

Safety and Efficacy of Rotational Thrombectomy for Treatment of Arterial Occlusions of the Lower Extremities: A Large Single-Center Retrospective Study

Sicherheit und Wirksamkeit der Rotationsthrombektomie zur Behandlung von arteriellen Verschlüssen der unteren Extremitäten: eine große monozentrische retrospektive Studie

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ZUSAMMENFASSUNG

Hintergrund Evaluierung der Sicherheit und Wirksamkeit der Rotationsthrombektomie (RT) in einer großen realen Kohorte eines einzelnen Zentrums bei totalen Gefäßverschlüssen der unteren Extremitäten.

Material und Methoden Die klinischen Aufzeichnungen und Bilder aller zwischen 2010 und 2020 mittels RT (Rotarex, BD) behandelten Patienten wurden ausgewertet. Es wurden demografische Daten der Patienten, klinische Daten, Verfahrensmerkmale und Ergebnisparameter dokumentiert. Insgesamt wurden 397 Eingriffe bei 293 Patienten eingeschlossen (Durchschnittsalter 69,8 ± 12,0 Jahre; 64,8 % Männer). Die Verschlüsse waren akut (47,5 %), subakut und akut-chronisch (22,2 %) und chronisch (30,3 %). Bei den Zielläsionen handelte es sich um die Arteria iliaca (7,1 %), die Arteria iliaca/femoropoplitea (5,0 %), die Arteria femoropoplitea (59,4 %), die Arteria femoropoplitea/unter dem Knie (27,0 %), die Arteria femoropoplitea unter dem Knie (1,5 %) und nach einer Bypassoperation (14,9 %). Die Läsionslänge betrug in 61,5 % der Fälle mehr als 20 cm.

Ergebnisse Eine klinisch erfolgreiche Revaskularisierung wurde in 90,4 % der Fälle erreicht. Eine zusätzliche Thrombolysen war in 32,0 % der Fälle erforderlich. Der arithmetische mittlere Knöchel-Arm-Index stieg von 0,33 ± 0,29 auf 0,81 ± 0,25 ($p < 0,0001$). Bei Bypasstransplantaten war die Wahrscheinlichkeit geringer, dass sie vollständig behandelbar waren und eine zusätzliche Lyse erforderlich wurde ($p < 0,001$). Die primäre Offenheit (keine klinisch bedingte Zielläsionsrevaskularisation) betrug 93,2 %, 88,8 %, 79,1 % und 72,4 % nach 1, 3, 6 bzw. 12 Monaten. Unerwünschte Ereignisse traten in 46,1 % der Fälle auf, wobei die periphere Embolie (22,4 %) am häufigsten war und in 67,4 % der Fälle eine interventionelle Behandlung erforderlich machte. Die RT stand in direktem Zusammenhang mit 7,1 % ($n = 28$) der Komplikationen, bei denen es sich um Perforationen (2,8 %), arteriovenöse Fisteln (1,3 %) und Dissektionen (2,0 %) handelte.

Schlussfolgerung Die Rotationsthrombektomie ist eine sichere und effiziente Methode zur Behandlung von Verschlüssen des arteriellen Kreislaufs der unteren Extremität, wobei

Bypassverschlüsse eine höhere Neigung zu Restthromben aufweisen, die eine weitere Lysetherapie erfordern.

Wichtige Punkte:

- Rotationsthrömbektomien waren sichere und wirksame Behandlungsmethoden von Verschlüssen der unteren Extremitäten.
- Rotationsthrömbektomien waren mit 7,1 % der Komplikationen verbunden.
- 22,4 % der Fälle zeigten distale Embolien, hiervon erforderten 67,4 % eine interventionelle Therapie.
- Die primäre Offenheit betrug 93,2 %/88,8 %/79,1 %/72,4 % nach jeweils 1/3/6/12 Monaten.

ABSTRACT

Purpose To evaluate the safety and efficacy of rotational thrombectomy (RT) in a large single-center real-world cohort for total vascular occlusions of the lower extremity.

Materials and Methods The clinical records and images of all patients between 2010 and 2020 treated via RT (Rotarex, BD) were assessed. Patient demographics, clinical data, procedural characteristics, and outcome parameters were documented. In total, 397 procedures in 293 patients were included (mean age 69.8 ± 12.0 years; 64.8 % male). Occlusions were acute (47.5 %), subacute and acute-on-chronic (22.2 %), and chronic (30.3 %). The target lesions were the iliac artery (7.1 %), iliac/femoropopliteal (5.0 %), femoropopliteal (59.4 %), femoropopliteal/below-the-knee (27.0 %), below-the-knee (1.5 %), and after bypass surgery (14.9 %). Lesion length was > 20 cm in 61.5 % of cases.

Results Clinically successful revascularization was achieved in 90.4 % of cases. Additional thrombolysis was necessary for 32.0 % of procedures. The arithmetic mean ankle-brachial in-

dex increased from 0.33 ± 0.29 to 0.81 ± 0.25 ($p < 0.0001$). Bypass grafts were less likely to be fully treatable and required additional lysis ($p < 0.001$). The overall primary patency (no clinically driven target lesion revascularization) was 93.2 %, 88.8 %, 79.1 %, and 72.4 % at 1, 3, 6, and 12 months, respectively. Adverse events occurred in 46.1 % of cases, of which peripheral embolization (22.4 %) was most frequent, requiring interventional treatment in 67.4 % of cases. RT was directly associated with 7.1 % ($n = 28$) of complications, which consisted of perforations 2.8 %, arteriovenous fistula 1.3 %, and dissections 2.0 %.

