Safety and Effectiveness of Lesion Preparation Techniques in Complex & Calcified Femoropopliteal Lesions and Occlusions.

The PACSS Registry

Prof. Dr. Grigorios Korosoglou

GRN Academic Teaching Hospitals Weinheim & Eberbach
Department of Cardiology and Vascular Medicine

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STÄTTE DER ZUSATZQUALIFIKATION Interventionelle Kardiologie

STÄTTE DER ZUSATZQUALIFIKATION Kardiale Computer-tomographie

STÄTTE DER ZUSATZQUALIFIKATION Kardiale Magnetresonanz-tomographie

STÄTTE DER ZUSATZQUALIFIKATION Interventionelle Therapie der arteriellen Gefäß-erkrankungen

ORIGINAL ARTICLE

Endovascular Versus Surgical Treatment for All Comer Patients With Prosthetic Bypass Graft Occlusion: The Multicentre ENSUPRO Study

Grigorios Korosoglou [a,*], Giovanni Torsello [b], Athanasios Saratzis [c], Giacomo Isernia [d], Nikolaos Kontopodis [e], Teresa Martín González [f], Karen Jacobs [g], Isabelle Van Herzeele [g], Hany Zayed [h], Konstantinos Stavroulakis [i], ENSUPRO Collaborative [i]

[a] GRN Hospital Weinheim, Cardiology and Vascular Medicine, Weinheim, Germany
[b] University Hospital Münster, Institute for Vascular Research, Franziskus Hospital, Münster, Germany
[c] Department of Cardiovascular Sciences, University of Leicester, Glenfield Hospital, Leicester, UK
[d] Department of Vascular and Endovascular Surgery, University Hospital of Perugia, Perugia, Italy
[e] Department of Vascular Surgery, University of Heraklion, Heraklion, Greece
[f] Department of Vascular Surgery, Centre Hospitaliere d'Arras, Arras, France
[g] Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[h] Department of Vascular Surgery, Guy's and St Thomas' NHS Foundation Trust, London, UK
[i] Department of Vascular Surgery, Ludwig-Maximilians-University Hospital Munich, Munich, Germany

VASCULAR MEDICINE

Original Research Article

Atherectomy-assisted endovascular therapy versus open repair for atherosclerotic common femoral artery disease: The multicenter ARISTON study

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Grigorios Korosoglou[1], Jason T Lee[2], Martin Andrassy[3], Drosos Kotelis[4], Marco V Usai[5], Mario D'Oria[6], Raphael Coscas[7,8], Nicola Troisi[9], Bahaa Nasr[10], Athanasios Saratzis[11], Solon Antoniades[12] and Konstantinos P Donas[13,14]on behalf of the ARISTON Collaborative

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Lesion preparation techniques for femoropopliteal lesions

HIGHLIGHTS

- Endovascular treatment is the most common first-line option for femoropopliteal disease.
- Endovascular therapy includes the use of vessel preparation and definitive treatment tools.
- Our global algorithm highlights lesion-specific strategies and patient-centered approaches.
- Despite high agreement among experts, future RCTs are warranted in this emerging field.

Global Algorithm JACC-Inte 2025, Korosoglou et al

Advantages of lesion preparation prior to endovascular repair:

- Provide lumen gain without barotrauma
- Plaque and calcification burden reduction
- Vessel compliance can be modified / improved
- Reduce bail-out stenting rates
- Enhance drug delivery to the vessel wall
- Increase technical / procedural success rates

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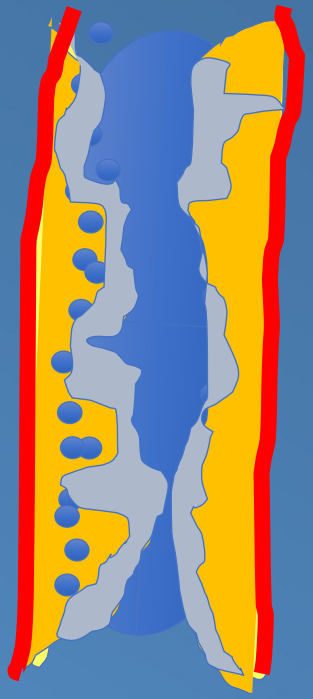
Atherectomy removes atherosclerotic / calcific tissue similar to surgical techniques, resulting in lumen gain without barotrauma

