Retrograd transpedale Revaskularisierung kru- raler Arterien bei Patienten mit kritischer Extremitätenschädigung und gescheitertem antegraden Revaskularisierungsversuch

Zusammenfassung


Ergebnisse: Bei 15 Patienten (93,8 %) fanden sich jeweils Diabetes, KHK und Hypertonie unter den Komorbiditäten. Nierenfunktionseinschränkungen und stattgehabte Amputationen fanden sich bei 7 Patien- ten (43,8 %). Bei 5/16 Patienten (31,3 %) bestand eine Kalzifizierung des punktierten Gefäßes, der mittlere Durchmesser betrug 1,75 +/-0,24 mm. Die Prozedurduar betrug 92,4 +/-23 min. Der technische Erfolg betrug 100 %. Die retrograde Lasionspassage war bei 12/16 Patienten (75,0 %), die Gesamtprozedur bei 10/16 Patienten (68,8 %) erfolgreich. Minorkomplikationen kamen bei 2/16 Patienten (12,5 %) vor. Der Extremitätenerhalt, bzw. Überlebensrate nach 12 Monaten betrugen 72,9 % und 100 %. Majoramputationen nach der Revaskularisierung wurden bei 2/16 Patienten (12,5 %) durchgeführt.

Schlussfolgerung: Nach gescheitertem antegrade- ren Revaskularisierungsversuch kann ein retro- grad transpedaler Zugang den Prozedurerfolg er-
Introduction

In addition to other supporting therapies, patients suffering from critical limb ischemia (CLI) with tissue loss require immediate revascularization in order to stimulate ulcer healing and minimize the risk of (major) amputation [1, 2]. Venous (popliteal-pedal) bypass has been advocated as the revascularization method of choice for below-the-knee (BTK) lesions owing to the acceptable patency rates [3]. However, in CLI patients limb salvage has been advocated as the major goal of revascularization with patency rates being less important [4], and many experienced centers prefer an endovascular approach first [5]. Reasons for this include but may not be limited to the minimally invasive character of the endovascular approach. The advantages of the endovascular approach include lower complication rates and perioperative risk due to comorbidities, no issues with a lack of conduits and cost-effectiveness compared to bypass surgery [1, 6]. As with all vascular lesions, a prerequisite of endovascular treatment is lesion crossing with the guidewire tip in an intraluminal position beyond it to start the revascularization procedure [7]. Crossing those lesions may be difficult, last but not least owing to the calcification of BTK arteries which is observed with above the risk of subintimal Läsionpassage the Reentry problematisch sein. After a failed attempt at antegrade revascularization of a BTK occlusion, a retrograde approach should be performed.

Revascularization technique

With the patient in a supine position, we regularly perform antegrade transfemoral puncture of the common femoral artery with either fluoroscopy and/or ultrasound guidance. Using Sel-dinger’s technique, a 10 cm long 4 – 6F introducer sheath (Radifo-

Materials and Methods

Study sample

We retrospectively searched through our electronic database to identify patients who had a BTK intervention in our interventional radiology department between 2/2014 and 8/2015. We identified 172 patients who underwent BTK vessel revascularization for CLI. 16/172 patients (9.3 %) had a retrograde transpedal/transstibial approach after an antegrade transfemoral approach had ultimately failed. The retrograde approach was carried out in the same session as the antegrade in all but two patients who were not able to lie in a supine position owing to discomfort. These patients had a staged procedure on days 3 and 5 after the antegrade approach had failed. All patients were discussed in our weekly interdisciplinary vascular board (interventional radiology, vascular surgery) and found to be poor candidates for either a pedal or tibial bypass. Patient and lesion characteristics are included in ▶ Table 1.

Table 1 Demographic and angiographic characteristics.

