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Wulf Ito
Oliver Zimmermann
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4. DGA-Interventionskongress und 49. Jahrestagung

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Sehr geehrte Damen und Herren,

nach einer sehr erfolgreichen Tagung 2019 in Leipzig steht der 4. DGA-Interventionskongress und die 49. Jahrestagung der Deutschen Gesellschaft für Angiologie – Gesellschaft für Gefäßmedizin e. V. vor der Tür. Die beiden Kongresse finden dieses Mal – erneut gemeinsam – vom 10. September bis 12. September 2020 in Kempten/Allgäu unter dem Motto „100.000 Kilometer in unserer Verantwortung“ statt.

Dieses Motto verbildlicht die Breite unseres Fachs. Wir behandeln Erkrankungen der arteriellen und venösen Strombahn, der mikrovaskulären Gefäße und der Lymphbahnen. Diesen liegen wiederum vielfältige Ursachen zugrunde, von arteriosklerotischen/degenerativen Veränderungen oder prothrombotischen Zuständen bis zu angeborenen und erworbenen Gerinnungsstörungen, chronischen Entzündungen, (auto-)immunologischen Prozessen oder Gefäßmalformationen. Begleiterkrankungen haben einen direkten Einfluss auf Gefäße. Gefäßerkrankungen wiederum beeinflussen maßgeblich deren Prognose. Hier ist insbesondere der Diabetes mellitus zu nennen.

Die enge Zusammenarbeit mit anderen Fachgebieten ist deshalb aus Gründen der Diagnostik und Therapie unerlässlich und manifestiert sich während dieses Kongresses in einer Reihe wichtiger Beiträge. Dabei freuen wir uns insbesondere über die aktive Teilnahme der Österreichischen Gesellschaft für internistische Angiologie, der Schweizer Gesellschaft für Angiologie und der Deutschen Gesellschaft für Gefäßchirurgie.

In den letzten Jahren hat sich neben dem großen Spektrum an diagnostischen Verfahren das therapeutische Spektrum der Angiologie deutlich erweitert. Einen maßgeblichen Anteil hat daran die Entwicklung neuer interventioneller Verfahren. Konsequenterweise werden auch in Kempten im Rahmen des 4. Interventionskongresses mittels Direktübertragungen und Übertragung zuvor aufgenommener Interventionen aus dem Katheterlabor verschiedene perkutane Behandlungsansätze für Gefäßerkrankungen präsentiert. Diese Art der Präsentation erlaubt es, nicht nur technische Lösungsansätze „live“ näherzubringen, sondern ist auch für die Kongressteilnehmer in Bezug auf den Umgang

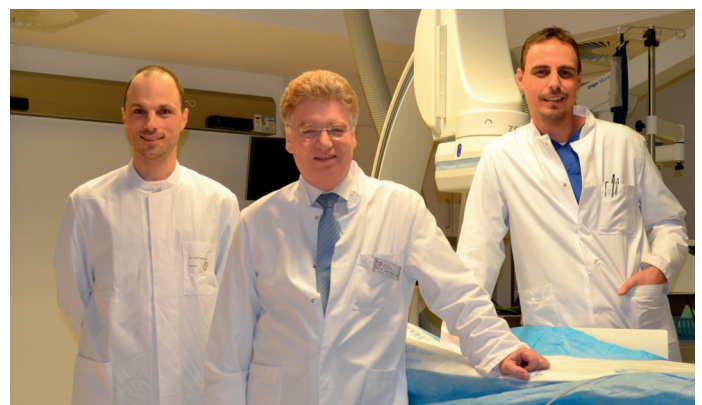
mit schwierigen Situationen sehr lehrreich. Letztendlich dienen sie auch der Vermittlung neuer Verfahren.

Neben der rasanten Entwicklung der interventionellen Angiologie hat u. a. die Einführung direkter Faktor Xa Inhibitoren, der DOAK und in letzter Zeit neuer Antidiabetika auch in der medikamentösen Behandlung von Gefäßerkrankungen ein neues Zeitalter eingeläutet. Spannende Fortschritte gibt es auch in der regenerativen Medizin. Wir wollen diesen Entwicklungen Rechnung tragen, indem wir neue Behandlungsstrategien auch konträr diskutieren sowie aktuelle Studienergebnisse präsentieren und in Bezug auf ihre Praxisrelevanz beleuchten.

Die DGA Jahrestagung wird seit jeher auch geschätzt als Weiterbildungskongress. Neben den oben bereits erwähnten „Live“-Präsentationen wird dies unterstrichen durch Informationen zu aktuellen Leitlinien, eine Reihe von praxisnahen Workshops, Falldiskussionen, der strukturierten angiologischen Fortbildung und Sonographiekurse.

Es freut uns, dass sich auch dieses Jahr die „Jungen Angiologen“ in vielfältiger Weise inhaltlich in den Kongress einbringen. So organisieren sie die „Hotline-Session“, eine Session „Angiologie meets Dr. House“, zwei Sessions für den Interventionskongress, eine Session für den Jahreskongress und zwei Interventionsworkshops. Sie demonstrieren damit noch einmal die Vitalität und Zukunftsträchtigkeit unseres Faches auf eindruckliche Weise.

Prof. Dr. W.D. Ito



(v.l.n.r.): Dr. med. Bastian Wein, Prof. Dr. med. Wulf Ito, Prof. Dr. med. Oliver Zimmermann)

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DGA Jahrestagung 2020 – Abstracts

100.000 Kilometer in unsere Richtung

Strukturierte Angiologische Fortbildung I

A-124

Prevalence and specialize ambulatory care of peripheral vascular diseases in Germany

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Background

Cardiovascular diseases are the leading causes of death in the industrialized world. In addition to coronary heart disease, PAD defines morbidity and is associated with increased mortality. Guideline-recommended therapy and specialized ambulatory care is essential for optimal treatment. Knowledge of the treatment structures, contact with dedicated specialists and pharmacotherapy in the outpatient area are essential for improving treatment, reducing symptoms and finally improve mortality in this high-risk population.

Methods

The study is based on the ambulatory claims data of the panel doctors services according to § 295 SGB V and drug prescription data according to § 300 SGB V. The prevalence of PAD in Germany (medical diagnoses of PAD ICD I70.2-9) was analysed by age and gender-specific characteristics with a timeframe of 10 years (2009–2018). In addition, the current ambulatory care structure was examined subdivided by vascular specialist (vascular surgeons and angiologists) or internal medicine physician. Additionally, the prescription of guideline-recommended pharmacotherapy like statins and antiplatelet inhibitors was analysed for the years 2012–2016.

Results

In 2018, overall 2.280.000 patients were diagnosed with PAD in Germany. The rise of PAD incidence strongly correlates with increased age (age group 50–59: 243.000, age group 60–69: 533.000, age group 70–79: 735.000, age group 75–79: 438.000, age group 80–89: 710.000) and more commonly affects males (55%) than females (45%). Access to specialized health care is low for all age groups: only 11% of patients receive care from vascular surgeons and only 9% from angiologists. However, almost every patient has access to a primary care physician 99%.

The data from the current analysis period indicates insufficient prescription of lipid-lowering drugs and platelet aggregation inhibitors, with only 51% ± 2% of patients receiving statins and 29% ± 0% receiving anti platelet medication.

Conclusions

There are relevant differences in age and gender-specific prevalence of peripheral vascular diseases (PAD) in Germany. In addition to the regular care provided by primary care physicians, PAD patients require frequent access to vascular specialists. Furthermore, more attention should be paid to the frequency of guideline-recommended prescriptions. Indeed, there is a considerable need to improve the treatment algorithm of high-risk PAD patients.

Strukturierte Angiologische Fortbildung II

A-144

Prevalence of peripheral artery disease in patients with interstitial lung disease

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Background

Interstitial lung diseases (ILD) are a heterogeneous group of severe parenchymal lung disorders accompanied by substantially decreased life expectancy. Possible causes of ILD are, amongst others, pulmonary sarcoidosis, and rheumatic diseases. Often, no underlying disease can be identified. Of those, idiopathic pulmonary fibrosis (IPF) is most common. Pathogenesis, especially of IPF, is poorly understood up to now and, likewise, are accompanying comorbidities. An associational factor of all ILDs, however, is inflammation. Deductively, it can be assumed, that inflammation in ILD not exclusively affects the lung but comes along with systemic manifestations. This study currently investigates prevalence of peripheral artery disease (PAD) and cardiac disease in patients with ILD. Presented data focuses on prevalence of PAD in patients with ILD attributed to stage IV sarcoidosis (S-IV-ILD), rheumatic diseases (RD-ILD), or IPF.

Methods

A total number of 56 consecutive patients (39% female) with diagnosed ILD (S-IV-ILD: n = 16; RD-ILD: n = 20; IPF: n = 20) were included at the time of analysis. Mean age was 64.2 ± 12.4 years. Mean body mass index was 26.8 ± 5.4 kg/m², mean smoked packyears were stated 13.1 ± 19.1. All patients underwent measurement of ankle-brachial-index (ABI) and colour coded duplex sonography of extracranial brain-supplying arteries and arteries of lower extremities, more precisely, common femoral artery, femoral artery, deep femoral artery, and popliteal artery.

Results

In total, 84% of patients with ILD presented with cerebrovascular artery disease (cPAD) and 85% suffered from PAD. Itemised by underlying diagnosis cPAD was found in 69% of patients with stage IV sarcoidosis, in 79% of patients with rheumatic diseases and ILD, and in 100% of patients with IPF. PAD was detected in 75% of patients with stage IV sarcoidosis, in 84% of patients with rheumatic diseases and ILD, and in 95% of patients with IPF. Interestingly, mean ABI ranged within reference (0.9–1.4).

Conclusions

According to acquired data, patients with ILD frequently suffer from PAD and cPAD. This correlation was most distinct in patients with IPF. The frequency of PAD and cPAD in ILD is much higher compared to average even though investigated sample mainly consisted of elderly men with history of smoking.

Interestingly, connection between sarcoidosis and rheumatic diseases respectively, and PAD mediated by systemic inflammation is commonly acknowledged, whereas, to our knowledge, prevalence of PAD in IPF has never been described on basis of a large, consecutive sample. Present results suggest that ILD-centred care should involve angiologic diagnostics and, if necessary, medicinal secondary prevention.

PRESTIGE Pilot – Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

A-106

PRESTIGE Pilot – Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

M. Lichtenberg

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Background

The purpose of this single-arm, exploratory, pilot study is to investigate if a lesion preparation strategy with Phoenix atherectomy before DCB usage in patients with PAD Rutherford Stage 4–5 and mild/moderate/severe calcium can improve outcomes including patency and limb salvage and evaluate safety and performance of the combination therapy.

Methods

Prospective, single-arm, multi-centre study with follow-up investigations at 30 days (phone-call or onsite visit), 6 months, 12 months and 24 months. Up to 75 subjects will be enrolled in up to 5 centres in Germany. Core lab adjudication for measures include acute imaging (angiography and IVUS) as well as duplex ultrasound at follow-up.

Results

First time presentation of clinical and technical endpoints to be shown:

Primary Efficacy Endpoint: Patency at 6 months. Patency defined as freedom from occluded target lesions (flow) verified by duplex ultrasound without re-Intervention

Primary Safety Endpoint: Composite Safety: Freedom from BTK major adverse limb events (MALE) and/or perioperative death (POD) at 30-days.

Conclusions

IVUS guided atherectomy followed by DCB angioplasty is a novel endovascular therapy strategy for critical limb ischemia patients with below the knee artery disease proving high safety and efficacy.

Methods

Consecutive patients who underwent endovascular revascularization for symptomatic peripheral artery disease and experienced dissections requiring treatment, were included in the prospective, single-center, single-arm study. Dissections were treated either by means of the 6F ATK (above the knee) or the 4F BTK (below the knee) Tack Endovascular System.