Facilitating low pressure balloon angioplasty



Simultaneously increasing drug delivery to the vessel wall

Decreasing the chance for dissection, avoiding additional stent placement 'leave nothing behind'

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Korosoglou, Lichtenberg et al, VER 2019

RCTs with atherectomy

	Cochrane meta-analysis [1]	Meta-analysis by Wu et al [2]	Meta-analysis by Abusnina et al [3]
Number of patients	425	296	749
Adjunctive treatment	POBA or DCB	POBA or DCB	POBA or DCB
Bail-out stenting	⇩ RR=0.26(0.09-0.74), p=0.001	⇩ RR=0.15(0.07-0.32), p<0.001	⇩ RR=0.32(0.21-0.48), p<0.001
Complication rates	⇔ RR=0.69(0.28-1.68), p=0.41	NA	⇔§ RR=1.08(0.31-3.79), p=0.91
Embolization rates	⇔ RR=2.51(0.64-9.80), p=0.19	NA	⇔ RR=1.66(0.58-4.78), p=0.34
Freedom from TLR at 12 months	⇔ RR=0.59(0.25-1.42), p=0.24	⇔ RR=0.68(0.25-1.82), p=0.44	⇧* RR=0.59(0.40-0.85), p=0.005
Primary patency at 12 months	⇔ RR=1.20(0.78-1.84), p=0.42	⇔ RR=0.76(0.46-1.25), p=0.28	⇔* RR=1.04(0.95-1.14), p=0.37
Mortality	⇔ RR=0.50(0.10-2.66), p=0.42	⇔ RR=0.32(0.09-1.12), p=0.07	⇔ RR=1.29(0.54-3.05), p=0.57
Amputation rates	⇔ RR=0.33(0.01-7.80), p=0.49	NA	⇔ RR=0.38(0.13-1.13), p=0.08

NA indicates not available, POBA; plain old balloon angioplasty, DCB; drug-coated balloon angioplasty and RR, risk ratios.

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RCTs with IVL

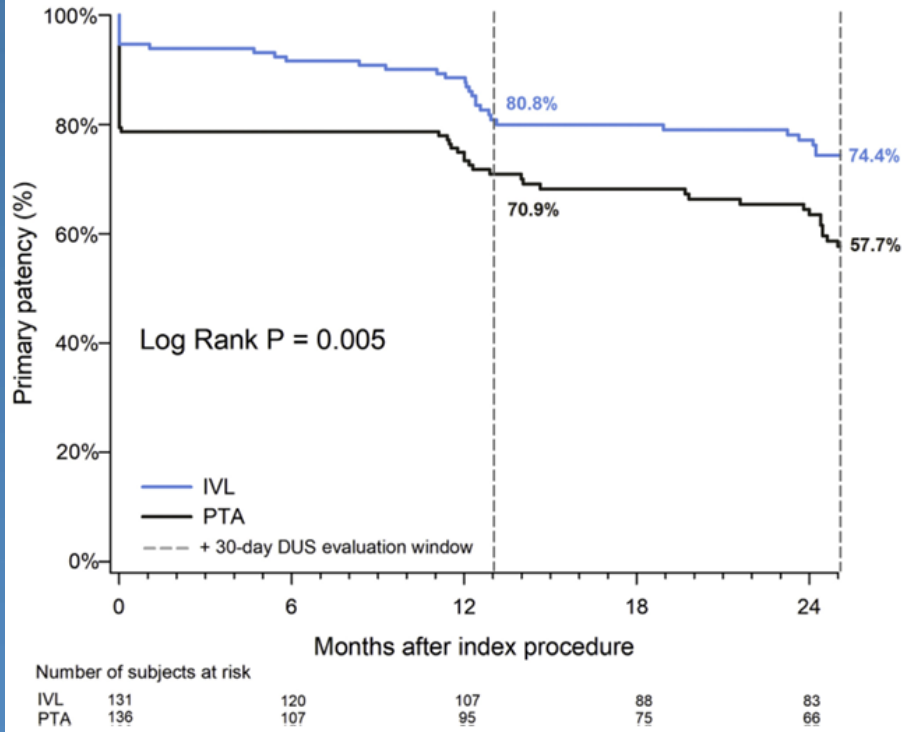

Figure 2. Kaplan-Meier estimate of primary patency through 2 years. Primary patency was significantly greater in the group receiving IVL treatment for lesion preparation than in the PTA group. Primary patency was defined as freedom from CD-TLR and freedom from restenosis by duplex ultrasound. Acute PTA failure requiring provisional stenting at any time during the procedure was counted as a loss of primary patency. CD-TLR, clinically driven target lesion revascularization; DUS, duplex ultrasound; IVL, intravascular lithotripsy; PTA, percutaneous transluminal angioplasty.

