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Erfassung der Lebensqualität von Patienten unter Langzeit-NMH-Therapie versus oraler Antikoagulation unter Selbstmessung

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Einleitung Niedermolekulare Heparine (NMH) stellen eine hoch-effektive Therapieoption zur Antikoagulation von Patienten dar. Aufgrund der Notwendigkeit der täglichen Selbstinjektionen und der damit verbundenen Belastungen werden diese Medikamente jedoch häufig nicht verordnet. Die Lebensqualität von antikoagulierten Patienten wurde bisher allerdings hauptsächlich bei oraler Antikoagulation (OAK) erhoben. Als Goldstandard diesbezüglich gelten Patienten mit Gerinnungsselbstmanagement. Das Ziel dieser Studie ist es herauszufinden, ob die Lebensqualität von Patienten unter einer Therapie mit NMH signifikant schlechter ist als die Lebensqualität von oral antikoagulierten Patienten unter Selbstmanagement.

Methoden Insgesamt wurden 40 Patienten in die Studie eingeschlossen, wovon 20 Patienten unter einer Langzeittherapie mit NMH und 20 Patienten unter einer oralen Antikoagulation mit Gerinnungsselbstmanagement standen. Die Lebensqualität wurde anhand der beiden gut validierten Fragebögen „Duke Anticoagulation Satisfaction Scale“ (DASS) und „Treatment Satisfaction Questionnaire for Medication“ (TSQM) erhoben.

Ergebnisse Signifikante Unterschiede ergaben sich bei insgesamt 11 von 38 der gestellten Fragen. Die Patienten der NMH-Gruppe waren durch mögliche Blutungskomplikationen in der Ausübung körperlicher Aktivitäten, bei der Inanspruchnahme ärztlicher Betreuung sowie im Alltag insgesamt weniger eingeschränkt. Auch in der Nahrungsmittelauswahl und durch die physischen und psychischen Auswirkungen der Nebenwirkungen zeigten sich weniger Einschränkungen. Weiters waren sie mit der Dauer des Wirkungseintritts zufriedener und die Behandlung wirkte sich insgesamt weniger auf ihren Alltag aus. Hingegen waren die Patienten der OAK-Gruppe in Bezug auf die Schmerzhaftigkeit und Anwenderfreundlichkeit zufriedener. Auch glaubten sie den Grund ihrer Therapie besser verstanden zu haben.

Schlussfolgerung Die Therapie mit einem NMH ist im Vergleich zur OAK unter Selbstmessung für den Patienten zwar schmerzhafter und unbequemer in der Anwendung, bietet dafür jedoch in anderen Bereichen Vorteile. Wir schließen daraus, dass Patienten unter einer Therapie mit NMH keine schlechtere Lebensqualität aufweisen, als oral antikoagulierte Patienten unter Selbstmessung.

Möglicher Zusammenhang zwischen Antiphospholipidantikörpern und erhöhtem BMI

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Einleitung Positive Antiphospholipidantikörper (APA) und Adipositas bzw. Metabolisches Syndrom sind beides unabhängige Risikofaktoren für venöse Thrombosen. Da auffällig ist, dass Patienten mit positiven Antiphospholipidantikörpern bzw. Antiphospholipidantikörpersyndrom häufig übergewichtig sind, wollten wir einen möglichen Zusammenhang zwischen erhöhtem BMI (Body-mass-Index) und Antiphospholipidantikörpern im Plasma mittels einer retrospektiven Studie untersuchen.

Methoden In die Studie eingeschlossen wurden insgesamt 1077 Patienten, die zwischen 2006 und 2010 nach stattgefundenen venöser Thrombembolie (VTE) in der Gerinnungsambulanz der Klinischen Abteilung für Angiologie der Medizinischen Universität Graz in Betreuung waren. Es wurden Lupusantikoagulans, Cardiolipin-Ak, Beta-2-Glykoprotein-1-Ak, Alter, Größe, Gewicht und BMI der Studienteilnehmer erhoben. Eine statistische Signifikanz wurde mit einem p-Wert von $< 0,05$ angenommen, es wurden Mittelwert, Median und Standardabweichungen mittels SPSS 17.0 errechnet.

Das Durchschnittsalter betrug 49,5 Jahre ($\pm 17,1$), das Durchschnittsgewicht 77 kg ($\pm 18,3$), die Durchschnittsgröße 168,1 cm ($\pm 21,2$) und der durchschnittliche BMI 26,5 ($\pm 5,9$). Insgesamt 105 Patienten wurden einmalig auf Lupusantikoagulans positiv getestet, 20 Patienten wurden mindestens 2x positiv auf LA getestet und 952 Patienten hatten gar keinen positiven Lupus-Inhibitor. Sieben der

getesteten Personen hatten rezidivierend positive Cardiolipin-Ak und weitere 3 Patienten hatten rezidivierend positive Beta-2-GP-1-Ak im Plasma.