Results

total of 51 patients with 51 lesions and 63 dissections were treated between January and June 2019. Lesions were revascularized with 2.3 ± 0.8 attempts such as standard balloon angioplasty, drug-coated balloon angioplasty, atherectomy, and lithotripsy. Most lesions (76.5%) were ≥ 10 cm in length, 64.7% were totally occluded, and 25.5% severely calcified. Fifty-six dissections (88.9%) were classified as severe. The Endovascular System was applied in 60 of 63 dissections (95.2%). All dissections of the femoral artery were treated with the ATK system, and all infrapopliteal dissections with the BTK system. Both systems were successfully applied in popliteal artery dissections. Dissection length predicted the number of Tack implants deployed. Technical success was achieved in 98.3% (59 of 60 dissections). No major adverse event or device related complication occurred upon completion of the procedure.

Conclusions

Acute results in effectiveness and safety of the Tack Endovascular System for infrainguinal dissection repair in a real-world setting are promising.

Strukturierte Angiologische Fortbildung III

A-112

XATOA: Baseline results of the German subpopulation, rationale and design of a prospective registry to assess real life use of rivaroxaban 2.5 mg twice daily plus ASA in patients with CAD or PAD

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Background

The phase III COMPASS trial demonstrated that treatment with rivaroxaban vascular dose 2.5 mg twice daily plus ASA (dual pathway inhibition [DPI] regimen) significantly reduced the risk of major adverse cardiovascular events (including peripheral ischemic events) as well as overall mortality versus ASS alone. Bleeding rates were low, and while major bleeding was increased there was no significant increase in bleeding events with irreversible consequences like ICH, critical organ bleed or fatal bleeding, versus ASA alone in patients with CAD, PAD, or both. The results of the COMPASS trial supported the regulatory approval of the DPI regimen in several geographic regions. However, it is unclear whether the patients selected for treatment with the DPI regimen in clinical practice will have a similar risk profile and event rates compared with the COMPASS trial population.

Session IV: Wie entkommen wir hohen Radialkräften und Stentbrüchen: Einsatzgebiet und Studienergebnisse von „Dissektion Repair Devices“

A-105

Practical Applications of Tack Implants for Infrainguinal Dissection Repair – a Single Center Experience

M. Lichtenberg

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Background

This study aimed to assess the practical application and acute outcomes of the Tack Endovascular System for infrainguinal dissection repair in a real-world setting.

Methods

The post-approval XATOA registry is an international, multi-center, prospective, single-arm study conducted in 22 countries around the world. XATOA aims to assess treatment patterns, as well as ischemic and bleeding outcomes in patients with CAD, PAD, or both, who receive DPI therapy in routine clinical practice. Up to 10,000 patients from at least 400 centers will be enrolled and all treatment will be at the discretion of the prescribing physician. The primary outcome will be to describe treatment patterns in patients with CAD, PAD, or both receiving rivaroxaban 2.5 mg bid plus ASA. Secondary outcomes include MACE, MALE, thromboembolic events, hemorrhagic events, and mortality, as well as procedures and hospitalization. Consenting patients aged ≥ 18 years with a diagnosis of CAD, PAD, or both receiving rivaroxaban 2.5 mg bid plus ASA within 4 weeks before study enrolment will be included. The follow-up period will be a minimum of 12 months from enrolment up to an expected maximum of 30 months, and follow-up visits will occur during routine practice but are anticipated at ~1, 3, 6 months, and then at 6-monthly intervals thereafter.

Results

Enrolment started in November 2018 and 4407 patients have been enrolled up to 6 March 2020 globally. 2600 patients are planned to be enrolled in a maximum of 175 centers in Germany and 2271 patients have been recruited up to March 2020. Of the overall enrolled patient 42.0% had PAD only, 45.1% had PAD and CAD and 28.2% had CAD only. Baseline Characteristic for the German sub population will be available.

Conclusions

The XATOA prospective registry will expand our knowledge of how rivaroxaban is prescribed in everyday practice and whether evidence from clinical trials can be translated to the broader cross-section of patients in the real world. Valuable insights about patient characteristic will be provided in patients with chronic CAD, PAD, or both in routine clinical practice in Germany. The study has been registered at www.clinicaltrials.gov (NCT03746275).

integrated into a stepwise diagnostic algorithm together with CRP-values (cut-off: > 2.5 mg/dl) and results of high-resolution compression sonography (hrTCS) of the temporal arteries (cut-off: wall thickness > 0.7 mm).

Results

The final clinical model consisted of 4 clinical variables (age > 70 , headache, jaw claudication, anterior ischemic optic neuropathy) and dichotomized patients in those with low clinical probability (score 0 or 1 points) and those with non-low clinical probability (score > 2 points). The diagnostic accuracy of the model for discrimination of patients with and without a final clinical diagnosis of cGCA was excellent in both the derivation cohort (AUC 0.96) and in the validation cohort (AUC 0.92). When integrated into the stepwise diagnostic algorithm (hrTCS in all patients with high clinical probability, hrTCS in patients with low-clinical probability only when CRP > 2.5 mg/dl), the positive predictive value of hrTCS improved substantially. Within the algorithm, 32.8% of patients in the derivation cohort and 49.1% in the validation cohort would not have been tested by sonographic imaging (low clinical probability with a score < 2 , CRP < 2.5 mg/dl). None of these patients had a final diagnosis of cGCA.

Conclusions

We propose a simple clinical prediction rule which, integrated into a stepwise algorithm, exactly discriminates patients with cGCA from those patients with alternative diagnoses. Prospective validation of the diagnostic algorithm is indicated.

Update angiologische Grundlagenforschung und Stammzelltherapie – from bench to bedside (Sitzung der Sektion Vaskuläre Biologie)

A-140

Insufficient target level achievement of low-density lipoprotein cholesterol despite increasingly high intensity statin use in patients with peripheral artery disease

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Background

Lowering low-density lipoprotein cholesterol (LDL-C) by use of lipid lowering agents such as statins is a key secondary therapeutic measure in patients with peripheral arterial disease (PAD). The 2019 ESC/EAS (European Society of Cardiology/European Atherosclerosis Society) guidelines for the management of dyslipidaemia recommend LDL-C levels of < 55 mg/dl for very high-risk subset such as PAD patients. We aimed to assess the trend of statin use over time and the fraction achieving the recommended target level in PAD patients.

Methods

This study comprises a total of 303 patients who were admitted for endovascular revascularization in three waves (2015/16 n=103, 2018 n=100 and 2020 n=100). Lipid-lowering medication including statins as well as cholesterol absorption inhibitors were documented. Lipid assessment including total serum cholesterol, triglycerides, high-density lipoprotein cholesterol (HDL-C) and LDL-C were analysed. For evaluation of lipid lowering therapy, patients were divided into 4 LDL-C-groups (LDL-C < 55 mg/dl, 55–69 mg/dl, 70–99 mg/dl and ≥ 100 mg/dl, respectively).

Ask the Expert – Vaskulitis, vaskuläre Malformation und funktionelle Gefäßerkrankungen

A-142

A diagnostic algorithm based on a simple clinical prediction rule for the diagnosis of giant cell arteritis

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Background

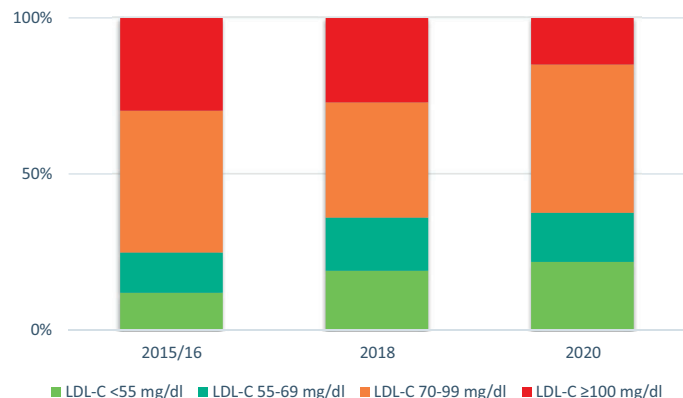
To establish a clinical prediction rule and a stepwise diagnostic algorithm for the rational diagnostic workup of suspected cranial GCA (cGCA).

Methods

Candidate items were derived from a literature review and from logistic regression analysis of a previously published cohort of patients with suspected cGCA (n = 87, 26 patients with a final diagnosis of cGCA). The clinical items were composed to a clinical prediction rule. The diagnostic accuracy of this prediction rule was tested in the derivation cohort and in an independent validation cohort (n = 114, 30 patients with cGCA) by receiver operator characteristics (ROC)-analysis. The model was

Results

Of 303 patients the mean age was 69 years, 71 % were male. The proportion of patients not on lipid lowering medication at admission was 12,5 %. Over the past 5 years the use of high intensity statins increased continuously (atorvastatin 28% (2015/16), 48% (2018) and 54 % (2020); rosuvastatin 0%, 1% and 8% respectively), whereas the rate of simvastatin use decreased from 59% to 30% and 27% in the same time intervals. The application of cholesterol absorption inhibitor ezetrol increased from 1% (2015/16) over 16% in 2018 to 30% in 2020. Mean LDL-C values diminished from 91±33 mg/dl in 2015/16, 87±37 mg/dl in 2018 and 79±34 mg/dl in 2020. The proportion of patients reaching recent guideline-recommended LDL-C target levels (<55 mg/dl) was 22%. The distribution of the 4 different LDL-C groups and the trend over time is illustrated in the figure.



LDL-C target level achievement in 5 years in PAD patients

Conclusions

Despite the increase in use of lipid lowering medication for secondary prevention in PAD patients, the fraction of patients achieving the guideline-recommended target levels of LDL-C is still less than a quarter of this high-risk population. Increasing the guidelines-adherence, not only in terms of statin use but also of the recommended target levels may lower the high cardiovascular risk in PAD patients.

A-139

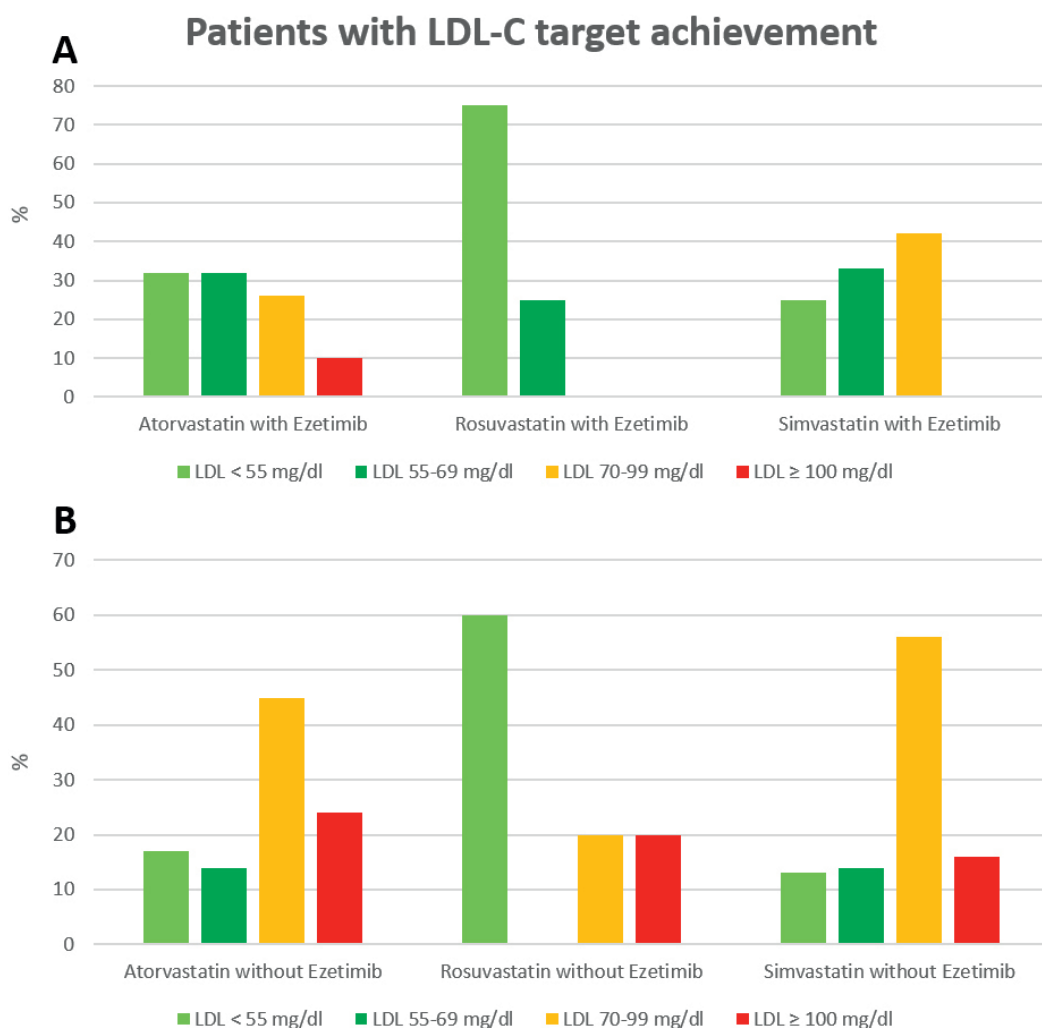
Impact of different statins on low-density lipoprotein cholesterol levels in patients with peripheral artery disease

