of the common hepatic and splenic arteries, the coronary gastric artery is ligated and the trunk is dissected from the celiac plexus, through the arcuate ligament and if necessary, the right crux of the diaphragm. A retropancreatic tunnel is quite easy to create at this step from the left lateral side of the suprarenal aorta to the left lateral side of the celiac trunk by severing the left crux of the diaphragm. In cases of increased fragility of aortic wall (i.g. aortic dissection) a too proximal approach of visceral arteries must be avoided.

Choice of the donor artery

Many failures of retrograde debranching derive from a bad

choice for the donor artery like a diseased iliac artery. Our, therefore, best choice is an aorto-aortic, aorto-(bi)iliac or aorto-(bi)femoral prosthetic graft. In AD cases, such a choice offers the opportunity of creating an aortic fenestration.

Preparation of the graft

A custom graft is created by assembling a main graft (MG) with a retrograde visceral graft (RVG). The choice for the MG can be any polyester or PTFE graft but for bifurcations, we prefer asymmetric bifurcations in the aorto(bi) iliac setting (Albograft 18x10mm, 16x9mm or 14x8 Lemaitre Burlington Massachusetts USA). For the RVG, some resistance to kinking is needed, therefore a polyester-coated PTFE graft (Fusion 10mm or 8mm, Maquet Getinge Merrimack, USA) is chosen. An elliptic hole is created on the left lateral side of the body of the MG using a cautery. The hole is positioned two centimeters above the aortic bifurcation or the bifurcation of the graft in order to maximize the length of the MG proximal to the anastomosis with the RVG and subsequently securing an adequate distal landing zone for the thoracic stentgraft. A beveled retrograde anastomosis is then made using a running polypropylene 5/0 suture end of the RVG to side of the MG.

Proximal anastomosis of the main graft

Systemic heparin (100 UI/Kg) is given prior to clamping. Sites of clamping and of anastomosis are carefully planned on pre-operative imaging and by intraoperative palpation. Attempts at clamping or suturing diseased, thrombosed or calcified aortic segments must be avoided. Typically, the clamp is applied one centimeter caudal to the most distally arising renal artery. Although our technique is compatible with a side to end anastomosis, we prefer an end to end anastomosis. The infrarenal aorta is then sectioned transversally one to two centimeters distal to the clamp. The proximal aortic section is then anastomosed to the MG end to end using a running 4/0 or 3/0 polypropylene suture. If the MG is bifurcated, it is important to position its bifurcation approximately at the same level as that of the native aortic bifurcation. Doing so leaves a long possible prosthetic landing zone proximal to the arising of the RVG.

Proximal anastomosis whenever dealing with an aortic dissection

When dealing with AD, even if all visceral arteries are repaired using the RVG, there is a major concern regarding the flow to upper lumbar or intercostal arteries, which can be impaired with an eventual spinal injury. In these cases, open fenestration is a solution to preserve perfusion to both lumens. It is then important to leave two to three centimeters between the level of clamping and the proximal anastomosis. Dissected tissues are particularly fragile. Therefore, clamping must be gentle and progressive, under moderate hypotension and using clamps with rubber-protected jaws. After clamping, the proximal section of the aorta is exposed using "stay sutures", allowing for a neat resection of the flap flush to the aortic wall and to the clamp. It is in those cases when it may be useful to

clamp the suprarenal aorta in order to ease the resection of the flap. The proximal anastomosis is then sutured, preferably using a running polypropylene Teflon-felt-reinforced running suture.

Distal anastomosis to the aortic bifurcation or distal anastomoses to iliac or femoral arteries is/are then made to allow flow to the lower limbs and pelvis and provide optimal tension of the MG.

Visceral debranching and repair

Visceral debranching and repair is then performed in a sequential caudal to cephalad order: IMA if considered necessary, most distal renal artery, most proximal renal artery, SMA and CT. Except for the IMA, every visceral artery to be treated is ligated or clipped at its ostium and sectioned at its most healthy level. The distal stump is beveled if smaller than 4mm or to give a good direction and transposed side to end to a hole punched on the RVG using a running suture of 5/0 or 6/0 polypropylene. If the IMA is treated, it is transposed via a small Carrel button of adjacent aortic wall. The best anastomotic position for the IMA is on the left lateral aspect of RVG one centimeter above its anastomosis with the MG. The best position for the renal arteries is the ipsilateral aspect of the RVG behind the taped LRV. The RVG must therefore be tunneled behind the LRV. Anastomosis to the LRA is in general easier than to the RRA. For the RRA, especially if its level of arising from the aorta is close to the ostium of the SMA, it is practical to sever firstly the SMA to facilitate the access to the RRA. All anastomoses to the visceral arteries must be performed without tension. For this reason, it is important to free a sufficient length of the artery to allow for its coming to the RVG without tension. If this is not possible due to anatomical or pathological reasons, it is advisable to interpose a short segment of prosthetic graft of an adapted size between the target artery and the RVG. This is particularly important for the SMA, which is optimally transposed on the frontal aspect of the RVG, either caudal or well proximal of the crossing of the RVG by the LRV, in order to avoid the creation of a nutcracker syndrome. The RVG is then tunneled behind the pancreas and anastomosed end to end to the distal section of the CT. Flow to every target artery is then checked using a continuous sterile doppler probe. In fat or normally adipose patients After completion of the visceral debranching the RVG can be covered using the left mesocolon and the pre-aortic tissue, whereas a trans-mesocolic omentoplasty can often be necessary to secure the graft.

Postoperative course and follow up

All patients were admitted in ICU during the first postoperative days then cleared to the ward in the absence of a complication. Major neurological, respiratory, renal, cardiac and digestive adverse events occurring until discharge were collected. Patients had duplex and CTA before discharge. After discharge, patients were followed up at 1 month, 6 months and yearly thereafter, clinically, with duplex or CTA.

Table 1: Demographic and comorbidities

Patients (N=19)	N (%) or mean±SD
Age	55±34y
Male	11(68%)
Women	5(32%)
BMI	24.7±5.1
Comorbidities	
Diabetes	1 (6%)
Hypercholesterolemia	6 (37%)
Smoking	3 (18%)
Renal insufficiency	1 (6%)
Hypertension	11 (69%)
Coronary artery disease (n, %)	6 (37%)
Peripheral artery disease (n, %)	4 (25%)
ASA, median	2 (1-3)

RESULTS

Intraoperative

From January 2015 to December 2019, fifteen patients were treated using this technique.

Mean age was 60 years old [38-78]. Other demographics and cardiovascular risk factors are given in Table I. Table II details indications and outcomes. The indication was an AD in 9 (60%) cases, a TAA in 3 (20%) cases, and mesenteric occlusive disease in 3 cases (20%). Nine patients had prior vascular interventions, two of whom including abdominal aorta replacement, providing a suitable MG at the time of debranching.

A total of 65 target arteries were debranched and repaired through a single-stemmed-RVG: 5 target arteries were treated in 8 (53%) cases, 4 in 4 (27%) cases and 3 in three (20%) cases. Aortic fenestration was performed in 8 (53%) cases. Four (27%) procedures included the insertion of a tubular aortic stent-graft, two in a single-stage operation and two in a second procedure. Mean operative time was 354±72 minutes.

Out of the four patients who received TEVAR, 3 had spinal fluid drainage. One, who was operated on an emergency setting and was under 2 antiplatelet agents, had no drainage and experienced secondary paraplegia.

Treated pathologies

Type A aortic dissection: patients #1 and 2

These two patients had both open repair of their AD (Bentall procedure). The first patient developed a type 1 dissecting TAA during follow up. The second patient presented later on with a 45mm left common iliac artery dissecting aneurysm and all of the visceral arteries were dissected. His descending thoracic aorta was 42mm in diameter.

Chronic type B aortic dissection: patients #3-6

These patients were previously treated medically (#5),

with TEVAR (#4) or open surgery (#3,6). Later on, they developed various degree of visceral/ renal malperfusion along with enlargement of their descending thoracic aorta or abdominal aorta requiring aneurysm exclusion and visceral/ renal vessels revascularization.

Acute type B aortic dissection: patients #7-9

Indication was persistent hypertension, visceral/ renal malperfusion and/ or rapid enlargement of their aorta.

Thoraco-abdominal aortic aneurysm: patients #10-12

These patients had TAA and were deemed unfit for total open repair, not amenable for total endovascular repair for anatomic reasons, or were treated in emergency.

Occlusive disease: patients #13-15

Patients in this group presented with chronic mesenteric ischemia and aorto-iliac occlusive disease and retrograde bypass was favored over antegrade reconstruction.

Postoperative course

There were three (20%) postoperative deaths recorded. Two patients succumbed on the 2nd and 45th day due to multi-organ failure (MOF) whereas the third patient deceased on 51st postoperative day after discharge to a rehabilitation center due to aspiration associated pneumonia and respiratory failure. No death was related to RVG occlusion. Among survivors, acute renal insufficiency was the most frequent complication; 7 (47%) patients, two of which requiring temporary dialysis. There were four (27%) pneumonias and three (20%) cases of colonic ischemia, one requiring colectomy. One septicemia was treated with antibiotics. Overall two patients did not experience any complication, 7 patients experienced 1, 2 experienced 2, 1 experienced 3 and 1 experienced 5 complications (Table II).

Table 2: Preoperative, intraoperative and postoperative (immediate and during follow up) details of the patients. Indication for visceral debranching (VD), previous surgery, intraoperative and postoperative details are given. ARF: Acute renal failure. ARDS: Acute respiratory distress syndrome.

80	Sex, age	Initial disease	Indication of VD	Previous surgery	Technique	Debranched arteries	Postoperative period	ICU stay	Hospital stay	FU (days) Status	Target vessel occlusion / endoleaks
1	M, 34	Type A AD	Type 2 TAA	Bentall surgery	VD, TEVAR 2 months later	IMA, LRA, RRA, SMA, CT	ARF, no dialysis	8	26	1273 well	IMA/ No
2	M, 63	Type A AD	45mm left CIA aneurysm, visceral artery dissection.	Bentall surgery	VD + Surgical fenestration,	AMI, LRA, RRA, SMA, CT	Pneumonia, ARF-no dialysis Ischemic colitis medically treated	12	42	858 well	No/ NA
3	F, 69	Chronic Type B AD	Juxta-renal AAA, visceral artery dissection.	Type 1 TAA 6 years before	VD + Surgical fenestration	IMA, LRA, RRA, SMA, CT	Pneumonia	2	6	400, well	No/ NA
4	M, 57	Chronic type B AD	Persistent visceral/ renal malperfusion following TEVAR, Right kidney infarction, 50mm AAA aneurysm	TEVAR	VD + Surgical fenestration	IMA, LRA, SMA, CT	ARF, no dialysis	11	19	1465, well	IMA/ NA
5	M, 75	Chronic type B AD	Mesenteric ischemia + lower limb claudication	-	VD + Surgical fenestration	IMA, LRA, RRA, SMA, CT	ARF, temporary dialysis	12	20	1943, well	No/ NA
6	M, 69	Chronic type B AD	Extension of dissection to visceral artery, 40mm diameter DTA	Aortic arch surgery 7 years before	VD + Surgical fenestration	IMA, LRA, RRA, SMA, CT	Septicemia	8	22	827, well	No/ NA
7	M, 67	Acute type B AD	Hypertension (4 drugs) Visceral/ renal malperfusion	-	VD + Surgical fenestration + Aortic arch surgery (Thoraflex) 24 months later	IMA, LRA, RRA, SMA, CT	Uneventful	1	8	1310, well	No/ NA
8	M, 38	Acute type B AD	Hypertension (3 drugs) Visceral/ renal malperfusion	-	VD + Surgical fenestration	IMA, LRA, RRA, SMA, CT	Pneumonia	7	20	292, well	No/ NA
9	M, 75	Acute type B AD	Dissection down to SFA, 67mm diameter type 1 TAA	-	VD + Surgical fenestration + Aortic arch surgery (Thoraflex) 1.5 months later + TEVAR 6 months later	LRA, RRA, SMA, CT	Ichemic colitis (left colon resection), ARF no dialysis	10	80	194, well	No/ No
10	F, 77	Type 1 TAA Surgery delayed due to coronary stenting	Emergency (chest pain, left pleural effusion)	-	VD TEVAR during same procedure	LRA, RRA, SMA, CT	Pneumonia, secondary (day 3) paraplegia, MOF	45	45	45 Death	NA/ NA
11	M, 69	Type 3 TAA	Severe comorbidities, Kidney cancer (left nephrectomy)	AAA open repair, 8 years before	VD from previous aortic graft	RRA, SMA, CT	ARDS, Ischemic colitis, MOF, Death before second stage	2	2	2 Death	NA/ NA
12	M, 78	Type 2 TAA	60mm Visceral patch aneurysm	Open repair of type 2 TAA 8 years before	VD from previous aortic graft, TEVAR 14 days later	LRA, RRA, SMA, CT	ARF, no dialysis	24	31	51, Death (food swallowed the wrong way)	No/ No
13	F, 65	Occlusive disease	Chronic mesenteric ischemia and lower limb claudication	Iliac and SFA stenting	VD	IMA, SMA, CT	Uneventful	1	7	145, well	No/ NA
14	M, 71	Occlusive disease	Chronic mesenteric ischemia and lower limb claudication	Kissing Iliac stenting CT stenting	Median laparotomy, aortobifemoral bypass, visceral debranching	LRA, SMA, CT	Pneumonia, Acute renal Insufficiency, ACS (stent), duodenal bleeding, confusion	26	47	85, well	No/ NA
15	F, 68	Occlusive disease	Chronic mesenteric ischemia and lower limb claudication	No	Median laparotomy, aortobifemoral bypass, visceral debranching	IMA, LRA, RRA, SMA, CT	ARF, no dialysis Ischemic colitis (medical ttt)	4	8	523 Well (visceral herniation)	No/ NA

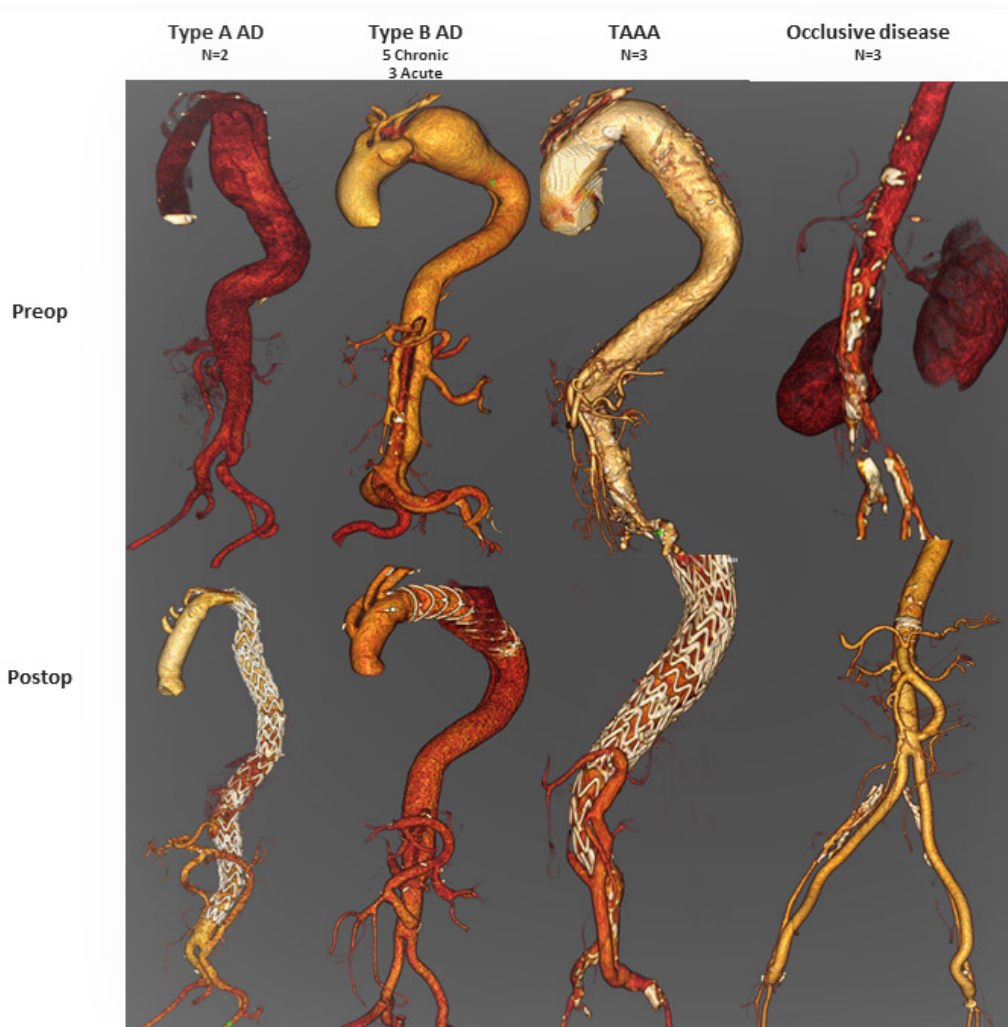


Figure 2: Representative preoperative and postoperative CT scan of the different categories of patients.