Peripheral Arteries

Eur J Vasc Endovasc Surg (2025) 69, 118—129

SYSTEMATIC REVIEW

Systematic Review and Network Meta-analysis of Vessel Preparation Techniques With Plain Balloon Angioplasty, Atherectomy, or Intravascular Lithotripsy Before Application of a Drug Coated Balloon to Treat Atherosclerotic Femoropopliteal Disease

Janice Yiu [a,†], Ravali Tippireddy [a,†], Lukla Biasi [a], Sanjay Patel [a], Prakash Saha [a], Athanasios Saratzis [b], Konstantinos Katsanos [c], Hany Zayed [a,*]

[a] Department of Vascular Surgery, Guy's and St. Thomas' Hospital NHS Foundation Trust and King's College London, London, United Kingdom
[b] NIHR Leicester Biomedical Research Centre, Leicester, United Kingdom
[c] Patras University Hospital, Rion, Greece

Conclusion: This review found that intravascular lithotripsy or atherectomy did not appear to incur a statistically significant advantage in freedom from target lesion revascularisation, major amputation, or mortality rate at one year. There was moderate certainty of evidence that bailout stenting is significantly reduced after vessel preparation with intravascular lithotripsy and atherectomy.

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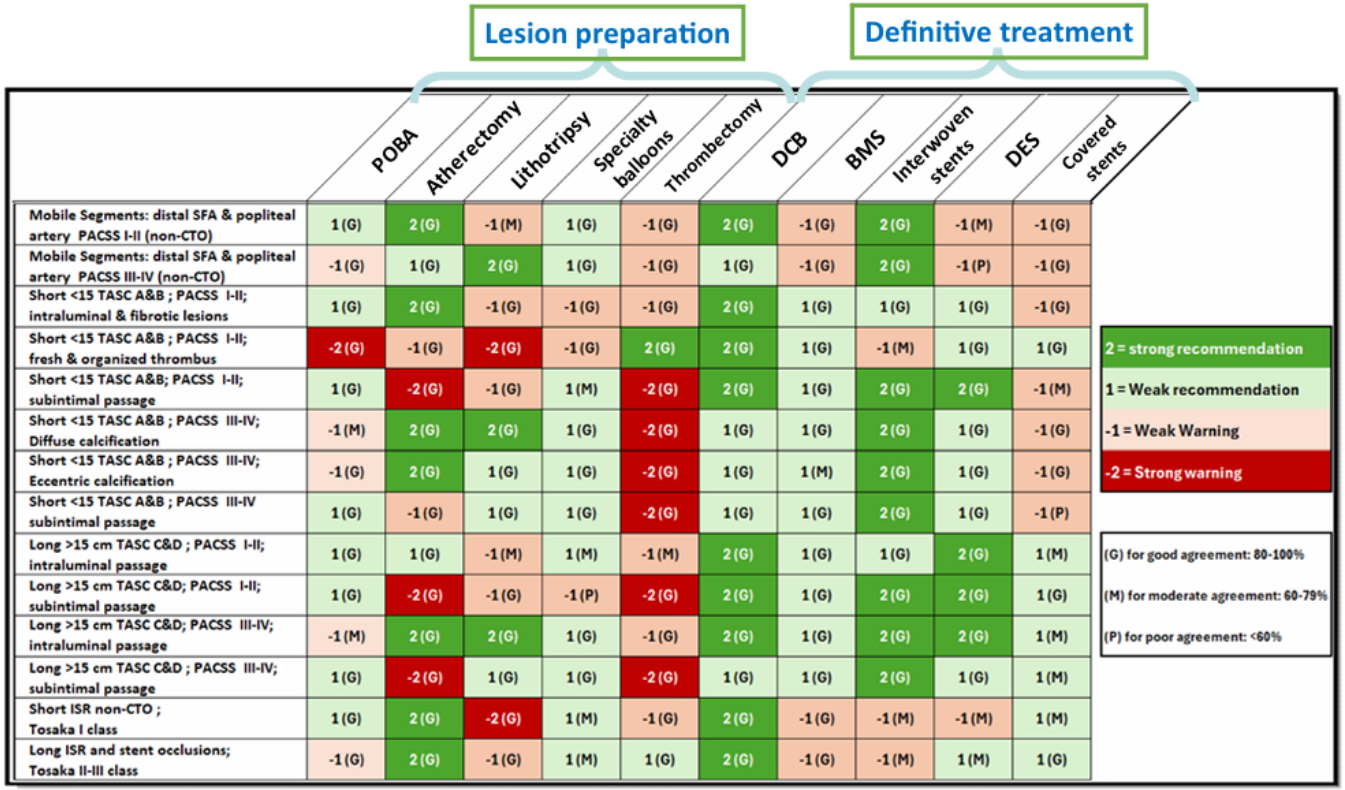
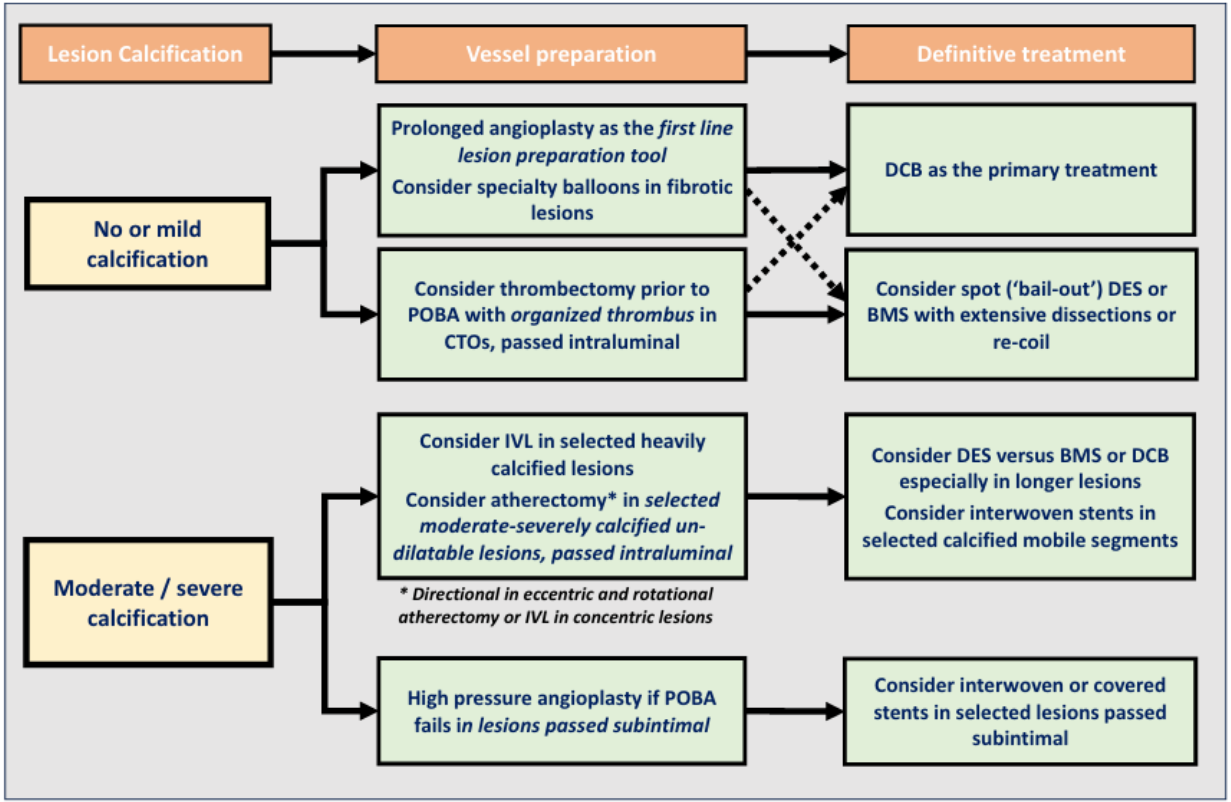
FIGURE 1 Delphi Consensus for the Lesion Preparation and Definitive Treatment Tools



Global Algorithm JACC-Inte 2025, Korosoglou et al

FIGURE 2 Lesion Preparation and Definitive Treatment Algorithm Based on Lesion-Specific Characteristics