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Background

Patients with peripheral arterial disease (PAD) are at high risk of cardiovascular events and limb threatening complications. According to the 2019 ESC/EAS (European Society of Cardiology/European Atherosclerosis Society) guidelines for the management of dyslipidaemia high intensity statins and ezetimibe are recommended for low-density lipoprotein cholesterol control (LDL-C). We assessed the impact of different types of statins on the lipid profile of patients with PAD and its effect on LDL-C target level achievement.



Methods

This study comprises a total of 256 consecutive PAD patients admitted for endovascular revascularization between 2015 and 2020 who were on lipid lowering medication at time of admission. Simvastatin, atorvastatin and rosuvastatin as well as cholesterol absorption inhibitor ezetimibe were documented and their effect on LDL-C target level achievement was investigated. Patients were divided into 4 LDL-C-groups (LDL-C <55 mg/dl, 55–69 mg/dl, 70–99 mg/dl and ≥100 mg/dl, respectively).

Results

The proportion of patients achieving target LDL-C level < 55 mg/dl was 13% in the group with simvastatin, 17% with atorvastatin and 60% with rosuvastatin use. In patients with intake of ezetimibe additional to statins the rate of target level achievement was 25% in simvastatin, 32% in atorvastatin and 75% in the rosuvastatin group, respectively.

Conclusions

LDL-C target level achievement in PAD patients is more frequent with use of high intensity statins (rosuvastatin and atorvastatin). Combination therapy with cholesterol absorption inhibitor ezetimibe enhances target level achievement. Whether the higher rates of target levels results in reduced rates of clinical events in PAD patients has to be proven in prospective studies.

Stellenwert der Farbduplexsonographie bei iatrogenen Komplikationen und der Diagnostik angeborener Vaskulopathien (Case Reports) (Sitzung der Sektion Ultraschall)

A-143

Transocular sonography in acute arterial occlusions of the eye in elderly patients: diagnostic value of the white spot sign

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Background

To establish the diagnostic yield of the sonographic white spot sign in elderly patients suffering from acute arterial occlusions of the eye(s).

Methods

Consecutive patients aged > 50 years with acute central retinal artery occlusion (CRAO), branch retinal artery occlusion (BRAO) or anterior ischemic optic neuropathy (AION) diagnosed between 01/2016 and 12/2019 were included. Clinical characteristics were assessed and videos of transocular B-mode sonography, performed with an 8 MHz linear transducer, were reviewed for the presence of the WSS. Group comparisons were made between CRAO-patients with and without the WSS.

Results

A total of 123 patients were included, 46 of whom had evidence of a CRAO. A positive WSS was seen in 32 patients with CRAO and in 7 patients with BRAO. The WSS was not found in any of the three patients with arteritic CRAO secondary to cranial giant cell arteritis (cGCA). In patients with CRAO, those without the WSS were significantly more commonly active smokers (35.7 vs. 6.3%, p = 0.02) and more frequently had evidence of a persistent foramen ovale (PFO) by transesophageal echocardiography (83 vs. 11%, p = 0.01). On the contrary, patients with the WSS significantly more frequently had a medical history of cardiovascular disease (62.8 vs. 21.4%, p = 0.03) and left heart valve pathologies by echocardiography

(51.9 vs. 10%, p = 0.03). Interobserver agreement for the sonographic detection of the WSS was excellent (kappa 0.98).

Conclusions

Beyond the excellent negative predictive value for exclusion of cGCA, the WSS is useful in guiding the diagnostic workup in patients with CRAO.

Freie Vorträge Intervention I

A-134

Chronic postthrombotic syndrome following proximal deep-vein thrombosis – effects of interventional therapy

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Background

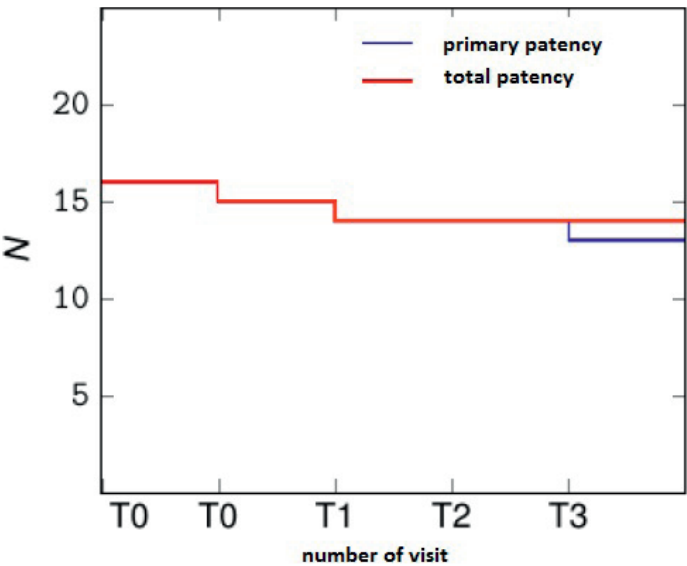
Chronic postthrombotic syndrome (PTS) remains the major complication after proximal deep-vein thrombosis (DVT) leading to chronic limb pain, swelling, venous claudication or leg ulcers. Standard therapy of acute DVT is immediate therapeutic anticoagulation and compression therapy, which, in case of chronic proximal vein occlusion, is associated with a high risk for developing symptomatic PTS. In patients with severe PTS interventional therapy can be discussed on an individual basis for relief of symptoms especially in case of May-Thurner-anatomy with insufficient collateralisation.

Methods

In the present all-comer study we retrospectively analysed 18 patients with symptomatic PTS after chronic proximal deep-vein thrombosis who underwent revascularization of occluded iliac veins with or without stent implantation at the University Hospital Ulm between October 2011 and September 2017.

Results

Median age was 45.5 years, 55.6% (10/18) patients were female. In 3/18 (16.7%) May-Thurner anatomy has been identified as the most presumable



Primary and total patency of the iliac vein after interventional therapy. T0: day after interventional therapy; T1: after one month; T2: after three months; T3: after six months.

cause of DVT. Additionally, patients with cancer compression or other causes of DVT were included in the study. Oral anticoagulant therapy and compression stockings were used for at least six months after revascularization. Patient selection included Duplex ultrasound examination, MR-venography, venous congestion plethysmography, Villalta Score and treadmill ergometry to assess venous claudication.

Using ultrasound examination primary and secondary patency of the iliac veins were 13/16 (81.3%) and 14/16 (87.6%), respectively. Symptoms decreased from 100% at baseline after one (83.3%), three (66.7%) and six (53.8%) months. Patients reported less symptoms as well as relief in severity of symptoms.

Conclusions

In this all-comer study of patients with highly symptomatic PTS after proximal DVT interventional therapy in the chronic state lead to a substantial relief of symptoms and reduction of reported symptoms as well. Thus, in these patients recanalization of chronic occluded iliac veins should be considered as an effective therapy on an individual basis to relief symptoms.

A-146

Safety and efficacy of routine day case angioplasty

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Background

Peripheral artery disease is a growing medical need worldwide. Urgently indicated revascularization may be delayed due to restricted availability of hospital beds (or perceived necessity for surgery cover on site). Day case angioplasty may be a safe and effective means of meeting the growing and urgent demand for timely angioplasty.

Methods

To evaluate the safety and efficacy of day-case angioplasty in a UK spoke vascular service we retrospectively analysed all patients undergoing endovascular revascularization August 2018–March 2020 at East Surrey Hospital, Redhill, UK. We compared patient and procedural characteristics, technical success, peri-procedural complications, and reimbursement of angioplasties performed in patients as (a) day cases, (b) overnight stay, (c) planned hospitalization for combined intervention, or (d) already hospitalized patients.

Results

A total of 138 patients (age 75±12 years; 60% diabetes mellitus) underwent endovascular arterial procedures (92% critical limb ischemia; baseline ankle brachial pressure index [ABPI] 0.39±0.29). A total of n=63 (45%) were treated as planned day-cases and n=21 (15%) required overnight admission due to them living alone without a person to stay with them. Within the treated in-patients n=15 (11%) were planned admissions combined with other procedures (e.g. minor amputations or debridements) and n=39 (28%) were patients hospitalized following emergency department admissions. Overall the technical success was 92%, ABPI increased by 0.29±0.24, all patients received vascular occlusion devices, and there were no major peri-procedural complications. One minor access site related bleeding (0.7%) occurred during a day case procedure requiring 24 h observation in hospital. The mean length of stay of in-patients was 25±25 and 54±27 days, respectively and the income for day-case and over-night angioplasty was significantly lower as compared to in-patients.

Conclusions

Day case angioplasty allows safe and effective treatment even for patients with critical limb ischemia and complex multi-level procedures that may reduce burden on healthcare system.

A-104

Venovo venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions: short-term results from the Arnsberg venous registry

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Background

We sought to determine the patency and clinical symptom relief of the Venovo venous stent in the endovascular treatment of non-thrombotic (NIVL) or post-thrombotic venous obstruction (PTO) of the iliofemoral track over a period of 36 months

Methods

A total of 80 patients (45 female, mean age 57 years) treated in 2016 and 2017 were included in the Arnsberg venous registry. Clinical improvement was determined by the revised venous clinical severity score (rVCSS) as well as the clinical, etiologic, anatomic and pathophysiologic (CEAP) score. Primary and secondary stent patency was evaluated using duplex ultrasound.

Results

Overall 36-months patency rates were 98% for primary and 100% for secondary patency. For NIVL primary patency was 97%, whereas for PTO primary patency was 96%. Clinical improvement with a gain of ≥2 rVCSS levels was observed in 51%. CEAP scores decreased from 4.3 to 2.7.

Conclusions

In this first time registry report the novel Venovo venous stent showed adequate patency rates associated with reasonable clinical improvement and low device-related complications throughout a 36-months-follow-up in both NIVL and PTO

A-138

Demographic and Procedural Characteristics in the REcording COurses of vascular Diseases (RECCORD) Registry – the first 1000 patients

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Background

The REcording COurses of vascular Diseases (RECCORD) registry established by the German Society of Angiology – Society for Vascular Medicine (DGA) aimed to address the lack in contemporary real-world data regarding current practice of medical and interventional care in vascular patients. We herein report the demographic and procedural characteristics of the first 1000 patients undergoing endovascular revascularization (EVR) for symptomatic peripheral artery disease (PAD).