Ergebnisse Patienten mit einmalig erhöhtem Lupusantikoagulans hatten einen signifikant höheren BMI ($p = 0,0001$) und auch ein höheres Körpergewicht ($p = 0,02$) im Vergleich zu Patienten ohne positivem Lupus-Inhibitor.

Bei den Patienten mit mehrmals positiv getestetem Lupus-Inhibitor fand sich keine statistische Signifikanz im Vergleich zu Patienten ohne positiven Lupus-Inhibitor (BMI $p = 0,4$, Körpergewicht $p = 0,7$). Das Patientenkollektiv für die Testung von Cardiolipin-Ak und Beta-2-GP-1-Ak bei erhöhtem BMI war zu klein, um statistisch signifikante Ergebnisse zu erzielen.

Schlussfolgerung Der Grund, warum Patienten mit einmalig getestetem positivem Lupus-Inhibitor einen statistisch signifikant höheren BMI und höheres Körpergewicht hatten und Patienten mit mehrmals getestetem positivem Lupus-Inhibitor nicht, könnte darin liegen, dass nach einmalig getesteter Antiphospholipidantikörper-Positivität eine Therapie mit oralen Antikoagulantien eingeleitet wird. Eine Bestimmung des Lupus-Inhibitors ist unter oraler Antikoagulation nicht möglich. Die Antikoagulation wird in der Regel nicht mehr abgesetzt, um erneut auf APA-Positivität zu testen. Deswegen war auch die Anzahl der Personen mit mehrmals positiv getestetem Lupusantikoagulans sehr niedrig ($n = 20$).

Massive Pulmonary Embolism Caused by Internal Iliac Vein Thrombosis with Free Floating Thrombus Formation in the Inferior Vena Cava

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Nowadays compression ultrasound (CUS) is the golden standard for the routine diagnosis of deep venous thrombosis (DVT). The drawback of CUS is the low sensitivity concerning the diagnosis of isolated pelvic vein thrombosis, especially referring to isolated internal iliac vein and ovarian vein thromboses. Therefore MR venography has become a valuable alternative.

We present a 45 year old female patient with a massive pulmonary embolism (PE) with the indication for thrombolytic therapy due to severe right ventricular overload. We were not able to detect a DVT in this patient in the lower limbs with CUS. However, further DVT-work up by MR venography showed a free floating thrombus formation originating from the right internal iliac veins into the inferior vena cava. Due to the fact that this thrombus was free floating surgical removal of the thrombus was scheduled and performed successfully.

In some patients it might be important to look for so called rare causes of PE, even then when CUS of the lower limbs does not reveal any deep venous thromboses. The diagnostic procedure of choice for these patients seems to be MR phlebography, as with this procedure iliac and pelvic veins can be evaluated without radiation exposure.

Percutaneous Transluminal Angioplasty versus Primary Stenting in Infrapopliteal Arteries in Critical limb Ischemia

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Purpose In endovascular recanalisation of infrapopliteal arteries, studies have already pointed out the value of balloon angioplasty but for stent implantation very few randomized controlled data exist so far.

We conducted a randomized prospective trial in patients with CLI comparing the effect of PTA versus primary stenting in infra-

popliteal arteries, concerning 1-year clinical benefit and reobstruction rate.

Results 54 patients were either randomized for primary stenting (balloon expandable stent) or PTA alone 33 patients were assigned to the PTA group, 21 patients to the Stent group. The whole follow up period of 12 months was completed by 46 patients. Improvement by at least one Rutherford classification was reached by a total of 33 (75.0%) of patients at month 12, 22 (81.5%) in the PTA group and 11 (64.7%) in the Stent group. A complete ulcer healing at month 12 showed 21 (63.6%) of all patients, with a significantly higher percentage in patients treated with PTA alone (16 [80.0%] vs 5 [38.5%]).

50.0% of all patients showed significant re-obstruction over the follow-up period, 39.4% of the PTA and 66.7% of the stent group. At month 3 loss of primary patency was nearly equal in both groups (23.3% PTA vs 25.0% stent), but drifted apart with the duration of the follow-up period to the disadvantage of primary stenting (month 12 51.9% vs 64.7%). As for secondary patency rate at month 12 the stent group showed a worse secondary patency rate than the PTA group (52.9% vs 70.4%).

