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BALLOON INDUCED RE-LAMINATION AND FALSE LUMEN THROMBOSIS (BAILOUT) IN CHRONIC TYPE B AORTIC DISSECTION: TECHNIQUE AND LONG-TERM RESULTS

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Introduction and Objective: To evaluate the safety, feasibility, and effectiveness of the Balloon Induced re-Lamination and false Lumen Thrombosis (BAILOUT) as a simple technique to address the retrograde false lumen (FL) perfusion and subsequent aneurysmatic degeneration of the thoracic aorta due to a stent-graft crimped in a small TL in Chronic Type B dissections.

Methods: Observational, retrospective, single-center study analyzing a non-consecutive cohort of 8 patients affected by chronic type B aortic dissections already treated with TEVAR and with an FL lumen backflow corrected with BAILOUT between 2006 to 2020. After a standard distal extension of the previously implanted graft, the distal end of the graft area was ballooned to completely rupture the dissection lamella to relaminate the aorta hindering the FL backflow. Computed tomography was routinely performed within the first postoperative week before discharge and then at 3 months, at 6 months, and yearly thereafter. The technical and clinical success rates were analyzed. Primary outcomes were safety and feasibility of the technique, secondary ones included FL thrombosis evaluation and total aortic diameter analysis at the above-defined levels during the follow-up. Safety was defined if clinical success was reached. Feasibility was intended as technical success obtaining.

Results: The technical and clinical success achieved was 100% with the complete interruption of FL backflow stating the safety and feasibility of the BAILOUT technique. No early procedure re-interventions were recorded and during a median follow-up of 62.5 months [IQR range 43.2-94.1], only one death unrelated to the procedure was recorded. Freedom from aortic-related adverse events at 1-month, 3-months, 1 year, 5 and 7 years was 87.5%, 62.5%, 62.5%, 62.5% and 62.5% respectively. During the follow-up, no one increment of the diameter of the thoracic aorta was documented and all the patients at 3-years of CTA showed a complete FL thrombosis.

Conclusions The BAILOUT technique demonstrates to be safe and feasible in this small cohort of patients as a simple and quick way to overcome the issue of FL backflow in chronic type B dissection. Small cohort and retrospective designs were limitations of the study.

INTRAOPERATIVE PREDICTORS OF IN-HOSPITAL MORTALITY AFTER OPEN REPAIR OF RUPTURED ABDOMINAL AORTIC ANEURYSMS

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BACKGROUND: Several models and scores have been released to predict early mortality in patients undergoing surgery for a ruptured abdominal aortic aneurysm (rAAA). These scores included above all preoperative factors and they could be useful to deny surgical repair. The aim of the study was to evaluate intraoperative predictors of in-hospital mortality in patients undergoing open surgical repair (OSR) for a rAAA.

METHODS: Between January 2007 and December 2020, 265 patients were admitted at our tertiary referral hospital for a rAAA. Two-hundred-twenty-two patients underwent OSR. Intra-operative factors were analyzed by means of univariate analysis (step 1). Associations of procedure variables with in-hospital mortality rates were sought based on a multivariate Cox regression analysis (step 2).

RESULTS: Overall, in-hospital mortality rate was 28.8 % (64 cases). Multivariate Cox regression analysis reported that operation time >240 minutes (P=.032, OR 2.155, CI 95% 1.068-4.349), and hemoperitoneum (P<.001, OR 3.582, CI 95% 1.749-7.335) were negative predictive factors for in-hospital mortality. Patency of at least one hypogastric artery (P=.010; OR .128, CI 95% .271-.609), and infrarenal clamping (P=.001; OR .157, CI 95% .052-.483) had a protective role in reducing in-hospital mortality rate.

CONCLUSIONS: Operation time >240 minutes, and hemoperitoneum affected in-hospital mortality in patients undergoing OSR for rAAA. Patency of at least one hypogastric artery, and infrarenal clamping had a protective role. Further studies are needed to validate these outcomes. A validated predictive model could be useful to help the physicians in communication with patients' relatives.

OUTCOMES OF ILIAC BRANCH ENDOPROSTHESIS IMPLANTATION ASSOCIATED WITH INTENTIONAL OCCLUSION OF INTERNAL ILIAC ARTERY DISTAL BRANCHES

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Introduction and Objectives: Endovascular exclusion of abdominal aorto-iliac aneurysms with Iliac branch endoprostheses (IBE) may require additional embolisation of internal iliac artery (IIA) collateral branches, when distal landing in the IAA is not suitable. The aim of this study is to evaluate the early and late clinical results in this cohort of patients, and to compare them with those submitted to standard IBE implantation.

Methods: This retrospective single-centre study includes patients who underwent elective IBE implantation for abdominal aorto-iliac or isolated iliac aneurysms between 2017 and 2021. Patients were assigned to StG group if submitted to standard IBE implantation (distal landing in the IIA), and to EmbG group if submitted to IBE implantation (distal landing in a IIA branch) associated with single or multiple IIA branch embolisation. Demographics and risk factors, intra and postoperative data at 30 days and at last follow-up (FU, mean 24±19 months), were collected and analysed. Technical success was defined as successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or type III endoleak, branch occlusion, or graft limb obstruction. Early endpoints were procedure duration, dose area product (DAP), technical success, in-hospital major adverse event (MAE) rate, need of blood transfusion, length of stay (LOS), 30-day branch thrombosis and reintervention rate. Late endpoints were IBE-related endoleak, branch thrombosis, reintervention, and buttock claudication at FU.