Methods

RECCORD is an observational, prospective, multicenter, all-comers registry. Only patients undergoing EVR for symptomatic PAD are included and followed up for at least 1 year. Demographic characteristics, comorbidities, previous peripheral vascular interventions, medication, clinical stage of lower extremity artery disease (Rutherford category), hemodynamic parameters, and procedural data including complications are recorded via an entirely web-based platform.

Results

Of the first 1000 patients (mean age 70 ± 10 years, 35% female) with 1096 EVR at 1477 vascular segments of the lower extremities, 25.0% were at the stage of chronic limb threatening ischemia (CLTI) and 75.0% at non-CLTI. The femoropopliteal segment was the dominant target lesion site (61.0%), followed by iliac (26.4%) and below-the-knee EVR (10.3%). Only angioplasty was performed in 130 EVR (11.9%), adjunctive drug coated balloons (DCB) in 498 (45.4%), additional stenting in 633 (57.8%). Debulking devices were used in 106 (9.7%) EVR. Clinical (Rutherford categories) and hemodynamic parameters (ankle-brachial-index) as well as secondary preventive medication were significantly improved post EVR. Periprocedural complications occurred in 63 (5.7%) EVR with pseudoaneurysm as the leading complication type in 26 (2.4%) EVR.

Conclusions

The baseline data of the first 1000 patients from the RECCORD registry representing the real-world setting illustrate that the majority of EVR are performed in patients with claudication. Adjunctive use of DCB and stenting are the dominant types of EVR, while periprocedural complications are at an acceptable low rate.

A-132

Venovo venous stent for treatment of non-thrombotic or post-thrombotic iliac vein lesions – long-term efficacy and safety results from the Arnsberg venous registry

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Background

Endovascular venous stenting with dedicated venous stents for the treatment of chronic venous outflow obstruction is developing as efficacious alternative to conservative therapy or open surgery. However, so far, mid- and long-term evidence on effectiveness and safety is poor.

Methods

The prospective, single-center, observational study enrolled consecutive patients with chronic non-thrombotic iliac vein lesions (NVIL) or post-thrombotic iliofemoral obstructions (PTO). From February 2016 to April 2017, patients underwent implantation of open cell, self-expandable dedicated venous stents. Short-term symptomatic improvement, patency, and complication rate were favorable. Evaluation at 2-years included improvement in the revised venous clinical severity score (rVCCS), patency, stent migration, major target limb events, clinically important pulmonary embolism, major bleeding, and all-cause mortality

Results

A total of 79 patients (57 ± 16 years, 44 female) were evaluated. At 2 years, rVCCS improved by 4.3 ± 2.7 ($p < 0.001$). Substantial clinical improvement of ≥ 2 score points was achieved in 86.4% (38 of 44) of patients. Improvement was not associated with thrombotic pathogenesis (regression coefficient [B] with PTO = 0.6 [95%CI: -1.1 to 2.3], $p = 0.48$). At 2 years, all ulcers (in 6 of 79 patients) were healed and none occurred. Two-year primary patency was 95.5% (95%CI: 86.5 to 98.5) with no difference between NVIL- and PTO-patients (log-rank $p = 0.83$). Target vessel revascularization was conducted in two PTO- and one NVIL-patients in the period of 34 days to 156 days from index procedure, resulting in a secondary patency of 100%. No stent migration, target limb deep vein thrombosis, major amputation, pulmonary embolism, or death occurred.

Conclusions

Venovo venous open cell self-expanding stent implantation for chronic outflow obstruction was efficacious and provided a sufficient level of safety throughout 2 years.

A-145

Lithotripsy as a reliable interventional method for un- or hardly treatable lesions

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Background

We have treated severely calcified lesions in mostly common femoral artery (CFA) and popliteal artery with intravascular lithotripsy (IVL – ShockWave) and evaluated the safety and the success of this method.

Methods

We have performed 14 endovascular interventions, including IVL in massive calcified lesions (mean age 76.2 ± 6.1 years, 7 men). The lesions included external iliac artery ($n = 2$), CFA ($n = 7$), superficial femoral artery ($n = 6$), deep femoral artery ($n = 4$), popliteal artery ($n = 5$), subclavian artery ($n = 1$).

We have used the peripheral intravascular lithotripsy system – ShockWave – with the balloons from 3.5 mm to 6.5 mm in diameter and 60 mm length.

Results

The primary study outcomes included the ability to deliver IVL to the target lesion (100%), the acute gain in percent stenosis (from 85% to 23.2%), the need for provisional stenting (6 lesions from 25 totally), and angiographically defined complications (4 dissections). There was no perforation, distal embolization, thrombus or abrupt closure of the vessel.

Conclusions

Our results indicate that calcified, stenotic lesions which are traditionally treated operatively because of their location or severe calcification can be safely and successfully treated using the lithotripsy system. This method allows also an alternative for the patients who cannot be operated or increases the success of balloon dilatation and helps to prepare the lesions for stents for a better outcome.

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Session XIV – Immer noch Kontrovers – Venöse Interventionen! Indikationen und Einsatz

A-135

Acute proximal deep-vein thrombosis – effects of early interventional therapy

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Background

In proximal acute deep-vein thrombosis early diagnosis and therapy is essential to avoid

complications like pulmonary artery embolism and chronic postthrombotic syndrome (PTS). Standard therapy of acute DVT is immediate therapeutic anticoagulation and compression therapy. However, proximal DVT is still associated with a high risk for developing symptomatic PTS. Diagnosis and treatment of proximal deep-vein thrombosis is challenging, since in patients with May-Thurner-anatomy new efforts were made by the availability of interventional revascularization. However, accurate patient selection on an individual basis is required for reasonable indication.

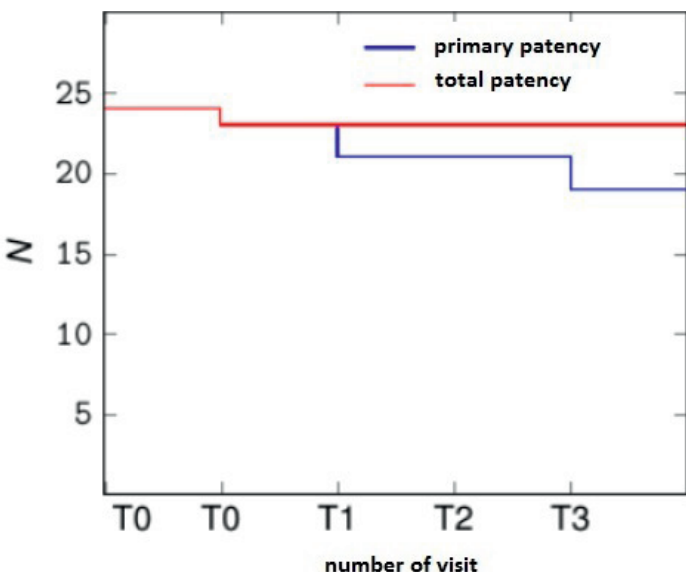
Methods

In the present all-comer study we retrospectively analysed 31 patients with acute proximal DVT who underwent interventional revascularization of acute proximal DVT with or without stent implantation at the University Hospital Ulm between October 2011 and September 2017.

Results

Median age was 36 years, 61.3% (19/31) patients were female. In 15/31 (48.4%) May-Thurner-anatomy has been identified as the most presumable cause of DVT. Oral anticoagulant therapy and compression stockings were used for at least six months after revascularization. Follow up of 24 patients included Duplex ultrasound examination, venous congestion plethysmography, Villata Score and treadmill ergometry to assess venous claudication.

Using ultrasound examination primary and secondary patency of the iliac veins were 19/24 (79.2%) and 23/24 (95.8%), respectively. Symptoms decreased from 100% at baseline after one (42.9%), three (33.3%) and six (42.9%) months. Patients report less symptoms as well as relief in severity of symptoms. No clinically relevant PTS was observed after six months.



Primary and total patency of the iliac vein after interventional therapy. T0: day after interventional therapy; T1: after one month; T2: after three months; T3: after six months.

Conclusions

In this all-comer study of patients with highly symptomatic acute DVT early recanalization of the pelvic vein lead to a substantial and fast relief of symptoms and reduction of reported symptoms as well. Thus, in these patients recanalization of acute proximal DVT should be considered as an effective therapy on an individual basis to relief symptoms and avoid severe PTS.

Risikoreduktion durch e-Zigaretten – Trug oder Schluss und Vorstellung Curriculum zum Internisten mit Gefäßexpertise in der Rehabilitation

A-103

Assessing the impact of switching to the Tobacco Heating System on cardiovascular disease: Translating basic science into clinical benefit

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Background

Cigarette smoke (CS) is causally linked to the development of cardiovascular diseases (CVD). Tobacco harm reduction, by virtue of substituting cigarettes with less harmful products, is a complementary approach to current strategies for smokers who would otherwise continue to smoke. The Tobacco Heating System (THS) 2.2 is a novel tobacco product that heats tobacco instead of burning it, never allowing the temperature to exceed 350°C, thereby preventing the combustion process from occurring and producing substantially lower levels of toxicants than CS.

Methods

Philip Morris International's (PMI) assessment program aims to demonstrate that switching to THS has the potential to reduce the risk of smoking-related diseases compared with continued smoking.

The program includes in vitro/in vivo toxicology testing methods that follow OECD guidelines and Good Laboratory Practice, a systems toxicology approach, and randomized, controlled clinical studies that follow the principles of Good Clinical Practice.

Results

The results of the THS assessment program demonstrated that cardiovascular toxicants are reduced by an average of >92% in THS aerosol relative to CS and that THS aerosol contains no solid carbon-based nanoparticles.

The effects of THS aerosol on the adhesion of monocytic cells to human coronary endothelial cells in vitro are significantly reduced. Switching to THS halted the progression of CS-induced atherosclerotic changes in ApoE^{-/-} mice in vivo.

Biomarkers linked to the development of smoking-related diseases were analysed following a 6-month randomized, controlled clinical study with THS, which demonstrated a consistent improvement of biomarkers in different pathophysiologic pathways leading to atherosclerosis.

Conclusions

The evidence available to date indicates that switching to THS has the potential to reduce the risk of smoking-related diseases such as CVD. As a next step, PMI will complement its THS assessment program with cardiovascular outcome studies intended to further support the clinical benefits of switching to THS over continuous smoking.

Young Investigator Sitzung

A-133

TSLP limits atherogenesis in apolipoprotein E – deficient mice

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Background

Atherosclerosis is a disease with chronic, low-grade inflammation. The accumulation of monocytes and macrophages in the artery wall leads to plaque progression and is promoted by cytokines like IFN γ and IL12, whereas IL4 or IL10 are associated with slower atherogenesis. TSLP is a major regulator that switches inflammatory responses to an IL4 and IL10 dominant phenotype.

Methods

To investigate the role of TSLP/TSLPR signaling on atherosclerosis, we generated Apolipoprotein E –/– TSLPR – deficient (ApoE –/–/TSLPR –/–) mice and compared atherogenesis with ApoE –/– litter mates.

Results

ApoE –/–/TSLPR –/– mice developed more atherosclerotic plaques in the aortic roots, with similar monocyte/macrophage infiltration. Flow cytometry suggested a general change in the Th1/Th2 balance due to intracellular GATA3 expression in CD4 T cells, whereas Tbet and ROR γ t were unaffected. Regulatory T cells (CD4/CD25/FoxP3) were decreased in ApoE –/–/TSLPR –/–. Further, we found a decrease in non-classical monocytes.

Next, ApoE –/– mice were injected with recombinant TSLP (rTSLP) on 5 consecutive days at the age of 1.5 and 4.5 months. Mice with rTSLP injections had significantly smaller plaques at the age of 6 months. No significant changes of T cells or monocytes were observed at sacrifice.