Conclusion From our own data we draw the conclusion that PTA alone with the application of modern hydrophilic balloon catheters is superior to primary stenting with balloon expandable stents in infrapopliteal arteries.

Safety and Efficacy of Periprocedural Anticoagulation with Enoxaparin in Patients Undergoing Peripheral Endovascular Revascularisation

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Background Anticoagulation is used in endovascular procedures to prevent acute re-occlusion of the target vessel. Consecutive bleeding events are feared complications.

Material and Methods We performed a prospective, single center, open label phase III study comparing two different regimes of enoxaparin peri-interventional to peripheral EVR stratified into a low and a high risk group according to the reocclusion-risk due to their vessel morphology.

Results 184 patients were analyzed, 44 patients in the low risk group and 140 in the high risk group.

Concerning the primary safety endpoint a total of 25 (13.59%) bleedings occurred until day 30, 5 of them in the low risk (11.36%) and 20 (14.29%) in the high risk group ($p = 0.809$ for low vs high risk).

Concerning primary efficacy none of the patients showed an acute reocclusion until day 30. Concerning the second endpoint of prevention of chronic re-obstruction, at day 180 ABI has decreased in the low risk group from mean 0.94 at day 30 to mean 0.89 and from 1,28 at day 30 to 0.85 after 6 months in the high risk group. No significant reobstruction was found in the low risk group, whereas 5 significant reobstruction events were objectified in the high risk group.

Conclusion We conclude that LMWH either in a low dose or high dose regime during a peripheral EVR is safe concerning bleeding complications and acute reobstructions.

The longterm follow up showed no significant difference between our high and our low risk group concerning reobstruction.

Silverhawk Atherectomy Versus Primary Old Balloon Angioplasty (POBA) in Femoropopliteal Stent Re-obstructions – a Randomized Controlled Pilot Trial

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Background Due to intimal hyperplasia instent reobstruction in the femoropopliteal arterial segment is still an unsolved problem, even despite application of dual antiplatelet therapy in most patients for at least 3 months postprocedural. Different techniques have been discussed in case of reintervention to guarantee longlasting patency rate. The Silverhawk atherectomy device has been praised as at least equal to POBA in prevention of reobstruction in lower extremity interventions.

Patients and Methods We conducted a randomized controlled pilot trial comparing POBA and silverhawk atherectomy in patients with a first instent reobstruction in the femoropopliteal arterial segment. The procedures were performed by the same interventionalist, who had had adequate experience using the atherectomy device. All patients were on dual platelet therapy at least 7 days before the procedure and at least 3 months afterwards. To obtain measurements of intima media thickness (IMD) within the treated segment, as a parameter of recurrence of intimal hyperplasia, all patients showed up for a monthly duplex scan of the treated arterial segment. At every follow up visit ankle brachial index (ABI), laboratory parameters, Rutherford category and adverse events were recorded.

Results In a total 20 patients were included, 11 patients in the atherectomy device and 9 patients in the POBA arm. The mean age of the patients was 72.2 ± 5.3 years, 6 were females and 14 male. IMD within the treated segment was statistically significantly elevated in all patients treated with the silverhawk device versus the patients treated with POBA ($p < 0.05$). The differentiation in IMD started at month 2 (max IMD SH 0.178 mm vs IMD POBA 0.100 mm) with a spike at month 5 (max IMD SH 0.206 mm vs IMD POBA 0.145 mm). The values for mean IMD performed the same way. Concerning hemodynamic relevance ABI levels corresponded to the performance of IMD thickness.

Conclusion Although silverhawk atherectomy provides good results at first sight, in the midterm follow up of treatment of first instent restenosis it performed less well as treatment with POBA elevated by reoccurrence of intimal media hyperplasia.

Seasonal Variation of Endothelial Function in Scleroderma Related and Idiopathic Raynaud's Phenomenon

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Introduction Raynaud's phenomenon (RP) is characterised by a sudden acral pallor and subsequent reddish and/or livid discoloration, especially affecting the fingers. This disease has a broad geographic and seasonal volatile prevalence. RP can occur idiopathic without an underlying disease, this mostly affects young women. As a secondary form, RP can also be related to scleroderma. In early stages of scleroderma, RP may present the first and unique symptom of this connective tissue disease, but it has been proven that also endothelial damage and endothelial dysfunction are already present at these early stages. Our aim was to evaluate the presence of a seasonal variation of endothelial function among patients with scleroderma related and idiopathic RP.