Results: A total of 88 patients (84 males; mean age, 73±8 years) were included in this study: 78 patients in the StG (88.6%) and 10 in the EmbG (11.4%). Both groups were homogeneous as regards risk factors and demographics. No significant differences in procedure duration and DAP were observed. The overall technical success rate was 98.7% in the StG and 100% in the EmbG. In-hospital MAE rate [StG, 12.8% vs EmbG, 0%; $p=0.596$] and need of blood transfusion [StG, 16.7% vs EmbG, 10%; $p=1.0$] were similar in both groups. LOS resulted lower in the EmbG [StG, 2.91±1.36 days vs EmbG, 1.7±0.95 days; $p=0.008$]. Thirty-day branch thrombosis [StG, 0 (0%) vs EmbG, 1 (10%); $p=0.113$] and re-intervention [StG, 0 (0%) vs EmbG, 1 (10%); $p=0.113$] rates were not significantly different. At FU, endoprosthesis branch thrombosis was observed more frequently in the EmbG group [StG, 0 (0%) vs EmbG, 2 (20%); $p=0.011$]. No statistically significant difference at FU was found as regards endoleak [StG, 5 (6.4%) vs EmbG, 0 (0%); $p=1.0$] and reintervention [StG, 2 (2.6%) vs EmbG, 0 (0%); $p=1.0$] rates. In particular, 2 IBE-related endoleaks requiring reintervention were detected, both in the StG group and due to the loss of sealing on IAA distal landing zone (type IIIc). They were treated by embolisation of a pudendal branch

and IBE distal extension. Buttock claudication rate was similar in the two groups [StG, 5.2% vs EmbG, 10%; $p=0.461$].

Conclusions: According to this single-centre analysis, IBE implantation associated with IIA branches embolisation does not entail significant changes in perioperative outcomes as compared to controls. At follow-up, increased thrombosis of the endoprosthesis iliac branch may be observed, even if they were not associated with higher reintervention rates or buttock claudication. Conversely, standard IBE implantation may be associated with development of type IIIc endoleak at follow-up. Longer assessment and larger cohort studies are needed to confirm these initial observations.

ROLE OF CONTRAST ENHANCED ULTRASOUND IN THE FOLLOW-UP AFTER ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR

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Introduction and Objective: Endovascular abdominal aortic aneurysm repair (EVAR) has several advantages over traditional open surgical aneurysm repair, including lower invasivity and shorter hospital stay. However, its main drawback is the need for a life-long follow-up. Clinical practice guidelines regarding the optimal follow-up strategy, suggest Computed Tomography Angiography (CTA) as the best method. Computed Tomography Angiography (CTA) has good accuracy and reproducibility, but it is burdened by high cumulative dose radiation exposure and contrast agent nephrotoxicity, especially if used annually over a long period of time. The aim of this study was to assess whether contrast enhanced ultrasound (CEUS) shows a false negative rate close to zero and therefore is suitable as the main non-invasive follow-up strategy for long-term monitoring after endovascular aortic repair (EVAR).

Methods: We included all consecutive patients who underwent CEUS as follow-up after EVAR at our center between January 2017 and December 2021. The follow-up protocol consisted in Duplex ultrasound (DUS) with CEUS at 1, 3, 6 months post operatively and every 6 months thereafter. All patients underwent computed tomography angiography (CTA) at 1 and 12 months and when indicated by the operator.

Results: A total of 125 patients (male=114, 91%, mean age 74.6±7.3) underwent, in total, 228 CEUS. The aneurysm sac (preoperative mean diameter 56±13mm) showed shrinkage in 80 patients (64%), stability in 32 patients (25.6%), enlargement in 13 patients (10.4%). 29 (23.2%) patients showed type 2 endoleak, 13 patients underwent one or more reinterventions for the following indications: type 1 endoleak (four type 1A, three type 1B, one type 1C), type 3 endoleak (six patients), type 2 endoleak with sac enlargement (five patients). In detecting any endoleak, the sensitivity of CEUS vs DUS was 100% vs 75% ($P>0.0001$). In classifying type 2 endoleak, CEUS compared to

DUS showed sensitivity 93.2% vs 59.4%, specificity 99.3% vs 99.3%, PPV 98.6% vs 97.7%, NPV 96.8% vs 83.6%. In the detection of type 1 or 3 endoleak, CEUS and DUS did not show any discrepancies. For both techniques, sensitivity was 84,6%, specificity was 100%, PPV was 100% and NPV was 99,1%.

Conclusions: CEUS showed higher sensitivity compared to DUS in the detection of type 2 endoleak. For this reason, it is a valuable tool in the follow-up of patients undergoing EVAR, as it permits the identification of a subset of patients requiring a stricter follow-up protocol.

