

Advanced Interventionen an den Unterschenkelgefäßen

R. Kickuth

Infrapopliteale Angioplastie – die vergessene Region?

H.-J. Wagner¹, G. Rager²

¹ Abteilung Strahlendiagnostik (Leiter: Prof. Dr. K. J. Klose)

² Abteilung Allgemeinchirurgie (Leiter: Prof. Dr. M. Rothmund) Klinikum der Philipps-Universität Marburg

- Publikationen über infrapopliteale PTAs eher selten
- Entwicklung hydrophiler Führungsdrähte, verbesserter Kathetermaterialien und dedizierter Ballonkatheter
- Hierdurch PTA distal der A. poplitea Standardverfahren
- Verbesserungen im periinterventionellen medikamentösen Management
- Zu erzielende initiale technische und klinische Resultate: ausgezeichnet

Infrapopliteale Angioplastie – die vergessene Region?

H.-J. Wagner¹, G. Rager²

- Klinischer Vordergrund: Erhalt der betroffenen Extremität
- Unter diesem Aspekt zufriedenstellende Resultate
- Jedoch Langzeitergebnisse unbefriedigend: Rezidive mit nachfolgenden notwendigen Reinterventionen
- Erfordernis der Entwicklung therapeutischer Strategien
- Hierdurch möglicherweise Hemmung von Restenosierungen

¹ Abteilung Strahlendiagnostik (Leiter: Prof. Dr. K. J. Klose)

² Abteilung Allgemeinchirurgie (Leiter: Prof. Dr. M. Rothmund) Klinikum der Philipps-Universität Marburg



Universität Würzburg

Perkutane transluminale Angioplastie

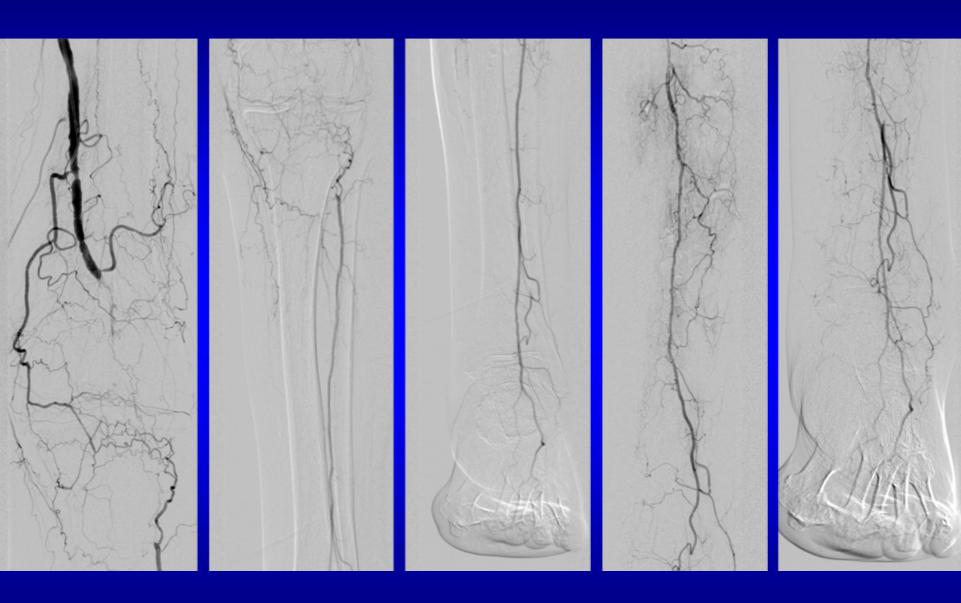
Tibioperoneal (Outflow Lesion) Angioplasty Can Be Used as Primary Treatment in 235 Patients With Critical Limb Ischemia Five-Year Follow-Up

Gerald Dorros, MD; Michael R. Jaff, DO; Ari M. Dorros, MD; Lynne M. Mathiak, RN; Thomas He, PhD

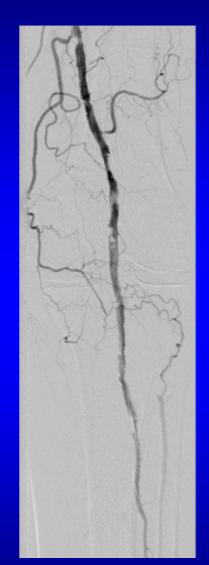
Background—In a prospective, nonrandomized, consecutive series of tibioperoneal vessel angioplasty (TPVA), critical limb ischemia (CLI) patients' data were analyzed with regard to immediate and follow-up success.

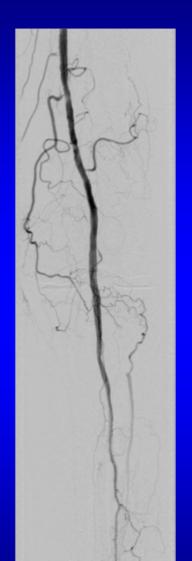
Methods and Results—TPVA was successful in 270 of 284 critically ischemic limbs (95%), with 167 limbs (59%) requiring dilatation of 333 ipsilateral inflow obstructions to access and successfully dilate 486 of 529 (92%) tibioperoneal lesions. A clinical success (relief of rest pain or improvement of lower-extremity blood flow) was attained in 270 limbs at risk (95%). Clinical 5-year follow-up of 215 of 221 successful CLI patients (97%) with 266 successfully revascularized limbs revealed that bypass surgery occurred in 8% and significant amputations in 9% of limbs; 91% of the limbs were salvaged. The cohort's probability of survival was 56%: 58% for Fontaine class III and 33% for class IV patients. Class III compared with class IV patients had significantly (P<0.05) fewer surgical bypasses (3% versus 16%) and amputations: above-knee, 1% versus 4%; below-knee, 3% versus 12%; and transmetatarsal, <1% versus 21%.

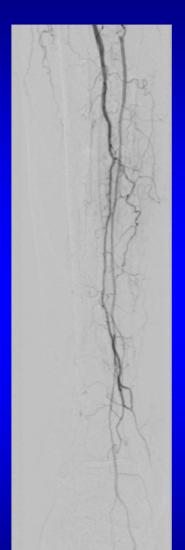
Conclusions—TPVA, often in combination with inflow lesions, is an effective primary treatment for critical limb ischemia. The poor cumulative survival reflects the existence of severe comorbidities, which could potentially be affected by aggressive and effective cardiovascular diagnostic and therapeutic strategies. (Circulation. 2001;104:2057-2062.)