Conclusion Rotational thrombectomy is a safe and efficient method for the treatment of occlusions of the arterial circulation of the lower extremity with bypass occlusions having a higher propensity for residual thrombi requiring further lysis therapy.

Key Points:

- Rotational thrombectomy was safe and efficacious for treating occlusions of the lower extremities.
- Rotational thrombectomy was associated with 7.1 % of complications.
- Distal embolization occurred in 22.4 % of cases with 67.4 % requiring interventional treatment.
- Primary patency was 93.2 %, 88.8 %, 79.1 %, 72.4 % after 1, 3, 6, and 12 months, respectively.

Citation Format

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Introduction

Peripheral artery disease (PAD) is a broad spread disease and manifests as impaired blood flow to the extremities due to gradual arterial stenosis or complete occlusion [1–3]. Along with medical management and surgical therapy, endovascular interventional therapy is a mainstay of treatment for PAD, particularly for patients with advanced disease and comorbidities predictive of poor surgical outcomes. Advancements in traditional percutaneous procedures include mechanical thrombectomy, which detaches the occluding material, aspirates it without additional suction, fragments it, and drains it into a collection bag [4, 5]. Mechanical thrombectomy excels in this regard, mainly as it may not require pharmacologic lysis and, therefore, can be used in patients with contraindications to thrombolytics, including recent stroke, one of several pathologies for which patients with PAD are at increased risk [6, 7]. It has been hypothesized, but not yet scientifically proven, that debulking of vessels in high-grade stenosis or chronic total occlusion (CTO) allows the removal of both superimposed acute and better-organized chronic thrombotic material, resulting in less stress on vessel walls than either balloon angio-

plasty alone (POBA) or drug-coated balloon angioplasty (DCB) as a therapeutic approach. Vessel preparation via rotational thrombectomy (RT) is expected to reduce the risk of flow-limiting dissection and mural recoil and improve drug uptake into the vessel wall [8, 9].

The existing data for RT are convincing. However, these studies often do not assess outcomes in more complex real-world settings where RT is used in combined procedures with additional thrombolysis to treat native vessels or occluded limb bypasses [10–12]. However, real-world data are lacking, and most studies are based on selected cohorts, which often have a particularly favorable distribution pattern of arterial occlusions, or on small retrospective cohorts.

The aim of this study is to evaluate the safety and efficacy of RT in a real-world cohort that included all patients treated with RT at our institution. This included patients with acute, subacute, and chronic infrarenal arterial occlusions of native vessels, in-stent occlusions, and bypass grafts.