Follow-up

The mean ICU/ hospital stay was 11/ 25 days. Among the four patients with endograft, one had residual type 1B endoleak distal to his thoraflex arch hybrid prosthesis. This endoleak was sealed with TEVAR 6 months later. Over a mean follow-up of 21 months, no additional death was noted, all target vessels were patent except from two IMAs (97% of patency). One patient developed visceral herniation. The four patients received a stent-graft remained free from any endoleak. (Figure 2)

DISCUSSION

Technique

Single-stemmed RVG (SSRVG) is a safe and efficient method for abdominal debranching. All target vessels but two IMAs of our series remained patent to the last follow up. IMA is notoriously known to be provided with backflow from collaterals stemming from the SMA or the hypogastric arteries. We retrospectively believe that repair of the two occluded IMAs was probably redundant. To our knowledge, the use of a SSRVG to revascularize all four (LRA, RRA, SMA and CT) even five (IMA) visceral arteries is original. In the literature, visceral rerouting

techniques include customized Y-grafts, reversed bifurcated grafts, trifurcated grafts or even four-vessel visceral debranching graft as previously described by others^{5,7-11}. All these techniques inherit the disadvantages of the “octopus” technique: several retrograde small conduits with questionable hemodynamics, complex routing and a definite risk of visceral fistula formation. Our single-stemmed set-up has on the contrary the following advantages: There is only one healthy donor artery, only one proximal anastomosis between two prosthetic grafts and only one main conduit with a patency maintained by the united flow to all target vessels. The graft is short and large while optimizing its room in the abdomen and well-protected against a visceral fistula behind the LRV and the pancreas. We indeed had no visceral fistula in the series. Finally, after a learning curve, this technique is considered easier than the complex multiple-branches technique. All our major target vessels (IMA excluded) remained patent to the last follow-up, comparing favorably with patency rates ranging between 90-97% reported elsewhere^{12,13,8}. To our opinion, this is the result of the hemodynamic optimization brought by the single-stem concept: a high flow in a large conduit. This provides our solution with the lowest possible hemodynamic impedance and

is supported by a recent computational fluid model work¹⁴. In this work, Yuan and coll. showed that, from a hemodynamic standpoint, the use of CIA rather than aorta for the inflow site, leads to a dramatic decrease in flow to the visceral organs. Moreover, their hemodynamic model favored the use of less branches to perfuse visceral organs. In our single stem technique, should moreover one target-vessel occlude, this would not impact the patency of the others. Although all our cases have been performed through a transperitoneal approach, the technique is feasible through a retroperitoneal approach. However, such a retroperitoneal approach limits the access to the distal SMA and the distal RRA, even in the pre-renal plane. Moreover, access to the SMA and the RRA through a retroperitoneal route necessitates a thorough and extensive mobilization of the visceral segment of the aorta which should be avoided in this cohort of patients considered for debranching.

Our mortality and morbidity rates are high underlining the severity of the treated disease and the comorbidities of the patients selected for debranching. Of note, the three deaths occurred in the TAA group of patients, who were clearly the most fragile and in one case operated on an emergency setting. Mortality rates range between 10% to 15%^{12,13,5} in the literature, but is highly associated with patients comorbidity. However, we would like to underline the fact that none of our complications was due to occlusion of a target-vessel or the presented technique in general.

Despite limitations due to a small number of patients and its retrospective nature, the present work describes a promising technique of abdominal debranching. Comparison of debranching or hybrid surgery between open repair and totally endovascular alternatives is clearly outside of our focus. The high proportion of AD in this series shows the usefulness of our technique in this subgroup of complex aortic patients. Moreover, and as shown above, SSRVG and open aortic fenestration are highly compatible, offering an efficient solution in challenging cases.

Of course, our conclusions deserve confirmation among larger cohorts with a longer follow-up. They stress the importance of maintaining a high degree of open surgical competence among vascular surgeons, even in the endovascular era.

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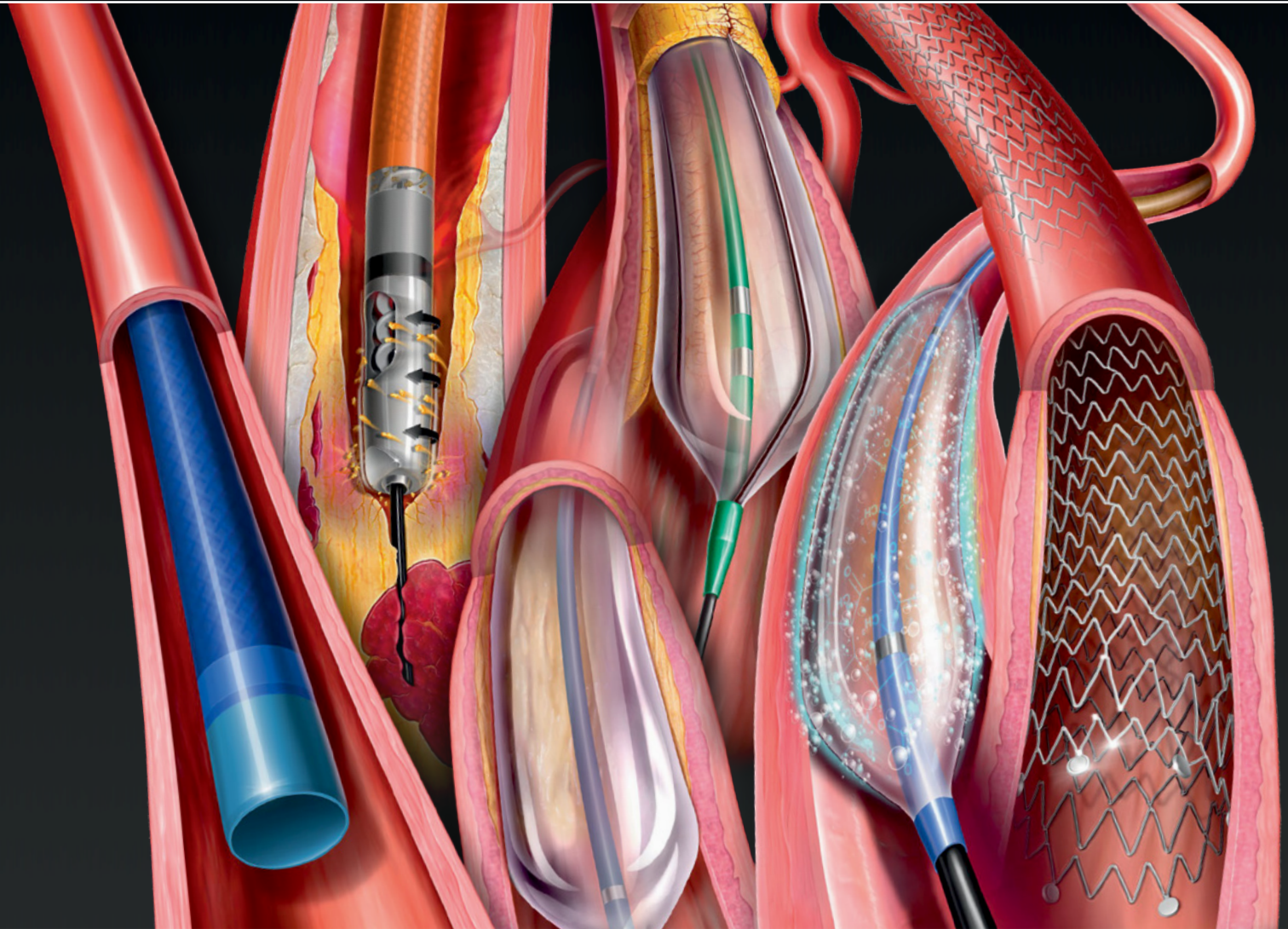


¹ Torsello et al. Safety and effectiveness of the INCRAFT[®] AAA Stent Graft for endovascular repair of Abdominal aortic aneurysms. JOURNAL OF VASCULAR SURGERY; January 2015, Volume 61, Number 1. Pages 1-8.

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Outpatient treatment of truncal veins insufficiency

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Abstract:

Introduction: Chronic venous disease is a common clinical problem with an increasing incidence that constitutes a financial burden for healthcare. Minimal invasive techniques and procedures in an outpatient basis may help decompressing the healthcare system. The aim of this study is to evaluate the effectiveness and safety of endovenous closure of the truncal veins with n butyl- cyanoacrylate adhesive on an outpatient basis.

Methods: We treated 100 cases of venous insufficiency with endovenous NBCA glue closure of the truncal veins on an outpatient basis. Patients were usually admitted to the vascular surgery department at the time of the procedure. The surgery took place in the general operation room, under local anesthesia. We didn't use compression stockings and patients were instructed to walk immediately after the operation.

Results: There was a 100% successful obliteration of the target vein in day 0, 2weeks, 3-months and one year. The majority of patients (98%) reported improvement of the symptoms, whereas 60 patients (60%) had complete elimination of symptoms. The appearance of varicose veins improved in 96% of the cases. There were no major adverse effects observed during follow-up. A percentage of 28% presented erythema and tenderness along GSV and 15 of those patients were treated with anti-inflammatory drugs (Ibuprofen) and 5 with antibiotics (Amoxicillin-Clavulanic acid).

Conclusion: Outpatient treatment of venous insufficiency with endovenous glue closure is a safe and efficient method. It increases patient satisfaction, permits rapid return to normal activities and reduces the risk of hospital transmission of infectious diseases and hospitalization costs.

INTRODUCTION

Chronic venous disease (CVD) is one of the most common clinical problems, where chronic lower limb superficial venous disease affects approximately 35% of adults¹. It is responsible for substantial morbidity as 1% to 4% presents serious complications at more advanced stages with a healed or active venous ulcer^{2,3,4}. Limb heaviness, aching, soreness, fatigue, burning, oedema, and pigmentation are usual troublesome signs and symptoms of the disease^{5,6,7}.

The prevalence of CVD is very high and affects many millions of persons worldwide and incurs high costs for treatment. The incidence of CVD is almost 1 in 1000 persons per year, that meaning at least 150,000 new cases in the United States annually. In Western countries it consumes up to 2% of healthcare budgets⁸. The chronic character of CVD and its high prevalence affect the lifestyle of many people. As a result, CVD must be seen as an important health, economic and social problem.

Even more, CVD is a condition that tends to worsen with age, while western population is aging constantly and rapidly. As a result, the prevalence of CVD is projected to increase substantially, and the need to treat CVD patients will induce large increases in the healthcare resources and costs⁸.

The rationale of venous disease treatment is to decrease ambulatory venous hypertension. Traditional surgical techniques, with stripping, high ligation of the great saphenous vein (GSV), and avulsion of varices, involve significant discomfort and require anaesthesia and hospitalization. The newer minimally invasive vein surgery procedures even though require only local anaesthesia and are considered as one day procedures, they are still performed in most centers with a few hours' hospitalization⁹.

In this study, we report our experience of superficial vein insufficiency treatment in an outpatient basis. The aim of the current study was to evaluate the treatment of superficial vein insufficiency in a totally outpatient basis, as far as effectiveness (anatomical success and clinical outcomes) and safety is concerned.

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PATIENTS AND METHODS

Patients

The study was a purely retrospective review of the record. We present the results of 100 cases in 96 patients treated with endovenous embolization of truncal veins with NBCA, during the period between November 2019 and December 2021 in

an outpatient setting. The procedure was performed under local anesthesia, did not require overnight stay and all patients were discharged within one hour from the operation. We used the VenaSeal Closure System™ (Medtronic Plc, Dublin, Ireland) with slowly polymerizing, high viscosity cyanoacrylate glue. All patients signed a consent form before entering the study. Only patients who had completed their follow-up were selected. The study included 61 women (63.5%) and 35 men (36.4%) with a mean age of 53 years (range 27-87). All patients had symptomatic GSV or SSV insufficiency. Patients were evaluated preoperatively with clinical examination and were classified according to 2004 CEAP (Clinical, Etiological, Anatomical and Pathophysiological) classification and the revised Venous Clinical Severity Score (rVCSS)¹⁰. They were examined with a deep and superficial vein duplex ultrasound with the patient both in supine and upright positioning, which was conducted by an independent certified radiologist. All patients were also subjected to a second duplex ultrasound, performed by the lead author, using a General Electric LOGIQ V2 (General Electric Healthcare) prior to any decision making.

Study eligibility inclusion criteria were: age over 18 years, ability to give informed consent, CEAP C2-C6, symptomatic venous insufficiency with reflux > 0.5sec on color Duplex and symptoms including heaviness, fatigue, soreness, burning, pruritus, discomfort and edema.

We evaluated our results by means of effectiveness and safety. Effectiveness includes anatomical and clinical success. Anatomical success as indicated by GSV occlusion rate on ultrasound examinations, is defined as no segments of patency longer than 3 cm and clinical success is assessed by the quality of life (QoL) using the revised Venous Clinical Severity Score. Regarding safety, all complications during and after the operation and all adverse events were documented.

Postoperative evaluation was conducted at 2 weeks, 3 months and one year. Follow up included clinical examination and repetition of the rVCSS, as well as duplex ultrasound to ensure successful target vein closure and exclude the pres-

ence of deep vein thrombosis.

Methods and Procedural protocols

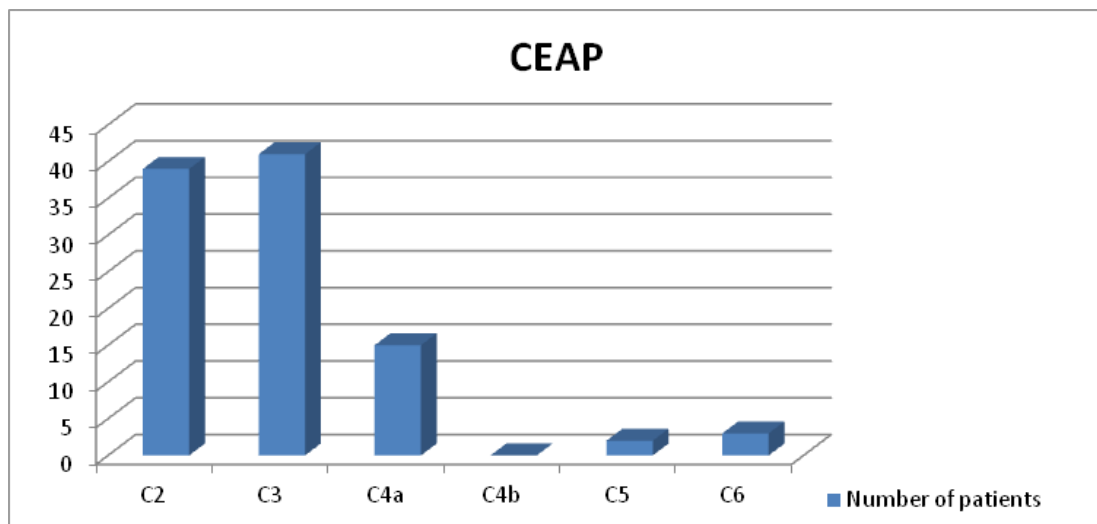
Patients were usually admitted to the vascular surgery department at the time of the procedure. The surgery took place in the general operation room, under local anesthesia. We used the Vena Seal Closure System™ (Medtronic Plc, Dublin, Ireland). The GSV is accessed at the distal point of reflux percutaneously with direct puncture or with a micropuncture introducer kit. When this approach is not feasible, a small incision (3mm) is made to facilitate open access to the vein. Usually this distal point is just above the medial malleolus, but it can be in every point along the saphenous vein path. The IFU of Vena Seal Closure System™ were followed for vein occlusion through glue delivery. When finished, the catheter is removed; compression is applied to the catheter entry site, as well as sutures in case of cut-down. Successful occlusion of the entire treated vein was confirmed by on-table duplex ultrasound.