CONCOMITANT TRANSCATHETER AORTIC VALVE IMPLANTATION AND ENDOVASCULAR AORTIC ANEURYSM REPAIR

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Introduction and Objective: Transcatheter aortic valve implantation (TAVI) has become the standard treatment for severe aortic valve stenosis in patients with high or intermediate risk. Transfemoral access is the preferred route due to its reduced invasiveness and lower perioperative morbidity and mortality than trans-axillary, aortic and apical routes. Concomitant aortic aneurysms may require associated endovascular treatment with theoretically increased perioperative risks, though literature on the matter is currently lacking. The aim of this study is to report the outcomes of concomitant endovascular abdominal (EVAR) or thoracic (TEVAR) aortic aneurysms repair and TAVI.

Methods: This is a single center observational study. Twelve consecutive cases of concomitant EVAR or TEVAR and TAVI were prospectively collected, and data was retrospectively analyzed by a dedicated study group composed by cardiologists and vascular surgeons. Technical success (TS), mortality, morbidity and reinterventions were assessed as early outcomes within 30 days from the procedure. Readmission, reinterventions and survival were evaluated during follow-up.

Results: From 2017 to 2022(July) 12 cases of concomitant aortic aneurysm repair and TAVI were performed: EVAR - 10 (83%), TEVAR - 2 (17%). The median age and aneurysm diameter were 81(IQR:10) years and 68 (IQR:13) mm, respectively. Patients with ASA III and IV were 10(83%) and 2(17%), respectively. Procedures were performed under local anesthesia in 4 (33%), and general anesthesia in 8 (66%) cases. Surgical femoral access was used in 6(50%) patients, percutaneous access in the other 6(50%). Median procedure and fluoroscopy times were 191(18) and 28(13) minutes, respectively. The median iodinated contrast media administration was 126 (15) mL and in 10 (83%) cases CO2 automated angiography was used. Technical success was achieved in all cases and no patient died within 30 days. The median hospitalization was 5(1) days. There were no postoperative cardiac, pulmonary or neurological complication. There was one case of transient postoperative renal function worsening. No patient required

30-day readmission nor reintervention. The median follow-up was 18 (12) months with no cases of aortic or cardiac related mortality. One patient died on the 45th post-operative day due to COVID-19 infection.

Conclusions: Concomitant T/EVAR and TAVI is safe and effective with excellent technical success and satisfactory early and mid-term clinical outcomes. This combined approach may reduce the perioperative risks and costs compared with sequential procedures.

CHRONIC ORAL ANTICOAGULATION AND CONTEMPORARY OUTCOMES OF ELECTIVE ENDOVASCULAR AORTIC ANEURYSM REPAIR

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Introduction and Objective: Impact of chronic anticoagulation on endoleak risk after EVAR has been conflicting. Our aim was to assess how anticoagulation at time of EVAR can impact endoleak risk after EVAR.

Methods: A retrospective review of all patients submitted to elective EVAR for infra-renal abdominal aortic aneurysms from January 2018 to December 2021 was performed. Patients with isolated iliac aneurysms, complex repair (F/BEVAR) or presenting with rupture or symptomatic aneurysms were excluded. Patient demographics, procedural and post-operative outcomes were reviewed. Outcomes were defined according the SVS Reporting standards for endovascular aortic aneurysm repair. Primary endpoint was the impact of chronic anticoagulation type II EL after EVAR. Post-operative complications and reinterventions were also addressed. Survival analysis was preferred to compare endoleak occurrence among groups. Cox regression was performed to evaluate independent anticoagulation effect on type II EL occurrence.

Results: A total of 99 patients were identified, with 19 (19.2%) of these on chronic oral anticoagulation at time of EVAR. All anticoagulated patients were male and were older than non-anticoagulated patients (mean age 76.4 ±8.5 vs 71.4 ± 7.9, p=0.017). Patients on oral anticoagulation were more likely to have cardiac arrhythmia, with no other differences regarding baseline comorbidities. There were no differences in type of anaesthesia or intra-operative complications. Four patients on anticoagulation were submitted to an additional procedure in the first 30-day (21.1% vs 7.5%, p=0.096). Mean follow-up was 18,9 ± 15,25 months. During follow-up, a total of 10 patients developed type II endoleak (EL): four patients in the anticoagulation group (21,1%), vs 6 non-anticoagulated patients (7,5%), p=0.032). After adjustment for age and gender, anticoagulated patients were at greater risk for type II EL (HR: 8.92, CI95% 1.65-48.12, p=0,011). Three-year overall survival was worst for anticoagulated patients, 49,1% vs 87,7%, p<0.001 (Fig.1).