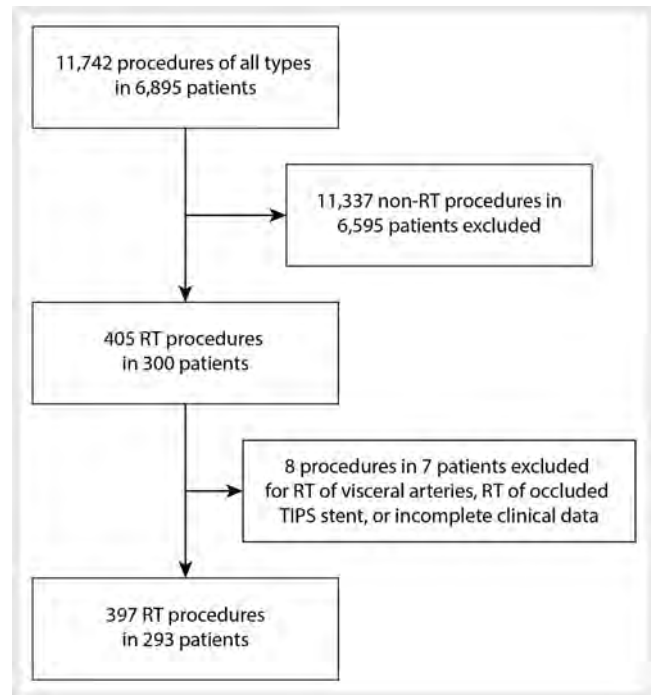
Materials and methods

Patient cohort

The retrospective study received institutional review board approval with a waiver of informed consent (No.XXX). A retrospective search of the clinical data system since the introduction of RT (Rotarex, BD) at a single institution in December 2010 through January 2020 yielded 405 RT procedures in 300 patients. The final study cohort comprised 397 RT procedures in 293 patients with all kinds of stages of PAD (peripheral arterial disease), since procedures in visceral arteries, occluded TIPS, and incomplete datasets were excluded, see ► **Fig. 1**. The mean age of the subjects was 69.8 ± 12.0 years, and 64.8% ($n = 190$) were male. Acute (intervention < 3 days after symptom onset) events accounted for 47.5% of cases ($n = 182$), subacute (intervention 3–14 days after symptom onset) and acute-on-chronic (clinically relevant chronic stenosis with additional acute occlusion) events for 22.2% of cases ($n = 85$), and chronic (intervention > 14 days after symptom onset) events for 30.3% of cases ($n = 116$). For 3.5% of patients ($n = 14$), the age of occlusion could not be definitively determined. Rutherford categories 3 (23.5%, $n = 69$) and 4 (32.1%, $n = 94$) were most prevalent. Cardiovascular risk factors were frequently present, as summarized in ► **Table 1**. The median diameter of the reference vessels as measured via DSA ($n = 373$) was 6 mm (range: 2.5 to 12 mm). Further characteristics of the target lesions are summarized in ► **Table 2**. The median procedure duration was 78 minutes (interquartile range 55 and 106.25). Cross-over vascular access was performed in 55.3% of cases ($n = 219$) and ante-grade access was performed in 41.9% ($n = 166$). 2.8% of accesses ($n = 11$) were performed retrograde from the popliteal or tibial-pedal arteries, retrograde from the brachial artery, or both cross-over from the contralateral common femoral artery and retrograde from the ipsilateral popliteal or tibial-pedal arteries. A 6F RT catheter was used in 92.2% of cases ($n = 365$); an 8F catheter was used for the remaining cases. Additional catheter-directed thrombolysis was performed in 32.0% of procedures ($n = 127$). The timing of thrombolysis was available for 123 procedures. Among these cases, thrombolysis was performed before RT in 8.9% ($n = 11$), peri-interventionally in 13.0% ($n = 16$), after RT in 58.5% ($n = 72$), or before and after RT in 19.5% of cases ($n = 24$). The thrombolytic was available in 120 cases: urokinase was used in 65.0% of cases ($n = 78$), alteplase in 32.5% ($n = 39$), and abciximab or argatroban in 2.5% ($n = 3$). Patients underwent thrombolysis for a median of 18.3 hours (interquartile range: 8.3 to 21.3 hours). RT was followed by POBA in 68.0% of cases ($n = 270$), DCB angioplasty in 37.5% ($n = 149$), and stenting in 41.1% ($n = 163$).

Data Collection

Clinical data and risk factors, clinical stage of disease at the time of intervention, procedural data, and technical and clinical success rates were recorded. The stage of PAD was determined according to the Rutherford classification and further stratified into acute, subacute and acute-on-chronic, and chronic. Angiographic images of the index procedure were reviewed, and lesion length, vessel diameter, and the presence or absence of vascular calcifica-



► **Fig. 1** Subject enrollment data. All subjects were enrolled beginning December 2010 (initiation of rotational thrombectomy at study institution) through January 2020. RT: rotational thrombectomy; TIPS: transjugular intrahepatic portosystemic shunt.

► **Table 1** Demographic data. SD: standard deviation.

	n (%), 293 total subjects
Age in years (mean ± SD)	69.8 ± 12.0
Gender	
Male	190 (64.8)
Female	103 (35.3)
Rutherford category	
0	0 (0)
1	4 (1.3)
2	37 (12.6)
3	69 (23.5)
4	94 (32.1)
5	27 (9.2)
Cardiovascular risk factor	
Arterial hypertension	241 (82.3)
History of nicotine abuse	151 (51.5)
Dyslipidemia	144 (49.1)
Adiposity (BMI > 30 kg/m ²)	65 (22.2)
Coronary artery disease	100 (34.1)
Diabetes mellitus	95 (32.4)
Chronic renal insufficiency	66 (22.5)

tions were assessed by consensus of two experienced interventional radiologists with nine and ten years of experience (*blinded to review*) and one resident with three years of specialty training (*blinded to review*). Calcifications of the target lesion were visually graded on CT angiography images on a four-point scale (none, minimal, medium, severe). In the case of minimal, no more than one-third, in the case of medium, one-third to two-thirds, and in the case of severe, more than two-thirds of the vessel's cross-sectional area was calcified. Treatments and procedures in addition to RT (e. g., POBA, DCB, or stent placement) were recorded. Procedures were deemed clinically successful if sufficient blood flow was achieved to the limb at the interventionist's discretion at the end of the procedure or additional catheter-directed thrombolysis. As an outcome, primary patency, as clinically driven target lesion revascularization (CDTLR) free patency, and freedom from amputations were recorded through July 2020. Adverse events were recorded for the index procedure and during the hospital stay through discharge and were classified according to the CIRSE classification system [13].

Interventional procedure

Target lesions were identified and characterized via digital subtraction angiography (DSA). A guidewire was used to cross the target lesion. Rotational thrombectomy was performed using a 6F or 8F RT catheter with four or more catheter passes across the occlusion. DSA was performed again, and the procedure was repeated selectively as needed to achieve angiographically apparent vessel patency. In the case of persistent thrombi or emboli in the infra-popliteal arteries, additional lysis therapy was administered. These cases were classified as "not fully treatable" with RT. Persistent underlying chronic stenoses were treated with POBA, DCB, or stent angioplasty. Covered stents were used in cases of vascular perforation. Periinterventional medications included anticoagulation with 5000 international units (IU) of unfractionated heparin with an additional 2500 IU of heparin administered for long procedures or severely obese patients at the discretion of the interventionist. Patients with confirmed HIT received argatroban at a flow rate of 2 µg/kg body weight/min as a continuous infusion. In cases of persistent smaller thrombi, or linear non-flow-limiting dissections, perfusor-assisted full heparinization was performed for 48 hours. All patients received a loading dose of dual antiplatelet therapy with 500 mg acetylsalicylic acid (ASA) and 300 mg clopidogrel. This was followed by sustained administration of 100 mg ASA and 75 mg clopidogrel for 4 weeks and, if DCB angioplasty was performed, for 12 weeks.