Patients left the operating table walking. They were instructed to walk mildly and stay in the hospital for 45 minutes before being evaluated and then discharged. There was no post-operative use of bandages or compression stockings. They were encouraged to walk and were instructed to resume normal activities within a day. Postoperative ultrasound examination was performed immediately after surgery, at 15 days, three months and one year.

RESULTS

Patients' CEAP classification was between C2 and C6. More specifically, 39 patients had varicose veins C2 (39%), 41 patients were in stage C3 (41%) with venous edema, 15 patients in C4a (15%) presenting pigmentation or venous eczema, 2 patients in C5 (2%) with healed venous ulcer and 3 in C6 (3%) with active venous ulcer. (Table 1) The mean preoperative rVCSS was 6.8. Specifically, the VCSS for this cohort of patients is depicted analytically on table 2.

Table 1: Preoperative CEAP (Clinical- etiological- anatomical-pathophysiological) Classification). Number of patients at each class



All patients underwent local anesthesia. In 63 patients (63%) there was a percutaneous approach via direct puncture, (10 patients needed a double puncture and one needed three punctures). A short 3 mm cut-down to expose the target vein was performed in 37 patients (37%). The access point was near the medial malleolus in 57 cases (57%), below the knee in 19 cases (19%), at the thigh in 10 cases (10%), while in three cases (3%) the SSV was the target vein. Five cases (5%) presented double GSV. All patients underwent an on-table completion ultrasound to verify successful ablation closure of the treated venous segment and to inspect the common femoral vein for deep venous thrombosis via compressibility test. There was a 100% successful obliteration of the target vein in day 0, 2weeks, 3-month and one year follow up.

The vast majority of patients (98%) reported improvement of the symptoms, whereas 60 (60%) had complete elimination

of symptoms. The appearance of varicose veins improved in 96% of the cases. Thirty-three patients (33%) presented complete obliteration of varicose veins, while 63% showed significant improvement of the appearance of varicose veins. All patients with an active venous ulcer (3) presented improvement of the ulcer within 2 weeks of the procedure and total healing in 3 months. All patients improved their rVCSS. Postoperative rVCSS was 2.3 with a mean 66% decrease (mean preoperative rVCSS was 6.8). (Table 3)

There were no major adverse effects observed during follow-up (pulmonary embolism, skin necrosis, TIA, nerve injury, infection). A percentage of 28% (28 patients) presented erythema and tenderness along GSV which was observed between second and seventh post-operative day, lasting approximately one week and gradually getting better. Of those who presented erythema the majority had a superficially placed GSV, out of the saphenous compartment, with very limited distance from the skin. Fifteen of those patients (15%) were treated with anti-inflammatory drugs (Ibuprofen) and five (5%) with antibiotics (Amoxicillin-Clavulanic acid). In 3 cases (3%) there was postoperative skin hyperpigmentation and in one case (1%) there was a superficial stitch abscess.

Table 2: Preoperative rVCSS (revised Venous Clinical Severity Score) of the patients

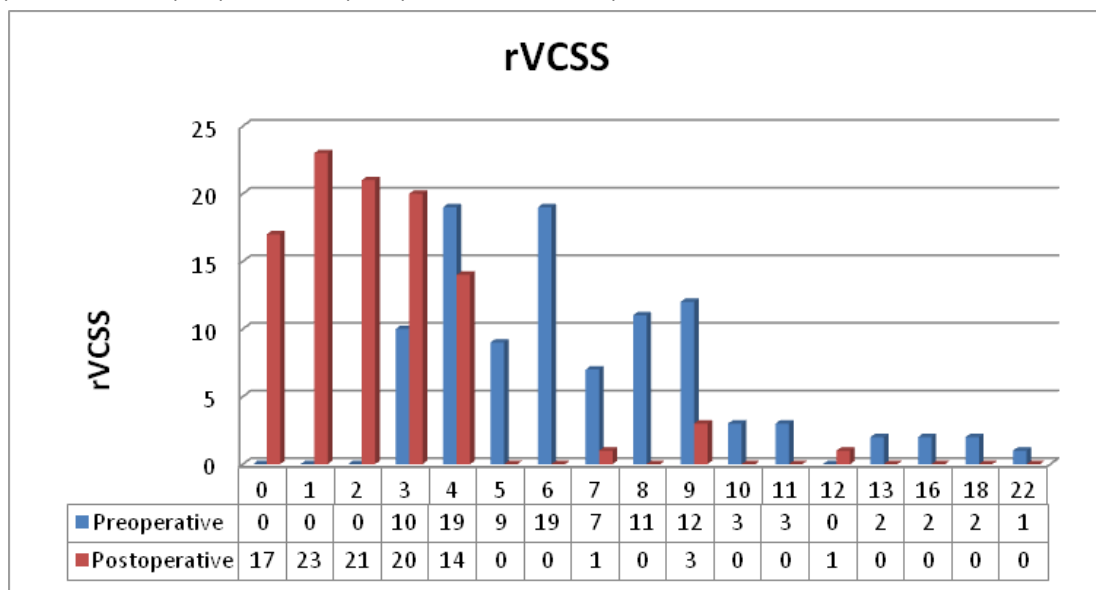
Preoperative VCSS	Number of patients
3	10
4	19
5	9
6	19
7	7
8	11
9	12
10	3
11	3
13	2
16	2
18	2
22	1

DISCUSSION

The treatment of CVD in the medical literature goes back since the time of Hippocrates^{11,12} and although since that time the treatment of CVD has evolved the standard open operation with high ligation and stripping of the GSV remained for many years the gold standard.

In modern medicine there is a trend towards less invasive and thus more comfortable for the patient and probably safer treatments, together with at least equal or even better results. Chronic venous disease is not an exception to that, so the concept of minimally invasive procedures becomes in our days the new gold standard in vein surgery.

Table 3: Comparison between preoperative and postoperative rVCSS of the patients treated



During the mid-20th century Robert Muller presented a technique using hook dissectors and multiple small skin incisions to treat superficial varices in an ambulatory way^{13,14}. He named his technique “ambulatory phlebectomy” and brought the first ambulatory treatment of superficial venous insufficiency into the modern world as we know today^{15,16}.

Although this was an improvement, the real changes occurred during the last two decades with the appearance of the endovenous techniques. Open surgery methods, such as ligation and stripping, are associated with more complications, including hematoma and paraesthesia, with long recovery times and are considered risky and disfiguring¹⁷.

The treatment for venous disease focuses on decreasing ambulatory venous hypertension. Various strategies and new technologies have been evolved to treat all forms of venous disease in a more minimal way.

As endovenous techniques were evolving the traditional surgical therapy has been replaced with minimally invasive methods. These techniques include thermal ablation by laser or radiofrequency and non-thermal ablation by foam sclerotherapy or mechano-chemical obliteration of the insufficient venous trunks. Because of the results of the newer techniques over the standard ones, endovenous techniques are nowadays recommended as first-line treatment for venous trunk reflux, both in the USA and the UK.

In 2013 the National Institute for Health and Care Excellence (NICE) guideline on diagnosis and management of varicose veins that were updated in March 2018, recommends thermal techniques as the first option for the treatment of insufficient veins, foam and liquid sclerotherapy as the second, and open surgery only if the previous methods are unsuitable^{18,19}.

The goal of ambulatory treatment of CVD is to treat patients without any need for hospitalization, not even for a few hours. The aim is to confine patient’s stay “in hospital” just as long as it is the duration of the procedure, in the same way as a visit to a dentist. In our study we reported patients that were treated on a totally outpatient basis.

We’ve chosen endovenous application of n-butyl cyanoacrylate glue for the closure of the incompetent GSV and small saphenous vein (SSV). All endovenous methods have their pros and cons but in regard with the ambulatory concept, we think that the use of cyanoacrylate glue closure offers more advantages compared to other endovenous modalities. A great advantage is that it does not require perivenous tumescent anaesthesia. The application of tumescent anaesthesia causes some pain and disturbance to the patient, as well as post-operative annoyance and bruising^{20,21}. Moreover, tumescent anaesthesia is time consuming adding anxiety to the patient. The need of tumescent anaesthesia is the reason why in many centers the thermal ablation treatment is used under mild sedation or even under general anaesthesia, so the patient can’t leave immediately after the end of the procedure.

The axial ablation can be combined with superficial phlebectomy in a single setting or in two stages. A debate still exists as to whether the two procedures should be performed simul-

taneously or in a staged fashion^{22,23}. In our study, per protocol, we didn’t treat the varicose veins during the initial procedure. but we let them shrink without reflux supply and treated them only if they were visible after three months. The rationale behind this decision was firstly to minimize the discomfort of our patients, as all procedures were done under local anaesthesia, and secondly to treat fewer varicose veins if needed, cause most of them could have been reduced in size and number, without the reflux-derived supply. This hypothesis proved to be true as the appearance of varicose veins improved in 96% of the cases. Thirty-three patients (33%) presented complete obliteration of varicose veins, while 63 patients (63%) showed significant improvement of the appearance of varicose veins. As a result, only 4 patients (4%) needed complementary treatment.

We evaluated our results regarding effectiveness and safety. At first, we evaluated anatomical success as indicated by GSV occlusion rate on ultrasound examinations, defined as no segments of patency longer than 3 cm. To evaluate treatments in modern medicine, we cannot only report technical success. This is particularly true when we evaluate treatments for chronic venous disease, where there is a strong socio-economic effect²⁴. Moreover, when we try to evaluate an outpatient method, socioeconomic, QoL, and clinical aspects must be assessed. In our study, to evaluate our results, apart from the technical success, we also reported the clinical outcomes, the relief of symptoms, the improvement of disease severity and the cosmetic results

In literature, researchers have used many assessment tools to evaluate the severity of venous disease and to provide standardized reports on effectiveness. Unfortunately, although many methods for venous outcomes assessments have been in use for many years, currently, there isn’t any universally accepted scoring system to compare the outcomes of venous treatments. On the contrary, there are many different outcome assessment tools available, targeting clinical outcomes or quality of life. In part, this reflects different emphasis within each scoring system. As a result, for accurate assessment of the various venous treatments, a combination of clinical scores with quality of life (QoL) outcome measurements system(s) is needed^{9,25,26}.

In an effort to standardize reporting in CVD research the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification system was proposed in 1995. The CEAP clinical classification for chronic venous disease (CVD) is based on physician-evaluated clinical signs of CVD and since its introduction it has been used in a number of clinical investigations to classify CVD clinical presentation and to measure change in CVD over time²⁷.

The CEAP classification system for chronic venous disease proved very useful to classify stages of venous disease and enabled patient comparison among different centres and studies. The problem with the CEAP is that it categorizes the severity of lower limb venous disease at a single point in time and it is relatively static and insufficient for determining changes in venous disease severity. Increasingly, patient-reported quali-

ty of life (QOL) is an important component in evaluating outcome, providing important information about the burden of illness and especially for changes in illness severity over time. For chronic conditions such as CVD, assessment of QOL can provide important information regarding burden of illness that may not be adequately captured with traditional physician-based measures of morbidity or mortality^{28,29,30}.

The VCSS was designed to assess changes in venous disease in response to treatment over time with some components subjectively determined by the patient and assessed by the provider. This system Venous Clinical Severity Score (VCSS) was proposed in 2000 from the American Venous Forum (AVF), Ad Hoc Committee on Venous Outcomes Assessment^{10,31,32}.

The VCSS system includes 10 clinical descriptors (pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, number of active ulcers, duration of active ulceration, size of ulcer, and compressive therapy use). Each one is scored from 0 to 3, so changes in response to therapy can be assessed. The VCSS has the advantage of minimal intraobserver and interobserver variability and has gained through time general acceptance and is used widely for clinical and research purposes^{10,33}. The VCSS that was introduced by Rutherford, has been used successfully in several studies to evaluate various vein treatments and a revised VCSS has been developed to clarify ambiguities, update terminology, and simplify application of the first version^{10,33}.

In our study, in order to evaluate our clinical results, we used both the CEAP and the VCSS. The CEAP classification system categorizes the severity of lower limb venous disease based on objective clinical findings, where the VCSS assess changes with some components determined subjectively from the patient's point of view. Of the many different venous severity assessment tools available, it has shown to correspond reliably with the severity of venous disease^{34,35,36}.

Our results showed great clinical improvement, cause all patients improved their rVCSS. The postoperative rVCSS was 2.3 with a mean 66% decrease (mean preoperative rVCSS was 6.8).

As far as technical success is concerned the method was effective cause all target veins were obliterated. Our results were comparable to most studies in the literature where the anatomical success of the method is very high. Comparing the cyanoacrylate closure to other endovenous treatment modalities such as laser ablation and RF ablation, no differences were observed in occlusion rates between the three modalities, although maybe a slight variation exists in favour of cyanoacrylate closure^{37,38,39,40,41,42,43,44}.

As far as safeness is concerned, the side effects were mild. Moreover, there wasn't any problem from the early discharge from the operating room. The most common side effect in our study was the well-known post-procedural phlebitis of the treated vein which in our series occurred in 28 patients (28%). This phlebitis, which is somehow or other benign and self-limited, occurs after the second postoperative day and usually lasts less than a week. In most cases when it happens it doesn't need any medication. In few cases (15%) anti-inflammatory drug (Ibuprofen) was prescribed.

flamatory drug (Ibuprofen) was prescribed.

The advantages of the procedure in an outpatient setting are too many: it heightens patient satisfaction and minimizes patient stress. Patients don't have to stay at the hospital overnight, that is a stressful experience for many individuals. People can continue to work at home and participate in their daily routine. Especially during COVID era, patients worry less about hospital transmission of COVID by being discharged immediately after the procedure and day-of-surgery discharge decreases the risk of hospital transmission, by shortened length of stay and reduced interaction with other patients and hospital personnel. Finally, it decreases hospitalization costs. When overnight hospital stay is avoided, there is less use of hospital facilities, bedding, food, and drugs.

CONCLUSION

Outpatient treatment of axial veins insufficiency of the lower extremities, using cyanoacrylate closure is a safe and efficient method. It offers many advantages because it heightens patient satisfaction and minimizes patient stress, permits rapid return to normal activities, reduces the risk of hospital transmission of infection diseases, and decreases hospitalization costs. The side effects are mild, and the early discharge doesn't seem to add any possible risk.

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Perioperative Management of Antiplatelet and Anticoagulation Therapy in Vascular Surgery

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Abstract:

Treatment of patients taking anticoagulant therapy (ACT) and antiplatelet therapy (APT) is a daily challenge for doctors of all specialities, and a special problem is the adequate care of these patients in the immediate perioperative period during vascular surgical procedures. This paper presents the current findings and recommendations on the perioperative use of ACT and APT and considerations of therapeutic modalities in frequent clinical cases of vascular patients. An overview of the most commonly used anticoagulant and antiplatelet drugs in clinical practice is also presented.

Vascular surgical patients represent a population of patients in whom platelet coagulation and aggregation mechanism are dysregulated in many cases. There is still no broad consensus and unequivocal evidence that can direct the physician towards the right modality of therapy. The final decision rests with the physician, who should, based on the individual assessment of each patient, determine the risk and thus determine the modality of anticoagulant and antiplatelet therapy.

Keywords: anticoagulant therapy, antiplatelet therapy, vascular surgery, perioperative period

1. INTRODUCTION

Treatment of patients taking anticoagulant therapy (ACT) and/or antiplatelet therapy (APT) is a daily challenge for doctors of all specialities, and the adequate care of these patients in the immediate perioperative period during vascular surgical procedures represents a unique problem¹. Discontinuation of therapy may increase the risk of thromboembolic events during and after surgery, while continuing therapy may increase the risk of bleeding during surgery and cause several other adverse events in the immediate postoperative period^{2,3}. Therefore, the question arises in which situations the therapy should be stopped, and when it is necessary to extend the use of anticoagulant and antiplatelet drugs in the immediate perioperative period.