Methods 52 patients with present RP (25 idiopathic and 27 scleroderma related RP patients) and 20 healthy subjects were included in the study. Endothelial function was evaluated by flow-mediated dilatation (FMD) of the brachial artery once in the cold season (October until March) and once during summer-time (April until September). All FMD-measurements were performed according to the present guidelines by the same trained technician.

Results The mean FMD between the 2 measurements was $3.9 \pm 3\%$ among scleroderma patients, $4.6 \pm 4.6\%$ among idiopathic RP patients and $5.5 \pm 2.4\%$ among the control subjects (n. s.). We observed a trend towards lower FMD-values during the cold season: scleroderma summer $4.4 \pm 3.2\%$ vs winter $3.4 \pm 4.4\%$, idiopathic RP summer $5.2 \pm 4.2\%$ vs winter $4.0 \pm 6.5\%$, and control subjects summer $6.5 \pm 3.7\%$ vs $4.5 \pm 6.5\%$. This trend of lower FMD-values during the cold season was statistically not significant within these groups, but we observed a significant difference between mean summer- and winter FMD-values of the whole study group with values of $5.3 \pm 3.8\%$ and $3.9 \pm 4.9\%$ respectively ($p = 0.029$).

Discussion Endothelial dysfunction has previously been proven in scleroderma patients. The method of flow-mediated dilatation by Celermajer showed a seasonal variation among the whole study group, independent to the underlying disease of RP, in idiopathic and scleroderma related forms. However, it is not proven, whether this reduction of FMD is also associated with an indeed decrease of endothelial function. If FMD is considered as a parameter of endothelial function in future studies, it seems essential to define the point of time of FMD-measurement.

Flow-Mediated Dilatation and Brachial Intima-Media Thickness and the Long-Term Cardiovascular Risk after Percutaneous Revascularization in Peripheral Arterial Disease

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Aims Peripheral arterial disease (PAD) is associated with an increased cardiovascular risk, which is not limited to restenosis after endovascular revascularization, but also applies to myocardial infarction, stroke and vascular death. Decreased flow-mediated dilatation (FMD) and enlarged intima-media thickness (IMT) are proven markers for functional and structural vascular damage respectively, both correlated with an increased cardiovascular risk. However, there is no data regarding these parameters and subsequent long-time cardiovascular events after percutaneous revascularization in PAD patients.

Between 2002 and 2004 we conducted a restenosis-trial which included 128 consecutive patients with PAD in Fontaine stage IIB after percutaneous revascularization of iliac and femoropopliteal arteries. We were able to prove enlarged brachial intima-media thickness (B-IMT) as an independent risk factor for restenosis within a follow up of 12 months. In contrast to the B-IMT results, this study could not prove a correlation between FMD and restenosis.

The aim of our study was to evaluate the long-term cardiovascular risk after percutaneous revascularization and the association between these two markers, B-IMT and FMD, and subsequent cardiovascular events.

Methods and Results Between January and October 2011 we evaluated the appearance of cardiovascular events among all 128 patients from the mentioned restenosis-trial. We conducted a telephone interview and collected all necessary data regarding cardiovascular events, cardiovascular risk and concomitant therapy. Cardiovascular events include cardiovascular death, death independent from cardiovascular disease, myocardial infarction, stroke and amputation. Statistics were calculated by a linear and univariable logistic (IMT, FMD) regression model. Statistical significance was assumed for p-values below 0.05. The study was approved by the local ethics committee.

The mean age of patient cohort during inclusion in the previous trial was (mean \pm SD) 66.5 ± 10.9 years. The follow-up after the revascularization of peripheral arteries during the preceding restenosis trial was 8.8 ± 0.7 years. Thirty-six patients (28.1%) were smokers, 27 patients (21.1%) were non-smokers and 65 out of 128 (50.8%) were former smokers. A total of 57 patients (44.5%) were suffering from diabetes mellitus, 103 patients (80.5%) from hyperlipidemia and 103 patients (89.9%) from arterial hypertension.

Mean values for FMD and B-IMT at study entry were $3.53 \pm 3.55\%$ and 0.29 ± 0.14 mm respectively. IMT was significantly associated

to overall death ($p = 0.037$) and vascular causes of death ($p = 0.016$). In addition, a correlation between IMT and any cardiovascular event ($p = 0.029$) was observed. In contrast to these data, we could not observe a statistically significant correlation between FMD and cardiovascular events ($p = 0.361$) or cardiovascular death ($p = 0.303$).

Conclusions We observed a correlation between the brachial IMT and subsequent cardiovascular events in PAD-patients, who had already undergone endovascular revascularization. The IMT may thus be regarded as an independent risk factor. In contrast to these results, we could not prove a correlation between FMD and cardiovascular events in a longer observation period after endovascular therapy. The lacking predictive value of FMD may be related to the broad vascular damage observed in PAD-patients.