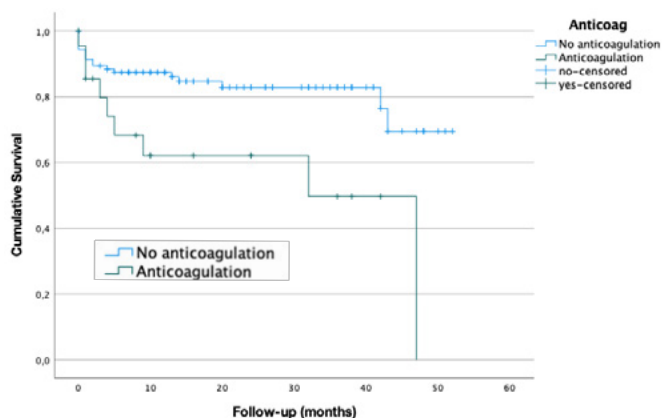


Fig. 1. Kaplan-Meier survival analysis of anticoagulated patients vs non-anticoagulated patients.

Conclusions: Chronic oral anticoagulation at time of EVAR might bring an increased risk in the development of type 2 endoleak, even after adjusting for age and gender, which did not translate in more reinterventions during follow-up. Survival of anticoagulated patients was worst, which may be related to the underlying cause for anticoagulation or to adverse events of this therapy.

OUTCOME OF CHIMNEY TECHNIQUE IN PATIENTS WITH PARARENAL ANEURYSM WITH MURAL AORTIC THROMBUS

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Introduction and Objective: Endovascular repair (EVAR) is currently the most used treatment option for abdominal aortic aneurysms. Chimney technique can be used to treat patients with urgent pararenal aortic aneurysm unfit for open surgery and not suitable for custom made fenestrated endograft due to production time. Since almost one in five patients undergo a reintervention within three years, features associated with higher risk of complications need to be investigated in order to tailor the follow-up schedule to each patient. The aim of our study was to assess the impact of mural thrombus in the pararenal aorta on perioperative and follow-up complications after Chimney Technique.

Methods: All consecutive patients undergoing Chimney Technique at our center from 2016 to 2022 were included in a retrospective study. Collected variables included number of target vessels, stentgraft size, presence and severity of mural thrombus in pararenal aorta, which was evaluated on pre-operative computed tomography angiography and reported with a scoring system from 0 to 10 based on thrombus type, thickness area and circumference. Outcomes included peri-operative and follow-up complications such as endoleaks, chimney stent complications (including partial or total thrombosis, intrastent stenosis, displacement), renal function worsening and mortality.

Results: A total of thirty-one patients underwent Chimney

Technique during the study period. Twenty-seven patients underwent Chimney technique for pararenal abdominal aneurysm instead four patients underwent ChEVAR for a type 1A endoleak after previous endovascular repair. The number of target vessels was 1 in 17 patients (55%), 2 in 12 (39%), 3 in 1 (3%) and 4 in 1 (3%). The mean mural thrombus score was 5.9. Complications were the following: type 1A endoleak in 4 cases (13%), chimney stent complications in 7 cases (23%), renal function worsening during follow-up in 8 cases (26%). Of those patients who had chimney stent complications, 2 patients had partial stent thrombosis, 1 patient had total stent thrombosis and 4 patients had stent displacement. Decline of the eGFR during the follow up was mild in 1 patient (89-60 ml/min/1,73 m²), moderate in 6 patients (59-30 ml/min/1,73 m²), severe in 1 patient (15-29 ml/min/1,73 m²). No one of our patients needed renal replacement therapy. Overall survival was 90% at two years. Patients with severe mural thrombus showed lower freedom from chimney-related complications (28% vs 59% at two years, p=0.023). No correlations have been found between number of target vessel and post-operative complications.

Conclusions: Our results show that the presence of severe pararenal aortic mural thrombus is associated with complications in patients undergoing Chimney Technique for pararenal aortic aneurysm repair with lower freedom from chimney related complications.

A NEW METHOD OF AORTIC TISSUE DECELLULARIZATION FOR SCAFFOLDS DEVELOPMENT

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Introduction and Objective. Decellularized biological scaffolds from vascular tissue can potentially replace artificial vascular conduits, which will help solve the issues of donor vessel shortage and the recipients' immune response. A variety of decellularization techniques have been described and used to achieve effective immunogenic agent removal from a developed vascular scaffold. Although several decellularized vascular grafts are currently on the market, clinical outcomes are still poor due to graft-associated thrombosis, infection, and aneurysm. Given the increasing number of cardiovascular procedures in the world it is necessary to improve existing grafts and look for new methods for scaffolds development.

Methods. Two human thoracic aortas were harvested from cadaveric material and decellularized with 1% formaldehyde and hexane pure for analysis. Hematoxylin-Eosin staining and Raman spectroscopy were used to confirm complete decellularization. The samples were made electron-conductive and were investigated with electron microscopy to evaluate the structure of the aortic grafts. For an *in vivo* experiment two grafts from human saphenous veins were decellularized

using the same protocol. Afterwards they were implanted in two Flemish Giant rabbits in the abdominal aorta position with “end-to-side” anastomoses. After surgeries the rabbits received food and water *ad libitum*. A grafts patency was assessed with contrast computer tomography (CT) and ultrasound method. A Doppler ultrasound was used to measure velocity characteristics of blood flow through the conduits. On days 14 and 28 grafts were harvested and embedded in paraffin. Hematoxylin-eosin staining and light microscopy were used to estimate cell repopulation of decellularized implants.