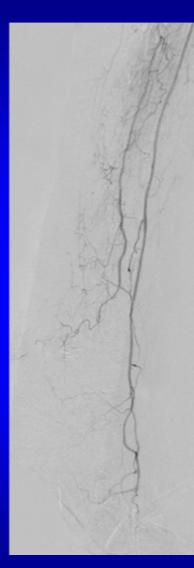










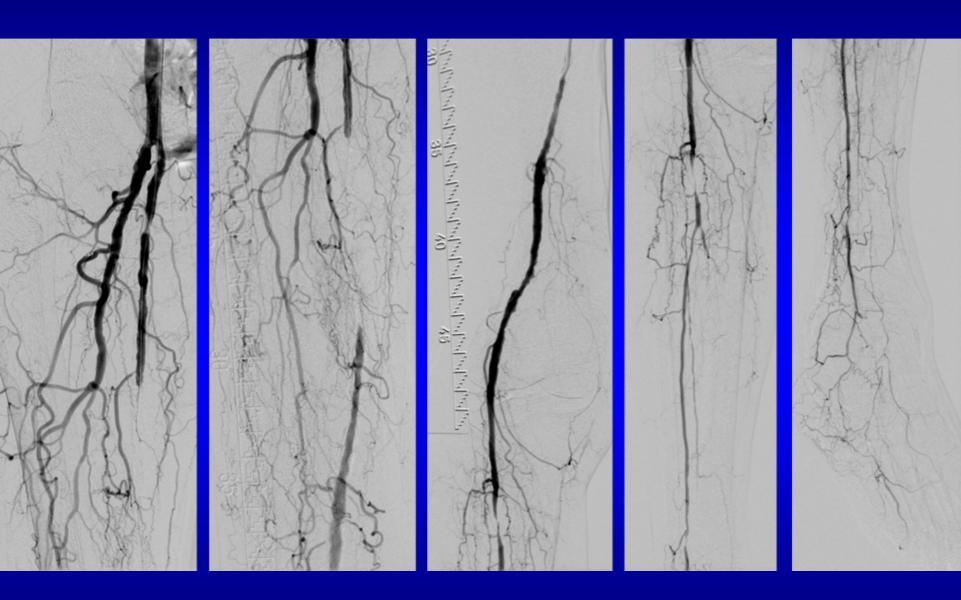


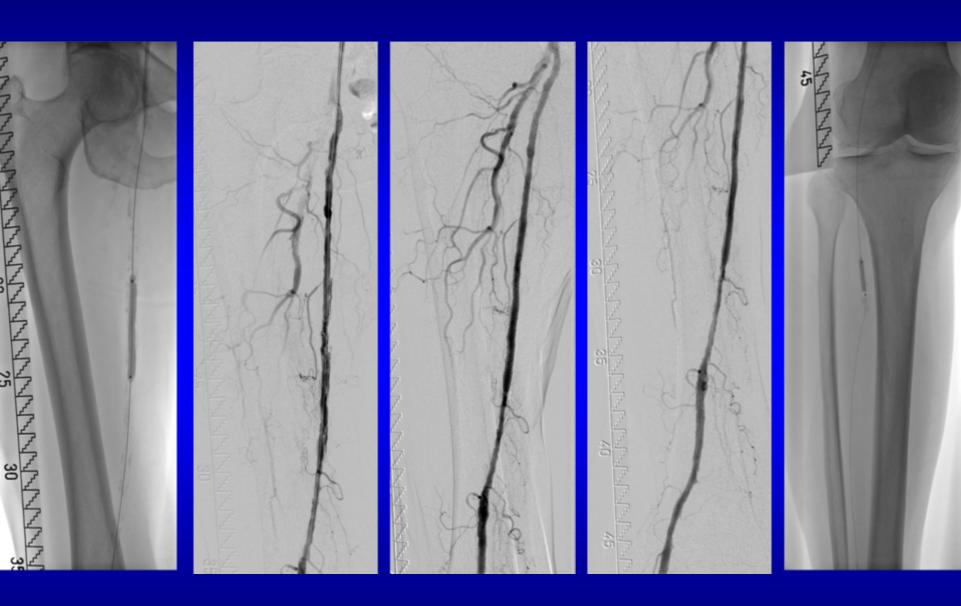
Universität Würzburg

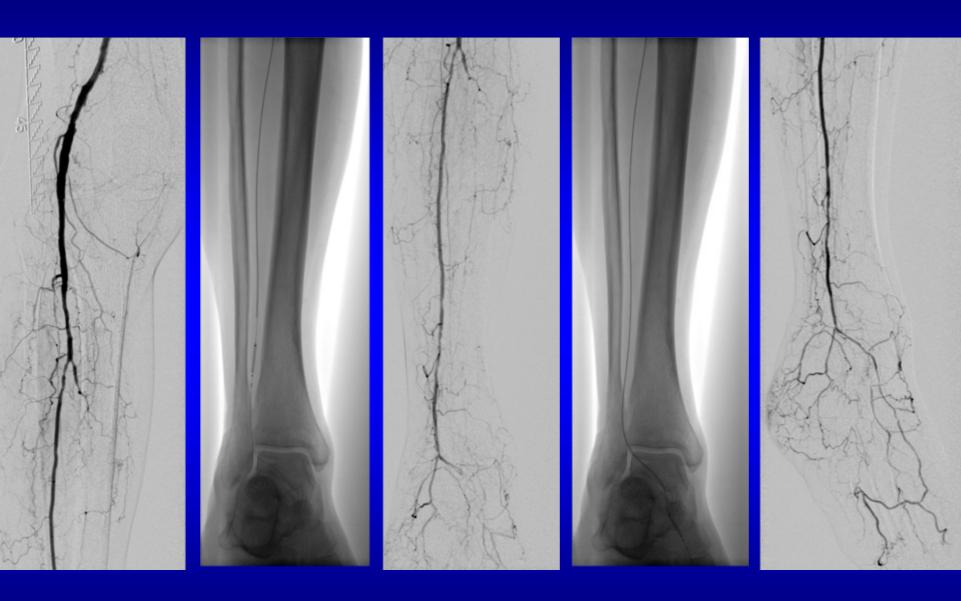
Grundlegende Erkenntnisse:

- Bei kritischer Ischämie Zugrundeliegen einer Mehretagen-AVK
- Je kürzer das Verschluss-/stenosesegment, desto besser die Primärergebnisse
- Diabetiker bekannt als Patientengruppe mit erhöhtem Risiko für das Auftreten einer Stenose oder Okklusion

(Bates MC et al., J Endovasc Ther, 2004) (Tsetis D et al., Br J Radiol, 2004)







Universität Würzburg

Stentimplantation

Primary Stent-Supported Angioplasty for Treatment of Below-Knee Critical Limb Ischemia and Severe Claudication

Early and One-Year Outcomes

Andrew J. Feiring, MD, FACC, FCSAI, Amy A. Wesolowski, RN, Susan Lade, RN Milwaukee, Wisconsin

OBJECTIVES

The objective of this study was an investigation of the safety and efficacy of primary below-knee stent-supported angioplasty (BKSSA) for restoring straight inline arterial flow in patients with critical limb ischemia (CLI) or lifestyle-limiting claudication (LLC).

