Thieme

Assessment of Efficacy and Complications of Endovascular Interventions for Critical Limb Ischemia in Germany: A Nationwide Study

Wirksamkeit und Komplikationen von endovaskulären Interventionen bei kritischer Extremitätenischämie in Deutschland

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ABSTRACT

Purpose Endovascular interventional radiological procedures have become the mainstay for the treatment of critical limb ischemia (CLI) due to arterial stenosis or occlusion. Open surgical or endovascular procedures, such as percutaneous transluminal angioplasty (PTA) or stenting can be used as a treatment strategy. The aim is to evaluate the success and major complication rates of interventional radiology treatments for CLI in Germany in 2021, and to compare these results with internationally published data.

Materials and Methods Data for PTA and stenting in CLI for 2021 was obtained from the quality management system of the German Society of Interventional Radiology (DeGIR). 16 393 PTA procedures, 701 stenting procedures, and 8110 combined procedures were documented for 2021. Data was analyzed for technical and clinical success rates, as well as major complication rates documented mainly as major bleeding, distal embolization, and aneurysm formation.

Results PTA had technical and clinical success rates of 96.3 % and 92.33 %, respectively. Stenting had technical and clinical success rates of 98.7 % and 96.15 %, respectively. PTA and stenting combined had success rates of 98.71 % and 96.91 %, respectively. The major complications were mainly: major bleeding (PTA: 0.40 %; stenting: 1.28 %; PTA and stenting: 0.54 %), distal embolization (PTA: 0.48 %; stenting: 1 %; PTA and stenting: 0.96 %), and aneurysm formation (PTA: 0.19 %; stenting: 0.43 %; PTA and stenting: 0.19 %). All procedures showed high technical and clinical success rates, while the complication rates were low.

Conclusion Interventional radiologists in Germany perform effective and safe treatment for CLI, achieving outcomes that tend to surpass internationally published data.

Key points

- German interventional radiologists provide safe and effective critical limb ischemia treatment.
- Major complications occurred at maximum in 1.28 % of cases.
- Outcomes tend to surpass international data, indicating strong performance.

ZUSAMMENFASSUNG

Zweck Endovaskuläre interventionelle radiologische Verfahren sind neben der chirurgischen Intervention der Goldstandard bei der Behandlung der kritischen Extremitätenischämie aufgrund arterieller Stenosen oder Verschlüsse geworden. Offen chirurgische oder endovaskuläre Verfahren wie die perkutane transluminale Angioplastie (PTA) oder das Stenting können als Behandlungsstrategie eingesetzt werden. Das Ziel dieser Studie ist die Bewertung der Erfolgsraten und der Rate schwerwiegender Komplikationen bei interventionellen radio-

logischen Behandlungen von kritischer Extremitätenischämie in Deutschland im Jahr 2021 und der Vergleich dieser Ergebnisse mit international veröffentlichten Daten.

Material und Methoden Die Daten für PTA und Stenting bei kritischer Extremitätenischämie im Jahr 2021 wurden aus dem Qualitätsmanagementsystem der Deutschen Gesellschaft für Interventionelle Radiologie (DeGIR) gewonnen. Für das Jahr 2021 wurden 16 393 PTA, 701 Stentings und 8110 kombinierte Verfahren dokumentiert. Die Daten wurden auf technische und klinische Erfolgsraten sowie auf schwerwiegende Komplikationsraten analysiert, die hauptsächlich als schwere Blutungen, distale Embolien und Aneurysmabildung dokumentiert wurden.

Ergebnisse Die PTA wies technische und klinische Erfolgsraten von 96,3 % bzw. 92,33 % auf. Das Stenting hatte technische und klinische Erfolgsraten von 98,7 % bzw. 96,15 %. Die kombinierte Anwendung von PTA und Stenting führte zu Erfolgsraten von 98,71 % bzw. 96,91 %. Schwere Komplikationen waren hauptsächlich schwere Blutungen (PTA: 0,40 %; Stenting: 1,28 %; PTA und Stenting: 0,54 %), distale Embolien (PTA: 0,48 %; Stenting: 1 %; PTA und Stenting: 0,96 %) und Aneurysmabildung (PTA: 0,19 %; Stenting: 0,43 %; PTA und Stenting: 0,19 %). Alle Verfahren zeigten hohe technische und klinische Erfolgsraten, während die Komplikationsraten niedrig waren.