Statistical analysis

Statistical analyses were evaluated using Jmp (version 15. SAS Institute Inc.) and Spss (IBM Spss statistics for Windows, version 26.0). An alpha error of less than 0.05 was regarded as statistically significant. Normally distributed continuous values were compared via Student's T-test. Nonparametric procedures (Mann-Whitney U-test) were used for nonnormally distributed data. Pearson's chi-squared test was used to determine the relationship between nominal and ordinal scaled variables. Two-sided Monte Carlo significance tests were performed with 10 000 sample tables.

► **Table 2** Features of target lesions. *TASC score was assessed in native vessels only. ** Only digital subtraction angiography images were saved during the procedure. Hence, the characterization of calcification required concurrent CT angiography, since calcifications were evaluated for 194 of 397 total lesions. TASC: Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (version TASC II); ISR: in-stent-restenosis (ISR).

Angiographic details of target lesions	n/total (%)
Lesion length:	
▪ <20 cm	153/397 (38.5)
▪ >20 cm	244/397 (61.5)
Vessel type:	
▪ Native	338 /397 (85.1)
– Without stent	148/397 (37.3)
– ISR	190/397 (47.9)
▪ Bypass graft	59/397 (14.9)
– Without stent	45/397 (11.3)
– ISR	14/397 (3.5)
TASC score:	
▪ A	10/338 (3.0)
▪ B	87/338 (25.7)
▪ C	144/338 (42.6)
▪ D	97/338 (28.7)
Degree of associated calcification:	
▪ None	44/194 (22.7)
▪ Minimal	57/194 (29.4)
▪ Medium	76/194 (39.2)
▪ Severe	17/194 (8.8)
Location of target lesion:	
▪ Iliac arteries	28/397 (7.1)
▪ Iliac and leg arteries	20/397 (5.0)
▪ Arteries of the entire leg	107/397 (27.0)
▪ Solely arteries of the thigh	236/397 (59.4)
▪ Solely arteries of the lower leg	6/397 (1.5)

The effect size was expressed as Cramér's V. Primary patency was assessed using Kaplan-Meier estimates.

Results

A guidewire was passed across the target lesion in 100 % of cases. 90.4 % of procedures were deemed clinically successful (n = 359), defined as sufficient blood flow to the limb at the interventionist's discretion at the end of the procedure or additional catheter-directed thrombolysis. Insufficient or no flow was present after RT in 9.1 % of cases (n = 36). RT catheter technical failure was observed in 1.8 % of cases (n = 7). Overall, 6.5 % of patients (n = 26) required minor amputation post-RT during the entire follow-up period. In 38.5 % of these patients (n = 10), amputation was planned prior to the index RT procedure, and the intervention was

► **Table 3** Primary patency. Primary patency is defined as clinically driven target lesion revascularization [CDTLR] free patency and freedom from amputations). The table shows primary patency rates for acute (intervention < 3 days after symptom onset) events (47.5% of cases (n = 182)), sub-acute (intervention 3–14 days after symptom onset) and acute-on-chronic (clinically relevant chronic stenosis with additional acute occlusion) events (22.2% of cases (n = 85)), and chronic (intervention > 14 days after symptom onset) events (30.3% of cases (n = 116)). In addition, primary patency with or without the use of a DCB in the setting of adjuvant therapy is presented. DCB: drug-coated balloon.

Time	Acute (% [n])	Subacute (%[n])	Chronic (% [n])	DCB (% [n])	No DCB (% [n])	Overall (%)
1 month	90.1 (163)	95.3 (81)	97.4 (113)	95.1 (142)	91.1 (226)	93.2
3 months	85.0 (152)	91.8 (78)	92.2 (107)	93.2 (139)	85.5 (210)	88.8
6 months	77.2 (137)	84.7 (72)	80.2 (93)	85.8 (127)	75.3 (184)	79.1
1 year	69.7 (111)	81.2 (63)	70.5 (77)	78.2 (107)	68.6 (151)	72.4

considered clinically successful in enabling wound healing by revascularization of the amputation stump. The pre-procedural mean ABI was 0.33 ± 0.29 (n = 176), corresponding to severe PAD. The mean post-procedural ABI increased to 0.81 ± 0.25 (n = 198; $p < 0.0001$). Walking distance was available in 147 cases before RT and after in 48 cases. Of these 48 cases, the proportion of patients with a walking distance of fewer than 200 m decreased from 93.9% to 22.9% ($p < 0.0001$) during the hospital stay of the index procedure.