BACKGROUND

Surgical tibial bypass for CLI and severe LLC is associated with significant morbidity, mortality, and graft failure, whereas percutaneous angioplasty is suboptimal.

METHODS

Below-knee stent-supported angioplasty was attempted in 82 patients (92 limbs) with either CLI (68%) or severe LLC (32%). Patients received daily aspirin, thienopyridine, and glycoprotein IIb/IIIa agents during the procedure. One-month major adverse events (MAEs) were defined as death, myocardial infarction, major unplanned amputation, need for surgical revascularization, or major bleeding. Clinical success was defined as improved resting ankle brachial index by ≥0.10, relief of resting pain, healing of ulceration or amputation, and improvement of claudication.

RESULTS

Mean age of patients was 74 \pm 17 years. In 86 limbs, straight inline flow was restored to at least one tibial vessel. Technical success was 94% for de novo lesions and there were no MAEs. Ankle brachial indexes increased for all groups (CLI = 0.32 ± 0.13 to 0.9 ± 0.14 and LLC = 0.65 ± 0.09 to 0.95 ± 0.12 ; p \leq 0.0001, pre vs. post). Relief of rest pain and healing of ulcerations and amputations were seen in 96% (47 of 49) of patients with CLI who underwent successful intervention.

CONCLUSIONS

Below-knee stent-supported angioplasty for CLI and LLC improves ankle brachial indexes comparable to tibial bypass, heals amputations and ulcerations, relieves rest pain, and improves ambulation. Because BKSSA is associated with minimal MAE, it may hold promise as an alternative therapy for patients with CLI and LLC. (J Am Coll Cardiol 2004;44: 2307–14) © 2004 by the American College of Cardiology Foundation

CardioVascular and Interventional Radiology © Springer Science+Business Media, Inc. 2005 Published Online: 17 October 2005 Cardiovasc Intervent Radiol (2006) 29:29–38 DOI: 10.1007/s00270-005-0276-9

CLINICAL INVESTIGATIONS

PTA Versus Carbofilm-Coated Stents in Infrapopliteal Arteries: Pilot Study

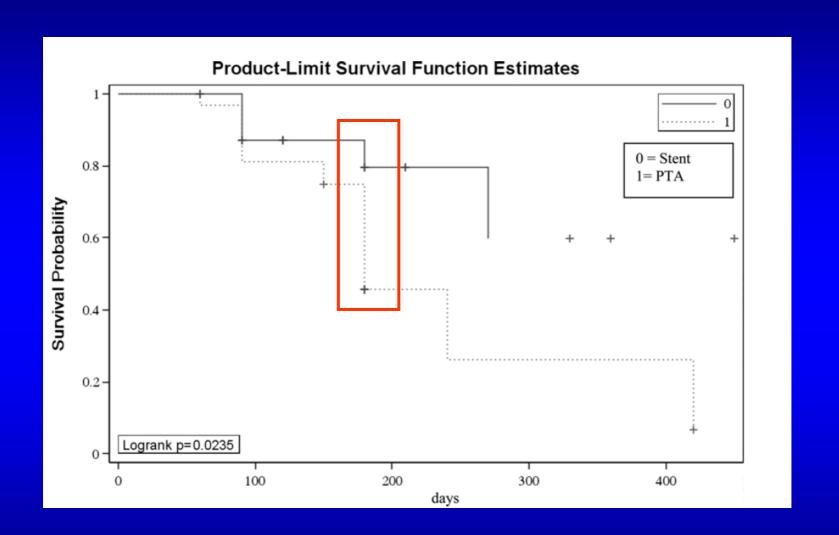
- T. Rand, A. Basile, M. Cejna, D. Fleischmann, M. Funovics, M. Gschwendtner,
- M. Haumer,⁴ I. Von Katzler,¹ J. Kettenbach,¹ F. Lomoschitz,¹ C. Luft,⁵ E. Minar,⁴
- B. Schneider, M. Schoder, J. Lammer 1

Purpose: To determine the primary success and short-term patency of stent application as a primary treatment modality for high-grade lesions of the infrapopliteal arteries compared with treatment with percutaneous transluminal angioplasty (PTA) in critical limb ischemia in a randomized prospective study.

Methods: Endovascular therapy was performed on 95 lesions in 51 patients (mean age 72.0 years, range 47–80 years) who presented clinically with Fontaine stages III and IV. One patient underwent treatment in both limbs. After angiographic lesion identification, patients were randomized for treatment by PTA (53 lesions in 27 patients) or stent application (42 lesions in 24 patients). Follow-up by clinical investigation and conventional angiography or spiral CT angiography was performed in 37 patients (57 lesions) 6 to 12 months after the procedure, or when clinically indicated. Evaluation was performed by two observers, double-blinded, with thresholds for lesion restenosis of 50% and 70%. Statistical evaluation was performed on a lesion basis by Kaplan-Meier estimated probability rates, and log-rank and Wilcoxon tests. The primary endpoint was the angiographic patency rate of treated lesions.

Results: The inter-reader agreement was high ($\kappa = 0.82$). For the stent group the cumulative primary patency at 6 months was 83.7% at the 70% restenosis threshold, and 79.7% at the 50% restenosis threshold. For PTA, the primary patency at 6 months was 61.1% at the 70% restenosis threshold and 45.6% at the 50% restenosis threshold. Both results were statistically significant (p < 0.05).

Conclusion: Infrapopliteal stent application is an effective treatment modality for high-grade lesions in chronic critical limb ischemia. Compared with PTA, higher patency rates can be expected after 6 months.



Initial Clinical Experience with the 4-F Self-expanding XPERT Stent System for Infrapopliteal Treatment of Patients with Severe Claudication and Critical Limb Ischemia

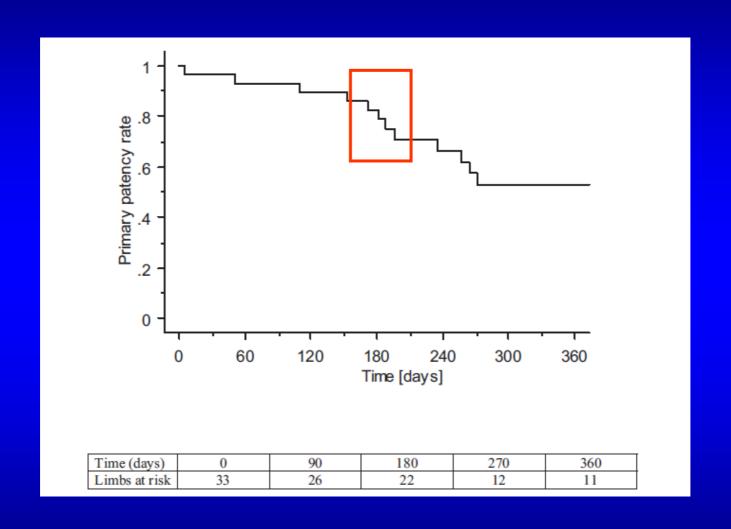
Ralph Kickuth, MD, Hong Hak Keo, MD, Jürgen Triller, MD, Karin Ludwig, MD, and Dai-Do Do, MD