Schlussfolgerung Interventionelle Radiologen in Deutschland führen eine wirksame und sichere Behandlung für die kritische Extremitätenischämie durch, die dazu neigt, international veröffentlichte Daten zu übertreffen.

Kernaussagen

- Eine sichere und effektive Behandlung von kritischer Extremitätenischämie wird durch interventionelle Radiologen in Deutschland gewährleistet.
- Schwerwiegende Komplikationen traten höchstens in 1,28 % der Interventionen auf.
- Die klinischen Ergebnisse scheinen internationale Vergleichsdaten zu übertreffen.

Zitierweise

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Introduction

Critical limb ischemia (CLI) is a wearing condition characterized by insufficient blood flow to the limbs due to arterial stenosis or occlusion typically associated with peripheral artery disease (PAD). Worldwide the prevalence of PAD is estimated to be over 200 million people, with 1–2 % suffering from CLI, thus showing the relevance of this condition [1]. A standard classification used to categorize the grade of ischemia in PAD is the Fontaine Classification: Stage I asymptomatic, Stage II intermittent claudication (IIa walking distance > 200m; IIb walking distance < 200 m), Stage III ischemic rest pain, Stage IV ulceration or gangrene or both [2].

In Germany, the prevalence of symptomatic PAD has been increasing with estimates suggesting that up to 1.8 million individuals may be affected by the condition [3, 4]. Early stages of PAD (Fontaine I and IIa) can be treated conservatively, while advanced stages require interventional or surgical treatment. CLI presents as an advanced form of PAD with Fontaine stages III and IV, and therefore typically presents as chronic, severe pain, non-healing wounds, and can ultimately lead to limb loss if left untreated. Furthermore, limb loss and cardiovascular events are more likely to occur in the short term in individuals with CLI, than early stages of PAD [5].

In the past, open surgical procedures were the primary approach to managing PAD. However, in recent years, we have seen an increase in endovascular interventional procedures. These minimally invasive techniques, including percutaneous transluminal angioplasty (PTA) and stenting, have gained prominence owing to their high safety profiles and reduced invasiveness compared to traditional open surgery [6–9]. PTA entails the expansion of narrowed or obstructed arterial segments via catheter-based techniques, while stenting involves the deployment of stents via catheters to preserve the patency of arteries [10]. Both procedures have consistently demonstrated favorable outcomes in the restoration of blood flow, effectively improving patient outcomes and relieving suffering [11]. While interventional procedures exhibit high success rates and good safety profiles, it is essential to acknowledge that major complications, although infrequent, can have profound consequences, potentially leading to extended hospitalization, increased morbidity and mortality, and a significant reduction in the quality of life.

In Germany, medical facilities performing interventional radiological procedures in association with the German Interventional Radiological Society (DeGIR) are encouraged to document patient data by means of DeGIR's quality management system [4]. This system systematically and anonymously collects pre-, intra-, and post-operative data, including complications and their respective levels of severity.

Despite the strides made in Germany's healthcare landscape, to date, a comprehensive nationwide evaluation of the effectiveness and complication rates associated with endovascular interventions for CLI within the country has not yet been performed. This study thus aims to assess the success rates and major complications associated with interventional radiological treatments for CLI. Specifically, this study is focused on PTA and stenting procedures performed within Germany throughout the year 2021. Moreover, the intent is to compare these findings with internationally published data, thus providing a broader perspective on Germany's standing in the global landscape of CLI management.