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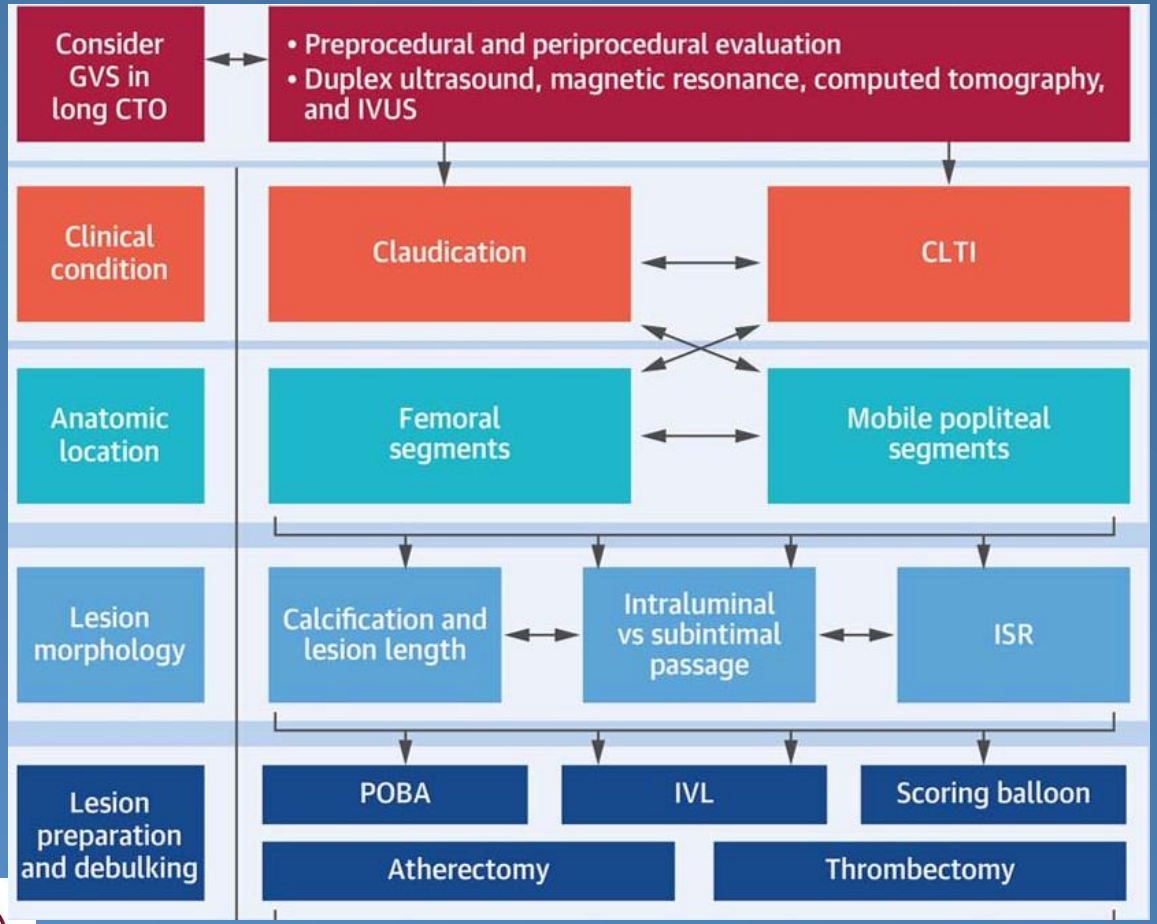