Periodontal Treatment Decreases Asymmetrical Dimethylarginine (ADMA) Concentrations and Increases the Plasma L-Arginine/ADMA Ratio in Patients with Severe Periodontitis

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Purpose Epidemiologic data support the hypothesis that poor oral health and tooth loss increase the risk for cardiovascular disease. Periodontitis has been associated with endothelial dysfunction and periodontal treatment improves endothelial dysfunction in patients with severe periodontitis. The mechanisms by which periodontal disease impairs endothelial function are not well understood. The purpose of study was to elucidate if altered concentrations of L-arginine and the endogenous nitric oxide synthase inhibitor ADMA may contribute to vascular impairment in patients with severe periodontitis.

Methods Patients with severe periodontitis were eligible for participation in the study. Healthy volunteers matched for age and sex served as controls. Severe periodontitis was treated including both mechanical and pharmacological therapy according to published guidelines. Plasma concentrations of L-arginine and ADMA were studied at baseline and three months after end of treatment.

Results L-arginine concentrations were significantly lower in patients with periodontal disease before treatment when compared to healthy controls ($70.3 \mu\text{mol/l} \pm 13.4$ vs $79.4 \mu\text{mol/l} \pm 19.7$; $p = 0.04$). ADMA concentrations were similar in both groups at baseline ($0.65 \mu\text{mol/l} \pm 0.08$ in patients with periodontitis vs $0.64 \mu\text{mol/l} \pm 0.08$ in controls; $p = 0.56$). The L-arginine/ADMA ratio was lower in patients with periodontal disease (109.3 ± 20.9 vs 126.1 ± 32.5 ; $p = 0.02$).

On regression analysis using age, sex, smoking status, BMI and HDL-C as covariates the difference of the L-arginine/ADMA ratio in patients and controls remained significant.

Three months after treatment L-arginine concentrations and the L-arginine/ADMA ratio significantly increased (from $70.6 \mu\text{mol/l} \pm 13.5$ to $87.8 \mu\text{mol/l} \pm 15.7$; $p < 0.01$ for L-arginine and from 109.3 ± 21.3 to 143.9 ± 27.9 ; $p < 0.01$ for L-arginine/ADMA ratio). ADMA concentrations significantly decreased from $0.65 \mu\text{mol/l} \pm 0.08$ to $0.62 \mu\text{mol/l} \pm 0.08$; $p = 0.01$.

Conclusions Treatment of severe periodontitis reduces ADMA concentrations and increases L-arginine concentrations and the L-arginine/ADMA ratio which may contribute to improvement of endothelial dysfunction.

Intraarterial Platelet Reactivity and its Possible Influence on Development of Reobstruction in the Superficial Femoral Artery After Percutaneous Transluminal Angioplasty

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Background Inhibition of platelet reactivity with aspirin is standard therapy after percutaneous intervention (PTA) in peripheral arteries. Nevertheless reobstruction rate especially in the superficial femoral artery (SFA) is high. Interaction of activated platelets and the endothelium in the region of intervention could be one reason for this fact. We therefore conducted a prospective study evaluating the platelet reactivity measured in the region of percutaneous intervention and its possible influence on the development of reobstruction after PTA.

Material and Methods A total of 45 patients were included in this prospective study. Arterial blood was taken in the PTA region immediately after intervention of the SFA. Platelet function was performed on a Lumi-Aggregometer (Chronolog 700, Chronolog Corp., Havertown, PA) using collagen (2 mg/ml) in standard concentrations and results were analyzed using the Aggrolink 8.1.2.2 software package (Chronolog). After 3, 6, 12, and 24 months duplex sonography was performed and reobstruction rate was evaluated.

Results A total of 12 patients developed a hemodynamically relevant reobstruction in the PTA region during the 24 months follow up period. Platelet reactivity induced with collagen was higher in patients developing reobstruction compared to patients without reobstruction (amplitude mean \pm SD 30.8 ± 36.9 vs 22.0 ± 35.9 ; slope mean \pm SD 59.2 ± 23.7 vs 49.2 ± 26.2 ; AUC mean \pm SD 253.5 ± 293.3 vs 177.3 ± 296.4), however the difference was not statistically significant ($p = 0.48, 0.24, 0.45$).

Conclusion There are statistically not significant differences in the collagen induced platelet reactivity in patients developing reobstruction after PTA in the SFA region. Whether this might influence development of reobstruction must be evaluated in further studies.

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