Materials and Methods

Study design

This study examines the safety and efficacy of the interventional treatment of CLI in Germany in 2021, using data from the DeGIR quality management data system. The technical/clinical success and major complication rates were the primary focus of the analysis. Technical success was defined as the restoration of blood flow in the area of the target lesion, by confirmed angiographic flow. The intervention was considered clinically successful when symptom relief or improvement was reported immediately intra-operatively or post-operatively until discharge from the clinic. Major complications, as per SIR, encompass conditions that necessitate therapy with brief hospitalization (< 48 h), demand significant intervention leading to an unplanned escalation in the level of care and prolonged hospitalization (> 48 h), result in permanent adverse sequelae, or ultimately lead to death [12].

Patient selection

This analysis includes data from patients who underwent endovascular treatments for CLI in Germany in 2021with Fontaine stages III and IV. The data originates from the quality management system managed by the German Interventional Radiology Society (DeGIR), designed to gather information on interventional procedures, such as pre-, intra- and post-operative data.

Statistical analysis

A retrospective descriptive analysis of DeGIR quality management system data was performed to determine the efficacy and safety of interventional radiological treatments for CLI. Microsoft Excel (Version 16.34, Microsoft, Redmond, WA, USA) was applied to determine the effectiveness and rates of major complications, focusing on clinical and technical success rates.

Results

The DeGIR quality management system recorded 16 393 PTA procedures in 208 different hospitals, 701 stent procedures in 136 hospitals, and 8110 combined PTA/stent procedures in 201 hospitals.

PTA

Among 16 393 patients treated by means of PTA for CLI, a technical success rate of 96.3 % and a clinical success rate of 92.33 % were reported (▶ **Table 1**). The most frequent complications included distal embolization (0.48 %), major bleeding (0.40 %), and aneurysm formation (0.19 %) (▶ **Table 2**). Further complications were organ failure (0.08 %), cardiac decompensation (0.05 %), intracranial bleeding (0.02 %), pulmonary dysfunction (0.012 %), and post-operative infection/abscess (0.012 %). The lowest rates with 0.006 % were parenchyma ischemia, organ damage under

▶ **Table 1** Technical and clinical success rates of percutaneous transluminal angioplasty (PTA), stenting, the combined intervention (PTA & stent), and overall rates in critical limb ischemia in Germany 2021.

Success rates	PTA (n = 16 393)	Stent (n = 701)	PTA & stent (n = 8110)	Overall (n = 25 204)
Technical success (in %)	96.3	98.7	98.71	97.14
Clinical success (in %)	92.33	96.15	96.91	93.91

▶ **Table 2** Displayed are the frequent major complication rates of percutaneous transluminal angioplasty (PTA), stenting, the combined intervention (PTA & stent), and overall rates in critical limb ischemia in Germany 2021.

Major complication (rate in %)	PTA (n = 16 393)	Stent (n = 701)	PTA & stent (n = 8110)	Overall (n = 25 204)
Major bleeding	0.40	1.28	0.54	0.47
Distal embolization	0.48	1.0	0.96	0.65
Aneurysm formation	0.19	0.43	0.19	0.20
Organ failure	0.08	–	0.06	0.07
Cardiac decompensation	0.05	0.29	0.11	0.07
Intracranial bleeding	0.02	–	–	0.01
Stent dislocation	–	–	0.07	0.02
Other	0.11	0.14	0.14	0.16
Overall	1.33	3.14	2.07	1.65

PTA, and drug side effects. Other complications were reported in 0.11 % of cases.

Stenting

Among 701 patients treated solely by stenting for CLI, a positive technical success of 98.7 % and a clinical success of 96.15 % were reported (▶ **Table 1**). The most frequent major complications were distal embolization (1 %), major bleeding (1.28 %), and aneurysm formation (0.43 %) (▶ **Table 2**). Further complications were cardiac decompensation (0.29 %,) and other complications (0.14 %).

PTA/stent

In 8110 cases of combined PTA and stenting for CLI, a technical success rate of 98.71 % and a clinical success rate of 96.91 % were observed (▶ **Table 1**). The most frequent major complications were distal embolization (0.96 %), major bleeding (0.54 %), and aneurysm formation (0.19 %) (▶ **Table 2**). Cardiac decompensation and pulmonary dysfunction were reported in 0.11 % of cases. Further complications were stent dislocation (0.07 %), organ failure (0.06 %), and other complications (0.14 %).