In planning elective operative procedures, the surgeon must address whether AK therapy should be paused, continued or bridged with heparin or low-molecular-weight heparins (LMWHs). This decision is influenced by several factors, such as various patient characteristics (kidney function, indications

for ACT, age, history of bleeding or thromboembolic events), as well as surgical factors (risk of perioperative bleeding etc.)².

2. AETIOLOGY AND EPIDEMIOLOGY

Atrial fibrillation (AF), deep vein thrombosis (DVT) and pulmonary embolism (PE) are the main indications for prescribing ACT. AF is the most common long-term cardiac arrhythmia in adults⁴. In the US alone, between 3 and 5 million people suffer from AF, and estimates are that this number will increase to 8 million by 2050, while the number of patients with AF in Europe could be almost 18 million by 2060^{5,6}. The trend of increasing prevalence and incidence of AF will continue in the next 30 years, especially in countries with a medium sociodemographic index⁵.

APT is the basis of the treatment of patients with cardiovascular diseases. Patients undergoing percutaneous coronary intervention (PCI) are usually on dual antiplatelet therapy (DAPT), as well as patients with a previous history of stroke, aortocoronary bypass, essential thrombocytosis, etc¹. Acetylsalicylic acid (ASA) is one of the most commonly prescribed drugs in the world and the most commonly prescribed antiplatelet drug in the treatment of cardiovascular and cerebrovascular diseases⁷. More than 30% of people over the age of 50 in the USA have been reported to use ASA to prevent adverse cardiovascular events⁸. DAPT, on the other hand, involves combining ASA with a P2Y12 inhibitor (clopidogrel, prasugrel, ticagrelor)⁹. Based on estimates from 2015, between 1.4 and 2.2 million patients annually have an indication for DAPT after PCI or myocardial infarction (MI) worldwide. Based

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Table 1. Properties of the most commonly prescribed antiplatelet drugs

Drug	Class	Mechanism of action	Method of application	Elimination	Irreversible inhibition of platelet aggregation	Time required for recovery of platelet function
ASA	Salicylates	COX inhibition	oral	Liver	Yes	30% in 48h
Clopidogrel	Thienopyridines	P2Y12 receptor blockade	oral	Liver	Yes	40% in 72h
Prasugrel	Thienopyridines	P2Y12 receptor blockade	oral	Liver	Yes	48-72h
Cangrelor	ADP analogue	P2Y12 receptor blockade	I.V.	Plasm	No	60-90 minutes
Ticagrelor	CPTAP	P2Y12 receptor blockade	oral	Liver	No	50% in 24h
Dipyridamole	PDE inhibitor	PDE inhibition	oral	Liver, enterohepatic recirculation	No	48h
Cilostazol	PDE III inhibitor	PDE III inhibition	oral	Liver	No	48h

^a Modified according to Hall et al. ¹⁰ ADP - Adenosine diphosphate; ASA - Acetylsalicylic acid; COX - Cyclooxygenase; CPTAP - Cyclopentyltriazolopyrimidine; IV - Intravenous; PDE - Phosphodiesterase.

on more than 35 randomized clinical trials, which included more than 225 thousand patients, it was concluded that DAPT is among the most common treatment options in the field of cardiovascular medicine⁹. An overview of the most commonly used antiplatelet drugs is given in Table 1.

3. PHARMACOLOGY

3.1. Antiplatelet drugs

3.1.1. Acetylsalicylic acid

Small doses of orally administered acetylsalicylic acid irreversibly inhibit platelet cyclooxygenase (COX) 1 and 2 (significantly more inhibits the COX-1 isoenzyme), thereby preventing the enzymatic creation of thromboxane A₂, a strong activator of platelet aggregation and vasoconstriction^{7,11}. Although a daily dose of 30 mg is sufficient to completely inhibit COX-1 in platelets, a daily dose of 75-150 mg for long-term prevention and a daily dose of 150-325 mg for rapid and complete inhibition of platelet aggregation is recommended in cardiovascular patients¹².

3.1.2. Nonsteroidal anti-inflammatory drugs

Nonsteroidal anti-inflammatory drugs (NSAID), unlike ASA, reversibly inhibit COX-1 and COX-2 isoenzymes. Their effect on platelet function is short-term and normalizes within three days. However, this can vary between different drugs in the group. For short-acting drugs such as ibuprofen, diclofenac and indomethacin, 50% of platelet function is restored by 6 hours after the last dose and normalizes after 24 hours^{7,10,12}.

3.1.3. Thienopyridines (Clopidogrel and Prasugrel)

Drugs from this group achieve their antiplatelet effect by irreversibly inhibiting the P2Y12 receptor on platelets, thus preventing the binding of adenosine diphosphate (ADP) and platelet activation mediated by it^{7,10}. Clopidogrel is not used as the first-choice drug in monotherapy unless there is a proven hypersensitivity of the patient to ASA^{10,12}. However, new studies show the advantage of clopidogrel monotherapy compared with ASA in reducing mortality and morbidity in patients after PCI with drug-eluting stents (DES)¹³. According to numerous studies, prasugrel has been shown to be a superior drug

compared to clopidogrel in terms of inhibition of aggregation, but not in terms of the risk of bleeding, which is higher with this drug compared to clopidogrel^{10,14}. Due to the irreversible mechanism of action, it is recommended to discontinue these drugs 5 to 7 days before elective non-cardiac surgery^{1,15}.

3.1.4. Ticagrelor and cangrelor

This group consists of relatively new drugs with different mechanisms of action compared to the drugs known so far. Ticagrelor is an orally administered reversibly binding agent that selectively and potently blocks ADP-induced P2Y12 receptor signalling^{7,10}. Cangrelor is a drug that is administered intravenously, it is a strong and directly acting platelet ADP inhibitor, with a rapid onset of action. Due to the interaction of metabolites of thienopyridine antiplatelet drugs with cangrelor, caution is necessary when transferring patients to clopidogrel or prasugrel therapy; this should be done only after the cangrelor infusion has been stopped to ensure P2Y12 inhibition⁷.

3.1.5. Glycoprotein IIb/IIIa inhibitors

Drugs that directly block the glycoprotein (GP) IIb/IIIa receptor have been shown to be more effective in inhibiting in vivo platelet aggregation than ASA and clopidogrel and are associated with superior early clinical outcomes in patients with coronary artery disease and those undergoing PCI. Three drugs from this group, that have been approved by the Food and Drug Administration (FDA) are abciximab, tirofiban and eptifibatid⁷.

3.2. Anticoagulant drugs

3.2.1. Vitamin K antagonists (coumarins)

The most commonly used drug from this group is warfarin, which has been on the market for over 50 years¹⁶. Its mechanism of action is based on the inhibition of the enzyme responsible for the conversion of vitamin K from oxidized to the reduced form. Vitamin K, on the other hand, is a necessary cofactor in the carboxylation reaction that leads to the activation of coagulation factors II, VII, IX and X¹⁷. In practice, warfarin is a drug whose therapeutic dose is difficult to achieve, due to a large number of pharmacological interactions and genetic variations that can affect its metabolism. ¹⁷.

3.2.2. Direct-acting oral anticoagulants (DOACs)

The basic mechanism of action of these drugs, which include rivaroxaban, apixaban and edoxaban, is direct inhibition of factor Xa. In addition to them, this group of drugs also includes a direct thrombin inhibitor, dabigatran¹⁸. The advantages of prescribing DOACs are their short half-life and quick onset of action, which allows for the easier interruption and resumption of therapy after the operative procedure and does not require monitoring of the international normalized ratio (INR), which is an advantage compared to warfarin¹⁹. However, these drugs accumulate in patients with impaired renal function, there are no widely available tests to monitor their anticoagulant activity, and there are no widely available specific antidotes for neutralization in case of overdose and/or severe bleeding¹⁸. Only idarucizumab is currently available as an antidote to dabigatran. While for other DOACs, the antidote ciraparantag (aripazine) is in the final phase of testing. Adnexanet alfa is used as an antidote in the case of rivaroxaban and apixaban overdose, and the results of randomized studies for this drug are expected in the coming years.

3.2.3. Unfractionated heparin

By binding to antithrombin III (AT-III), the anticoagulant effect of heparin is realized. The complex formed by heparin and AT-III leads to irreversible inhibition of thrombin, as well as factor Xa²⁰. Anticoagulant response to heparin administration is monitored using activated partial thromboplastin time (aPTT). Major complications of unfractionated heparin therapy include bleeding (major bleeding, 0-7%; fatal bleeding, 0-3%) and heparin-induced thrombocytopenia (HIT, 1-5%)¹⁹.

3.2.4. Low Molecular Weight Heparins

LMWHs have higher bioavailability after subcutaneous injection, a renal clearance that is independent of dose, and a longer half-life (about 20h) compared to unfractionated heparin. Because of their predictable dose response, laboratory monitoring of anticoagulant activity is usually not necessary. Anti-Xa monitoring is an option in high-risk patient populations (renal insufficiency, obesity, pregnancy) where dose adjustments may be necessary¹⁹. LMWHs are the drugs most often used in bridging anticoagulant therapy¹⁹.

3.2.5. Fondaparinux

Fondaparinux (pentasaccharide) achieves its effect by indi-

rectly inhibiting factor Xa, binding to antithrombin, thereby potentiating its activity. The anticoagulant activity lasts up to 4 days after the last dose of the drug in a person with preserved kidney function¹⁹. A comparison of certain pharmacological properties of heparin and its derivatives is given in Table 2.

4. RISK ASSESSMENT

The approach recommended by several guidelines is based on four items intended to guide the physician through cases of elective surgery^{1,15,21,22}.

4.1. Thromboembolic risk assessment

The three factors with the greatest contribution to the risk for a thromboembolic event are atrial fibrillation, an artificial heart valve, and a previous thromboembolic event. The CHA₂DS₂VAS_c score is used to assess the risk of atrial fibrillation²³. Location, type of valve, number of prosthetic valves, and other cardiac risk factors are used in risk stratification of patients with prosthetic valves. As for thromboembolism, the time after the episode and the risk of recurrence will determine the degree of risk. Venous thromboembolism includes DVT and PE and can be classified as provoked (carries a higher risk of recurrence) when a causative event can be identified, or unprovoked when a cause cannot be identified²⁴. An example of induced VTE is a patient with persistent risk factors such as congestive heart failure, hereditary thrombophilia or paraneoplastic syndrome¹. The degree of risk is given in Table 3.

4.2. Bleeding risk assessment

When assessing the risk of bleeding, it is very important to consider the type of surgical procedure the patient is to undergo. Procedural bleeding risk can be divided into low risk (0-2% two-day bleeding risk) or high risk (2-4% two-day bleeding risk)¹. Vascular surgical procedures belong to the series of procedures in which the risk of acute coagulopathies and large blood loss is considerable, and in these cases, additional caution is necessary^{25,26}. In addition, other characteristics of the patient should be taken into account. The HAS-BLED score is used for risk assessment (Table 4)²⁷. Each positive item earns 1 point, and a HAS-BLED score >3 indicates a high risk of bleeding.

Table 2. Comparison of pharmacological properties of heparin and its derivatives

Property	UFH	LMWH	Fondaparinux
Source	Biological	Biological	Synthetic
Molecular Weight (Da)	15000	5000	1500
Coagulation factor	Xa:IIa	Xa>IIa	Xa
Bioavailability (%)	30	90	100
Half-life (h)	1	4	17
Renal excretion	No	Yes	Yes
Protamine reversal	Complete	Partial	No
HIT incidence (%)	<5%	<1%	Extremely rare

^a Modified according to Alquwaizani et al. ¹⁹. HIT - Heparin-induced thrombocytopenia; LMWH - low molecular weight heparins; UFH - Unfractionated heparin.

Table 3. Risk stratification for thromboembolic events

Risk	AF	Artificial heart valve	VTE
Low (annual risk of VTE <5%)	CHA ₂ DS ₂ VASc score 1-4	bicuspid artificial aortic valve without other risk factors for CVI	VTE >12 months ago without other risk factors
Moderate (annual risk of VTE 5-10%)	CHA ₂ DS ₂ VASc score 5-6 CVI or TIA >3 months ago	bicuspid aortic valve with one or more risk factors: >75 years, CHF, AF, previous CVI or TIA	VTE 3-12 months ago recurrent VTE active malignant disease thrombophilia ^b
High (annual VTE risk >10%)	CHA ₂ DS ₂ VASc score >7 CVI or TIA <3 months ago rheumatic valve disease	artificial mitral valve caged-ball or disc-type artificial aortic valve CVI or TIA <6 months ago	VTE <3 months ago severe thrombophilia ^c

^a Modified according to Douketis et al.²⁵. AF - Atrial fibrillation; CHF - Congestive heart failure; CVI - Cerebrovascular insult; TIA - Transient ischemic attack; VTE - Venous thromboembolism.

^b Heterozygotes for factor V Leiden, heterozygotes for prothrombin gene mutation;

^c Protein C and S deficiency, antithrombin deficiency, antiphospholipid syndrome, homozygotes for factor V Leiden, homozygotes for prothrombin gene mutation.

Table 4. HAS-BLED score system

Clinical feature	Criterion	Score
Hypertension	Systolic blood pressure >160mmHg	1
Abnormal liver or kidney function	Liver: chronic hepatitis, cirrhosis, bilirubin >2x UL with transaminases >3x UL Kidneys: dialysis, transplantation, creatinine > 200µmol/L	1 or 2
Cerebrovascular insult	Previous stroke, especially lacunar	1
Bleeding	Recent bleeding, anaemia	1
INR	Unstable/high INR or TTR <60%	1
Age	> 65 years	1
Use of drugs and alcohol	antiplatelet drugs or NSAIDs	1 or 2

INR - international normalized ratio; NSAIDs - non-steroidal anti-inflammatory drugs; TTR - therapeutic time in range; UL - upper limit.

4.3. When (not) to stop therapy?

The basic rule in the decision to stop or continue ACT or APT is the assessment of the benefit that the patient would have to depend on the decision. Patients at increased risk for bleeding would benefit from discontinuation of therapy, while patients at increased risk for thromboembolism would benefit from "bridging" therapy or the shortest possible period without ACT. Some of the scenarios often encountered in vascular surgery are given below.

4.3.1. Venous Thromboembolism (VTE)

In patients with a recent episode of VTE (<3 months, especially <1 month) the risk of recurrence can be up to 40% depending on risk factors. "Personalization" of risk factor assessment could optimize the benefit-risk ratio by reliably identifying patients at lower or higher risk of recurrent VTE and deciding whether to continue or discontinue ACT²⁸. Numerous scoring systems can be used for this purpose, but what the latest European Society of Cardiology (ESC) guide points out is that in light of the increasing use of DOAC, these scoring systems must be revised²⁹. Current recommendations for patients on warfarin therapy for VTE as the only indication for AK therapy are that bridging LMWH therapy is not necessary, and warfarin should be stopped at least 5 days before the procedure. This does not exclude the possibility of using prophylactic dos-

es of LMWH in the perioperative period. Perioperative bridging therapy is also recommended for patients with a high risk of VTE²⁵.

New guidelines dealing with the continuation of warfarin therapy after a surgical procedure recommend continuation of therapy within 24 hours of the procedure. It is also advised that resumption of therapy should be started at the dose the patient used before discontinuation, even in procedures with a high risk of bleeding, with the simultaneous use of LMWH until therapeutic INR values are achieved³⁰.

4.3.2. Coronary stenting

In the clinical practice of vascular surgeons, patients with previously implanted coronary stents are often encountered. It is estimated that between 15% and 20% of patients require non-cardiac surgery up to 2 years after coronary stent implantation³⁰. It is advised that in patients who have had a stent implanted less than 3 months before a vascular procedure, DAPT should be continued in case of a procedure with a low bleeding risk or P2Y12 inhibitor should be excluded, and ASA therapy should be continued in case of major surgery. If coronary stents have been placed between 3 and 12 months, it is possible to stop P2Y12 inhibitors and continue ASA therapy. Clear recommendations regarding the return of patients to DAPT have not been given, but it is considered that in the

case when patients are not excluded from therapy with ASA, it is possible to return to therapy with clopidogrel up to 24-72 hours post-procedural in the loading dose²⁵.