Results. Hematoxylin-eosin staining of the aortas after decellularization demonstrated a complete elimination of cell nuclei. Analysis of the Raman spectra revealed a decrease in the intensity peak specific for deoxyribonucleic acid (DNA) in the decellularized aortas. On the electron microscopic images preserved aortic extracellular matrix with elastic lamellae is observed. All animals survived after surgeries. CT and ultrasound showed good patency of the grafts without signs of stenosis and thrombosis. The mean peak systolic velocity in the first third of the conduits was 122 ± 13 cm/sec and the blood flow rate - 100 ± 3 ml/min. After the 14th and 28th days of implantation we observed cell recellularization of the decellularized extracellular matrix and the formation of neointima on the histological images. At the 14th day the infiltration of immune cells outside of the graft persisted and at the 25th day no prolonged inflammation was observed.

Conclusions. A new method of aortic implants decellularization with formaldehyde and hexane application makes it possible to achieve a complete elimination of cellular and nuclear contents. The small animal model demonstrated the adequate patency of the grafts, consistent cell repopulation of the extracellular matrix and absence of the hyperinflammatory immune response in a short-term period. Further investigations are required, like quantitative determination of residual DNA within the grafts after decellularization, immunohistochemistry for phenotyping of cells repopulating decellularized material after implantation.

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HIGH PREVALENCE OF THORACIC AORTIC DISEASE IN PATIENTS WITH CONTEMPORARY LUNG CANCER: AN OBSERVATIONAL STUDY.

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Introduction and Objective: Lung cancer and thoracic aortic disease, including aortic aneurysm and dissections, intramural hematoma and penetrating aortic ulcer (PAU), share multiple risk factors. This study aims to investigate the contemporary prevalence of these two conditions.

Methods: This was a single-centre, retrospective, observational study. All patients who underwent thoracic surgery for contemporary lung cancer between October 2019 and June 2021 were considered eligible to be part of this study. Demographic and risk factor data were obtained, and patients' tomography-computed angiography scans were used to investigate the whole aorta. Multilinear regression modeling was used to evaluate the independent associations of multiple variables on the presence of thoracic aortic disease.

Results: Among 264 patients who underwent thoracic surgery, only 148 had primary lung cancer. Of them, 62% were male and the mean age was 71 ± 8.7 . The main histotype was adenocarcinomas (70%), followed by squamous cell carcinoma (20%), small cell carcinoma (3%) and other types (7%). Smoker people were more than nonsmokers (79%). Of these patients, 27% have already undergone vascular surgery. Angio-CTs showed that ascending aorta medium diameter was $35 \text{mm} \pm 4.9 \text{mm}$, the arch medium diameter was $26 \text{mm} \pm 3.2 \text{mm}$ and the thoracic aorta medium diameter was $27 \text{mm} \pm 3.75 \text{mm}$. The prevalence of thoracic aorta aneurysm in the cohort was 12%, penetrating aortic ulcer was 10%, thoracic aortic dissection was 2% and intramural hematoma 1.35%.

Conclusions: In our experience lung cancer and thoracic aortic disease share similar risk factors and patients with lung cancer who approach surgery have a high rate of incidence of vascular diseases. In the future, a significant reduction of CT radiation exposure may be obtained by the simultaneous screening for both pathologies. Furthermore, it could allow an earlier diagnosis of thoracic aortic disease in populations of patients that are not routinely screened for, such as women.

RESULTS AFTER INNOMINATE ARTERY GRAFTING

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Introduction and Objective. Atherosclerotic lesion of the innominate artery (brachiocephalic trunk) in patients with cerebrovascular diseases occurs in 0.5-2% of cases and causes cerebral and upper limb ischemia. Today, most specialists perform innominate artery grafting for such lesions, which has proven to be an intervention providing long-term patency and

freedom from neurological deficits.

Objective: to evaluate the results of innominate artery grafting in atherosclerotic lesions.

Materials and Methods. The results of 79 intrathoracic reconstructions performed for hemodynamically significant atherosclerotic lesions of the brachiocephalic trunk at the A.V. Vishnevsky National Medical Research Center of Surgery were analyzed from 1983 to 2020. Long-term results were studied in 65 (82%) patients out of 79. The average follow-up was 143.4±33.1 months (about 12 years), maximum was 455 months (almost 38 years).

Results. In the majority of cases linear innominate artery grafting was performed - 52 (65,8%), in the remaining cases - multiple aortic arch branch grafting - 27 (34,2%). In the group of the multiple prosthetics of the aortic arch branches in 17 cases (21,5%) the main prosthesis was inserted into the brachiocephalic trunk or right common carotid artery with the side insertion into the left common carotid artery or right subclavian artery, in 10 cases (12,7%) bifurcation prosthesis was performed.

In hospital complications: thrombosis - 3 (3.8%), strokes (right hemisphere) in 3 (3.8%) cases, bleeding for which resternotomy was performed in 4 (5.1%) cases, mediastinitis - 6 (7.6%), myocardial infarction - 4 (5.1%), deaths in -3 (3.8%) cases. Patients with prosthesis thrombosis in the postoperative period were significantly more likely to develop stroke ($p=0.003$) and mediastinitis ($p=0.000$).