Discussion

The results of the analysis of the DeGIR quality management system data in 2021 show a high success rate and relatively low major complication rates for endovascular radiological treatment of CLI by PTA and/or stenting procedures. The technical success rates for both procedures exceeded 96 %, suggesting that these methods are efficient at treating CLI. Clinical success rates were similarly high, which indicates that these methods are also effective at relieving symptoms associated with CLI.

Current research has shown comparable results regarding complications and technical success. Cardiovascular complication rates < 30 days after endovascular therapy for CLI by Faber et al. were reported in 3.2 % of cases [11]. Farber et al. also found that in patients treated for critical limb ischemia who had an adequate great saphenous vein, the incidence of major adverse limb events or death was significantly lower in the surgical group than in the endovascular group. Based on these results, a surgical strategy could also be considered in these patients [11]. Technical success for CLI treatment has previously been reported as minimum 92 % [13] and 90 % [14]. Additionally, a systematic review and meta-analysis showed a technical PTA success rate of 91.1 % in 44 studies [15]. Furthermore, a Cochrane systematic review reported the technical success to be 93.7 % and 97.6 % for PTA and stenting, respectively. The Cochrane review also showed procedural complications in 7.4 % of PTA procedures and 6.3 % of stenting procedures [16].

Major complication rates were under 1.3 % across all three categories of procedures, which suggests that they have a good safety profile. The most common complications were distal embolization and major bleeding, both of which are known complications of interventional radiological procedures [16–18]. The overall low complication rates reflect positively on the quality and safety of these treatments. The results also showed that a combined PTA and stenting procedure had a higher technical and clinical success rate compared to PTA and stenting alone. A previous systematic review found similar results and explained this finding by the fact that stenting in addition to PTA can resolve PTA-associated complications [16].

However, this study is not without limitations. The retrospective study design limits the ability to control confounding variables or establish causality. The voluntary nature of DeGIR system reporting and potential reporting biases could impact the validity of findings. Additionally, regional differences in data input, coupled with incomplete or missing entries, influence data accuracy [19, 20]. Nevertheless, this is the first study of its kind in Germany evaluating endovascular treatments for CLI on a nationwide scale. A previous study analyzing the DeGIR quality database highlighted the importance of follow-up data to fully draw a conclusion on the efficacy of interventions [21]. In the future quality assessment should be extended by this point of interest. Lastly, only data from 2021 was included in this study, which may not fully represent long-term trends for CLI treatment. Despite these limitations, the findings of this study provide valuable insights into the nationwide effectiveness and safety of interventional radiology treatment for CLI in Germany and will help to identify areas for improvement.

In conclusion, treatment of critical limb ischemia by PTA and/or stenting procedures by interventional radiologists in Germany is effective and safe. The results are consistent with published international data and suggest a trend towards surpassing international benchmarks. A study of this size can potentially contribute to the establishment of international/national quality standards for the management of critical limb ischemia. In future studies, it is important to keep track of the outcomes over a longer period of time by observing patients at 30 days, 6 months, and ideally for up to 1 year. This will give further information on the long-term effects and results of the treatments combined with initial high operative success rates and low complication rates.

CLINICAL RELEVANCE

- The study approves the high efficacy and safety of radiological endovascular treatments for critical limb ischemia in Germany.
- For clinicians, this study affirms that their therapeutic approaches in critical limb ischemia are both effective and safe.
- The study offers a clear view on the effectiveness of current practice, provides a benchmark for future interventions, and potentially shapes guideline recommendations.

Conflict of Interest

The authors declare that they have no conflict of interest.