However, each case should be approached individually and a decision made following the patient's characteristics and illness.

A practical classification of vascular procedures concerning the risk of bleeding and thromboembolic events in patients after coronary stenting was given by Rossini et al.³⁰. It should be emphasized that the overall risk of thromboembolic events was assessed based on several parameters such as the type of stent, clinical and angiographic characteristics and time from PCI procedure to surgery.

Table 5. Vascular procedures concerning the risk of bleeding and suggestions for the use of antiplatelet and anticoagulant therapy in the perioperative period depending on the risk of a thromboembolic event.

Bleeding risk	Vascular procedure	Lek	Thrombosis risk		
			Low	Moderate	High
Low	Carotid endarterectomy Extremity bypass procedure Limb amputation EVAR TEVAR	ASA	Continue	Consider PTA or stenting Elective procedure: not contraindicated Urgent procedure: continue	Consider PTA or stenting Elective procedure: postpone the procedure for at least 30 days after the PCI Urgent procedure: continue
		P2Y12 inhibitor	Discontinue 5 days before the procedure for clopidogrel/ticagrelor, discontinue 7 days for prasugrel; continue 24-72h after surgery (loading dose)	Consider PTA or stenting Elective procedure: not contraindicated Urgent procedure: continue	Consider PTA or stenting Elective procedure: postpone the procedure for at least 30 days after the PCI Urgent procedure: continue
		DOACs		Stop at least 24-48h before the procedure Continue within 48-72h (consider bridging therapy)	
Moderate	Open surgery of the abdominal aorta	ASA	Continue	Elective procedure: postpone or consider EVAR Urgent procedure: continue	Elective procedure: postpone or consider EVAR Urgent procedure: continue
		P2Y12 inhibitor	Discontinue 5 days before the procedure for clopidogrel/ticagrelor, discontinue 7 days for prasugrel; continue 24-72h after surgery (loading dose)	Elective procedure: postpone or consider EVAR Urgent procedure: continue	Elective procedure: postpone or consider EVAR Urgent procedure: continue
		DOACs		Stop at least 24-96h before the procedure Continue within 48-72h (consider bridging therapy)	
High	Open surgery of the thoracic and thoracoabdominal aorta	ASA	Discontinue	Elective procedure: postpone or consider TEVAR Urgent procedure: continue	Elective procedure: postpone or consider TEVAR Urgent procedure: continue
		P2Y12 inhibitor	Discontinue 5 days before the procedure for clopidogrel/ticagrelor, discontinue 7 days for prasugrel; continue 24-72h after surgery (loading dose)	Elective procedure: postpone or consider TEVAR Urgent procedure: continue	Elective procedure: postpone or consider TEVAR Urgent procedure: continue
		DOACs		Stop at least 24-96h before the procedure Continue within 48-72h (consider bridging therapy)	

^a Modified according to Rossini et al.³⁰. ASA - acetylsalicylic acid; DOACs - direct-acting oral anticoagulants; EVAR - endovascular aortic aneurysm repair; PCI - percutaneous coronary intervention; PTA - percutaneous transluminal angioplasty; TEVAR - thoracic endovascular aortic aneurysm repair.

4.3.3. Atrial fibrillation

The presence of atrial fibrillation in patients with the peripheral arterial occlusive disease (POAB) is not uncommon. Some studies report that about 20% of patients with atrial fibrillation have a pedobrachial index <0.90³¹. Also, it is estimated that 5-10% of patients after a vascular procedure develop postoperative atrial fibrillation²³.

The recommendations are that in the perioperative period, patients suffering from atrial fibrillation should be treated in such a way that, based on an individual assessment, as well as different scoring systems (HAS-BLED, CHA₂DS₂-VASc), the use of different AK modalities or "bridging" therapy should be decided, in depending on the risk of a thromboembolic event or bleeding²³.

4.3.4 Triple therapy

It should be noted that around 10% of patients with recent PCI have AF and others could have VTE, so choosing the right antithrombotic regimen can be a challenge, especially in the setting of a potential vascular surgical procedure. Usually, the use of triple therapy (DAPT and anticoagulant) is not recommended for most patients due to an increased risk of bleeding. However, there are cases in which triple therapy is needed to achieve the best outcome for the patients, but currently, there are no clear guidelines for the management of triple therapy in the perioperative period. It is suggested that, for patients presenting with AF appropriate for an OAC who have a prior history of cerebrovascular disease and are currently receiving APT who have undergone recent carotid endarterectomy, stopping all APT and treating with an ACT alone (DOAC preferred) when considered safe from the risk of postoperative bleeding, typically 3 to 14 days after surgery³². It should be noted that in these circumstances continuing only ASA and bridging therapy could be the safest option, but more evidence is needed in this regard.

Table 5 provides an overview of vascular procedures concerning the risk of bleeding, with the suggestion of using antiplatelet and anticoagulant therapy in the perioperative period

depending on the risk of a thromboembolic event.

However, a clinical assessment of stopping or continuing ACT or APT is imperative, because there are no scores or calculators that would directly and unambiguously classify the patient into one of the categories.


5. BRIDGING THERAPY

The bridging ACT consists of replacing a long-acting anticoagulant (warfarin) in the perioperative period with a short-acting anticoagulant (LMVH) when the INR is below the therapeutic level, to limit the time of subtherapeutic levels of anticoagulation and reduce the risk of thromboembolism²⁵. Despite growing evidence of limited or even no benefit to bridging therapy, it is still used on a case-by-case basis. Also, few studies and guides are dealing with this type of therapy in vascular patients. In a study by Siegal et al.³³ it was shown that there is no statistically significant difference concerning the risk of a thromboembolic event in patients who were on "bridging" therapy and those who only stopped warfarin. On the other hand, the risk of bleeding was up to 3 times higher in the group of patients on bridging therapy. However, this meta-analysis has been criticized a lot because of the heterogeneity of the studies included in it. The latest guidelines also advise against bridging therapy. Douketis et al.²⁵ state that in cases where it is necessary to stop warfarin therapy in patients with mechanical valves, atrial fibrillation or when the use of warfarin is indicated only because of VTE, bridging therapy with LMWH is not necessary, however, the level of evidence for this recommendation is low, and the authors themselves point out that despite this new knowledge, uncertainty remains regarding best practice for most issues of perioperative use of ACT. It is emphasized that an analysis of each case is necessary and that patients with a high risk for a thromboembolic event (Table 3) should receive adequate bridging therapy. Douketis et al.²⁵ state that it is not necessary to introduce bridging therapy in patients using DOAC due to the known pharmacokinetic properties of the drugs (Table 6).

Table 6. The regime of DOAC usage in the perioperative period

DOAC	Bleeding risk	Preprocedural suspension of DOAC therapy (day)						Operation/Procedure (Day 0)	Postprocedural continuation of DOAC therapy (day)			
		-6	-5	-4	-3	-2	-1		+1	+2	+3	+4
Apixaban	High							Operation/Procedure (Day 0)				
	Low/moderate											
Dabigatran (CrCl ≥ 50ml/min)	High											
	Low/moderate											
Dabigatran (CrCl < 50ml/min)	High											
	Low/moderate											
Edoxaban	High											
	Low/moderate											
Rivaroxaban	High											
	Low/moderate											

^a Modified according to Douketis et al.²⁵. CrCl - creatinine clearance; DOAC - direct-acting oral anticoagulant.

^b  No DOAC that day

6. CONCLUSION

Vascular surgical patients represent a population of complex patients in whom platelet coagulation and aggregation mechanism are dysregulated in many cases. Although there are currently numerous studies and guides that directly or indirectly deal with the perioperative use of anticoagulant and antiplatelet therapy, there is no broad consensus and unequivocal evidence that can guide the physician towards the right modality of therapy, especially in complex vascular patients. The final decision rests with the doctor, who should, based on the individual assessment of each patient, determine the risk and thus determine the modality of anticoagulant and/or antiplatelet therapy.

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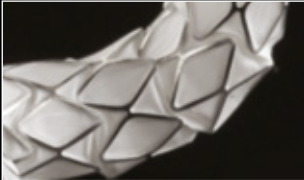


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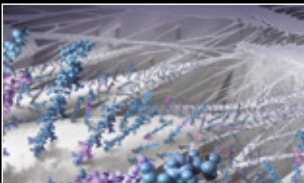
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Bilateral axillary aneurysm repair by open surgery: A case report

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Abstract:

Axillary aneurysms are rare pathologies and although most of them are the result of traumatic events, there is a percentage that is due to atherosclerotic disease or is the result of a degenerative process over time. Once the aneurysm develops, it can cause distal ischemic events and/or neurological symptoms related to embolism or compression. Therefore, the diagnosis and treatment of axillary aneurysms is crucial for the patient. Most of them can be treated effectively by surgical excision and vascular grafting. We present a case of a patient with bilateral axillary aneurysms diagnosed after embolic complications.

Keywords: axillary aneurysm, aneurysm repair, axillary masses, open surgery, axillo-humeral bypass

INTRODUCTION

Axillary artery aneurysms are rare pathologies that usually develop after upper extremity trauma. They may also occur iatrogenically or as a post-stenotic lesion due to thoracic outlet syndrome or due to the chronic use of crutches. Atherosclerosis as a cause of axillary aneurysms is very rare. They usually go unnoticed and asymptomatic, until they produce symptoms of arterial ischemia in the hand and/or neurological symptoms. Fortunately most of them can be treated effectively with surgical excision and vascular grafting.

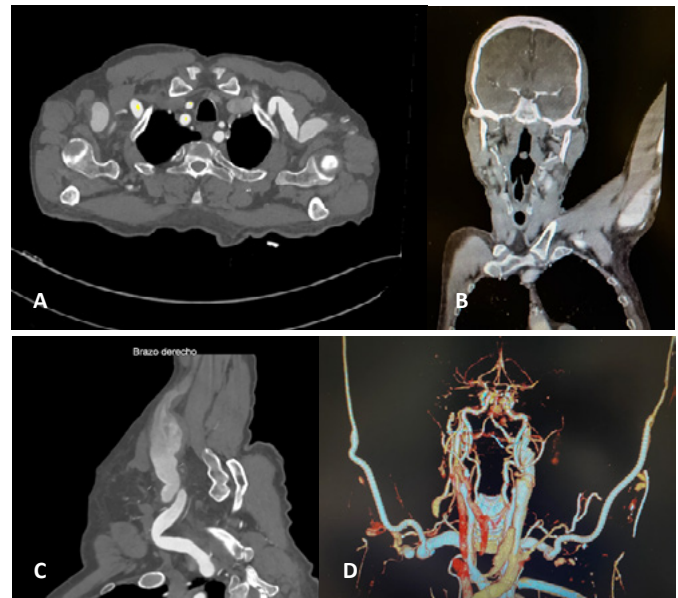
CASE REPORT

A 68-year-old man, anticoagulated due to atrial fibrillation, with a history of hypertension, diabetes, and smoking, presented for evaluation after several bilateral brachial artery embolectomies. A thorough clinical examination revealed bilateral pulsatile axillary masses. A CT angiography of the upper limbs followed, which confirmed the diagnosis of bilateral axillary artery aneurysms with great tortuosity and turbulent flow inside (3 cm in diameter on the right side and 2.5 cm on the left). Since they were symptomatic and in order to prevent future embolic events, surgical treatment was decided by open surgery.

The surgery was scheduled in two stages: first the right aneurysm was approached and then the left one, both by infra-clavicular incision, systemic heparinization and tunneling of a 6 mm in diameter PTFE graft below the minor pectoralis mus-

cle. A proximal end-to-end and distal end-to-side anastomosis was performed on both occasions, from the axillary to the brachial artery, excluding both aneurysms. Recovery of bilateral distal pulses was achieved.

The postoperative course was uneventful, with absence of palpable axillary masses, no signs of ischemia and recovery of distal pulse. A follow-up CT angiography after one year, showed that both bypasses were patent, aneurysmal sacs were thrombosed, and distal vessels were patent. No further embolic events occurred during follow-up.



A CT angiogram revealing bilateral axillary aneurysms

B Left axillary aneurysm

C Right axillary aneurysm

D CT scan one year after reconstruction

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DISCUSSION

Axillary artery aneurysms are very rare clinical entities, comprising 0.5% to 1% of all peripheral arterial aneurysms. Atrau-

matic axillary artery aneurysms secondary to atherosclerosis are rarely seen, and the patients are usually asymptomatic.

The risks of an untreated axillary aneurysm are both vascular and neurological. Vascular complications include aneurysm rupture and thromboembolism, since thrombus within the aneurysm sac is present in 91% of patients. Neurologically, the enlarging aneurysm may cause compression of the brachial plexus, leading to transient or permanent sensorimotor deficits.

In our case, the patient had presented with ischemic symptoms on several occasions, and had been treated surgically by embolectomy. The fact that the patient had an obvious cause of arterial embolism, namely atrial fibrillation, had prevented any further diagnostic investigation for other causes of acute ischemia.

In the literature, axillary artery aneurysms are mostly unilateral. Bilateral axillary artery aneurysms have only been reported in two Marfan syndrome patients. In this case, the physical and laboratory examinations did not reveal collagen tissue disease and the aneurysms were attributed to atherosclerotic disease.

Although literature indicates open surgical resection and repair as the standard treatment, endovascular stenting is being used with increasing frequency over the past few years. Although open repair allows complete resection of the aneurysmal lesion with alleviation of compression on surrounding structures, thus removing the risk of rupture and thromboembolism, the appropriate treatment depends on both patient and surgical factors. Surgical factors that have to be considered include the characteristics of the aneurysm (size, location, anatomical variation) and the availability of endovascular expertise.

Regarding the indication for intervention, most authors recommend operative intervention in symptomatic aneurysms or if the aneurysm measures more than 2 cm in diameter in asymptomatic individuals. For asymptomatic individuals, conservative management may be possible, but complications in up to 50% of patients have been reported, particularly thromboembolism, rupture, and compression on adjacent structures.

In our patient, we decided not to perform endovascular treatment, given the tortuosity of the aneurysms and the probability of endoleak after stent implantation due to the large sizes. Moreover, stent placement near a mobile joint carries the risk of stent deformation or breaking.

Aneurysmectomy and grafting with a saphenous vein is a contemporary treatment of choice for most patients with axillary artery aneurysms because of the favorable long-term patency, but the diameter of the vein may not be enough for bridging large vessels. On the other hand, synthetic grafts have fewer issues with size matching and can be used for medium and large arteries.

In our case, the patient's history (diabetes, active smoker, and hypertension) increased the risk of future cardiac surgery, in which the saphenous vein would have to be used, and, since he presented bilateral aneurysms, we decided to perform the surgery with a prosthetic conduit.

CONCLUSIONS

To date, surgical graft replacement with resection of the aneurysm is still the standard treatment, although endovascular stenting can be offered as a feasible and successful alternative. Treatment choice should be individualized, ultimately depending on a multitude of patient and surgical factors. The importance of CT angiography in the differential diagnosis in cases of recurrent acute ischemia of the upper limb should be emphasized.

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When even luck matters: a compendium of all possible complications during hybrid repair of a dissecting TAAA occurred in a single patient

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Abstract:

Purpose: A 73-year-old woman, already submitted to repair of the ascending aorta and subsequently to aortic valve substitution in redo sternotomy, presented to our attention with a dissecting TAAA with a distal aortic arch diameter of 6 cm. Our goal was to offer this extremely fragile patient the least invasive surgical treatment as possible.

Technique: We treated this patient in two stages. In the first stage we performed a carotid-carotid-subclavian bypass. In the second stage we performed a TEVAR in zone 1, extending from the brachiocephalic artery to the celiac trunk. Left subclavian artery was previously occluded with a plug. CSFD was not adopted by default.

Conclusion: This patient reported some extremely rare and unexpected complications that brought us to report this case. Hybrid techniques represent an extremely appealing opportunity to treat fragile patients affected by complex aortic diseases with relatively little invasive strategies, however, serious complications can occur even after these surgeries.