Conclusions

TSLP/TSLPR signaling is atheroprotective possibly due to its effect on Th1/Th2 balanced inflammation and may be a treatment option to restrain plaque development.

A-127

Endovascular treatment of peripheral artery disease is associated with improved central hemodynamics and ventricular function

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Background

Peripheral artery disease (PAD) is a major manifestation of atherosclerosis and a risk factor for morbidity and mortality. PAD itself is associated with increased arterial stiffness with impact on cardiac functions. Previous studies have demonstrated that augmentation index (AIx) and central blood pressure (CBP) correlate with increased cardiovascular mortality. This mechanism has been described as arterio-ventricular (AV) coupling with altered ventricular afterload and a depressed ventricular function, measured by global longitudinal strain (GLS). The impact of PAD-related

endovascular treatment on arterial stiffness, central hemodynamics and potential impact on AV coupling has not been elucidated until now.

Methods

To this aim 77 patients with known symptomatic PAD who underwent interventions in the iliac and femoropopliteal arteries were included in a cross-sectional study. AIx, CBP and GLS were determined using dedicated waveform analysis and echocardiography before and after endovascular treatment.

Results

Mean age was 65,1 $\pm$ 10,4 years with 66,2% male patients. Symptoms were classified by Fontaine classification (stage IIB 80,7%, stage III 5,8% and stage IV 13,5%). Iliac vessel intervention was performed in 16 and femoropopliteal intervention in 61 cases. A stentless approach was feasible in 55 patients with DCB treatment and atherectomy.

After endovascular treatment, peripheral perfusion was enhanced (ABI 0,45 $\pm$ 0,6 vs 0,81 $\pm$ 0,5, $p < 0,0001$). Moreover, central hemodynamics were improved (AIx 33,7 $\pm$ 3% vs 27,9 $\pm$ 2%, $p = 0,0008$; AP 17,8 $\pm$ 2 mmHg vs 14,0 $\pm$ 2 mmHg, $p = 0,0004$; central PP 52,4 $\pm$ 6 mmHg vs 46,4 $\pm$ 6 mmHg, $p = 0,0001$). Impressively, left ventricular function was also significantly improved (GLS –15,7 $\pm$ 2,3% vs –17,1 $\pm$ 2,8%, $p = 0,005$) with an improvement in AV coupling (PWV/GLS ratio –0,58m/sec% vs –0,56m/sec%, $p < 0,01$).

Conclusions

Our results demonstrate that endovascular treatment of the peripheral vessels is associated with an improvement of central hemodynamics and left ventricular function via enhanced AV coupling. These prognostic relevant markers of cardiovascular disease could point to an overall potential mortality benefit through PAD treatment. Further investigation of the underlying mechanisms of AV coupling in the setting of endovascular treatment of PAD with impact on cardiovascular mortality is needed in this high-risk population.

A-137

Quality of life 3 and 12 months after acute pulmonary embolism: analysis of 620 patients from the prospective multicentre FOCUS study

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Background

Few data are available on the long-term course and predictors of quality of life after acute pulmonary embolism. We aimed to evaluate the kinetics and determinants of quality of life at 3 and 12 months after acute pulmonary embolism.

Methods

The Follow-Up after acute pulmonary embolism (FOCUS) study prospectively followed consecutive adult patients with objectively diagnosed pulmonary embolism. For this analysis, we considered patients who completed the extensively validated Pulmonary Embolism QoL (PEmb-QoL) Questionnaire for the assessment of health-related quality of life at two predefined visits 3 and 12 months after pulmonary embolism. PEmb-QoL, studied as total score and in its six dimensions, ranges from 0 % (best quality of life) to 100 % (worst quality of life). We studied the course of PEmb-QoL and the impact of baseline characteristics using multivariable linear regression.

Results

In 620 included patients (44 % women, median age 62 years), overall quality of life improved from 3 to 12 months, with a decrease of the median total PEmb-QoL score from 19.4 % to 13.0 % (p-value < 0.001); Panel A. The mean intra-individual improvement in total PEmb-QoL score was 4.3 % (95 % CI: 3.2 % to 5.5 %). All six dimensions displayed statistically significant intra-individual changes, the largest being observed in work-related problems (7.7 %, 95 % CI: 5 % to 10.5 %) and social limitations (4.0 %, 95 % CI: 2.2 % to 5.8 %); Panel B.

The main factors independently associated with a worse quality of life at both visits were female sex (score vs men: at 3 months +8.6, 95 % CI 5.2–12.0; at 12 months +9.2, 95 % CI 5.9–12.4), older age (score for each additional year: +0.1, 95 % CI 0.001–0.2; and +0.2, 95 % CI 0.1–0.3), cardiopulmonary diseases (+10.6, 95 % CI 6.2–15.0; and +12.1, 95 % CI 7.9–16.3), and higher body mass index (score for each additional kg/m²: +0.6, 95 % CI 0.3–0.8; and +0.4, 95 % CI 0.1–0.6). Smoking worsened quality of life only

at 12 months (score vs non-smokers +6.6, 95 % CI 2.1–11.0). Worsening of quality of life became stronger over time for older age, weaker over time for higher BMI.

Conclusions

In a large cohort of patients with pulmonary embolism, we quantified the improvement of quality of life between 3 and 12 months after diagnosis. We identified factors independently associated with lower quality of life and slower recovery of quality of life that may reflect special patient needs. These estimates may facilitate the planning and interpretation of clinical trials with quality of life as a study outcome.

Literaturangaben

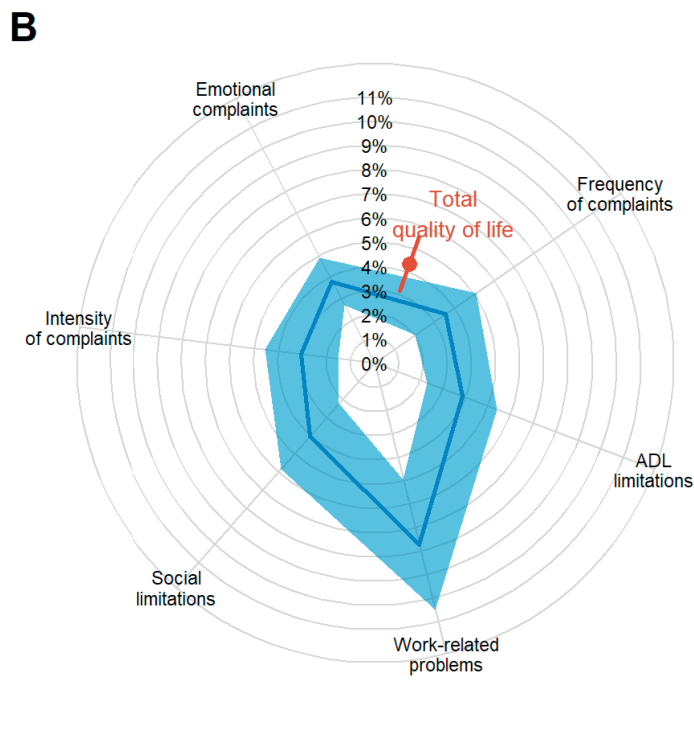
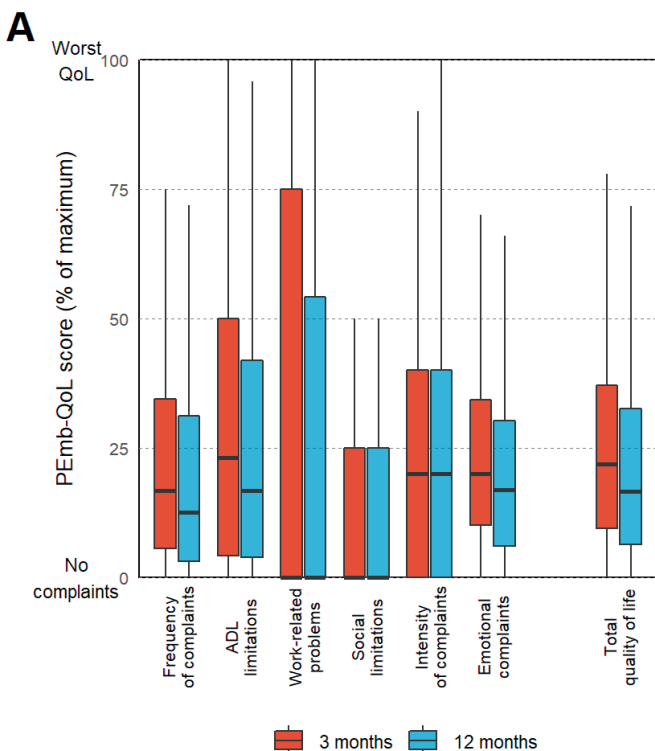
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Endovascular treatment patterns in relation to vascular segments in lower extremity peripheral artery disease – Insights from the RECCORD Registry

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Dimension-specific and total quality of life at 3 to 12 months (panel A: Tukey box plots; higher scores indicate lower quality of life) and mean individual change (95 % CI) from 3 to 12 months (panel B; positive differences indicate improvement).

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Background

Despite accumulating evidence for the presence or lack of efficacy of interventional devices in different vascular regions in patients with peripheral artery disease (PAD), the devices that are used for endovascular revascularization (EVR) differ substantially between operators and centers. We analysed data from the RECCORDing COurses of vascular Diseases (RECCORD) registry to assess the current real-world EVR treatment patterns in relation to vascular regions in lower extremity PAD patients in Germany.

Methods

RECCORD is an entirely web-based registry platform. Patients undergoing EVR for symptomatic PAD of the lower extremities were included at 18 vascular centers in Germany. Patients were subdivided into four groups according to their EVR regions: aorto-iliac, femoropopliteal, below-the-knee in combination with other intervention regions and exclusively below-the-knee.