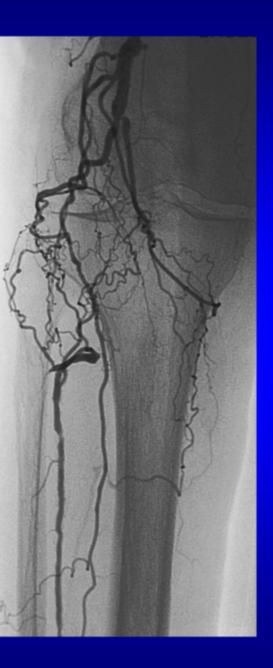
PURPOSE: To evaluate the primary success and short-term patency associated with a new 4-F sheath-compatible self-expanding nitinol stent after failed conventional angioplasty of distal popliteal and infrapopliteal lesions in severe lifestyle-limiting claudication (LLC) and chronic critical limb ischemia (CLI).

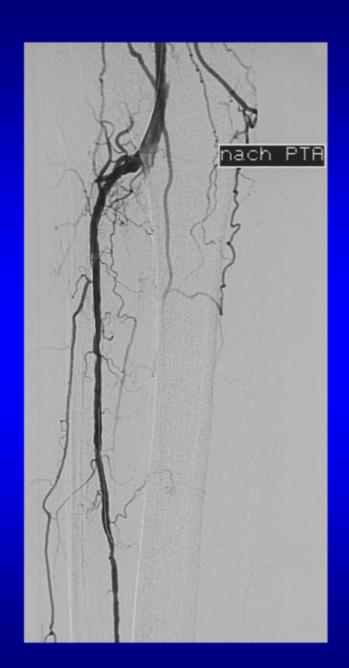
MATERIALS AND METHODS: Between May 2003 and July 2005, 35 patients with Rutherford category 3–5 disease (16 patients with CLI, 19 patients with LLC) underwent percutaneous transluminal angioplasty (PTA) and stent implantation. Indications for stent placement were residual stenosis, flow-limiting dissections, or elastic recoil after PTA. Before and after the intervention and during the 6-month follow-up, clinical investigation, color-flow and duplex Doppler ultrasonography, and digital subtraction angiography were performed. Technical success, primary patency at 6 months, clinical improvement as defined by Rutherford with clinical and hemodynamic measures, and complications were evaluated.

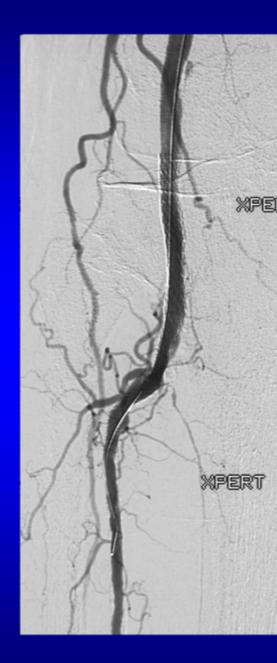
RESULTS: A total of 22 patients underwent distal popliteal artery stent placement and 13 underwent tibioperoneal artery stent placement. Stent implantation was successfully performed in all patients. After stent placement, the primary cumulative patency rate for the study group at 6 months was 82%. The mean resting ankle-brachial index at baseline was 0.50 ± 0.16 and significantly increased to 0.90 ± 0.17 at 12–24 hours after intervention and 0.82 ± 0.24 at latest follow-up (P < .001 for both). The sustained clinical improvement rate was 80% at the 6-month follow-up. The 6-month limb salvage rate regarding major amputation was 100%. The rate of major complications was 17%.

CONCLUSIONS: Infrapopliteal application of the new nitinol stent is a safe, feasible, and effective method with good short-term patency rate in the treatment of severe LLC and chronic CLI.









CLINICAL INVESTIGATION

Angioplasty or Primary Stenting for Infrapopliteal Lesions: Results of a Prospective Randomized Trial

C. Randon · B. Jacobs · F. De Ryck ·

F. Vermassen

Abstract Excellent results with small stents in coronary arteries have led endovascular therapists to their use in infrapopliteal vessels. However, to date no level I evidence exists to recommend primary stenting over infrapopliteal angioplasty alone. The aim of this randomized singlecenter trial was to compare their 1-year outcome. A total of 38 limbs in 35 patients with critical limb ischemia were randomized to angioplasty (22 pts) or primary stenting (16 pts). Target lesions were infrapopliteal occluded (36) or stenotic (20) lesions ranging from <2 to >15 cm in length. The mean age was 72 years. At 12 months, there was no statistical difference in survival (angioplasty, 69.3%; primary stenting, 74.7%), in limb salvage (angioplasty, 90%; primary stenting, 91.7%), or in primary and secondary patency (angioplasty, 66 and 79.5%; primary stenting, 56 and 64%) between the groups Renal insufficiency was the only significant negative predicting factor for limb salvage in both groups. In conclusion, the 1-year results for both groups were broadly similar. Stenting has its place in infrapopliteal angioplasty if the procedure is jeopardized by a dissection or recoil, but our results do not support primary stenting in all cases.













Sirolimus for Below the Knee Lesions: Mid-Term Results of SiroBTK Study

Philippe Commeau,* мр, ғsсы, Paul Barragan, мр, and Pierre O. Roquebert, мр

Objectives: To assess the safety and efficacy of sirolimus-eluting stents (SESs) in the treatment of severe intermittent claudication and critical limb ischaemia with "belowthe-knee" lesions, unsuitable for surgery. Background: Limited published evidence suggests that drug-eluting stents may offer significant improvements in the treatment of infrapopliteal lesions. Methods: Thirty consecutive patients with either severe intermittent claudication or critical limb ischemia (CLI), category 3-6 of Rutherford classification, and multivessel disease of infrapopliteal arteries (>2 vessels) were treated with SES. Sixty-two arteries were treated with 106 SES. Mean age was 73.9 years, 77% of patients were male and 36% diabetic. The primary endpoint was clinical improvement and healing of ulcers at short term (1 month) and mid term (7.7 months). The secondary endpoint was primary vessel patency rate (angiographic or duplex assessment). All patients received clopidogrel (75 mg daily) or ticlopidine (150 mg daily) for 2 months or longer. Results: Angiographic and procedural success was achieved in all patients. At 7 months (7.7 \pm 5.8), it was necessary to amputate 1 toe in one patient and 1 mid-foot in another. Limb salvage was obtained in 100% of patients. Other events were: two cardiac deaths unrelated to CLI, one stroke with hemiparesia, one initial reperfusion syndrome, one contralateral CLI, and three recurrent homolateral claudication cases. All surviving patients had a mid-term clinical improvement with 97% of primary patency (56 patent arteries on 58 arteries). Conclusion: Treatment of "below-the-knee" lesions with SES may provide an alternative treatment for patients with CLI. © 2006 Wiley-Liss, Inc.