INTRODUCTION

Repair of dissecting thoracoabdominal aortic aneurysms (TAAAs) involving the distal aortic arch remains challenging, especially in fragile patients. When traditional open repair cannot be performed, hybrid surgery represents an excellent therapeutic option.¹ Supra aortic trunks debranching associated with TEVAR has become in the last years one of the most used techniques for the treatment of aortic arch diseases, with excellent patency rates of extra anatomic bypasses and good clinical midterm result. However, these procedures are technically demanding and bring relevant rates of complications.² In adjunct, proximal endograft deployment brings a not negligible risk of type IA endoleak.³

We present the case of a 73-year-old woman, already submitted in emergency setting to repair of the ascending aorta for a type A aortic dissection and subsequently to aortic valve substitution for valvular degeneration in a redo sternotomy. In anamnesis she also reported: atrial fibrillation, hypertension, left nephrectomy for bleeding hemangioma and abdominoperineal resection for anorectal malignant melanoma. The patient presented to our attention with a residual dissecting TAAA with a distal aortic arch diameter of 6 cm. Our goal was to offer to this extremely fragile patient the least invasive surgical treatment as possible.

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TECHNIQUE

To split the surgical stress burden, we decided to treat this fragile patient in two different stages. In the first stage we performed a carotid-carotid-subclavian bypass using a 8 mm non-ringed ePTFE graft (Propaten, WL Gore, Flagstaff, AZ, USA). The graft was tunneled in the subcutaneous tissue without torsion or kinking. The patient was discharged home and subsequently readmitted after one month. In the second stage we performed a TEVAR in zone 1 with two overlapping tapered thoracic endografts (Bolton Relay Plus, Terumo Aortic, Vascutek Ltd., Inchinnan, UK), extended from the origin of the brachiocephalic artery to the origin of the celiac trunk. Left subclavian artery was previously occluded with a plug (Amplatzer Vascular Plug, St. Jude Medical Inc., St. Paul, MN, USA) at the beginning of the same procedure. CSFD was not adopted by default before initiating the procedure. Residual dissection of the abdominal aorta, with all the visceral vessels originating from the true lumen and a small aortic diameter, was not considered to be in need of treatment.

DISCUSSION

During the two postoperative courses this patient reported some extremely rare and unexpected complications that brought us to report this case. After the first intervention, on postoperative day (POD) 2, she developed a complete deficit in the pronation-supination and flexion-extension of the left arm: the electroneurography showed a transient stupor of brachial plexus, completely resolved after a few weeks with medical therapy and motor rehabilitation. On POD 6 the patient started developing progressive anemia, initially treated with red blood cell transfusions. On POD 8 she was submitted to an urgent CT scan, that revealed an enormous pelvic hematoma originating from a spontaneous rupture of the external iliac artery, treated with a covered stent (Vi-



Figure 1. Preoperative CT scan

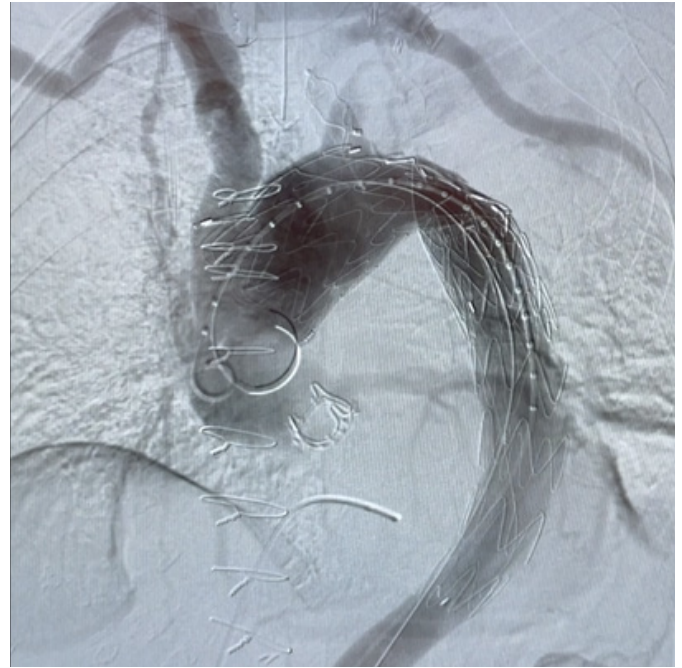


Figure 2. Final result after carotid-carotid-subclavian bypass and TEVAR.



Figure 3. The enormous pelvic hematoma originating from a spontaneous rupture of the EIA.

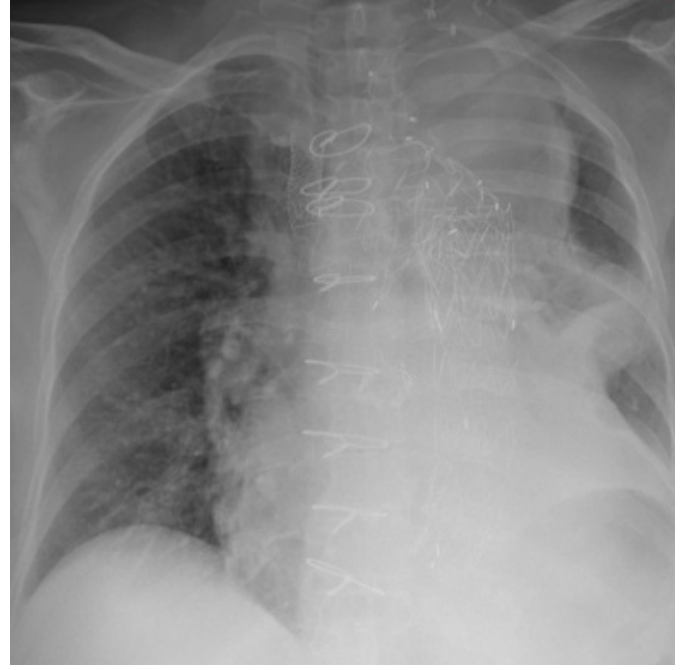


Figure 4. A chest X-ray shows the chimney technique used as rescue to preserve the IA patency.

abahn, WL Gore, Flagstaff, AZ, USA) with excellent result. In adjunct, during postoperative course, the patient contracted Sars-CoV-2 infection, requiring NIV for a few days. The second stage (TEVAR) was completed with a good angiographic result and without complications of any type. Patient was close to be discharged home when, on POD 3, she suddenly developed bilateral brachial hypotension, malaise and mental confusion. An urgent CT scan was performed and an almost complete

coverage of the brachiocephalic artery by the most proximal endograft was observed. The patient was urgently submitted to an endovascular relining of the brachiocephalic artery using two imbricated balloon expandable covered stents (VBX, WL Gore, Flagstaff, AZ, USA) post dilated with a semi-compliant valvuloplasty balloon, with good angiographic results and complete remission of symptoms.

CONCLUSION

Hybrid techniques offer vascular surgeons an extremely appealing opportunity to treat fragile patients affected by complex thoracoabdominal aortic diseases with relatively little invasive strategies. Despite this, as we experienced with this patient, serious complications can occur even after these surgeries. Prompt recognition and treatment of these complications should be in the armamentarium of the hybrid vascular surgeon. In particular, early proximal endograft migration is a complication not yet described in literature that can occur, as we experienced. Forces acting on proximally deployed endograft are complex and could have various effect, more often a distal migration of the endograft.⁴ However, it seems necessary to us a better comprehension of possible interactions between endograft and native aortic arch.⁵ More advanced total endovascular strategies are spreading quickly but long-term data are still lacking on this specific argument.⁶

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Chimney technique for left subclavian artery restoration -Two cases presentations

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Abstract:

Introduction: Left subclavian artery revascularization (LSA) is frequently performed in the setting of thoracic endovascular repair (TEVAR). In recent years, the chimney technique is a notable and effective method of reperfusion of the LSA.

Cases presentations: Two case reports analyze our experience in the chimney technique for the reperfusion of the LSA. In the first case, a young male underwent in a TEVAR due to an aortic isthmus rupture by an acute dissection type B of the thoracic aorta. In the second case, a male underwent in elective endovascular repair of thoracic aortic aneurysm and in the second time he underwent in an endovascular abdominal aortic aneurysm repair (EVAR). In 3 months postoperatively, the second man's follow-up CTA showed that the stents were well formed and no obvious endoleak was noticed.

Conclusion: The revascularization of the LSA in patients who underwent in TEVAR is able to decrease the risk of stroke, SCI and upper limb ischemia. Several minimally invasive procedures have been employed to manage this procedure, one of them is the chimney graft technique.

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) is a valuable approach for patients with thoracic aortic disease (TAD) (descending thoracic aortic aneurysm or type B aortic dissection (TBAD))¹. The endovascular management of the aortic arch, however, remains challenging because of its angulated morphology and involvement of the supra-aortic branches². Durable outcomes of TEVAR require an adequate proximal seal zone. It is estimated that 23% - 40% of TEVAR will require coverage of zone 2 to create a proximal seal³. The coverage of the left subclavian artery (LSA) during TEVAR to achieve a proximal seal is associated with increased risk of stroke, spinal cord ischemia, and upper extremity ischemia⁴.

In 2009, the Society for Vascular Surgery consensus statement recommended routine revascularization of the LSA when covered by TEVAR for proximal sealing in elective cases¹. Several strategies have been published in the literature to preserve the orifice of the LSA such as chimney technique, hybrid technique (carotid to subclavian bypass (CSB)) and fenestrated or branched stent graft technique². Notable results with use of fenestrated or branched stent graft in the aortic arch have been published. However, these approaches were limited by the morphological diversity of the aortic arch, necessitating patient specific and tailor-made devices^{2,4}.

Another endovascular approach to maintain perfusion of the LSA is the chimney technique, which was first applied in the aortic arch to rescue an inadvertently covered left subclavian artery (LSA). In recent years, the chimney technique has increased rapidly for the treatment of aortic arch disease, but the long-term efficacy remains unclear².

The aim of this study was to report our experience with the chimney technique for LSA preservation in TAD and to evaluate the short and mid-term outcomes in these patients.

CASE 1

A 21-year-old male patient, with unknown personal or family medical history, was transferred unconscious to our emergency department because of a mentioned traffic accident. He was intubated urgently in the emergency department. In full body computed tomography angiography (CTA) was observed an aortic isthmus rupture by an acute dissection type B of the thoracic aorta (Figure 1). The dissection was originated distal to the LSA and extended proximal to the celiac artery (C.A.). Moreover, it was observed a mandibular fracture.

The patient was immediately transferred to the operating room. A TEVAR was planned to cover the primary entry and reduce false lumen flow. Because of the short proximal neck (length: 4mm), it was preferred the chimney technique for LSA revascularization. Under general anesthesia, the right common femoral artery (CFA) and the left brachial artery was exposed. Two J guidewires were passed, the first one from the right CFA and the second one from the brachial artery to the ascending aorta. Aortic angiography was performed before stent-graft deployment. A possible rupture site in the false lumen of the descending aorta was identified. A Lunderquist® stent wire (Cook Medical, Bloomington, Indiana, USA) was used, and a Gore Comfortable Thoracic Stent Graft (31X31X10) (W. L. Gore and Associates, Flagstaff, AZ, USA) was deployed in the

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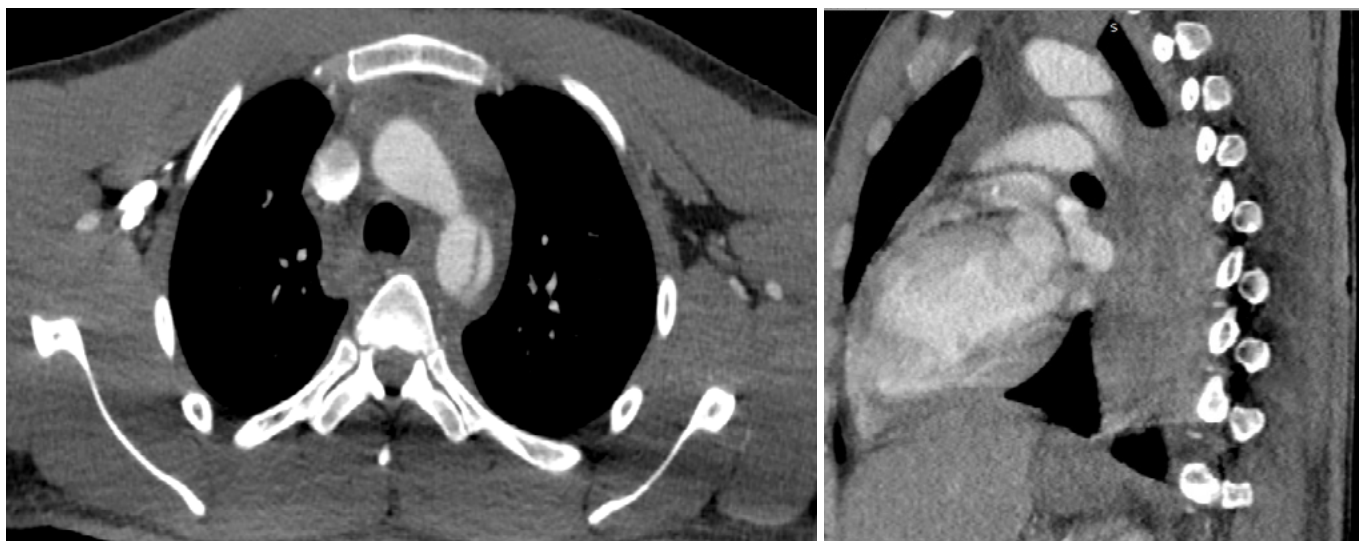


Fig 1: Aortic isthmus rupture by an acute dissection type B of the thoracic aorta

descending aorta. The chimney technique was accomplished via a VBX (W. L. Gore and Associates, Flagstaff, AZ, USA) (8 mm × 59mm ×) stent graft, which was placed appropriately at the ostium of the LSA to preserve its perfusion. At the end of the procedure, control aortography confirmed the proper positioning of the stent without evidence of a detectable leak and a patented LSA.

He presented an uneventful postoperative period, and he was transferred to the maxillofacial surgery department on the second postoperative day. One month later, a follow-up CTA revealed successful dissection exclusion with patent LSA chimney stent, and no significant endoleak was detected. Unfortunately, the patient was not appeared for subsequent follow-up.

CASE 2

A 75-year-old male patient had been admitted in our department for elective restoration of descending thoracic aortic aneurysm 6.7cm and infrarenal abdominal aortic aneurysm 6.5cm. His pertinent medical history included arterial hypertension, dyslipidemia, diabetes mellitus type II, chronic renal disease and chronic cardiac insufficiency (Ejection Fraction (E.F.): 60%). He underwent in open cholecystectomy and appendectomy.

It was preferred the staged restoration of these aneurysms. Firstly, he underwent a TEVAR to be restored the thoracic aortic aneurysm. Because of the short proximal neck (length: 12mm) (Figure 2), it was preferred the chimney technique for LSA restoration (as the previous case). Under general anesthesia, both common femoral arteries and the left brachial artery was exposed. The right CFA was chosen as the main access and the left CFA was used for control aortography that revealed the aortic arch anatomy and the descending thoracic aortic aneurysm. Two J guidewires were passed, the first one from the right CFA and the second one from the brachial artery to the ascending aorta. Aortic angiography was performed before stent-graft deployment. A Lunderquist® stiff

wire (Cook Medical, Bloomington, Indiana, USA) was used, and Gore Comfortable Thoracic Stent Graft (40X40X20) (W. L. Gore and Associates, Flagstaff, AZ, USA) was deployed in the descending aorta. It was implanted two thoracic grafts because of the great length of the descending thoracic aorta. The chimney technique was accomplished via a VBX (W. L. Gore and Associates, Flagstaff, AZ, USA) (11 mm × 79mm) stent graft, which was placed appropriately at the ostium of the LSA to preserve its perfusion. At the end of the procedure, control aortography via the left common femoral artery confirmed the proper positioning of the stent without evidence of a detectable leak and a patented LSA. The postoperative

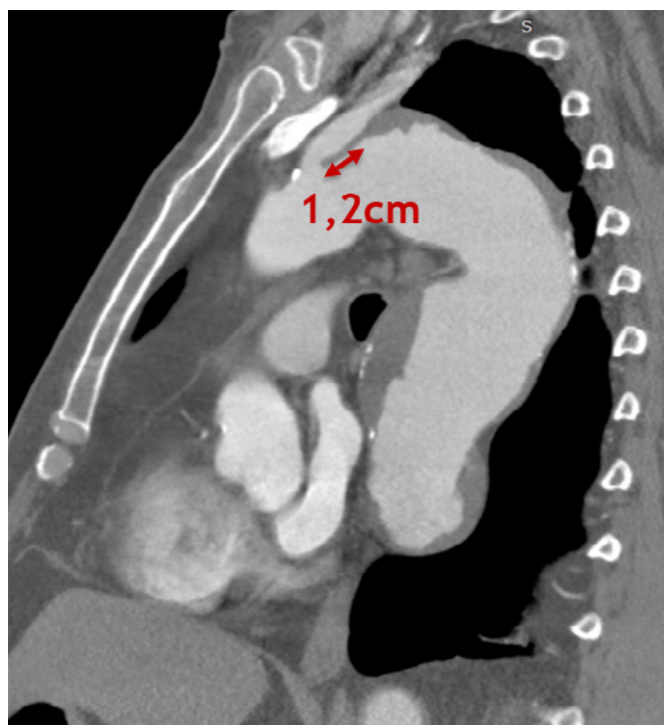


Fig 2: Short proximal neck of descending thoracic aortic aneurysm (length: 12mm)

course was unremarkable, and he was discharged on the 4th postoperative day.