The overall primary patency was 93.2%, 88.8%, 79.1%, and 72.4% after 1, 3, 6 and 12 months, respectively. Subacute occlusions treated via RT maintained the highest primary patency rate after one year at 81.2%. Patency rates are described in further detail in ► **Table 3** and ► **Fig. 2, 3**. CDTLR was required in 141 subjects (35.5%) during the entire follow-up period. 8.3% (n = 33) required CDTLR within 30 days of the index intervention. When subdivided into acute, subacute, and chronic subgroups, no significant difference in primary patency was observed between groups over the entirety of the follow-up period (log-rank test $p = 0.052$, see ► **Fig. 2**). When subdivided according to the use of a DCB during the index procedure, no significant difference in primary patency was observed over the follow-up period (log-rank test of $p = 0.135$, see ► **Fig. 3**). An exemplary case of a treated patient is shown in ► **Fig. 4**.

Complications

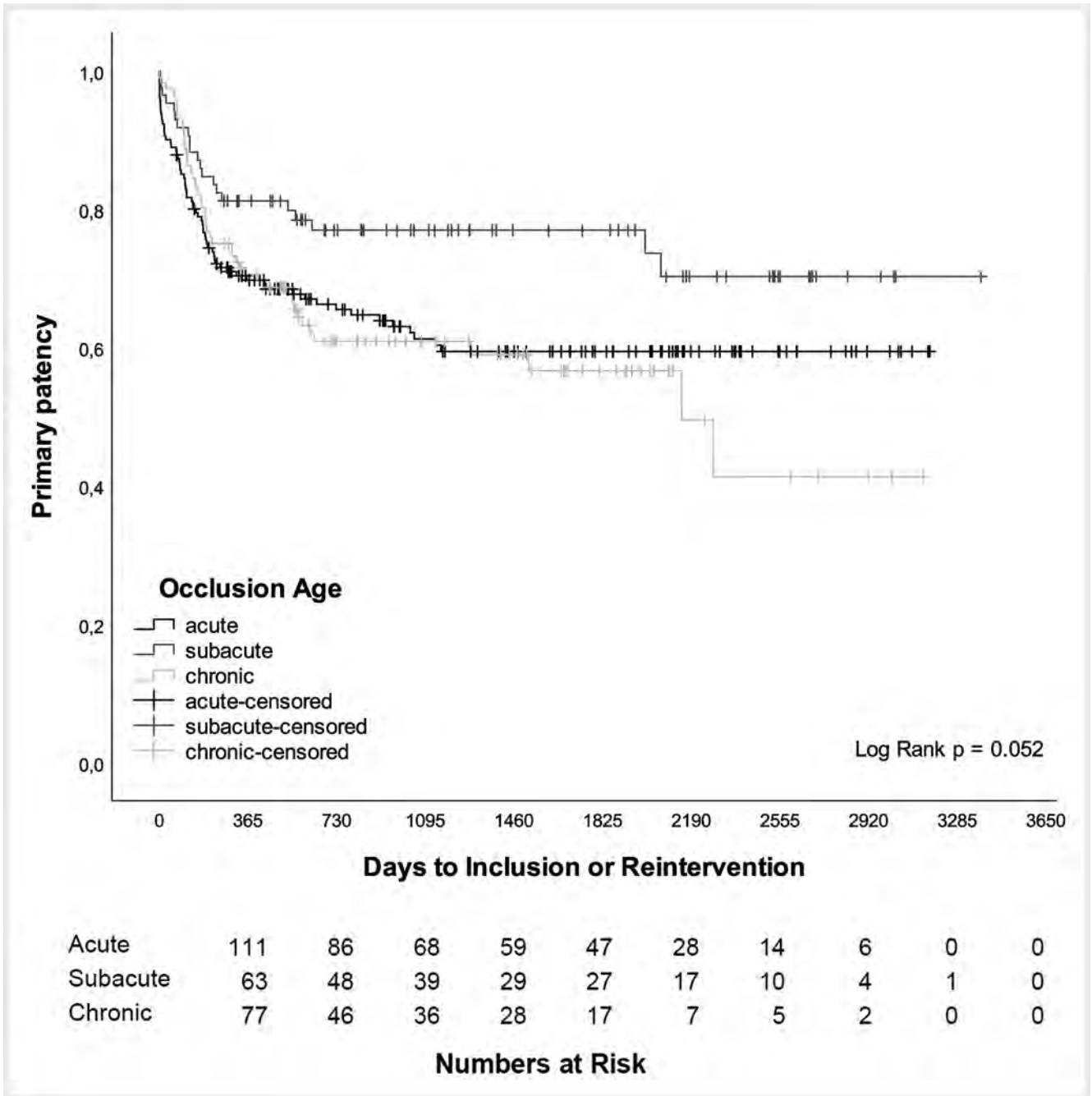
46.1% of procedures were associated with complications (n = 183 of 397). Distal embolism was the most common complication at 22.4% (n = 89 of 397). Of these, 65.2% of cases (n = 58 of 89) required further treatment by aspiration thrombectomy in 14.3% of cases (n = 8 of 56), aspiration with periprocedural administration of lysis in 37.5% of cases (n = 21 of 56), more extended use of RT in 5.4% of cases (n = 3 of 56) or subsequent thrombolysis in 27% of cases (n = 24 of 56), 27.0% (n = 24) received therapeutic-dose heparin over 48 hours, and seven minor embolizations did not require additional treatment. 98.9% (n = 88 of 89) of distal embolizations were CIRSE complication grade 1 to 3 without post-procedure sequelae, 1.1% (n = 1 of 89) developed intracerebral bleeding during subsequent thrombolysis (CIRSE complication grade 5). RT was directly associated with complications in 7.1% of cases (n = 28), which consisted of perforations 2.8% (n = 11), ar-