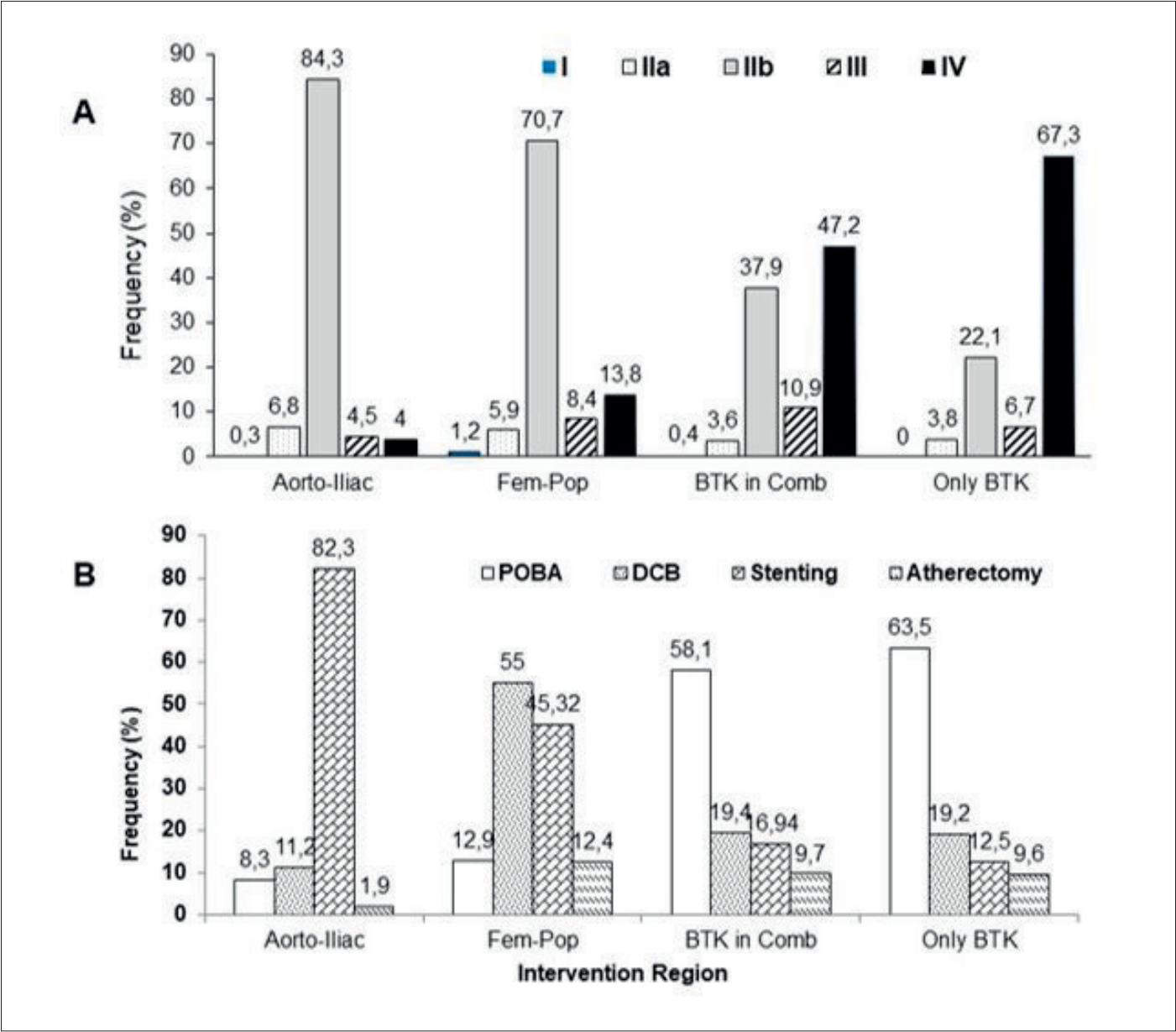
Results

In 1,661 patients 2,210 EVR regions were revascularized. Of those 616 (27.9%) were performed in aortoiliac, 1346 (60.9%) at femoropopliteal, 248 (11.2%) at infrapopliteal combined with proximal regions and 104 (4.7%) exclusively in below-the-knee regions. The fraction of critical limb ischemia (CLI) in relation to EVR region and the devices used for the EVR are illustrated in the figure.

Peri- and postprocedural complications occurred in 112 (6.7%) of all patients with pseudoaneurysm as the leading complication in 36 (2.2%) of all patients.

Conclusions

These data demonstrate the relationship between the EVR site and the clinical stage of PAD with aorto-iliac and femoropopliteal EVR in claudicants and below-the-knee EVR mainly in CLI patients. Plain old-balloon angioplasty plays a major role only in below-the-knee, while stents are still frequently used in above-the-knee and particularly in aorto-iliac segments.



Frequency of clinical stage according to Fontaine classification (Panel A) and of interventional devices used (Panel B) at the different intervention region in patients with peripheral artery disease in RECCORD registry.

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Complications after transradial arterial vessel access: comparison of two conventional compression systems

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Background

Transradial arterial access has been proven to be safe and effective for coronary interventions and has become the recommended access. Transradial is associated with lower mortality, fewer ischemic cardiac events, reduced severe bleeding, and other complications. Moreover, afterwards patients have not to stay in bed and the procedure is linked to reduced cost. Several compression systems have been approved for effective haemostasis at the injection site. Aim of the present study was to compare two widely used systems the TR-Band™ from Terumo Medical (JP) and SealOne® from Perouse Medical (FR) with regard to time to haemostasis and vascular complications.

Methods

We included 942 patients in this retrospective comparative study, all of whom underwent a diagnostic or therapeutic cardiac catheter examination via transradial vascular access half of them each with subsequent compression with a TR-Band or a SealOne, respectively. Baseline characteristics (age, sex, medication), interventional data (type of intervention, medication before, during and after the intervention), as well as postinterventional data (time to haemostasis, follow-up examinations and complications) were collected and analysed.

Results

Mean age of the patients was 71 years ± 12.21 (SD) and two thirds were male. Site of vascular access, medication and type of interventions were similar in both groups. We observed a significantly longer mean time to haemostasis at the puncture site of 1.67 hours in the group receiving the TR-Band (5.6 hours ± 2.42 SD) compared to those receiving the SealOne (4.0 hours ± 0.98 SD). After the intervention we performed clinically driven ultrasound in 10.6% (50/471) of the patients in the TR-Band group and 14.4% (68/471) in the SealOne cohort to detect complications. Both groups were associated with a low complication rate of 8.3% on average. In the TR-Band group we observed a complication rate of 7.2% and the SealOne group a non-significantly higher rate of 9.3%.

Conclusions

Following transradial cardiac catheterization both compression systems used in our retrospective comparative Study has been shown to be effective, safe and easy to use as haemostatic compression devices. The SealOne system was associated with a significantly shorter time to haemosta-

sis at the puncture site compared to the TR-Band and a similarly low rate of vascular complications.

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Outcomes of Endovascular Treatment for Infrapopliteal Peripheral Artery Disease Based on the Updated TASC II Classification

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Background

Endovascular therapy has become an established treatment option for revascularization of below-the-knee arteries. There is a lack of studies validating the updated TASC II classification against outcomes.

Methods

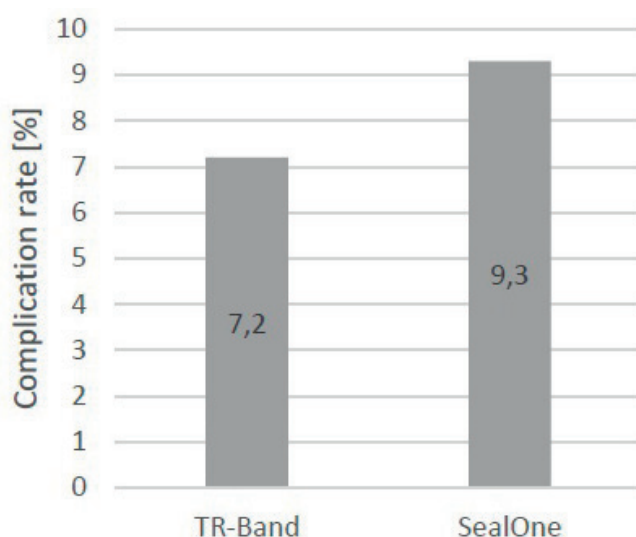
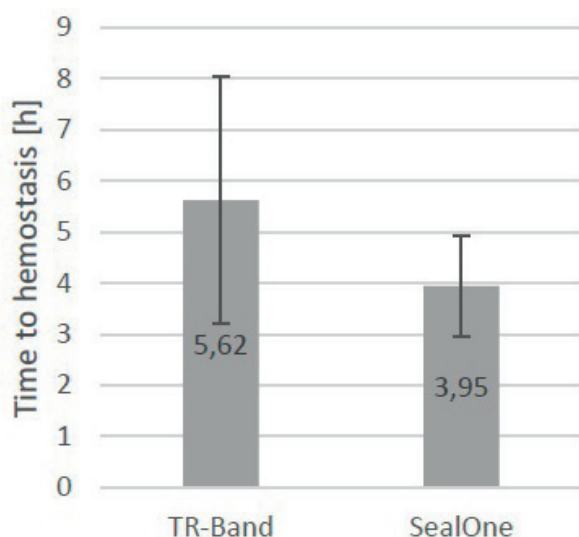
All endovascular procedures of infrapopliteal lesions performed at our institution between December 2008 and January 2018 (n=383) were retrospectively analyzed. The primary outcome was clinically driven target lesion revascularisation (TLR).

Results

The overall technical success rate was 97% and yielded 98% for stenoses (n=214) and 95% for occlusions (n=169). TASC II classification had no impact on success rates (TASC A + B vs. C + D; 96.5% vs. 96.9%, p=0.837). Freedom from TLR after 6 and 12 months was 88.3% and 77.2%. TLR was comparable for TASC A to C lesions and no difference was observed comparing groups of moderately complex TASC A/B lesions and more complex TASC C/D lesions (TASC A + B vs. C + D; 78.5% vs 74.2%, p=0.426). TLR was significantly lower in very complex TASC D lesions (TASC A + B + C vs. D; 79.7% vs 42.5%, p<0.001). Multivariate analysis identified TASC D lesions (hazard ratio D/A: 1.5; overall P=0.001), fontaine class III and IV (hazard ratio (III or IV)/(IIa or IIb): 2.357; P=0.009) and occlusive lesions (hazard ratio occlusion/stenosis: 2.437; P=0.016) as predictors for TLR.

Conclusions

Endovascular therapy for infrapopliteal artery disease is effective and accompanied with a promising long-term outcome.



Comparison of time to hemostasis (h) and complication rate in the TR-Band group and the SealOne cohort.

Freie Vorträge Intervention II

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Evaluation of Mortality Following Paclitaxel Drug-coated Stent Angioplasty of Femoropopliteal Lesions in Real World

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Background

A meta-analysis of randomized controlled trials reported an increased risk of long-term mortality after femoropopliteal angioplasty with paclitaxel-coated devices.

Methods

To evaluate the long-term mortality after paclitaxel-coated drug-eluting stent (DES) angioplasty and use of uncoated devices of femoropopliteal lesions in real world practice a retrospective mortality analysis of claudicants Rutherford-Becker class (RBC) 1–4 who underwent DES angioplasty or uncoated balloon or stent angioplasty of femoropopliteal lesions with a follow-up of 3 to 7 years was performed. Differences in baseline characteristics between uncoated devices and DES group were adjusted using propensity score matching.

Results

In 2010–2016 8377 patients were treated with femoropopliteal lesions. This analysis included 600 patients. Three-hundred-three patients were treated with an uncoated device and 297 patients with a DES. The mean follow-up period was 51.80±23.40 months (range 0–84). For the entire cohort mortality incidence was 32.3% after uncoated treatment and 22.6% after DES (p<0.033). Multivariate logistic regression analysis revealed for the entire cohort age (p<0.001), diabetes (p=0.010), renal insufficiency (p=0.001) and Rutherford 4 (p<0.001) as independent predictors for mortality. After propensity score matching mortality incidence was 32.5% (n=51) after uncoated treatment and 24.1% after DES (n=19) (p=0.264). After propensity score matching, independent mortality predictors were age (p<0.001), hyperlipidemia (p=0.035), diabetes (p=0.018) and Rutherford 4 (p<0.001).

Conclusions

In real world long-term mortality rate was lower after DES angioplasty than after treatment with uncoated devices. Mortality predictors were co-morbidities, risk factors, and disease severity.

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Evaluation of Mortality Following Paclitaxel Drug-coated Balloon Angioplasty of Infrapopliteal Lesions in Real World

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Background

Meta-analyses of randomized controlled trials suggested an increased long-term mortality risk following femoropopliteal and infrapopliteal angioplasty using paclitaxel coated devices.

Methods

To evaluate the long-term mortality after paclitaxel drug-coated (DCB) and uncoated balloon angioplasty (POBA) of infrapopliteal lesions in real

world practice a retrospective mortality analysis of patients with at least 3-year follow-up who underwent balloon based endovascular therapy of infrapopliteal lesions was performed. To achieve a better balancing of the groups regarding their major different baseline characteristic, a matched pair analysis was performed.