The survival rate at 5-year follow-up was 92%, 10-year follow-up was 78%, 15-year follow-up was 68%. The long-term patency at 5 years was 95%, at 10 years - 95%, at 15 years - 85%. Stroke freedom at 5 years was 88%, at 10 years - 72%, at 15 years - 60%. There were no statistically significant differences in the influence of the plastic material of the prosthesis (Dacron or PTFE) on the long-term patency. The development of prosthetic thrombosis was accompanied by the occurrence of neurological deficit in only one observation, and at no time did the stroke serve as a cause of death in the remote period.

Conclusion. Prosthetic replacement of the innominate artery has proved to be a safe and reliable technique providing long-term patency and freedom from neurological deficit in the practice of cardiovascular surgery.

INITIAL SINGLE-CENTER EXPERIENCE WITH NEW BIORESTORATIVE, POLYMER-BASED VASCULAR HEMODIALYSIS GRAFT

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Introduction and Objective: The aXess graft (Xeltis, Eindhoven, NL) is a new, biorestorative, polymer-based, electrospun graft used to create vascular access for hemodialysis (HD). Its porous structure allows it to naturally evolve into a living blood vessel when colonized by patient's own tissue. This process is

called Endogenous Tissue Restoration, or ETR, and has been widely characterized in pre-clinical models. Additionally, the graft includes a nitinol frame that provides kink resistance and vessel support in this highflow, high-pressure environment. The aXess graft is currently in a first-in-human clinical trial and we aim to present our single-center experience with it.

Methods: So far, we have enrolled 3 patients with end-stage renal disease. All patients have received a lower arm loop configuration, with the exception of one patient who had the out-flow anastomosis above the elbow. Follow-up visits have been performed according to aXess FIH protocol (NCT04898153).

Results: There were no intra-operative complications during all 3 procedures. Cumulative primary and secondary patency are 100%, with an average follow-up time of 5.8 months. In the patient with the graft crossing the elbow, the extra kink and crush resistance provided by the nitinol frame allowed for a straightforward and tension-free implant. Two of the patients haven't required dialysis yet. The patient who currently requires HD has completed approximately 60 successful HD sessions through the graft. Clinical surveillance demonstrates a palpable thrill across all the graft. Regular doppler ultrasound follow-up hasn't documented any imagiologic complications such as intimal hyperplasia or graft stenosis, and an increase in graft compliance can be observed over time, which can be explained by the ETR process.

Conclusions

The aXess HD graft is a promising device in the vascular access space. Initially implanted as a polymeric graft, aXess has the ability to transform itself into a living

vessel over time, potentially combining the advantages of arteriovenous fistulas and arteriovenous grafts.

FATE OF ILIAC ARTERIES AFTER OPEN REPAIR OF THE INFRARENAL AORTA WITH STRAIGHT TUBE-GRAFTS: A PROPENSITY MATCHED COMPARISON

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Introduction and Objectives: This study aims to evaluate the behaviour of iliac arteries (IAs) during follow-up after straight aortic tube-graft replacement of infrarenal abdominal aortic aneurysms (AAA), and to identify potential predictors for iliac aneurysmal evolution needing reintervention.

Methods: Data of patients who underwent AAA open repair with aorto-aortic straight graft reconstruction between January 2012 and December 2019 at a single Institution were retrospectively reviewed. Patients were included in the study if detailed pre-operative CT-scan images were available. Pre, intra and post-operative variables were tested for possible correlation with iliac aneurysmal evolution requiring reintervention during follow-up, using univariate and multivariate models. All screened IAs were divided in 2 groups according to their IAs pre-operative diameter: <18 mm (group A) or ≥18 mm (Group

B). Propensity score matching (PSM) was performed obtaining two homogeneous groups. Covariates included were: age, gender, hypertension, smoking habit, hyperlipidemia, and cardiac disease. Freedom from iliac reintervention was investigated in matched group A and B by Kaplan-Meier analysis.

Results: Two-hundred eighty-nine patients (261 males–90.3%; age: 72.0 ± 7.8 years) were included in the study, meaning that 578 IAs were analysed. Mean pre-operative diameter of common IA was 14.3 ± 4.3 mm. At a mean follow-up of 48.5 ± 28.1 months, 5 (1.7%) patients underwent an endovascular repair for aneurismal evolution of 6 common iliac arteries (CIAs): 5 aneurysms were treated with iliac-branch stent-grafts, and one with a standard stent-graft and concomitant occlusion of the internal iliac artery. The median time to reintervention was 35.4 (range 32.8 - 50.2) months. In subgroup analysis, 468 IAs (81%) were included in Group A, and 110 (19%) in Group B. Iliac arteries in group B were significantly more tortuous ($p < 0.001$, Pearson correlation: 0.175) and calcified ($p = 0.025$, Pearson correlation: 0.093). After PSM (1:1), 110 IAs per group were identified and tested for iliac related reintervention by using Kaplan-Meier analysis. Freedom from iliac reintervention at 5 years was 100% in Group A and 95,2% in Group B (log-rank test, $p = 0.043$).