<table>
<thead>
<tr>
<th>age</th>
<th>77.7 +/-8.8y (range: 52 – 95y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>sex</td>
<td>10 men (62.5 %), 6 women (37.5 %)</td>
</tr>
<tr>
<td>comorbidities</td>
<td></td>
</tr>
<tr>
<td>hypertension</td>
<td>16/16 (100 %)</td>
</tr>
<tr>
<td>coronary artery disease</td>
<td>15/16 (93.8 %)</td>
</tr>
<tr>
<td>hyperlipidemia</td>
<td>15/16 (93.8 %)</td>
</tr>
<tr>
<td>diabetes mellitus</td>
<td>15/16 (93.8 %)</td>
</tr>
<tr>
<td>chronic renal failure</td>
<td>8/16 (50.0 %)</td>
</tr>
<tr>
<td>dialysis dependency</td>
<td>3/16 (18.8 %)</td>
</tr>
<tr>
<td>Rutherford-Becker classification</td>
<td></td>
</tr>
<tr>
<td>category 5</td>
<td>10/16 (62.5 %)</td>
</tr>
<tr>
<td>category 6</td>
<td>6/16 (37.5 %)</td>
</tr>
<tr>
<td>prevent III score [21]</td>
<td></td>
</tr>
<tr>
<td>medium risk (4 – 7 points)</td>
<td>12/16 (75.0 %)</td>
</tr>
<tr>
<td>high risk (&gt; = 8 points)</td>
<td>4/16 (25.0 %)</td>
</tr>
<tr>
<td>side and vessel used for retrograde access</td>
<td></td>
</tr>
<tr>
<td>left</td>
<td>8/16 (50.0 %)</td>
</tr>
<tr>
<td>right</td>
<td>8/16 (50.0 %)</td>
</tr>
<tr>
<td>dorsal pedal artery</td>
<td>13/16 (81.25 %)</td>
</tr>
<tr>
<td>distal posterior tibial artery</td>
<td>3/16 (18.75 %)</td>
</tr>
<tr>
<td>lesion characteristics</td>
<td></td>
</tr>
<tr>
<td>total occlusion</td>
<td>16/16 (100 %)</td>
</tr>
<tr>
<td>lesion length</td>
<td>19.1 +/-7.0 cm</td>
</tr>
<tr>
<td>calcification present</td>
<td>7/16 (43.8 %)</td>
</tr>
<tr>
<td>Initial number of non-occluded run-off vessels</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>7/16 (43.8 %)</td>
</tr>
<tr>
<td>1</td>
<td>8/16 (50.0 %)</td>
</tr>
<tr>
<td>2</td>
<td>1/16 (6.3 %)</td>
</tr>
</tbody>
</table>

Key Points:

- Retrograde approaches via transpedal or transtibial vessels are safe and offer high technical success.
- One problem after technically successful puncture might be the re-entry following subintimal retrograde lesion crossing.
- After a failed attempt at antegrade revascularization of a BTK occlusion, a retrograde approach should be performed.

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cus®, Introducer II, Terumo, Tokyo, Japan) is inserted. 5000 units of heparin are administered via the femoral sheath. An angiogram using manual contrast injection is performed down to the foot (Fig. 1). In the case of femoral or popliteal lesions, these are addressed first, preferably by intraluminal lesion crossing. Following revascularization by plain old balloon angioplasty (POBA) in combination with either drug-eluting balloon (DEB) PTA or implantation of a stent or stentgraft, BTK lesions are addressed. As standard practice, we try to revascularize as many BTK vessels as possible in CLI patients. A 4F catheter was used to selectively intubate the diseased crural artery. In the case of an occluded vessel, we preferably use a 0.018” (V-18™ Control Wire, Boston Scientific, Marlborough, MA, USA) or 0.014” (Command ES™, Abbot Vascular, Diegem, Belgium) guidewire, supported by a vessel size-matching balloon catheter if needed. In the case of a stenosed vessel or for subintimal revascularization of an occluded one, an angled 0.018” guidewire (Radifocus®, Glidewire Advantage™, Terumo, Europe, N.V. Leuven, Belgium) is used. We do not regularly use support catheters. Following passage of the lesion, we perform POBA for 60s using either a 0.014” PTA balloon (Coyote™, Boston Scientific, Marlborough, NA, USA) or a 0.018” balloon (Saber™, Cordis, Tipperary, Ireland). In the case of failure to pass the lesion with a guidewire in an antegrade direction from above, we switch to the transpedal/ transtibial approach (Fig. 2). Before the foot and distal part of the lower extremity are prepared by sterile washing, the initial run-off angiogram is thoroughly examined to confirm a distal vessel segment that is long enough to be punctured and in which the pedal access sheath can securely be placed. Using a linear ultrasound probe (Sparq™, Philips Healthcare) in B-mode and Duplex mode, either the dorsal pedal or distal tibial artery is identified. Using a dedicated vascular access set (Micropuncture® Pedal Introducer Access Set, Cook Medical, Bloomington, USA), the target vessel is punctured under sonographic guidance until blood flow through the 21G needle is registered. In the case of an anterior tibial artery occlusion, the dorsal pedal artery is punctured as we find it easier to access compared with the distal anterior tibial artery – probably owing to a more superficial location and fixed position. In the case of a posterior tibial artery occlusion, the distal segment near the ankle is accessed. The 0.018” set guidewire...
is then introduced using fluoroscopy control. Following local anesthe- 
sia, a small incision over the puncture side, and removal of 
the needle, the 4F set sheath is placed over the wire. This sheath 
comes with a (Check-Flo®) hemostasis valve. A retrograde man-
ual angiogram via this sheath is performed to confirm the intra-
luminal position of the sheath as well as the configuration of the 
distal cap of the occlusion. We do not regularly use any intra-ar-
terial medication unless spasm occurs. The occlusion is then tra-
versed in a retrograde and preferably intraluminal manner using 
either a 0.014” or 0.018” straight CTO guidewire as mentioned 
above. In the case of a subintimal passage, we use an angled tip 
guidewire supported by a balloon catheter to penetrate the inti-
ma from the subintimal space thus gaining re-entry into a non-
or less-diseased vessel segment as has been reported earlier for 
femoro-popliteal revascularization procedures [12]. Support ca-
theters are not used. The intraluminal position is confirmed if 
the guidewire from below and another one inserted from above 
or a selective catheter touch each other as controlled by fluoro-
scopy. After that, we try to steer the guidewire from below into 
a selective catheter which has been pushed down as far as possi-
ble, and guide the wire out through the femoral sheath. If that 
fails, we push the guidewire from below all the way up to the 
groin and snare it in the proximal SFA and guided out via the femoral sheath.
sheath and by using a vascular closure device or manual compression at the discretion of the operator.