teriovenous fistula 1.3% (n = 5), dissections 2.0% (n = 8) and guidewire fractures 0.5% (n = 2). The data analysis by location of the target lesion revealed significantly more RT-associated iliac artery complications compared to femoropopliteal or below the knee vessels ($\chi^2(2) = 7.365$, $p = .025$, Cramér's $V = 0.140$, Monte Carlo significance $p = .022$). Severe complications (CIRSE grades 5 and 6) occurred in 7 patients, with not a single complication being directly related to RT. A detailed overview of observed complications is provided in ► **Table 4, 5**.

Discussion

This study demonstrated a technical and clinical success rate of revascularization in 90% of procedures with significant improvement in ABI and pain-free walking distance in a large retrospectively evaluated patient population of 293 patients and 397 procedures, demonstrating RT as a safe and effective treatment option. With approximately 50% acute and 30% chronic occlusions of the iliac or femoropopliteal vessels and more than 60% of patients with CLI, the patient population represents a challenging cohort that is grossly representative of real-world daily vascular practice. Complex TASC-C and TASC-D lesions with lengths greater than 20 cm comprised most of the study cohort. Our evaluation demonstrated clinical success and a significant improvement of the ABI and the pain-free walking distance. However, as the patient population was challenging, a relatively high risk of re-intervention was observed, which occurred in approximately one-third during the follow-up period, but in only 8.5% within the first 30 days after the index procedure. Overall, we documented 183 adverse events, with distal embolism being the most commonly observed in 22.4% of cases. Of these, 65.2% required further treatment by aspiration thrombectomy or subsequent thrombolysis, and 27.0% received therapeutic-dose heparin over 48 hours. In our opinion, this is because we included a larger proportion of patients after bypass surgery in our study [12]. The bypass diameter often exceeds the diameter of the native vessels and cannot be completely thrombectomized, which carries the risk of peripheral embolization after balloon PTA, for example.

To date, our study represents one of the largest and most comprehensive patient populations for evaluating rotational thrombectomy without excluding subgroups from the analysis. Such a



► **Fig. 2** Primary patency illustrated using Kaplan-Meier curves subdivided according to lesion age. Because cases were included between 12/2010 and 01/2020 and data collection of clinically determined target lesion revascularization (CDTLR) was 07/2020, cases were censored if they had primary patency at the time of data collection but were shorter in follow-up.

mixed cohort has only been studied previously by Lagana et al., but only in a comparatively small cohort of 22 patients [14]. Previous studies that had enrolled similar numbers of subjects excluded important subgroups encountered in daily vascular practice, including chronic occlusions, in-stent lesions, and bypass occlusion [10, 15, 16], thus limiting their general applicability in daily practice. It should be noted that the treatment of our cohort in which 71.3% of cases were classified as TASC-C or TASC-D lesions, resulted in technical and clinical success rates above 90%, which is in line with

the German S3 guideline on the diagnosis, treatment, and follow-up of peripheral arterial occlusive disease [17].

Furthermore, lesion length was not a predictor of clinical success, as most lesions exceeded 20 cm in length. The results align with a recently published study for RT in long lesions [18]. Because 89.5% of occluded vessels had underlying residual stenosis exposed by RT, adjunctive therapy was frequently employed, most commonly POBA, followed by DCB angioplasty, a combination of POBA and DCB angioplasty, and least commonly stenting. These