Infrapopliteal Application of Paclitaxel-eluting Stents for Critical Limb Ischemia: Midterm Angiographic and Clinical Results

Dimitris Siablis, PhD, Dimitris Karnabatidis, PhD, Konstantinos Katsanos, MD, Athanassios Diamantopoulos, MD, Nikolaos Christeas, MD, and George C. Kagadis, PhD

PURPOSE: To report the midterm (≤1 year) angiographic and clinical outcomes of a prospective study investigating the infrapopliteal application of paclitaxel-eluting stents (PES) in patients with critical limb ischemia (CLI).

MATERIALS AND METHODS: Infrapopliteal angioplasty was chosen as first-line therapy in patients with unilateral or bilateral CLI and additional femoropopliteal angioplasty was performed in case of multilevel disease. Implantation of coronary PES was performed in case of a suboptimal angioplasty result (eg, elastic recoil, residual stenosis >30%, or flow-limiting dissection). Patients were followed up with regular clinical evaluation, and digital subtraction angiography was scheduled at 6 months and 1 year. Life-table analysis and Kaplan-Meier plotting of angiographic and clinical variables were performed. Cox proportional-hazards regression analysis was employed to adjust for various covariates and search for independent adverse predictors of angiographic and clinical outcome.

RESULTS: Infrapopliteal procedures were performed in 29 patients with 32 limbs with CLI; 79.3% of the patients had diabetes and 34.5% had renal disease. A total of 62 coronary PES were deployed in 50 below-knee lesions (mean stent-implanted length, 25.51 mm ± 12.16). Technical success rate was 100%. The 1-year mortality rate was 16.9%, and the limb salvage rate was 88.5%. The 1-year angiographic in-stent primary patency rate was 30.0%, whereas the incidence of in-stent binary (>50%) restenosis was 77.4%. The 1-year incidence of clinically driven repeat interventions was 30.5%. The Cox model calculated renal disease as the only independent predictor of decreased primary patency and increased repeat intervention events. Initial occlusions also adversely affected primary patency.

CONCLUSIONS: Infrapopliteal PES achieved acceptable clinical results in CLI, even though they failed to inhibit vascular restenosis and decrease the need for repeat interventions. Renal disease and initial occlusions are adverse prognostic factors for infrapopliteal endovascular procedures.

J Vasc Interv Radiol 2007; 18:1351-1361

Infrapopliteal Application of Sirolimus-eluting versus Bare Metal Stents for Critical Limb Ischemia: Analysis of Long-term Angiographic and Clinical Outcome

Dimitris Siablis, MD, PhD, Dimitris Karnabatidis, MD, PhD, Konstantinos Katsanos, MD, Athanasios Diamantopoulos, MD, Stavros Spiliopoulos, MD, George C. Kagadis, BSc, MSc, PhD, and John Tsolakis, MD, PhD

PURPOSE: To present the 3-year angiographic and clinical results of a prospective registry investigating the performance of sirolimus-eluting stents (SESs) versus bare metal stents (BMSs) for critical limb ischemia (CLI) treatment.

MATERIALS AND METHODS: A single-center double-arm prospective registry included patients with CLI who underwent infrapopliteal revascularization with angioplasty and "bailout" use of an SES or BMS. Clinical and angiographic follow-up was scheduled at regular time intervals. Primary clinical and angiographic endpoints included mortality, limb salvage, primary patency, binary angiographic restenosis (ie, >50%), and clinically driven repeat intervention-free survival. Results were stratified according to stent type, and cumulative proportion outcomes were determined by Kaplan-Meier plots. Multivariable Cox proportional-hazards regression analysis was applied to adjust for confounding factors of heterogeneity.

RESULTS: In total, 103 patients were included in the analysis; 41 (75.6% with diabetes) were treated with a BMS (47 limbs; 77 lesions) and 62 (87.1% with diabetes) with an SES (75 limbs; 153 lesions). At 3 years, SES-treated lesions were associated with significantly better primary patency (hazard ratio [HR], 4.81; 95% CI, 2.91–7.94; P < .001), reduced binary restenosis (HR, 0.38; 95% CI, 0.25–0.58; P < .001), and better repeat intervention–free survival (HR, 2.56; 95% CI, 1.30–5.00; P = .006) versus BMS-treated ones. No significant differences were identified between SESs and BMSs with regard to overall 3-year patient mortality (29.3% vs 32.0%; P = .205) and limb salvage (80.3% vs 82.0%; P = .507).

CONCLUSIONS: Infrapopliteal application of SESs for CLI significantly improves angiographic long-term patency and reduces infrapopliteal vascular restenosis versus BMSs, thereby lessening the rate of clinically driven repeat interventions.

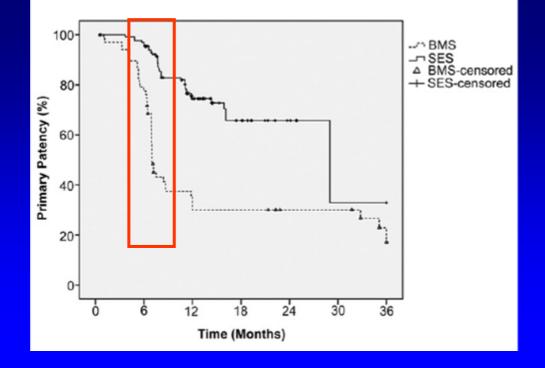


Table 5 Angiographic and Clinical Cumulative Proportion Outcomes of SES and BMS at 3 Years after Bivariable and Multivariable Analysis

Outcome	SES Group (%)	BMS Group (%)	P Value*	HR†	95% CI	Adjusted P Value
Primary patency In-stent binary restenosis In-lesion binary restenosis Recurrent obstruction Repeat intervention—free survival	32.9	17.1	<.001	4.81	2.91–7.94	<.001
	81.1	96.0	<.001	0.38	0.25–0.58	<.001
	83	95.6	<.001	0.45	0.29–0.68	<.001
	14.8	67.4	<.001	0.15	0.08–0.29	<.001
	77.6	70.3	<.049	2.56	1.3–5.0	.006

^{*} Calculated by log-rank bivariate analysis.

[†] Cox model adjusted for diabetes, renal disease, initial lesion grade (stenosis or occlusion), stent-implanted lesion length, and type of stent.