On the 51st postoperative day from the first operation, he was admitted for elective repair of infrarenal abdominal aortic aneurysm. Under spinal anesthesia, it was implanted a Gore - Conformable Excluder bifurcated stent graft (Main body: CXT361414E, Right endograft extension: PLC161000, Left endograft extension: PLC141000) without complication via a transfemoral artery exposition. Intraoperative digital subtraction angiography verified the correct stent placement and the absence of endoleaks. He was discharged from the hospital 4 days postoperatively.

However, despite the patient was asymptomatic, it was observed that he has a discrepancy in arterial pressure measurements between two upper limbs (30mmHg). In CTA thoracic and abdominal aortic, it was confirmed a significant stenosis in the chimney stent graft (Figure 3).

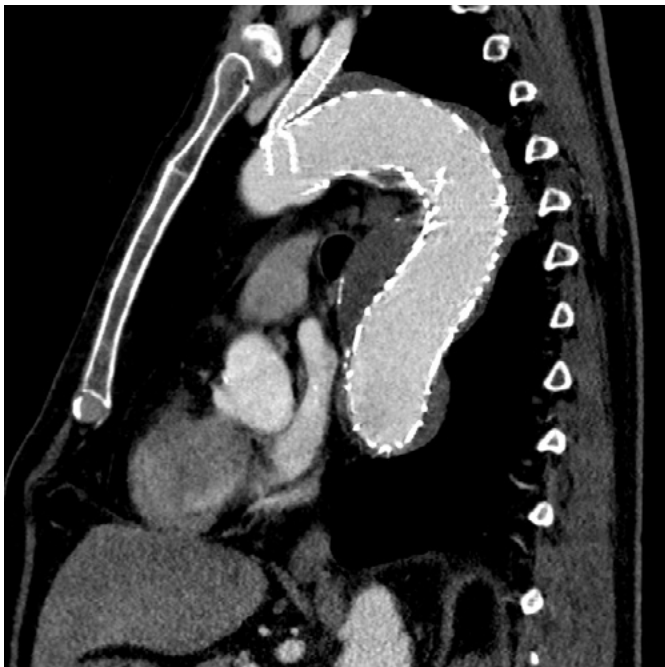


Fig 3: Stenosis in the chimney stent graft

On the 10th postoperative day from the second operation, he underwent an angioplasty of chimney stent graft. In the angi suit and under local anesthesia, it was implanted a balloon expandable bare metal stent (10x39) into the previous chimney stent graft via a left transbrachial percutaneous intervention. The intraoperative angiography confirmed the successful treatment of the stenosis. The patient was discharged on the 2nd postoperative day, uneventfully, and he received double antiplatelet therapy for 6 months. In 3 months postoperatively, the follow-up CTA showed that the stents were well formed and no obvious endoleak was noticed.

DISCUSSION

For patients with acute thoracic emergency, TEVAR is required

urgently and coverage of the LSA is necessary. The coverage of the left subclavian artery during TEVAR to achieve a proximal seal is associated with increased risk of stroke, spinal cord ischemia (SCI), and upper extremity ischemia. Xie et al., under their single center's experience (a total of 547 TEVARs were analyzed), concluded that comparisons between the unrevascularized and revascularized groups were significant for a higher rate of 30-day spinal cord ischemia (SCI) (10.7% vs. 1.4%, $p = 0.032$). However, the mortality, stroke, and left upper extremity ischemia were not statistically significant at 30-day or mid-term between those groups¹.

A report from the European Collaborators in Stent-Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR) registry of 606 patients demonstrated an SCI rate of 2.5% and found coverage of the LSA without revascularization was an independent risk factor for SCI (OR, 3.9; $P = 0.027$)^{1,5}.

Several minimally invasive procedures have been employed to manage aortic-arch lesions taking into considerations the supraaortic vessels. There are basically two main approaches: hybrid and total TEVAR. The hybrid procedure can be described as a combination of extra-anatomic bypass of supra-aortic vessels with endovascular stent-graft deployment⁶. TEVAR for aortic arch can be accomplished by fenestrated/branched stent graft or chimney technique in order to maintain blood flow to the vital organs. Fenestrated TEVAR is the delivery of a stent graft with fenestrations, which directed precisely to the target vessels⁶. Haulon et al. in 2014 performed a retrospective multicenter study for 38 patients with aortic-arch aneurysm repaired by a branch stent graft; the 30-day mortality rate was 13% and early cerebrovascular deficits were diagnosed in 16% of cases^{6,7}.

According to the Society for Vascular Surgery practice guidelines, the chimney technique was used to reconstruct LSA in zone 2 aortic arch disease⁸. If patient anatomy was not suitable, left common carotid artery (LCCA) to LSA bypass/transposition was performed when the patient had an incomplete Circle of Willis, dominant LSA, or aberrant right subclavian artery. However, complications of LCCA-LSA bypass/transposition include hemorrhage, wound infection, local nerve injury, etc. Compared with the hybrid technique, the chimney technique is more advantageous in terms of immediacy, reduced invasiveness, and improved safety^{2,8}.

Chimney graft is defined as a covered or bare stent graft that is deployed parallel to the main aortic graft stent to protect the perfusion of vital side branches⁶. It was first identified by Greenberg et al., who used it to preserve the renal-artery blood flow⁹. Yang et al. in 2012 conducted a systemic review to determine the safety and efficacy of the endovascular chimney technique for the preservation of supraaortic - branch blood flow. A total of eight articles with 51 patients who underwent TEVAR with the chimney technique from 1994 to 2011 were enrolled in the study. They concluded that the chimney-graft technique for aortic-arch pathologies is technically applicable in both elective and emergency situations and is associated with favorable perioperative outcomes with a success rate of 90.2%^{6,10}.

The main concern of the chimney technique is the risk of endoleak type IA (IA) from the gutters alongside the aortic stent graft, chimney stent, and thoracic aortic wall. To decrease the incidence of IA, different approaches have been reported. Theoretically, a covered stent may be helpful because it can decrease the blood flow through the mesh of the bare stent into the gutter. Beyond that, Wang et al. recommend at least 2 cm overlap between the aortic stent graft and the chimney stent to promote thrombosis in the gutter^{2,11}.

Ding et al. analyzed in their study the outcomes of chimney technique for preservation of the LSA in patients with type B aortic dissection. Totally, 159 patients were included in this study and the technical success of the intervention was nearly 80%. The three years mortality rate was approximately 5% and the three years grafts patency rate was 96,5%. The present study demonstrated that the chimney technique is safe and feasible for preservation of the LSA in patients with type B aortic dissection, but the durability of chimney stent needs to be evaluated carefully and the immediate type of Ia endoleak is a concern².

In the literature, a comparison between chimney graft technique and carotid-subclavian bypass had been published by Ramson et al³. Even though, the study analyzed a huge number of patients (n:81), in their majority they underwent in carotid-subclavian bypass (n:64). This is the main reason of insignificant outcomes. The authors concluded that the chimney stent graft technique offers equivalent early results as a minimally invasive alternative for the reperfusion of the LSA. However, more follow-up studies were needed to determine long-term results of the chimney stent treatment modality³.

CONCLUSION

The revascularization of the LSA in patients who underwent in TEVAR is able to decrease the risk of stroke, SCI and upper limb ischemia. Nowadays, this procedure is considered, especially in elective cases. Several minimally invasive procedures have been employed to manage this procedure, one of them is the chimney graft technique. However, even though the so far outcomes are very hopeful, more studies with longer follow-ups are warranted to further define the best treatment strategy.

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Covered Endovascular Reconstruction of Internal Iliac Bifurcation (CERIIB)

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INTRODUCTION

Current accepted definition of iliac artery aneurysm (IAA) is the dilatation of the artery > 1.5 times to its normal diameter: common iliac artery (CIA) of > 18-20 mm in men and 15 mm in women, and an internal iliac artery (IIA) of > 8 mm.^{1,2} IAAs are commonly associated with the presence of an aneurysm in the abdominal aorta (AAA) as aorto-iliac aneurysms rate ranges up to 10% of AAA, while isolated aneurysms of the internal iliac artery (IIAA) are a rare condition (0.4% of all intra-abdominal aneurysms).^{1,2} The IIAs' natural course is not well known because of the lack of evidence describing their natural history, and the fact that many of those are treated in smaller diameters when there is a need for the AAA to be treated; however, most of IIA are becoming larger and rupture, leading to significant mortality.³

Treatment of IIAA is challenging. In many cases, open surgical repair of IIAA poses difficulties due to their deep pelvic localization and, in case of previous open repair of AAA scar tissue may be present. According to the literature, 30-day mortality and complication-rate reach up to 10% and 16%, respectively.⁴ Thus, with the EVAR becoming the first choice of AAA treatment, endovascular techniques have been also applied for the IIAA treatment.⁵ The usual approach is the exclusion of the proximal part of the IIA orifice by deploying a stent graft along the common and external iliac arteries with or without coil embolization of the outflow branches and the IIAA sac itself. In cases where the aneurysm neck anatomy is suitable, an Amplatzer vascular plug has also been successfully used to exclude the arterial inflow and outflow.³

The main issue of those endovascular techniques is that either unilateral or bilateral IIA occlusion has been shown to carry a risk of significant ischemic complications in nearly one

quarter of patients. Especially bilateral IIA occlusion has been related to a significantly higher rate of buttock claudication and even serious ischemic complications regarding the rectum and buttocks. Endovascular techniques have evolved to side branch techniques preserving IIA patency leading to a significant improvement in the treatment of aorto-iliac aneurysms and have been associated with high technical success and low morbidity.⁶ Herein, we present a case of treatment of bilateral IIAAs using an off the shelf technique of Covered Endovascular Reconstruction of Internal Iliac Bifurcation (CERIIB).

CASE PRESENTATION AND TECHNIQUE

A 67-year-old male had a known history of open surgical repair of an infrarenal AAA 12 years ago. At that time, he underwent an aorto-bi-iliac reconstruction with a Dacron vascular graft from just below the renals to the iliac bifurcations. During follow up, a computed tomography angiography (CTA) revealed bilateral internal iliac artery aneurysms (both sides 30 mm in diameter). (Figure 1) The two possible solutions were overstenting of the orifice of the IIAs with the simultaneous coiling and deployment of a vascular plug of the IIAA in two staged procedures (one for the right and one for the left side), while the other one to attempt a CERIIB technique deploying two parallel balloon expandable covered stents (BXCS) in the outflow branches of each IIA, which would land in parallel fashion inside a previously deployed BXCS in the main trunk of each IIA, similarly to CERAB technique that is being used in the aortic bifurcation.

The patient was operated in supine position under general anesthesia. Cut down access was bilaterally used in the superficial femoral artery and in the left axillary artery. Systemic heparinization at 100 IU/kg with a target Activated clotting time (ACT) > 300 s was obtained. A 16 Fr sheath (33mm of length, W.L. Gore & Associates, Flagstaff, AZ, USA) was advanced over an Amplatz guidewire from the axillary artery into the descending aorta for stabilization, and then a long 9 Fr x80mm sheath was inserted up to the right common iliac artery. A 5 Fr Vertebral catheter over a hydrophilic guidewire was advanced in order to cannulate the right internal iliac artery and one of its two main branches. The wire was exchanged to an Amplatz wire again and a VBX (W.L. Gore & Associates, Flagstaff, AZ, USA) BXCS 11x39mm was implanted in the proximal part of IIA. Leaving the wire in place into the one main distal branch, the catheter was inserted parallel to the wire inside the 9Fr sheath, in order to cannulate the sec-

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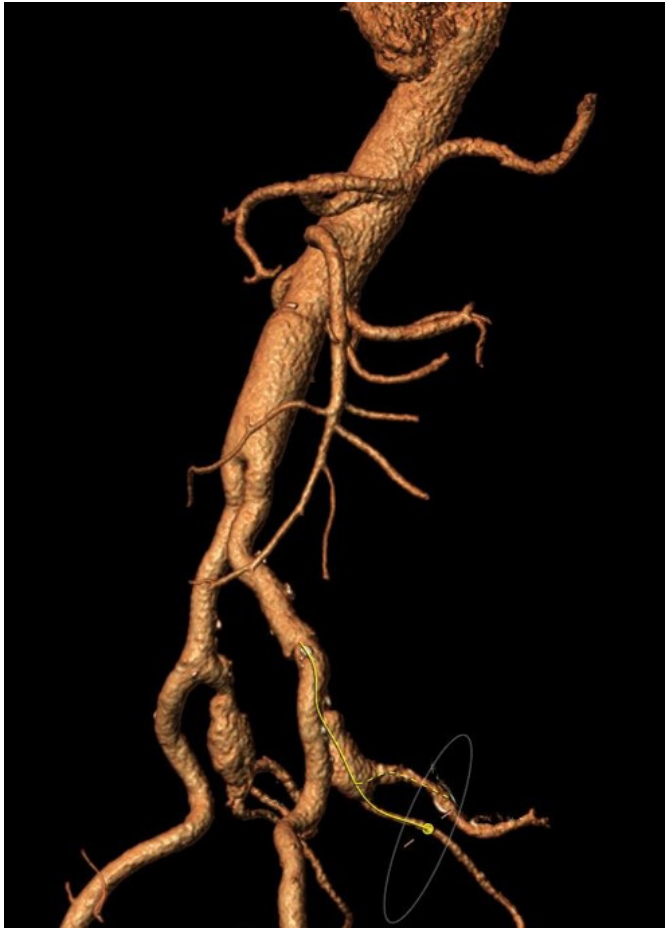


Figure 1. A computed tomography angiography (CTA) revealed bilateral internal iliac artery aneurysms (both sides 30 mm in diameter).

ond main distal IIA branch with a hydrophilic wire that was exchanged to another Amplatz guidewire. An angiography from the 9Fr sheath showed the distal landing zone of both IIA branches. The 9Fr sheath was then removed from the 16 Fr sheath, and a first VBX 5x39mm was inserted through the large 16Fr sheath and was appointed in the specific position inside the first IIA branch and inside the previously placed 11mm VBX. Then a second VBX 6x39mm was also inserted from the 16 Fr sheath over the second guidewire in parallel to the previous one, and was also put in place inside the second IIA branch. Both covered stents were then deployed having their proximal part into the 11mm VBX and their distal part into the two main branches. (Figure 2) After deployment, the balloons of the covered stents were retrieved more proximal outside the IIA branches and another kissing ballooning was undertaken with pressure than the nominal one in order to achieve better formation inside the 11mm VBX and thus to avoid any gutter endoleak.