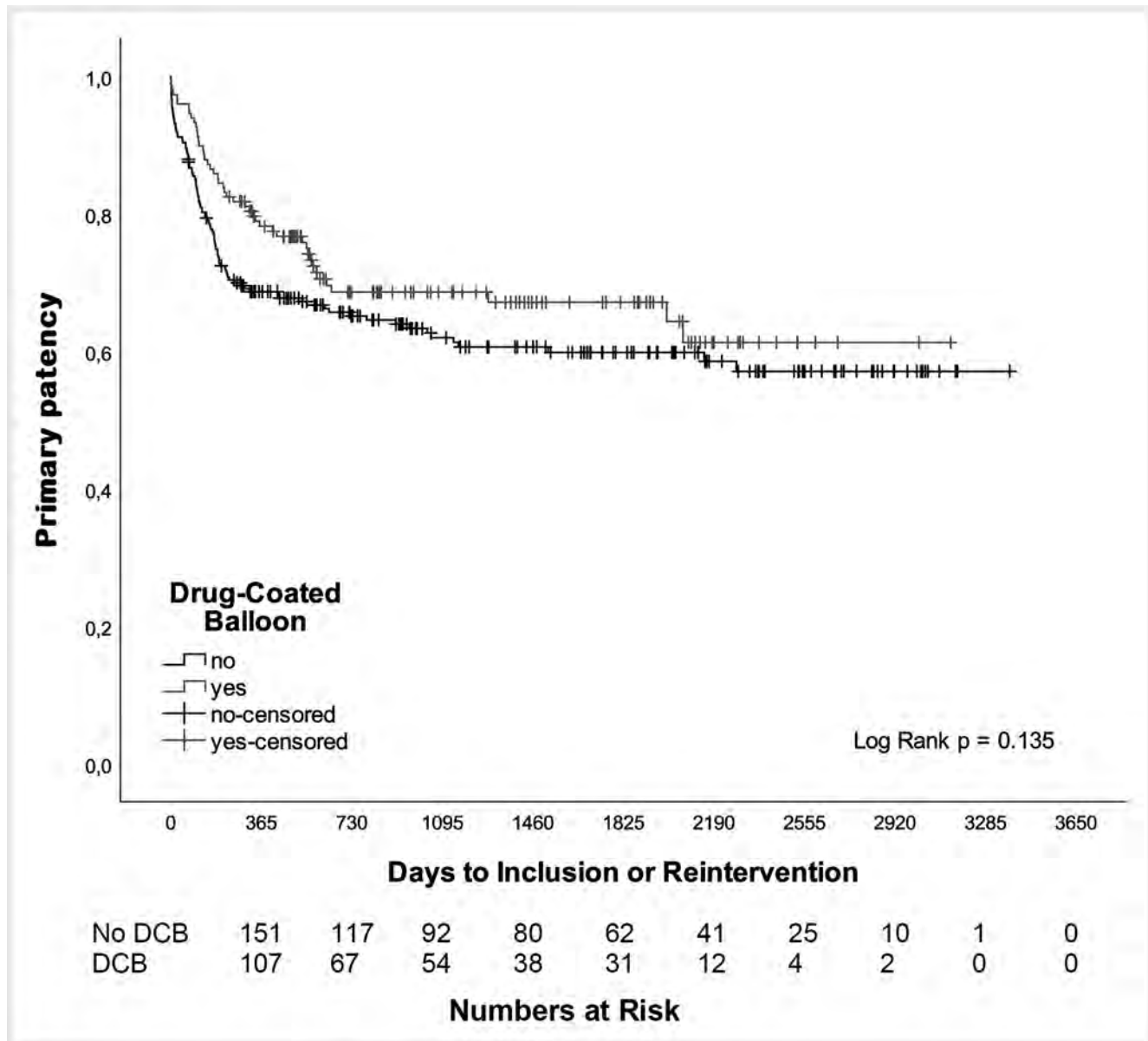


Fig. 3 Primary patency illustrated using Kaplan-Meier curves with or without the use of drug-coated balloon during the index procedure. Because cases were included between 12/2010 and 01/2020 and data collection of clinically determined target lesion revascularization (CDTLR) was 07/2020, cases were censored if they had primary patency at the time of data collection but were shorter in follow-up.

results are similar to prior studies focusing on populations with underlying chronic stenotic/occlusive mechanisms rather than acute embolic events in otherwise healthy arteries [19].

Additional thrombolytic therapy was used in 32.0% of cases ($n = 127$). 64.6% ($n = 82$) of cases utilizing thrombolytic therapy in addition to RT were in the setting of occluded bypass grafts, a slightly higher but comparable rate of adjunctive thrombolysis therapy as compared to a previous study [10]. As the majority of RT catheters used in this study were 6-F in diameter, we surmise that this caliber catheter is relatively undersized for use in occluded bypass grafts, leading to insufficient initial debulking during RT and necessitating additional thrombolytic treatment. Consequently, the use of an 8-F catheter should be considered for vessels with a luminal diameter of 5 to 8 mm. It should be noted that

patients with bypass grafts often have complex preoperative conditions that may inhibit the use of an 8-F sheath or increase the lysis-associated bleeding risk connected with 8-F access, necessitating a careful, patient-specific appraisal of the risks and benefits of both the choice of RT catheter size and additional employment of thrombolytics.

In this retrospective evaluation, primary patency was indirectly determined using CDTLR as a surrogate parameter over the entire observation period. Furthermore, the subjects in this study were found to continue the vast majority of their follow-up at the index institution, and there was no documented external intervention in any subject during follow-up visits or visits for other indications. Consequently, we surmise that CDTLR represents a robust and relevant alternate measure of primary patency.

CDTLR within the first year after the index procedure was necessary for 30.3% of the entire cohort, as further described in ► **Table 3** and ► **Fig. 2**. For the entire follow-up period, no significant difference was observed between the subgroups.

When subdivided according to the use of a DCB during the index procedure, no significant difference in primary patency was observed, as further described in ► **Table 3** and ► **Fig. 3**. These results are in contrast to a previous prospective trial by Latacz et al., who observed a reduction of restenosis rates from 45.5% to 12.5% [20] when combining RT and DCB. However, the cohorts differ regarding target vessels, lesion length, and patient demographics. The amputation rate during the observation period was 6.5%, which is consistent with previously published literature [21].