TASC II Empfehlungen:

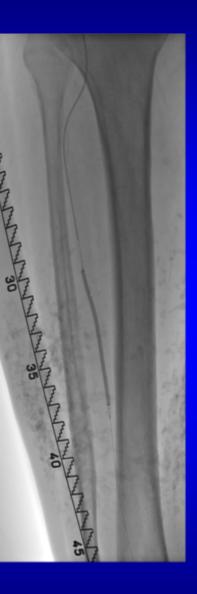
- Indikation für PTA distal der A. poplitea: Beinerhalt
- PTA einer kurzen A. tibialis anterior/posterior-Stenose in Verbindung mit poplitealer oder femoraler PTA
- Steigende Evidenz für die Empfehlung der PTA von Okklusionen bei CLI zur Verbesserung des Einstroms in den Fuß (bei existenter Komorbidität)
- Insuffiziente Evidenz für die Empfehlung der PTA und Stentimplantation bei Patienten mit CI

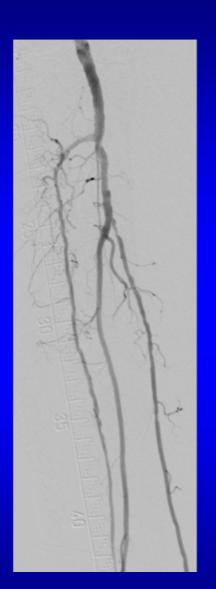


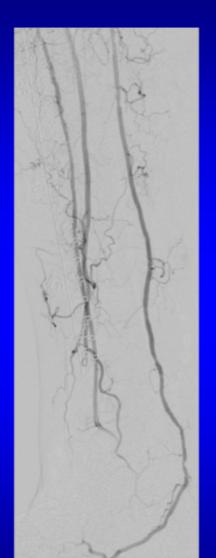


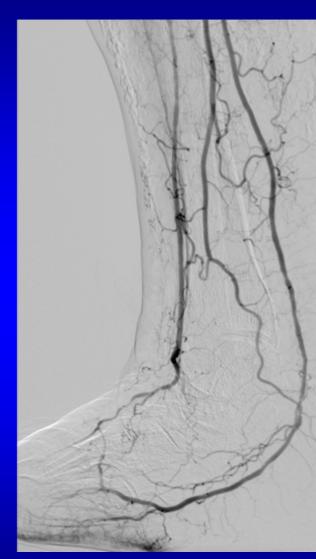








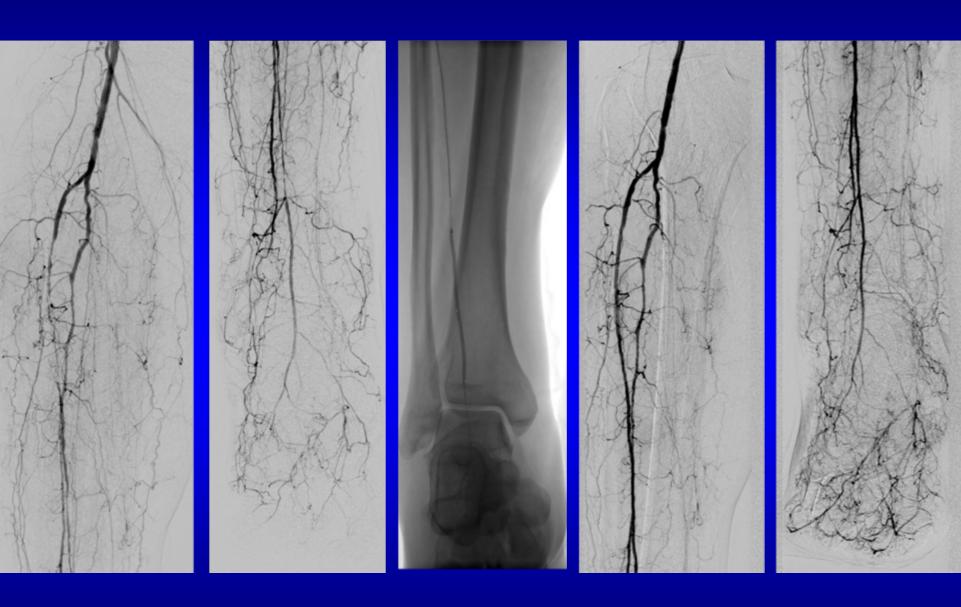






Periinterventionelle Behandlung/Stent:

- 5000 I.E. Heparin i.a. während der Intervention
- Clopidogrel 300 mg am Tag der Intervention
- Clopidogrel 75 mg/d f
 ür 4 Wochen
- ASS 100 mg/d lebenslang



Infragenicular Stent Implantation for Below-the-Knee Atherosclerotic Disease: Clinical Evidence From an International Collaborative Meta-Analysis on 640 Patients

Giuseppe G.L. Biondi-Zoccai, MD¹; Giuseppe Sangiorgi, MD²; Marzia Lotrionte³; Andrew Feiring, MD⁴; Philippe Commeau, MD⁵; Massimiliano Fusaro, MD⁶; Pierfrancesco Agostoni, MD⁷; Marc Bosiers, MD®; Jan Peregrin, MD⁹; Oscar Rosales, MD¹⁰; Antonio R. Cotroneo, MD¹¹; Thomas Rand, MD¹²; and Imad Sheiban, MD¹

Purpose: To report a systematic review of the literature published on the outcomes of stenting for below-the-knee disease in patients with critical limb ischemia (CLI).

Methods: Potentially relevant studies of stent implantation in the infragenicular arteries in ≥ 5 patients with ≥ 1 -month follow-up were systematically sought in BioMedCentral, ClinicalTrials.gov, The Cochrane Collaboration Register of Controlled Trials (CENTRAL), Google Scholar, and PubMed. Data were abstracted and pooled with a random-effect model to generate risk estimates with 95% confidence intervals (CI). Interaction tests were performed to compare different stent types. A risk of bias assessment was conducted separately, as were appraisals for small study bias, statistical heterogeneity, and inconsistency.

Results: Eighteen nonrandomized studies were retrieved comprising 640 patients. After a median follow-up of 12 months, binary in-stent restenosis occurred in 25.7% (95% CI 11.6% to 40.0%), primary patency in 78.9% (95% CI 71.8% to 86.0%), improvement in Rutherford class in 91.3% (95% CI 85.5% to 97.1%), target vessel revascularization in 10.1% (95% CI 6.2% to 13.9%), and limb salvage in 96.4% (95% CI 94.7% to 98.1%). Head-to-head comparisons showed that sirolimus-eluting stents were superior to balloon-expandable bare metal stents in preventing restenosis and increasing primary patency (both p<0.001); sirolimus-eluting stents were also better than paclitaxel-eluting stents in terms of primary patency (p<0.001) and repeat revascularizations (p=0.014).

Conclusion: Percutaneous infragenicular stent implantation after failed or unsuccessful balloon angioplasty is associated with favorable clinical results in patients with CLI. Notwithstanding limitations of primary studies, sirolimus-eluting stents appear superior to bare metal and paclitaxel-eluting stents in terms of angiographic and/or clinical outcomes.