The same technique was exactly used for the aneurysm in the left IIA. (Figure 3) Again, we deployed a VBX 11x39mm in the proximal part of the IIA and distally a VBX 6x39mm and a VBX 5x39mm in the two main branches of the left IIA, with their proximal part within the 11mm VBX. During the end of this second procedure, we noticed a 50% stenosis in the proximal part of the EIA, caused by a small malposition of the 11mm VBX in the proximal part of the left IIA. Another VBX 11x39mm was deployed (Figure 4) in the proximal part of the EIA and a kissing stent technique was undertaken (with a balloon just into the IIA stent) with an optimal outcome (Figure 5). The post-op course of the patient was uneventful and was he discharged at second post-op day on dual antiplatelet

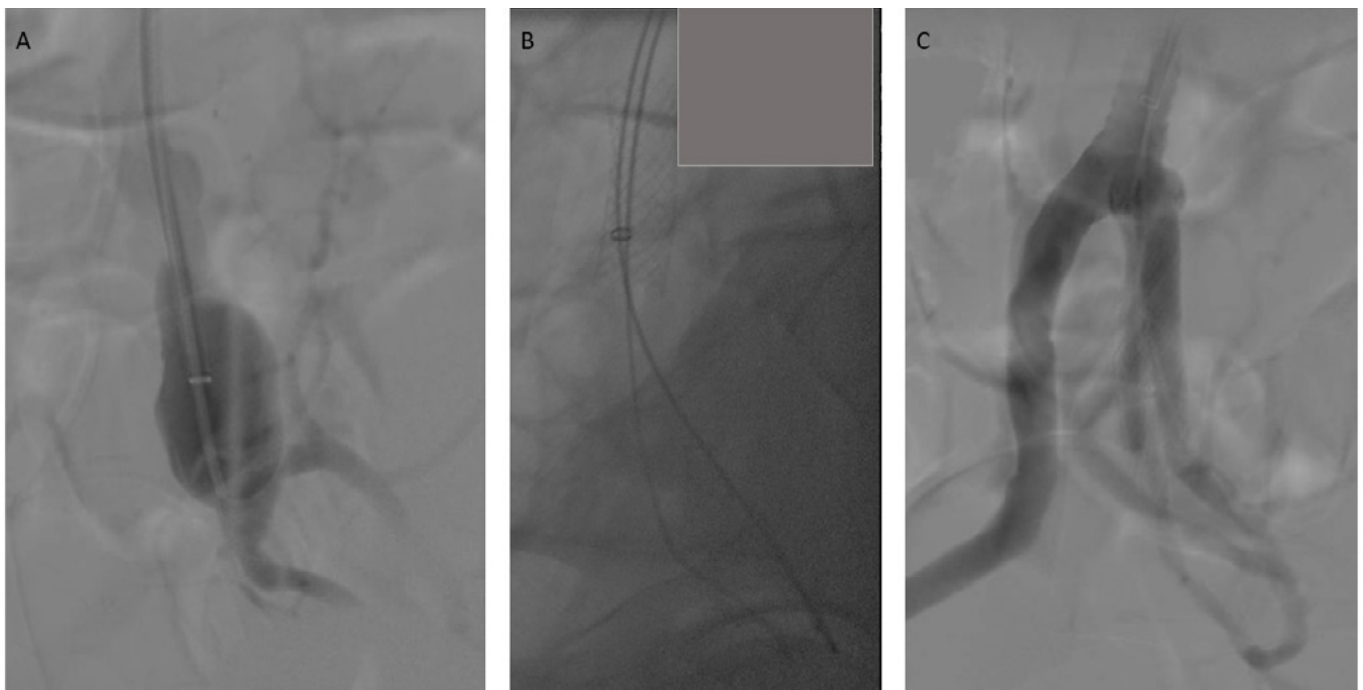


Figure 2. A. Intra-operative imaging of right internal iliac artery (IIA) aneurysm (IIAA) with the two large distal branches. B. The proximal balloon expandable covered stent (BXCS) was implanted in the proximal part of IIA. C. Both BXCSs have been deployed having their proximal part into the first BXCS and their distal part into the two main branches. Right external artery is also shown.

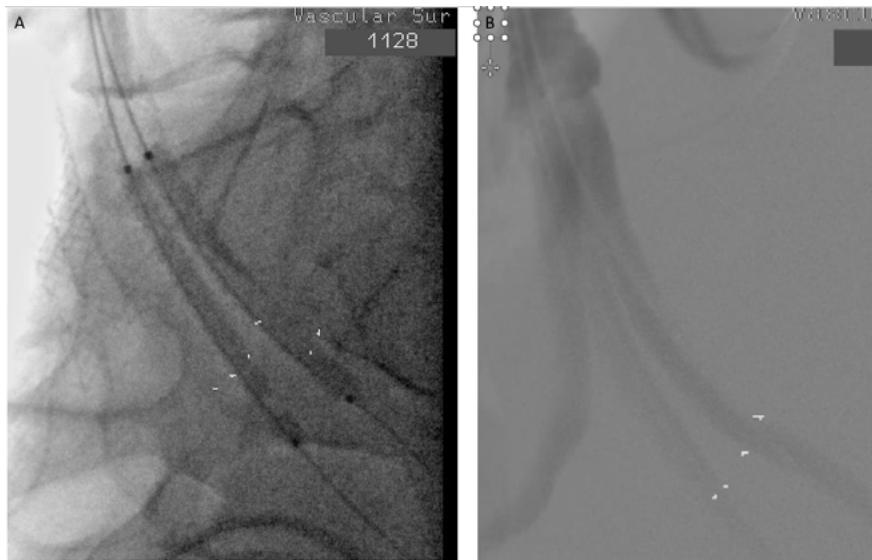


Figure 3. A. In the left side, both balloon expandable covered stents (BXCS) have been deployed having their proximal part into the first BXCS and their distal part into the two main branches. B. Both branches are patent.

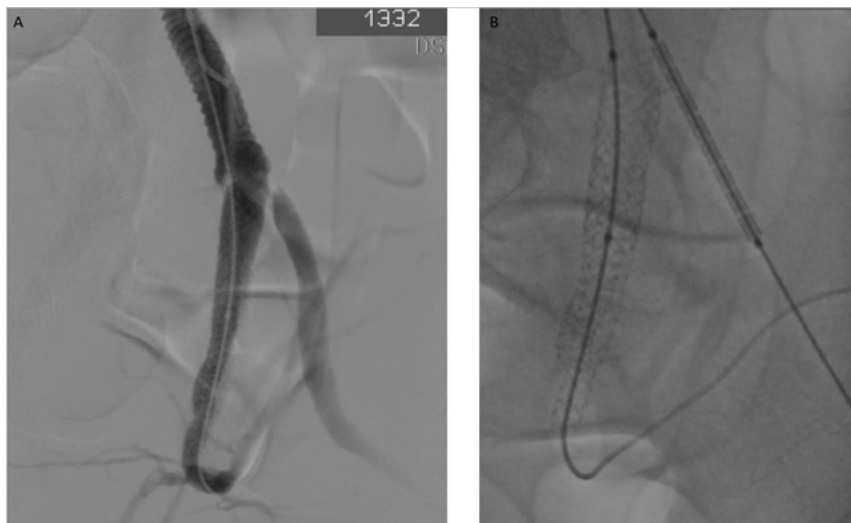


Figure 4. A. The stenosis in the proximal part of the external iliac artery (EIA) can be seen caused by a small malposition of the balloon expandable covered stent (BXCS) in the proximal part of the internal iliac artery. B. Another BXCS was deployed in the proximal part of the EIA.

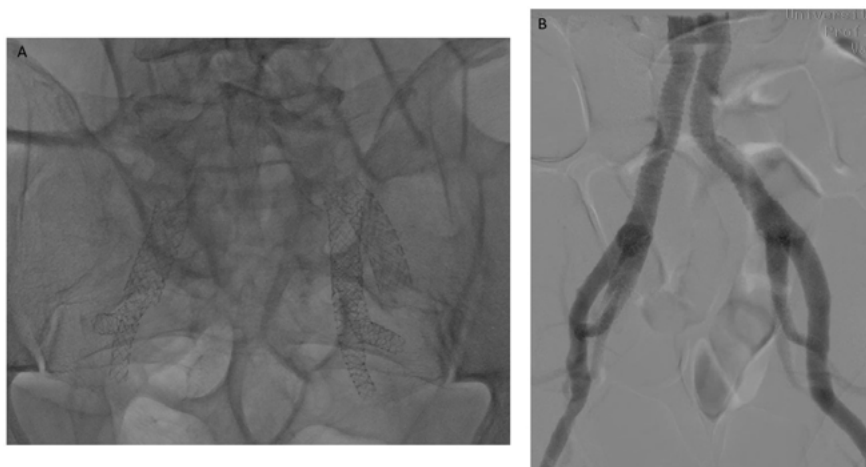


Figure 5. A. Final intraoperative imaging without contrast to present the formation of the balloon expandable covered stents (BXCS) in both sides. B. Intra-operative angiogram showing that both sides of internal iliac artery and its branches are patent without any endoleak.

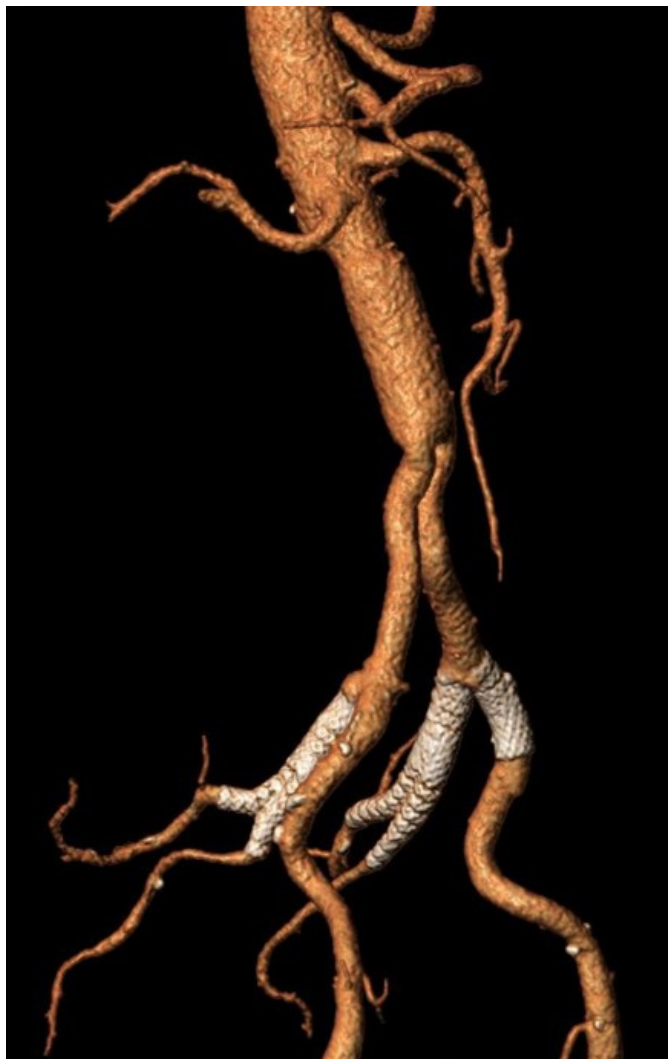


Figure 6. First month computed tomography angiography showing good patency of all balloon expandable covered stents in both sides without any endoleak.

treatment for a month. The 1st month CTA shows exclusion of the aneurysms, with no endoleak or stenosis of the covered stents (Figure 6). All distal branches of both IIAs were patent. The patient is under surveillance on clopidogrel, with a duplex examination scheduled 6 months after the procedure.

DISCUSSION

In this case report we presented the CERIIB technique (Covered Endovascular Reconstruction of Internal Iliac Bifurcation) in a patient with bilateral IIAs. The CIA is aneurysmal when its diameter exceeds 15–18 mm, and the general threshold for repair is 3 cm.^{7,8,9} The challenge of this case was that in both sides large distal branches were present. Someone could argue that an internal iliac branch device may be used, but this would be difficult due to the relative restrictive common iliac diameter, and because it would be necessary to land to one of those branches distally, increasing the risk of IIA occlusion due to poor run off or potential endoleak from the other branch even if it was coiled embolized.

Kim et al.⁷ have highlighted that even if endovascular treatment of IIA aneurysms may effectively prevent sac expansion, endoleak was more frequently observed in cases of technical failure and those in which distal IIA branches were embolized. Someone could suggest that there were many other options such as Iliac stent graft deployed over the ostium of the IIA following outflow embolization with or without embolization of the inflow and outflow of the IIA. Technical failure has been associated to incomplete embolization of IIA outflow, and this significantly determines the clinical outcome.⁷ Additionally, there was a high probability for serious complications due to bilateral IIA occlusion in an otherwise healthy patient, relatively young.

Open surgical techniques include exclusion of the aneurysm sac with proximal ligation alone or in conjunction with distal ligation of the hypogastric artery, formal resection of the aneurysm or proximal ligation of the artery combined with endoaneurysmorrhaphy.¹⁰ In the rare cases of bilateral disease and in order to prevent compromise of the pelvic arterial circulation, an interposition graft may be placed. The deep location of the aneurysm in the pelvic cavity, along with peri-inflammatory tissue reaction, creates considerable difficulties with dissection and aneurysm fixation, the risks of intraoperative hemorrhage are significant, and elective mortality rates of up to 11% have been reported. In emergency cases, the mortality figures may be as high as 50%.^{3,11}

In terms of clinical impact, literature data described a high rate of buttock claudication (12-19%) and symptoms occurred particularly after the use of coils and especially if they are placed in the outflow branches of the IIA (22-30%).^{12,13} Some literature data suggest that coil embolization of hypogastric aneurysm in its distal branches leads to higher rate of buttock claudication and even more serious pelvic ischemia.^{12,14} On the contrary, claudication is quite rare without coil embolization or after coil deployment in the proximal portion of the vessel. Coils deployment in the vascular district is not a precise procedure, and often the final coil position is changed by multiple forces (blood flow, arterial wall, coil bending). Coils may have been pushed distally by the flow, causing damage at distal arterial vascularization. Even though aneurysm embolization with vascular plugs has not been associated to pelvic complications, still endograft stenosis and thrombosis from vascular plug pressure have been the more frequent complications.¹² Grade of oversize probably plays a fundamental role in the genesis of these complications.

Unilateral or bilateral IIA occlusion during EVAR seems to carry a substantial risk of significant ischemic complications in nearly one quarter of patients. Bilateral IIA occlusion has been related to a significantly higher rate of buttock claudication and serious pelvic ischemia. IIA preservation techniques represent a significant improvement in the treatment of aorto-iliac aneurysms and have been associated with high technical success and low morbidity.⁶

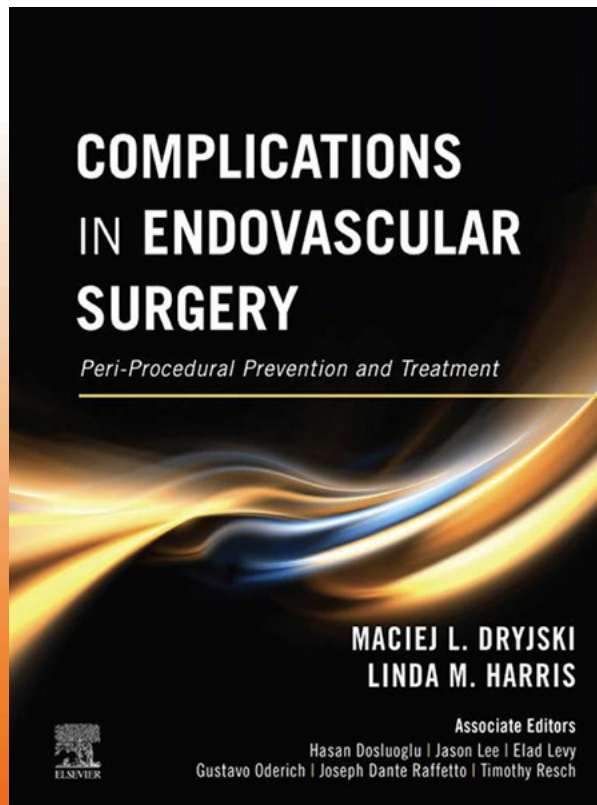
CONCLUSION

CERIIB technique is a novel off the shelf technique that can

be used for the treatment of IIAAs with large distal branches, treating the aneurysm and at the same time preserving the blood flow to the pelvic circulation. It requires adequate experience and logistics, and of course needs more evaluation and longer results to be established in the endovascular treatment of IIAAs.

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