References

[1] Song P, Rudan D, Zhu Y et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. Lancet Glob Health 2019; 7 (8): e1020–e1030

[2] Beard JD. ABC of arterial and venous disease: Chronic lower limb ischaemia. BMJ 2000; 320: 854–857

[3] Dohmen A, Eder S, Euringer W et al. Chronic critical limb ischemia. Dtsch Arztebl Int 2012; 109 (6): 95–101

[4] Mahnken AH, Nadjiri J, Schachtner B et al. Availability of interventional-radiological revascularization procedures in Germany – an analysis of the DeGIR Registry Data 2018/19. Fortschr Röntgenstr 2022; 194 (2): 160–168

[5] Kinlay S. Management of Critical Limb Ischemia. Circ Cardiovasc Interv 2016; 9 (2): e001946

[6] Wiseman JT, Fernandes-Taylor S, Saha S et al. Endovascular Versus Open Revascularization for Peripheral Arterial Disease. Ann Surg 2017; 265 (2): 424–430

[7] Ghoneim B, Elwan H, Eldaly W et al. Management of critical lower limb ischemia in endovascular era: experience from 511 patients. Int J Angiol 2014; 23 (3): 197–206

[8] Lumsden AB, Davies MG, Peden EK. Medical and endovascular management of critical limb ischemia. J Endovasc Ther 2009; 16 (2): II31–II62

[9] Conte MS, Bradbury AW, Kolh P et al. Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. Eur J Vasc Endovasc Surg 2019; 58 (1): S1–S109.e133

[10] Sherif M. Angioplasty and stenting for peripheral arterial disease of the lower limbs. Vol. 16, N° 8. e-Journal of Cardiology Practice. 2018

[11] Farber A, Menard MT, Conte MS et al. Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia. N Engl J Med 2022; 387 (25): 2305–2316

[12] Sacks D, McClenny TE, Cardella JF et al. Society of Interventional Radiology clinical practice guidelines. J Vasc Interv Radiol 2003; 14 (9): S199–S202

[13] Chow CY, Mathlouthi A, Zarrintan S et al. Outcomes of elective peripheral endovascular interventions for peripheral arterial disease performed in hospital outpatient departments, ambulatory surgical centers and office-based labs. J Vasc Surg 2023; 77 (6): 1732–1740

[14] Popplewell MA, Davies HOB, Renton M et al. Comparison of Outcomes Following Infrapopliteal Plain Balloon Angioplasty in the BASIL Trial (1999-2004) and in a Contemporary Series (2009–2013). Vasc Endovascular Surg 2020; 54 (2): 141–146

[15] Mustapha JA, Finton SM, Diaz-Sandoval LJ et al. Percutaneous Transluminal Angioplasty in Patients With Infrapopliteal Arterial Disease: Systematic Review and Meta-Analysis. Circ Cardiovasc Interv 2016; 9 (5): e003468

[16] Hsu CC, Kwan GN, Singh D et al. Angioplasty versus stenting for infrapopliteal arterial lesions in chronic limb-threatening ischaemia. Cochrane Database Syst Rev 2018; 12 (12): CD009195

[17] Gardiner GA, Meyerovitz MF, Stokes KR et al. Complications of transluminal angioplasty. Radiology 1986; 159 (1): 201–208

[18] Matsi PJ, Manninen HI. Complications of lower-limb percutaneous transluminal angioplasty: a prospective analysis of 410 procedures on 295 consecutive patients. Cardiovasc Intervent Radiol 1998; 21 (5): 361–366

[19] Nadjiri J, Schachtner B, Bücker A et al. Nationwide Provision of Radiologically-guided Interventional Measures for the Supportive Treatment of Tumor Diseases in Germany – An Analysis of the DeGIR Registry Data. Fortschr Röntgenstr 2022; 194 (9): 993–1002

[20] Nadjiri J, Schachtner B, Bücker A et al. Availability of Transcatheter Vessel Occlusion Performed by Interventional Radiologists to Treat Bleeding in Germany in the Years 2016 and 2017 – An Analysis of the DeGIR Registry Data. Fortschr Röntgenstr 2020; 192 (10): 952–960

[21] Bastian MB, Nadjiri J, Wessendorf J et al. Safety and efficacy of interventional treatment of acute limb ischemia in Germany 2021. CVIR Endovasc 2023; 6 (1): 43