J Endovasc Ther. 2009;16:251–260

Universität Würzburg

Grundlegende neuere Erkenntnisse:

- Verbesserung des technischen Erfolgs durch "Low-profile- PTA-Ballone/Stentsysteme"
- Einsatz von Stents sinnvoll in "Bailout-Situationen" (Residualstenose, Dissektion, Recoiling, Thrombus)
- Diskrepanz zwischen anatomischer Patency, klinischer Patency und Beinerhaltungsrate nach Intervention
- Diskrepanz bedingt durch Ausbildung von Kollateralen

(Biondi-Zoccai GGL et al., J Endovasc Ther, 2009)



Eigene Daten

Patienten:

- Zwischen 03/2009 und 08/2010 retrospektive Evaluation
- 26 konsekutive Patienten mit pAVK (11 w, 15 m; mittleres Alter 77 ± 12 Jahre)
- Behandlung distal poplitealer und infrapoplitealer Läsionen



Eigene Daten

Universität Würzburg

Patienten (n) (%)	26 (100%)	
Stadium Rutherford 3 (n) (%)	2 (8%)	
Stadium Rutherford 4 (n) (%)	7 (27%)	
Stadium Rutherford 5 (n) (%)	17 (65%)	
Risikofaktoren:		
Arterielle Hypertonie (n) (%)	24 (92%)	
KHK (n) (%)	16 (62%)	
Hypercholesterinämie (n) (%)	16 (62%)	
Diabetes mellitus (n) (%)	14 (54%)	
Vor-OP (Amputation, Bypass) (n) (%)	9 (35%)	
Cerebrovaskuläre Erkrankung (n) (%)	4 (15%)	



Patienten:

- Chirurgische Risiko: multiple Komorbiditäten, Alter > 80 Jahre, fehlende Bypassvene, schlechter AZ
- Mehretagenerkrankung: n = 20 (77%); hier zunächst Behandlung der mehr proximal gelegenen Läsionen
- Ziel: Verbesserung des Run-offs bzw. Einstroms wenigstens einer Unterschenkelarterie



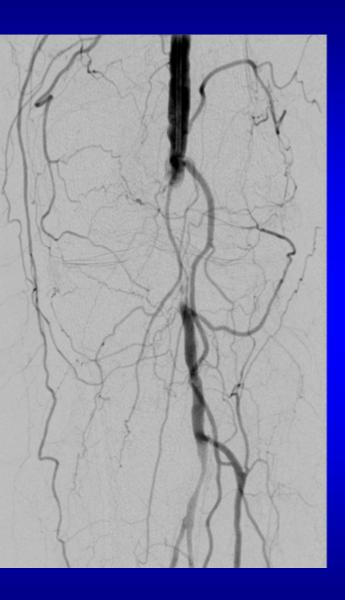
Technik:

- Low-profile PTA: Durchmesser 4 6 mm, Länge 20 – 80 mm
 - (Advance LP 14, Cook, Bjaeverskov, Dänemark; Pacific, Invatec, Roncadelle, Italien)
- Selbst-expandierbarer, helikaler Nitinolstent (SUPERA®, IDEV, Beuningen, Niederlande):
- Stentdurchmesser 4 − 6 mm, Länge 40 − 100 mm
- 5000 I.E. Heparin

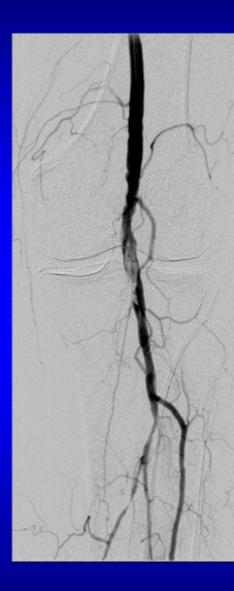


Indikationen:

- Residuale Stenosen
- Flusslimitierende Dissektionen
- Elastisches Recoiling nach PTA
- Therapieresistente Thrombusformation

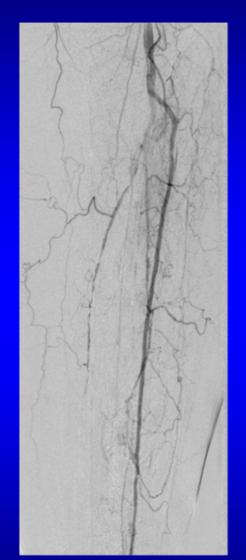


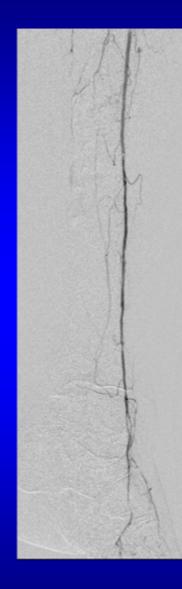














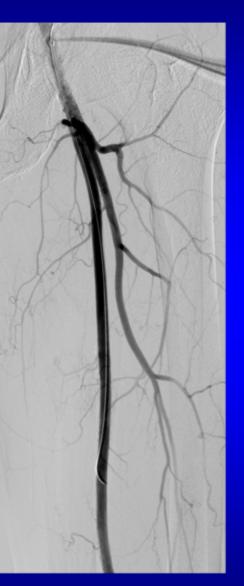
Follow-up:

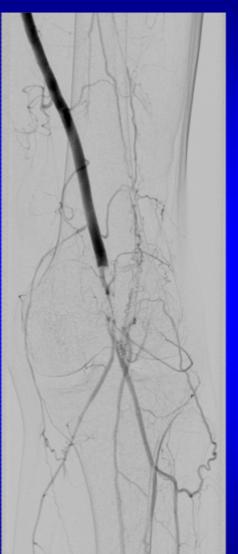
- Im Mittel 91 Tage (Range, 1 − 289 Tage)
- Bei 23/26 Patienten (88%) erhältlich
- Routine: Klinische Untersuchung, ABI-Messung, Duplexsonographie
- DSA bei V.a. Stenose oder Okklusion



Auswertung:

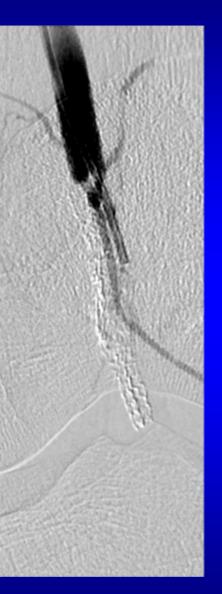
- Anatomische 3-Monats Offenheitsrate
- Technischer Erfolg
- Hämodynamischer Erfolg
- Klinisch/hämodynamische 3-Monats Offenheitsrate
- Beinerhaltungsrate
- Major- und Minorkomplikationen