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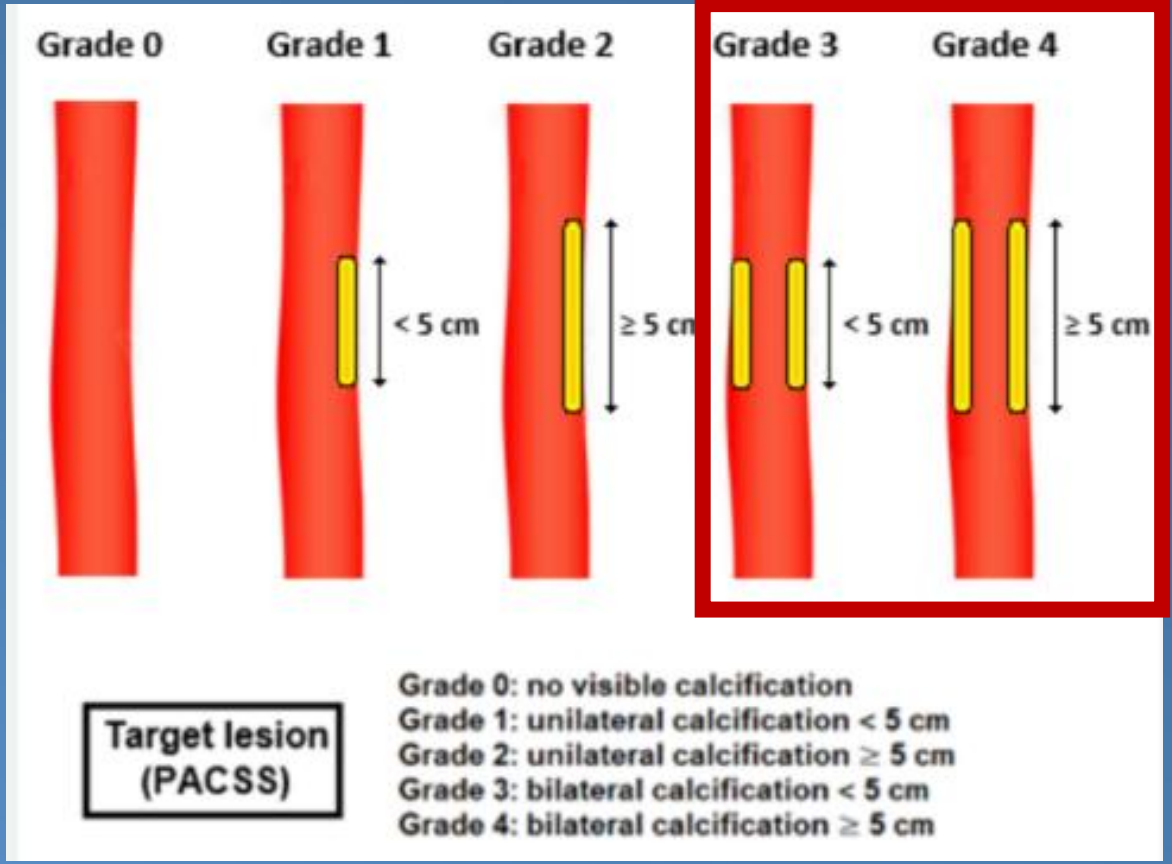
Objective: To investigate the safety and effectiveness of the different lesion preparation technique in patients who are referred to endovascular revascularization due to chronic symptomatic PAD.

Safety (perforation, dissection, distal embolization) measure as well as limb outcomes (see below) will be systematically analyzed.

Matching with be performed based on lesion complexity by lesion length and calcification (PACSS).


Grade 0
Grade 1
Grade 2
Grade 3
Grade 4
< 5 cm
≥ 5 cm
< 5 cm
≥ 5 cm
Target lesion (PACSS)
Grade 0: no visible calcification
Grade 1: unilateral calcification < 5 cm
Grade 2: unilateral calcification ≥ 5 cm
Grade 3: bilateral calcification < 5 cm
Grade 4: bilateral calcification ≥ 5 cm

Inclusion criteria

Study design: Multi-center, retrospective study.

Study population: All comers >18 years with symptomatic PAD.

Requirements:

1. Waived informed consent.
2. Symptomatic PAD Rutherford categories (RC) 2-5.
3. Femoropopliteal PACSS 2-4 lesions
4. Treatment with atherectomy (all devices allowed) versus IVL (all devices allowed) versus specialty balloons versus POBA.

Exclusion criteria:

1. Lesions with no or mild unilateral calcification (PACSS 0-2)
2. Asymptomatic PAD RC 0 or patients with large wounds RC6, indicating severe BTK disease.
3. Acute and subacute limb ischemia with presence of thrombus by angiography.
4. Technical failure of endovascular revascularization if crossing cannot be achieved by ante- or retrograde or re-entry devices and procedural failure in case of residual stenosis > 50% at the end of the procedure.

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Outcome measures (12 months of follow-up):

- CD-TLR
- Restenosis by ABI or if available by duplex sonography.
- Minor or major above ankle amputation.
- Clinical improvement defined as cumulative improvement of 1 class by Rutherford scale.
- Wound healing (WIfI threatened limb score if available).