Results

Overall 2679 patients with infrapopliteal lesions were treated within the study period. Five hundred seventy-six patients fulfilled the study criteria. Of those, 269 patients were treated with uncoated devices without crossover to a paclitaxel coated device during follow-up and 307 patients with DCB angioplasty. Mean follow-up was 46.48±31.77 months (range 0–129 months). Mortality incidence was 66.9% after POBA and 46.9% after DCB (p<0.001). In the matched pair cohort 94 patients died after uncoated treatment (69.1%) and 29 in the DCB group (42.6%), (p=0.004)). There was no correlation between DCB length and mortality rate (p=0.357). For the entire cohort, multivariate logistic regression analysis showed type of treatment (uncoated device vs. DCB, p<0.001), age (p<0.001), hyperlipidemia (p=0.013), diabetes mellitus (p=0.039), hypertension (p=0.034), renal insufficiency (p<0.001), coronary heart disease (p=0.003), and CLI (p<0.001) as independent predictors for all-cause mortality. After propensity score matching, independent mortality predictors were type of treatment (p=0.030), age (p<0.001), stroke (p=0.003), coronary heart disease (p=0.002), renal insufficiency (p=0.002) and CLI (p<0.001). There was no significant difference in mortality for the different groups of paclitaxel exposure.

Conclusions

In this real-world retrospective analysis, long-term mortality rate was lower after DCB angioplasty than after POBA of infrapopliteal lesions. Cardiovascular risk factors, renal insufficiency and disease severity were identified as mortality predictors.

A-101

The Lutonix BTK Global Registry: 24-Month Update

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Background

A prospective, multicenter, single-arm, real-world registry to assess safety and the clinical use and outcomes of the Lutonix[®] DCB in a heterogeneous patient population with below-knee peripheral vascular disease in real-world clinical practice

Methods

371 patients with below-knee peripheral vascular disease were treated at 26 international sites in Europe, the United Kingdom, and Saudi Arabia. Primary endpoints were 30-day freedom from major adverse limb events (MALE) and perioperative death (POD), and 6-month freedom from clinically driven (CD) target lesion reintervention (TLR). Secondary measures included improvement in Rutherford categories, freedom from all-cause death, and freedom from major amputation (i.e., above ankle) through 24 months.

Results

Freedom from MALE-POD was 98.4% at 30-days and freedom from CD-TLR was 99.2% at 6 months (Kaplan-Meier analyses) while freedom from MALE-POD was 90.7% and freedom from CD-TLR was 78.9% at 24 months. Additional secondary outcomes (all Kaplan Meier estimates) included freedom from major amputation of 93.4%, freedom from all-cause death of 80.5%, an improvement of at least one Rutherford category in 89.1% of patients, and 59.5% of patients showed improvement of ≥ 3 Rutherford categories at 24 months.

Conclusions

The Lutonix Global BTK Registry demonstrated the clinical benefits of the Lutonix DCB in a real-world setting; freedom from CD-TLR was 99.2% at 6 months and 78.9% at two years, most patients showed clinical improve-

ments in their Rutherford scores (59.5% improvement by ≥ 3 categories), and freedom from all-cause death and freedom from major amputation were 80.5% and 93.4%, respectively, at two years

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Evaluation of Mortality Following Paclitaxel Drug-coated Balloon Angioplasty of Femoropopliteal Lesions in Real World

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Background

A recent meta-analysis of randomized controlled trials suggested an increased long-term mortality risk following femoropopliteal angioplasty using paclitaxel coated devices.

Methods

To evaluate the long-term mortality after paclitaxel drug-coated (DCB) and uncoated balloon angioplasty (POBA) of femoropopliteal lesions in real world practice a retrospective mortality analysis of patients with at least 3-year follow-up who underwent balloon based endovascular therapy of femoropopliteal lesions was performed. This analysis was performed for the entire study population, and in order to better balance the groups regarding their major different baseline characteristic age, for a subgroup excluding patients beyond the age of 80 years. Furthermore, a matched pair analysis was performed.

Results

Overall 7,357 patients with femoropopliteal lesions were treated within the study period receiving either DCB or POBA. Of those, 1579 fulfilled the study criteria. Five-hundred-fourteen patients were treated with POBA without crossover to a paclitaxel coated device during follow-up and 1,065 patients with DCB angioplasty. Mortality incidence at mean follow-up of 52.0 ± 20.5 months (median 51 months) was 27.8% after POBA and 16.9% after DCB ($p < 0.001$). Equally, for a cohort excluding patients over 80 years of age, the mortality rate after POBA treatment was significantly higher (23.6% vs. 12.3%, $p < 0.001$). In the matched pair cohort 155 out of 800 patients died (POBA group 67 patients (25.2%), DCB group 88 patients (16.5%), $p = 0.047$). For the entire cohort, independent predictors for mortality were age ($p < 0.001$), type of treatment ($p = 0.009$), hyperlipidemia ($p = 0.010$), diabetes mellitus ($p = 0.010$), renal insufficiency ($p = 0.007$), stroke ($p = 0.017$), and Rutherford-Becker class 4 ($p < 0.001$). After propensity score matching, independent mortality predictors were POBA treatment ($p = 0.035$), age ($p < 0.001$), stroke ($p = 0.025$) and renal insufficiency ($p = 0.007$). DCB length was not correlated to mortality rate.

Conclusions

In this real-world retrospective analysis, long-term mortality rate was lower after DCB angioplasty than after POBA of femoropopliteal lesions. Known co-morbidities, risk factors, and disease severity were identified as mortality predictors but not paclitaxel.

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Treatment of Incompetent Truncal Veins with Cyanoacrylate glue – a Retrospective Multicenter Experience at 60 Months

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Background

Due to less invasivity and patient discomfort compared to conventional surgery, endovenous thermal techniques have been increasingly preferred for treatment of incompetent truncal veins (GSV/SSV). More recently, the non-tumescent, non-thermal and non-sclerosing cyanoacrylate adhesive (Cyanoacrylate Closure, CAC, VenaSeal™) has been advocated as an alternative with minimized procedural risks. Long-term results and aspects of foreign body implantation, however, are being discussed controversially so far.

Methods

Pooled data of a retrospective analysis in five centers in Germany using CAC in the years 2012 to 2020 with follow-up of 60 months.

Results

Three thousand thirty-eight patients with 5149 insufficient truncal veins (GVS / SSV, AASV, PASV) with a maximum diameter of 19 mm were treated with CAC in local anesthesia. Simultaneous mini-phlebectomies in 0–25% of the patients as well as post-operative compression therapy (0–14 days) were performed according to center-specific standards. After 7–10 days, a technical success with sufficient closure of cross veins was shown in 5148/5149 truncal veins. Accidental proximalisation of the adhesive was found in 10/5149 (0.19%) of the treated truncal veins to a small extent and without functional morbidity. There was one femoral vein thrombosis due to mechanical endothelial injury from the guidewire. After 36 and 60 months, 1175/1215 (96.7%) and 1477/1547 (95.5%) of the veins examined were free from reflux >5 cm distal to the saphenofemoral junction. No nerve lesions nor lymphatic complications were observed. Foreign body reactions in the form of transient reddening of the skin covering the saphenous area mostly on the distal thigh were present in 9.4% of the patients. Systemic allergic reaction was noticed in one patient (0.03%) with immediate response to pharmacologic intervention.

Conclusions

Treatment of truncal venous insufficiency with CAC is safe and appears efficient concerning both short and long-term results. Minimal postoperative discomfort and short rehabilitation, even in patients with occupational orthostatic stress appear as substantial advantages of the CAC closure technique, in which persistent thermal and/or tumescence-associated tissue damage are excluded.

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Endovascular Mechanical Thrombectomy versus Thrombolysis Only in Patients With Iliofemoral Deep Vein Thrombosis – a Systematic Review and Meta-Analysis

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Background

To compare effectiveness and safety of device-mediated, percutaneous mechanical thrombectomy (PMT) and thrombolysis alone (THR) in patients with iliofemoral deep vein thrombosis (IfdDVT).

Methods

Observational and randomized trials, published between January 2001 to February 2019 were identified by searching MEDLINE. Studies on iliofemoral DVT treated with either THR or PMT adjunctive to conventional anticoagulation and compressive intervention were included. Meta-analysis of proportions was conducted to assess effectiveness outcomes of successful lysis and 6-month primary patency, as well as safety outcomes.

Results

19 studies with 17 THR- and 13 PMT-cohorts including 1579 patients were eligible. Pooled proportion of successful lysis was similar between groups (THR: 95% [95%CI: 88 to 99%], I² = 68.4%; PMT 96% [95%CI: 91 to 99%], I² = 0%; Q_{bet} [Cochran's Q between groups] = 0.3, p = 0.61). Pooled proportion of 6-month primary patency was lower after THR than after PMT (66% [95%CI: 60 to 71%], I² = 0% and 94% [95%CI: 84 to 99%], respectively; Q_{bet} = 23.5, p < 0.001). Incidence of hematuria was lower after THR as compared to PMT (2% vs. 91.3%, I² = 56% and 91.7%, Q_{bet} = 714, p < 0.001). Incidences of valvular reflux and pulmonary embolism were similar (THR: 61% vs. PMT: 51%, Q_{bet} = 1.1, p = 0.29 and THR: 2% vs. PMT: 1%, Q_{bet} = 1.1, p = 0.30, respectively).

Conclusions

In patients with iliofemoral DVT, percutaneous mechanical thrombectomy was associated with a higher incidence of 6-month primary patency and a lower incidence of major bleeding compared to thrombolysis alone.

A-115

Moderate iliac artery stenosis – a diagnostic challenge between precision and intuition

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Background

Diagnostic and treatment of patients with symptomatic peripheral arterial disease (PAD) due to not severe iliac stenosis can be particularly challenging for vascular specialists. While severe iliac artery stenoses are likely to be verified by minimal diagnostics, e.g. physical examination, determina-

tion of the ankle-brachial-index (ABI) and duplex sonography, moderate iliac artery stenoses become hemodynamically relevant during exercise and are therefore often not detected under rest conditions.

The reason for this study was our personal experience that a moderate iliac artery stenosis could not be diagnosed in a precise manner just by visual assessment of angiographic and tomographic results but really needed functional diagnostics for verification.

With this study, we intended to clarify how vascular specialists categorises iliac arterial stenoses by visual assessment of angiographic images and how the estimated pressure gradients match the measured values.

Methods

Vascular specialists with several years of practical experience were asked to analyse angiographic images of iliac arterial stenoses. A questionnaire was used to firstly determine which was the affected artery (common iliac artery (CIA), external iliac artery (EIA)) and afterwards to estimate the severity of stenosis with its corresponding pressure gradient (mmHg).