Regarding complications, the observed peripheral embolization rate was relatively high at 22.4% (n = 89%), with approximately two-thirds requiring further treatment via aspiration or thrombolysis. Our data cannot distinguish whether peripheral embolization was caused directly by RT or incomplete thrombectomy followed by balloon angioplasty. Dissections occurred in 10.3% of cases (n = 30), but only 26.7% of dissections (n = 8) were directly attributable to RT, which is similar to data observed by Freitas et al. [10]. It has been argued that reopening of chronically occluded vessels is often associated with dissections, but a recent in vitro study demonstrated the superior safety of RT in terms of rates of significant macroembolism, dissection, and microscopic vessel injury as compared to alternative techniques [22]. Overall, the most common directly RT-associated complication in our cohort was vessel perforation, which occurred in 2.8% of cases (n = 11), followed by iatrogenic AV fistulas in 1.3% of cases (n = 5), which is similar to a previous study [16]. No correlation was observed between the degree of calcification and the risk of perforation in our study cohort, as has been hypothesized in the past [16, 23]. What was observed, however, was an increased rate of complications using RT in the iliac vessels. All perforations were successfully treated by the intraprocedural deployment of covered stents, and no surgical repair was required.

This study is limited by its retrospective design, which made systematic follow-up of patients difficult and did not allow direct determination of restenosis rates at one or two years. However, this was compensated for by using CDTLR as a surrogate parameter of primary patency with clinically meaningful impact. Another limitation arises from the disproportionately frequent use of a 6-F RT catheter versus an 8-F catheter, particularly at the beginning of the study period. We hypothesize that the employment of 8-F catheters more frequently, particularly for occluded bypass grafts, would likely have reduced the need for additional thrombolysis. This hypothesis will be the focus of future work. Finally, this study did not directly compare RT with alternative procedures, as RT had become the mainstay of therapy at the study institution during the retrospective period evaluated. In this study, only patients who received RT in the context of a CTO of the lower extremity were included. Of course, it is debatable to what extent, especially in the subgroup of acute occlusions, the primary use of adjuvant therapies and specifically lysis could have provided similar results. In the cohort of patients we investigated, there were numerous patients who had contraindications to classic lysis therapy (for example, condition after surgery, condition after insult or



► **Fig. 4** Case report of an 80-year-old patient who underwent femoropopliteal bypass surgery one year ago. Due to a stroke, the existing therapy with phenprocoumon was paused and an acute occlusion of the bypass with rest pain (Rutherford IV) occurred **A**. Because of the existing contraindication to lysis therapy, an 8-French rotational thrombectomy was performed for recanalization **B**. With this procedure, the patient's symptoms resolved completely.

hemorrhage) or relative contraindications (advanced age). Furthermore, rotational thrombectomy has been widely implemented in the clinical routine in our institution to reduce the rate of serious complications of lysis therapy. Also, in the patient population considered here, intracerebral hemorrhage occurred in three patients during adjuvant lysis therapy, which corresponds to the severe bleeding complication rates of 1–2% known from the literature [24]. Furthermore, RT allowed completion of therapy or a single-stage approach in 301 of the 397.

Conclusion

Rotational thrombectomy is a safe and efficacious method for treating arterial occlusions of the lower extremity, with a clinical success rate of 90.0%. Distal embolization was observed in 22.4% of cases. However, complications directly associated with RT were rare, with perforation (2.8%) and iatrogenic AV fistulas (1.3%) being the

► **Table 4** Complications. Complication category by cause in absolute number and percentage of final study cohort (n = 397 total interventions). Cases were classified as “unknown” if assignment to the categories RT, adjuvant therapy, and underlying disease was not possible from the retrospective data. The two fatal complications occurred in the setting of intracerebral hemorrhage during adjuvant therapy with lysis. RT: rotational thrombectomy.

Complication category	RT n (%)	Adjuvant therapy n (%)	Underlying disease n (%)	Unknown n (%)	Total
Dissection	8 (2.0)	30 (7.6)	0 (0)	3 (0.8)	41 (10.3)
Perforation	11 (2.8)	6 (1.5)	0 (0)	0 (0)	17 (4.3)
Pain	0 (0)	1 (0.3)	0 (0)	0 (0)	1 (0.3)
Arteriovenous fistula	5 (1.3)	1 (0.3)	0 (0)	1 (0.3)	7 (1.8)
Guidewire fracture	2 (0.5)	0 (0)	0 (0)	0 (0)	2 (0.5)
Compartment syndrome	0 (0)	0 (0)	7 (1.8)	0 (0)	7 (1.8)
Miscellaneous	2 (0.5)	4 (1.0)	5 (1.3)	0 (0)	11 (2.8)
Secondary hemorrhage	0 (0)	0 (0)	5 (1.3)	0 (0)	5 (1.3)
Death during hospital stay	0 (0)	2 (0.5)	1 (0.3)	0 (0)	3 (0.8)
Total	28 (7.1)	44 (11.1)	18 (4.5)	4 (1.0)	94 (23.7)

► **Table 5** CIRSE classification of adverse events. Distribution of observed complications according to the CIRSE classification system in absolute number and percentage. CIRSE: Cardiovascular and Interventional Radiological Society of Europe.

CIRSE	n/94 (%)
1	71 (75.5)
2	1 (1.1)
3	12 (12.8)
4	1 (1.1)
5	6 (6.4)
6	3 (3.2)

most frequent. It should be noted that occluded bypass grafts were observed to have a higher probability of residual thrombi requiring additional lysis therapy. We hypothesize that employing a larger-caliber RT catheter may reduce this rate at the risk of an increased rate of pseudoaneurysm or hemorrhage at the access site.

Conflict of Interest

The authors declare that they have no conflict of interest.

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