Conclusions: Reintervention rate for iliac aneurysmal evolution after open straight tube-graft repair of AAA is generally low at mid-term follow up. Pre-operative iliac diameter ≥ 18 mm is associated with an increased risk of late reintervention. Careful follow-up in these patients should be considered.

OPTIMIZATION OF ENDOVASCULAR TREATMENT OF PATIENTS WITH ACUTE LOWER LIMB ISCHEMIA WITH COVID-19.

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Introduction: currently, in the context of the new COVID-19 coronavirus infection, endovascular methods are taking an increasing place in the treatment of acute arterial obstruction.

Objective: to analyze the results of catheter thromboaspiration in acute arterial obstruction of the popliteal-ankle segment in patients with COVID-19.

Materials and methods: the results of catheter thromboaspiration performed in 37 patients with acute arterial obstruction of the lower extremities, developed against the background of COVID-19, who were treated at the O.M. Filatov City Clinical Hospital No. 15 in the period from October 2021 to February 2022, were studied. Among the operated patients there were 26 men (70.3%) and 11 (29.7%) women. The average age of the patients was 69.8 ± 6.7 years.

Results: immediate angiographic success of catheter thromboaspiration was achieved in 28 cases (73.6%). Repeated interventions were not required in 13 patients (35.1%). Repeated operations for recurrent thrombosis of the arteries of the lower extremities were performed in 14 patients (37.8%) (in 13 cases for retrombosis of the native artery and in one case

due to stent thrombosis). Post-operative extensive hematomas were reported in two patients (5.4%). Amputation of the lower extremities was performed in 6 patients (16.2%). 14 patients (37.8%) had a fatal outcome.

Conclusions: catheter thromboaspiration can be used for acute arterial obstruction of the popliteal-ankle segment in patients with COVID-19.

3Y RESULTS OF ENDOVASCULAR PROCEDURES ON INFRAINGUINAL GLOBAL LIMB ANATOMICAL STAGING SYSTEM (GLASS) GRADE 3-4 PATIENTS IN A SINGLE-CENTER EXPERIENCE

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Introduction and Objective: The Global Vascular Guidelines aim the decision making in Chronic Limb-Threatening Ischemia (CLTI) by providing a framework for evidence-based revascularization (EBR). The Global Limb Anatomic Staging System (GLASS) estimates the extent and anatomical distribution of the infrainguinal obstructive lesions reflecting the type of surgical revascularization. Aim of the study is to report the long-term outcomes following endovascular procedures on infrainguinal GLASS grade 3-4 in patients deemed unfit for open bypass.

Methods: This is an observational, retrospective, single-center experience of a tertiary referral center. From January 2016 to January 2022, all patients with CLTI affected by infrainguinal disease were identified. Infrainguinal GLASS grade 3 and 4 cases were split in the group A and B with 71 and 80 patients, respectively. A comparison between the two groups was conducted for demographics and operative details. Immediate outcomes were defined by technical and hemodynamic success (ABI improvement). Early outcomes were evaluated at 30 days in terms of mortality, thrombosis, reintervention and amputation (minor and major). Late results were analyzed at 3 years in terms of overall and groups estimations and defined by survival (all-cause mortality), freedom from target lesion revascularization (ff-TLR), freedom from reintervention (ff-R), late lumen loss and freedom from minor or major amputation.

Results: Mean age was 71.2 ± 10.3 . No significant differences were observed in terms of Rutherford's clinical stage ($p = .332$). Groups were homogeneous for baseline characteristics apart from COPD ($p = .008$) and Diabetes ($p = 0.045$), represented mainly in the B and the A group, respectively. 128 (84.7%) balloon angioplasty and 23 (15.3%) stent implantation were performed. The groups differ for type of balloon angioplasty ($p = .019$), in fact B group underwent DEB angioplasty in most cases. Technical success was achieved in 135 (89.4%) cases and hemodynamical success showed an ABI significant improvement (pre-operative vs post-operative, 0.25 ± 0.17 vs 0.63 ± 0.34 , $p = .001$). Early results showed 3 (1.9%) deaths, 9

(5.9%) thromboses, 2 (1.3%) reinterventions, 5 (3.3%) minor and 5 (3.3%) major amputations. Groups did not differ significantly for early results. Mean age of follow up was 26 ± 10 months. Overall survival was 61% and estimations did not differ between the groups (log-rank .184, $p = .668$). Overall ff-TLR was 57.2% with no differences between the groups (log-rank 1.555, $p = .212$). Overall LLL was 70.1% and LLL was observed mainly in the B group, but data did not show significant differences (log-rank 3.456, $p = .063$). Overall ff-R was 53.4% without any differences between the groups (log-rank 1.866, $p = .195$). Overall freedom from amputation was 70.9% for major and 80.5% for minor. Minor amputation affected mainly A group (ff-amputation A vs B, 68.2% vs 90.3%, log-rank 5.156, $p = .023$). No differences were observed for major amputations in the two groups (log-rank 2.470, $p = .116$).