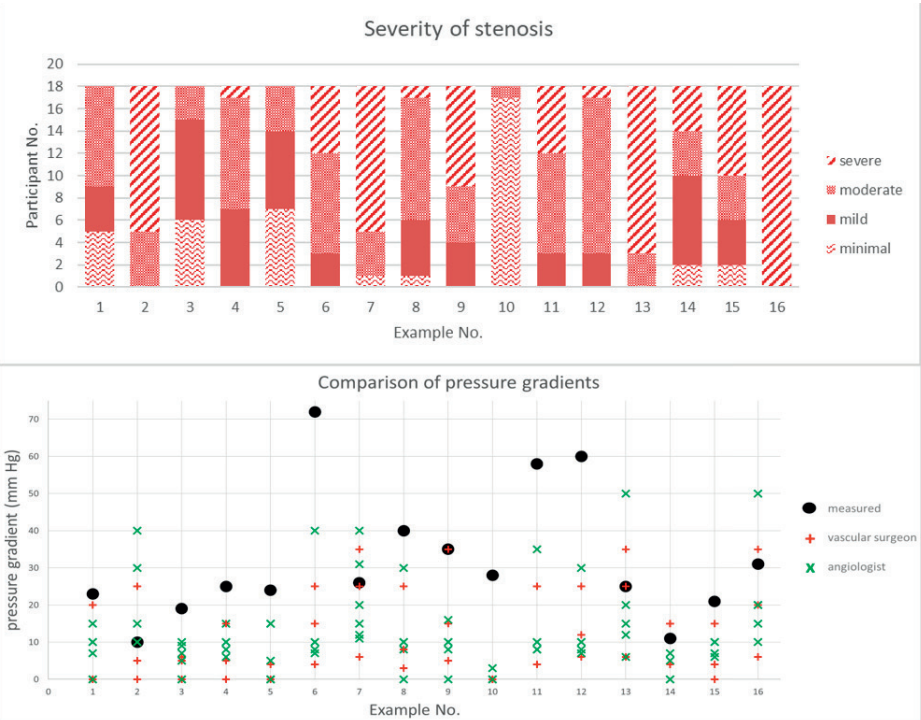
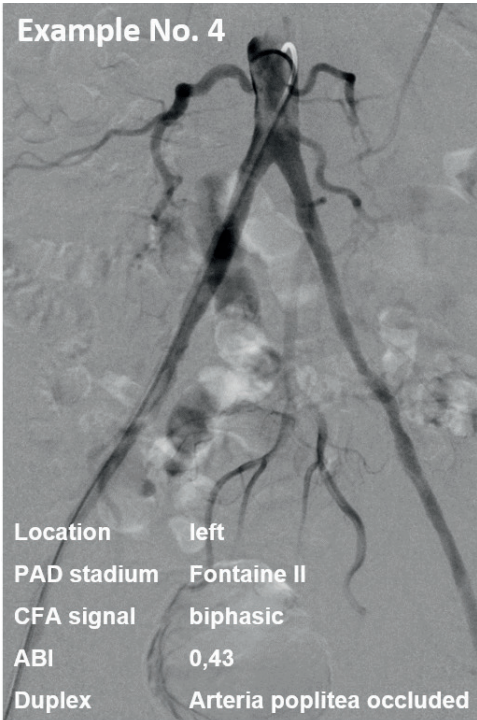
Results

Both, the determination of the diseased vessel and the estimation of the severity of stenosis with the corresponding pressure gradients showed a high variability independently from the discipline of the vascular specialist.

Conclusions

The evaluation of this study confirms our personal experience that the visual assessment of the angiographic images alone is by far not enough to determine the grade and the hemodynamic relevance of iliac arterial stenoses but precise functional diagnostics are needed to decide if an intervention would improve a patients' claudication.

Additional studies with more participants from different disciplines and a higher number of angiographic images could point out which type of stenosis is mainly underdiagnosed and at what point further diagnostics are essential to judge if the patient would benefit from an iliac intervention. Although the number of participants in this study does not allow any statistical proven statements, the key messages are still valid – moderate iliac artery stenoses are often underdiagnosed and underestimated; a correct visual assessment is barely possible.



A-125

Catheter directed thrombolysis in hypotenar hammer syndrome – a case series and review of the literature

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Background

Hypotenar hammer syndrome (HHS) represents a rare, underdiagnosed ischemic condition of the hand caused by acute or repetitive trauma to the distal ulnar artery at the hypotenar region. Symptoms vary from digital discoloration and cold intolerance to severe digital ischemia. Current therapeutic approach is often empiric, due to missing randomized trials or large series.

We evaluated our results of catheter directed thrombolysis (CDT) in HHS and systematically reviewed the scientific literature on this topic.

Methods

We retrospectively evaluated all cases of HHS with CDT, treated at our institution between 01 January 2016 and 31 Dec 2018. Furthermore, a Pubmed search of reports of thrombolysis in HHS was conducted.

Results

Between 01 January 2016 and 31 December 2018, 11 patients (all male, aged between 43 and 63 years) with diagnosed HHS underwent CDT at our institution. These patients complained about pain, pallor, cold intolerance and paresthesia of affected fingers. Furthermore, tenderness on palpation was present at the hypotenar region in all patients.

In 90.9% endovascular treatment was carried out with a brachial 4F sheath access and an endhole-micro catheter placed to the distal ulnar artery. Recombinant tissue plasminogen activator rtPA (Actilyse®) was administered with a fixed dose of 1.5 mg rtPA per hour via microcatheter. Additional unfractionated heparine was administered APTT-adjusted, combined with Alprostadil 0.4µg/h via the brachial sheath. This regimen was continued for a mean of 20.7 hours (min. 12, max. 24 hours).

All patients showed an improvement of digital perfusion, which was confirmed by angiography and acral oscillography. Complete arterial reperfusion of the ulnar artery was present in one case (9.1%). Four patients (36.4%) showed a complete relief of symptoms, three (27.3%) a near relief, and 3 (36.4%) an improvement with mild symptoms. No major bleeding complications were observed; neither did we observe any deterioration of symptoms during CDT.

Literature Review

We identified 32 reports of thrombolytic therapy in HHS reported between 1989 and 2018. Clinical presentation of these cases was similar to our series (digital pain 56.3%, pallor 37.5%, cold intolerance 18.8%, paresthesia 46.9%, cyanosis 40.6% or necrosis 12.5%). Thrombolytic therapy was carried out using femoral access in 13 cases (40.6%), or access on the arm in 19 cases (59.4%). Thrombolytic therapy included Urokinase in 16 cases (50%), rtPA in 10 cases (31.3%) and other agents in 6 cases (18.7%). Ulnar reperfusion was reported in 6 cases (18.8%). Clinically symptoms improved in 23 cases (71.9%), with missing improvement in 7 cases (21.9%).

Conclusions

Catheter-directed thrombolytic therapy is a promising option in HHS. The results of our case series and reports of the literature review indicate that clinical improvement can be expected in the majority of patients (79.1%). This significant clinical improvement is predominantly related to a reperfusion of occluded digital arteries.

A-126

Impact of atherectomy and debulking with Rotarex®S on vascular function in symptomatic peripheral artery disease – the SAVioR trial

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Background

Endovascular treatment of symptomatic atherosclerotic peripheral artery disease (PAD) is the primary revascularization strategy. Interventional strategies restore tissue perfusion but affect endothelial function, perpetuating dysfunctional vascular homeostasis.

PTA and drug-coated balloon (DCB) -only strategies do not provide sufficient primary patency rates in case of calcification. An adequate vessel preparation with atherectomy could improve outcomes and patency of DCB treatment and improve vessel functions.

Endothelial function and the vasomotion of the vessel wall can be measured by FMD (flow-mediated dilation) and arterial stiffness (pulse wave velocity, PWV).

The aim of this study is thus to investigate the impact of peripheral vascular interventions though atherectomy and debulking on local vascular function measured by FMD and PWV.

Methods

To this aim a single-center, investigator-initiated trial is conducted (Clinicaltrials NCT04092972). Patients with known PAD will undergo interventions using a dedicated atherectomy device (Rotarex S, Straub Medical) in the femoropopliteal artery followed by DCB and compared to controls (PTA and DCB).

Outcome measures will include safety, technical success of atherectomy in the SFA including the bail-out stenting rates, endothelial function and vessel vasomotion.

FMD and PWV will be determined before the intervention and with a six-month follow-up in the target limb, contralateral control limb and the brachial artery as a parameter of systemic arterial function. Additionally, ABI, walking distance and Fontaine classification will be assessed for each patient.

Results

For the validation of the methodology 50 patients were included and compared to 10 healthy controls. Mean age was 70.3±9.8 years with 34% female and 66% male patients. Brachial and femoral endothelial function was reduced in PAD patients as compared to controls (brachial 4.2±0.1 vs. 5.1±1.4, p=0.02; femoral 3.7±0.1 vs. 4.7±0.2, p<0.01) and showed a significant correlation comparing brachial and femoral FMD in controls (r=0.7; p<0.01) and PAD patients (r=0.4; p<0.01).

The final results of the SaVioR Trial will be presented.

Conclusions

Peripheral vascular interventions though atherectomy and debulking impact on local vascular function measured by FMD and PWV. This study will provide the optimal endovascular treatment strategy with emphasis on maintaining vessel functions.

A-131

Single Session Mechanical Thrombectomy in Iliofemoral DVT patients: Interim Analysis of Vetex Study

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Background

While Anticoagulation therapy remains the standard of care for patients with deep vein thrombosis, Pharmacomechanical Catheter Directed Thrombolysis (PCDT) has been shown to reduce acute leg pain and improve quality of life in patients with acute iliofemoral DVT

Methods

The VETEX study is an open label, prospective, non-randomised, multi-centre first-in-human evaluation of the Vetex Thrombectomy Device for treatment of acute iliofemoral deep vein thrombosis (DVT). The study objective is to evaluate its' safety and performance. The primary performance endpoint for the study is procedural success to achieve SIR Grade II Lysis in the treated vessels, with freedom from procedural related adverse events. The secondary endpoints included clinical symptom assessments through Villata and Venous Clinical Severity Score (VCSS) and patient quality of life measurement. This paper reports on the safety and performance of the device, for the first 15 patients, up to 30 days post-treatment.

Results

An SIR grading of II or higher was achieved in 15/15 (100%) of patients. There were no procedural related adverse events; therefore, the primary endpoint was achieved in all 15 (100%) of patients. Of the first 15 patients enrolled 13 (86.7%) did not have any lytics used during the mechanical thrombectomy procedure.

Conclusions

The VETEX study provides an initial indication that the Vetex thrombectomy device is a safe and effective option for removal of clot in acute iliofemoral DVT patients. Initial results demonstrate improvements in Villata and VCSS measurements with quality of life improvements. Future publications will provide longer term follow-up data.

Results

1808 patients treated for PAD were screened. 120 patients ≥ 80 years with PAD as primary diagnosis at time of admission and adequate follow up data were eligible. An equal sized control group of 121 patients < 80 years old served as a control-group. Due to incomplete data 24 octa- and nonagenarians and 2 controls had to be excluded.

During follow-up 31 deaths were documented and the remaining patients were censored at the end of their follow up.

Our data showed that Troponin levels are the major risk predictor of all-cause mortality in our study population. Patients with Troponin levels over the 99th percentile had a greater risk of death compared to patients with Troponin levels below the 99th percentile at baseline (HR 6.6 95% CI: 3.1–14; octa- and nonagenarians HR: 6.9 95% CI: 2.8–17.1). Clinical presentation according to Rutherford stage was the second most important predictor of mortality with Rutherford stage 4–6 implying a higher risk of death compared to patients with Rutherford stage 1–3 (HR 4.2 95% CI: 2–8.9; octa- and nonagenarians HR: 2.7 95% CI: 1–6.9). The Cox proportional hazards analysis on all patients including all 5 variables showed that Troponin blood levels and Rutherford stage were not influenced by confounding factors and remained significant risk predictors of mortality (HR 2.17 95% CI: 1.5–3.16 and 2.27 95% CI: 1–5 respectively).

The ROC analysis of all 5 variables yielded an area under the curve (AUC) of 0.819. This was even more pronounced in the octa- and nonagenarian subgroup with AUC of the ROC of 0.874.

Conclusions

Our study demonstrates Troponin blood levels and Rutherford stage as the primary predictive factors of mortality in PAD patients and particularly in the elderly. Further evaluation of risk prediction of this high-risk elderly population with PAD is warranted.

A-130

Mortality risk in octa- and nonagenarians with peripheral artery disease

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Background

Cardiovascular disease increasingly affects elderly people. With demographic changes aging progressively becomes a relevant risk factor in the pathogenesis of cardiovascular diseases. Data regarding predicting factors for the mortality in the elderly population with peripheral arterial disease (PAD) are however scarce.

Methods

Data of octa- and nonagenarians was collected from the 2016–2018 in a single-center retrospective fashion in a tertiary reference hospital. Clinical characteristics, risk factors, medication, and markers of myocardial injury (Troponin I) and heart failure (NT pro-BNP) were determined. Long-term follow-up of up to 2 years was conducted regarding all-cause mortality. Age, gender, Rutherford stage, Troponin levels and NT pro-BNP levels were assessed. Logrank tests, Cox regression analysis and (receiver operating curve) ROC-analysis were used for statistical evaluation of all-cause death prediction.

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