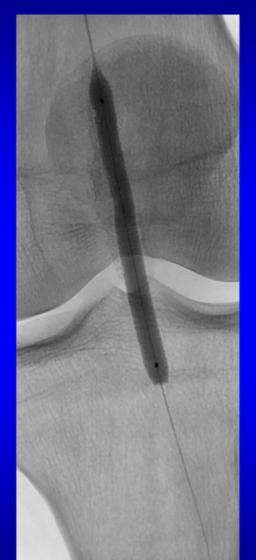




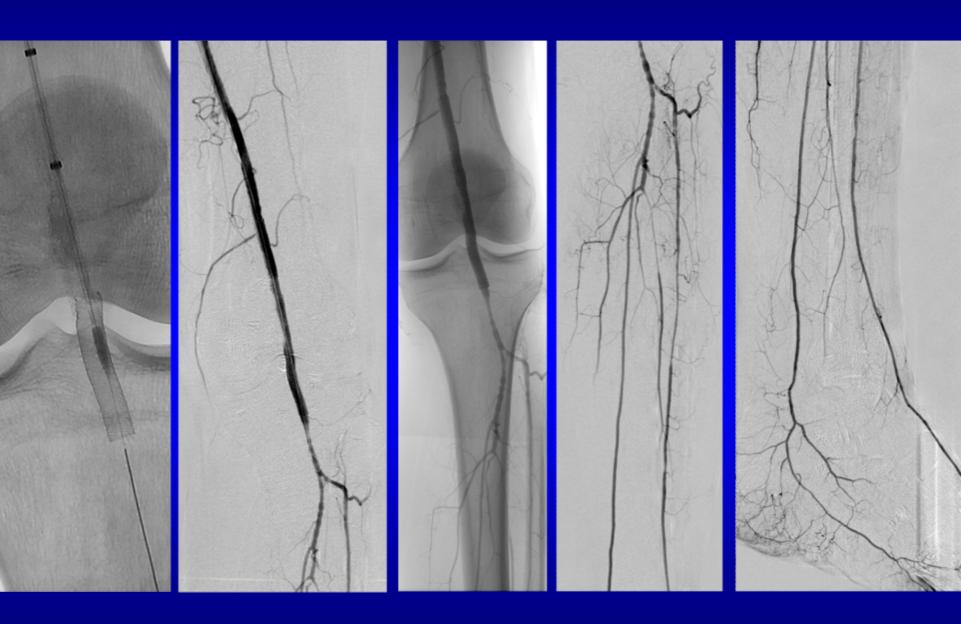


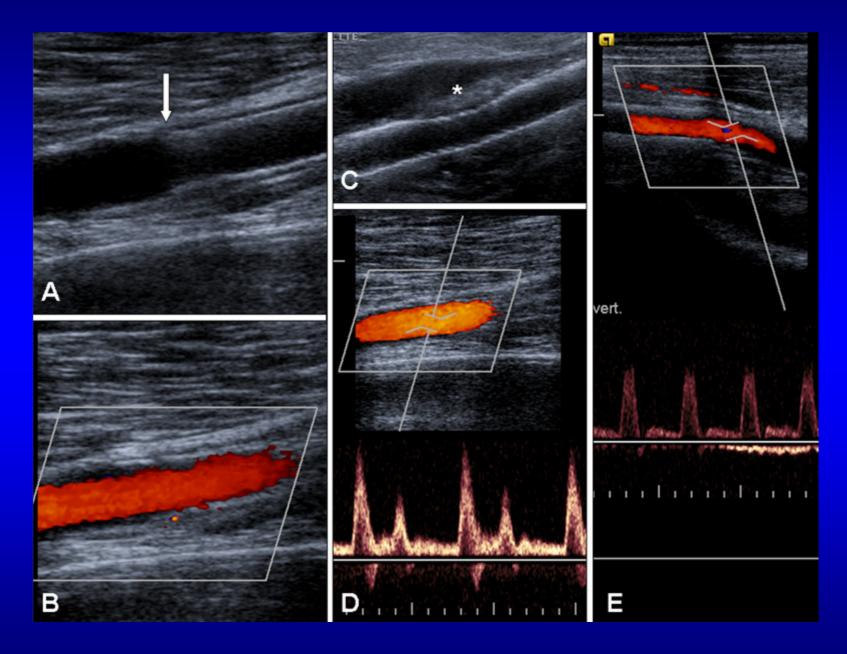














	Stenosen (n) (%)	Okklusionen (n) (%)
Lage der Läsion - Distal popliteal - Tibioperoneal Total	1 (4%) 0 (0%) 1 (4%)	24 (92%) 1 (4%) 25 (96%)



Technisches Outcome:

- Ipsilateraler antegrader Zugang: n = 25 (96%)
- Kontralateraler retrograder Zugang: n = 1 (4%)
- Stenosenlänge: 11.5 cm
- Okklusionslänge: 6.1 ± 4.0 cm
- Technischer Erfolg: 100% (26/26)



Technisches Outcome:

- Anzahl implantierter Stents pro Patient: n = 38(Mittel 1.5 ± 0.7 , Rang 1 - 3)
- 25 Stents distal popliteal, 1 Stent crural
- Einzelne Stentimplantation: n = 16 (62%)
- Stentüberlappung: n = 9 (38%)



Hämodynamisch/klinisches Outcome:

- Primäre anatomische 3-Monats Offenheitsrate: 83%
- Ausgangs-ABI: 0.30
- ABI nach 3 Monaten: 0.60 (p < 0.001)
- Klinisch/hämodynamische 3-Monats Offenheitsrate:
 80%
- Beinerhaltungsrate nach 3 Monaten: 96%



Komplikationen:

- Gesamtkomplikationrate: 27% (7/26)
- Majorkomplikationen: 19% (5/26)
- Klasse F (Exitus letalis): n = 1
- Klasse D (akuter Stentverschluss): n = 3
- Klasse C (Pseudoaneurysma/Thrombin): n = 1
- Klasse B (retroperitoneales Hämatom): n = 2



Schlussfolgerung

- PTA-Ballone/Stents ("Low-profile-Systeme") mit guten technischen und klinischen Kurzzeitresultaten
- Medikamentenbeschichtete Stents mit potentiellem Nutzen im Hinblick auf Offenheit und Reintervention
- Medikamentenbeschichtete Stents jedoch aktuell ohne Verbesserung der Amputationsraten
- Medikamentenbeschichtete PTA-Ballone als möglicher Ansatzpunkt, jedoch aktuell keine Datenlage

Schlussfolgerung

Universität Würzburg

- Mehr Evidenz notwendig (bessere/größere Datenlage) bzgl. der chronisch kritischen Ischämie
- Mehr Evidenz im Hinblick auf Claudicatio intermittens
- Berücksichtigung klinischer/morphologischer Aspekte (Diabetiker, Niereninsuffizienz, lange Gefäßläsionen)
- Berücksichtigung ökonomischer Gesichtspunkte