Statistical justification: Descriptive statistics. In addition, propensity matching will be assessed to adjust for any potential confounders using logistic regression models. Thus, case-controlled matching will be performed, including variables such as sex, age, lesion length, PACSS, RC, and number of BTK run-off vessels.

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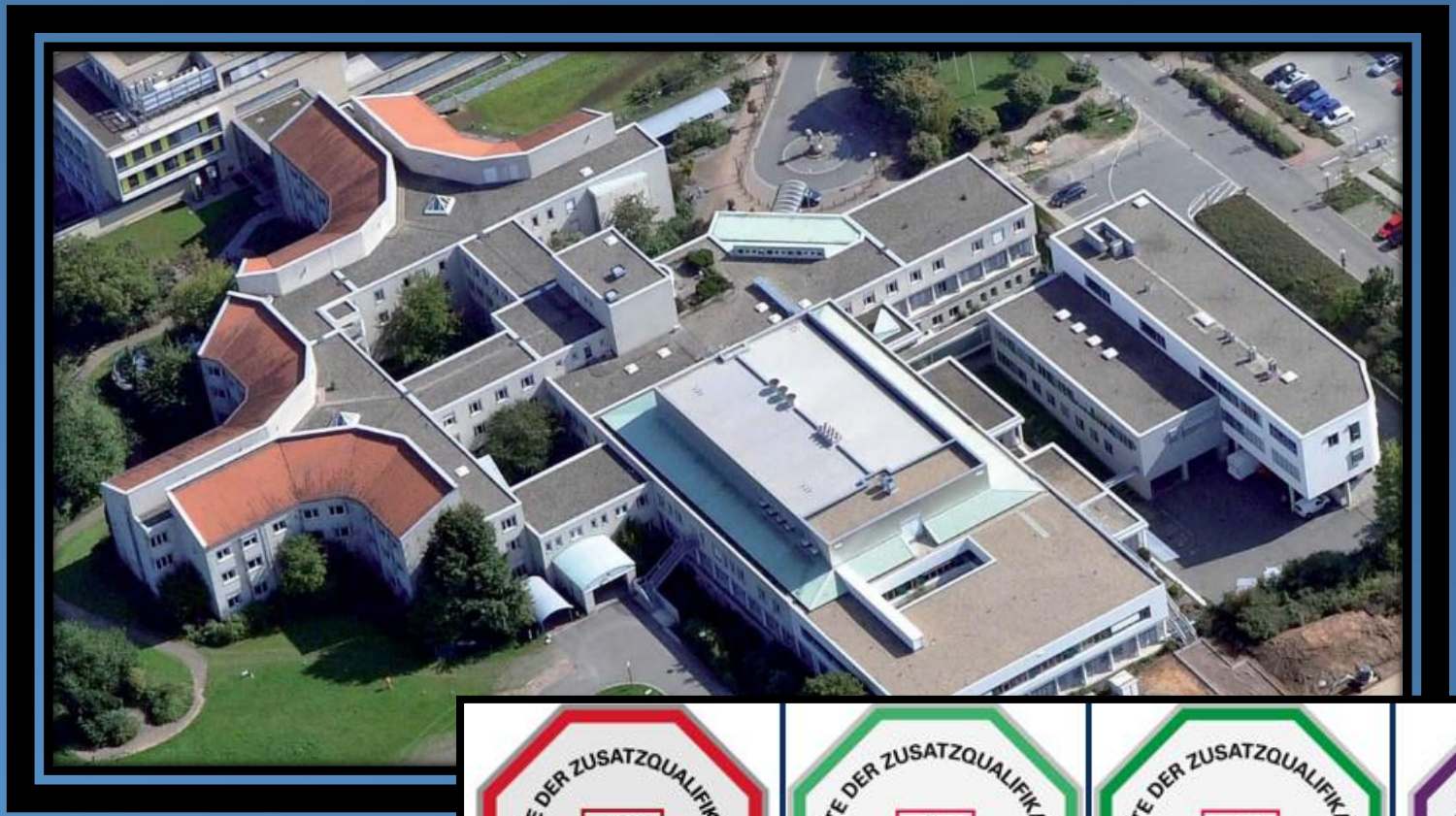

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