Conclusions: Long-term results of endovascular procedures reflected the new GLOBAL indications for surgery. No differences were found in terms of survival, late lumen loss, freedom from TLR and limb salvage rate, except for the minor amputation; this could be due to the higher prevalence of diabetes in the fem-pop group 3, in patients unfit for open bypass endovascular therapy could be an option with satisfactory results also in FP Grade 4 subjects.

ENDOVASCULAR TREATMENT OF THORACOABDOMINAL ANEURYSM RETROGRADE VS ANTEGRADE CANNULATION FOR BRANCHED ENDOVASCULAR AORTIC REPAIR: CASE CONTROL STUDY

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Introduction and Objective: An alternative approach to the antegrade branches using TFA compared with conventional UEA was introduced. The aim of our study was to evaluate branch-related outcomes of the TFA retrograde cannulation compared with the TAA antegrade cannulation.

Methods: From January 2015 to October 2022, 95 consecutive patients underwent F-B/EVAR. 32 patients underwent BEVAR for thoracoabdominal aortic aneurysm and 1 for dissection divided into two groups according to the TFA or TAA cannulation approach used. Early end points were technical success, time of intervention, fluoroscopy time, access and systemic complications. Branch instability was evaluated with Kaplan-Meier curves in the follow-up.

Results: The TFA group included 32 patients (median age, 74 years) Technical success was greater in the TFA group (100%) than in the UEA group (79%). The fluoroscopy time (median, 117 minutes; vs 122 minutes) and contrast agent volume were similar in both groups. The radiation exposure (median 448,6 vs 459,28) was lower and the operation time (median, 251 minutes vs 303 minutes) was shorter in the TFA group. Brachial access com-

plications and perioperative strokes/transient ischemic attacks occurred more in the UEA group.

Conclusion: Despite the limitations regarding the study design and limited population, our experience showed that a retrograde approach is safe and effective for branch cannulation during BEVAR by using steerable catheter, in both elective and urgent settings.

ANATOMICAL RECONSTRUCTION OF AORTIC BIFURCATION WITH ENDOLOGIX AFX UNIBODY STENT-GRAFT IN AORTO- ILIAC OBSTRUCTIVE DISEASE

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Introduction and Objective: Endologix AFX stent-graft is advocated for the endovascular aneurysm repair (EVAR) in infrarenal abdominal aortic aneurysm. The off-label adoption of the unimodular bifurcated part of the stent-graft (Unibody) may represent a tailored solution for anatomical reconstruction of aortic bifurcation especially in young patients affected by an aorto-iliac obstructive disease. Aim of our study was to evaluate the outcomes of endovascular reconstruction of aortic bifurcation with AFX Unibody in young patients affected by an obstructive arterial disease that involves the infrarenal aorta and the aortic bifurcation.

Methods: A retrospective review was conducted on 275 patients treated for aorto-ilio-femoral disease with endovascular or hybrid procedures from January 2016 to September 2022 at our department. We considered 31 patients (3 females, 9.7%) affected by infrarenal aortic obstructive lesions that underwent endovascular/hybrid (CFA endarterectomy) reconstruction of aortic bifurcation with AFX Unibody stent-graft. Obstructive lesions were classified with TASC II stages and Rutherford’s clinical categories identified the degree of peripheral arterial disease. Early results were analyzed in terms of 30-day thrombosis, amputation and death. Follow up results were analyzed by life-table analyses (Kaplan-Meier curves) in terms of 3-year primary and secondary graft patency, freedom from reintervention, amputation free survival and overall survival.

Results: Mean age was of 66.1 ± 8.8 years. Most of the lesions were TASC II D (25/31 – 80.6%) and Rutherford’s category 3 was predominant (20/31 – 64.5%). More than two-third of the cases were affected by an obstructive lesion of the aortic bifurcation (24/31 – 77.4%) and in the remaining cases the obstructions involved the infrarenal aorta below the level of renal arteries. Technical success (intention-to-treat analysis) was achieved in all the cases and no open surgical conversions were recorded. Surgical complications rate was 11.1% (3/27 cases) and no post-operative deaths were observed. Ankle-brachial index (ABI) improvement was significant (mean preoperative ABI – postoperative ABI, 0.42 – 0.83, $p = .0001$). One major amputation and thrombosis (iliac leg acute occlusion) were recorded at 30 days respectively and early survival

rate was 100%. The 90.3% (28/31) of the cases have an active follow-up and its mean age was 18.1 ± 12.9 months (Range 1 – 76 months). Estimated overall 3-year survival (all-cause mortality) was 71.3%. Estimated 3-year primary and secondary graft patency were 79.8% and 83.1% respectively. Estimated 3-year freedom from major amputation and freedom from reintervention were 100% and 96.4% respectively.

Conclusions: The off-labeled adoption of AFX Unibody stent-

graft in the anatomical endovascular reconstruction of aortic bifurcation for selected patients offered promising results in terms of effectiveness and safety. The reconstruction of the aortic bifurcation allowed surgeons to easily perform further up-and-over procedures especially in young patients with multilevel obstructive disease. Further studies are warranted to analyze the long-term advantages and the cost-effectiveness of the technique.