Endpoints and definitions
Technical success was defined as intravascular placement of the pedal access vascular sheath within the target vessel after retrograde puncture of the dorsal pedal or distal tibial arteries as confirmed by manual retrograde angiogram via the sheath.

Crossing success was defined as successful retrograde passing of the target lesion intra- or subintimally with the guidewire tip in an intraluminal position above the target lesion.

Procedural success was defined as residual stenosis of less than 30% following POBA.

Clinical success was defined as freedom from major amputation (limb salvage). Major amputation was defined as limb loss below or above the knee level, while minor amputation was defined as an amputation at the trans-metatarsal level or distal thereto.

Procedure time was defined as the time from the first image acquired to the last.

The diameter (mm) of the retrogradely accessed pedal vessels was determined by a) calibrated measurements on angiographic images from the initial run-off angiogram (n = 12) or b) by B-mode ultrasound images in axial orientation (n = 4).

Treatment complications were categorized on the basis of outcome according to the reporting standards of the Society of Interventional Radiology [13]. There were two categories of minor complications: those resulting in (A) no therapy and no consequence or (B) nominal therapy and no consequence including overnight admission for observation only. Major complications included four categories: those (C) requiring therapy, minor hospitalization (48 h); (D) requiring major therapy, unplanned increase in level of care, prolonged hospitalization (48 h); (E) resulting in permanent adverse sequelae; and (F) resulting in death.

Statistical analysis
Data collection was performed by Excel (Microsoft). Statistical analysis was performed using commercially available software (SPSS, Version 22.0.0.0, IBM, USA). Continuous variables were expressed as mean +/- standard deviation and range. Kaplan-Meier analysis was used to predict the overall and major amputation-free survival. Probability values lower than 0.05 were considered to be significant.
Results

The mean follow-up was 197.8 days. The mean dose area product (DAP) was 2048.6cGy*cm². The mean procedure time was 92.4 +/-23 min. The retrogradely accessed vessel showed calcification of the punctured segment in 5/16 patients (31.3 %). The mean diameter of the accessed vessels was 1.75 +/-0.24 mm. The technical success rate was 100 %. Crossing the lesion with the guidewire tip in an intra-luminal position from below was feasible in 12/16 patients (crossing success 75.0 %). In 4 patients it was not possible to achieve re-entry. Further treatment in those 4 patients was conservative (1 patient refused surgery on the grounds of religious beliefs, and 3 patients lacked a suitable conduit or distal target vessel for bypass surgery). In 1 of the 12 patients the retrograde passage was subintimal, while the others were intraluminal. In 2 of these 12 patients the residual stenosis was > 30 % following POBA and therefore procedural success was not achieved (procedural success in 10/16 patients (68.8 %) and in 10/12 patients in which the lesion had been successfully traversed (83.3 %)), although antegrade flow was documented. The guidewire from below was guided out via the femoral sheath using a transfemoral snare maneuver in 8/12 interventions (66.7 %), while the wire was steered into a diagnostic or balloon catheter inserted from above in 4/12 patients (33.3 %). Prior to retrograde access of a crural vessel, 3/16 patients (18.8 %) had successful revascularization of a femoro-popliteal lesion in the target limb during the same session. Hemostasis at the femoral access was achieved by manual compression in 14/16 patients (87.5 %) and by a vascular closure device in 2/16 patients (12.5 %). Manual compression of the pedal access site was performed in 4/16 patients (25.0 %) for less than 5 minutes, while in the remaining patients hemostasis was found immediately after the PTA balloon in the target lesion had been deflated. 7 of 16 patients (43.8 %) had undergone an ipsilateral minor amputation prior to retrograde revascularization. 1 patient (6.3 %) had already had a major amputation of the contralateral limb. At baseline 7/16 patients (43.8 %) had no patent BTK vessel, 8/16 patients (50.0 %) had 1 and 1/16 patients (6.3 %) had 2 patent crural vessels. At completion of the procedure, 2/16 patients (12.5 %) had no, 5/16 (31.3 %) had 1, 8/16 had 2 (50.0 %) and 1/16 (6.3 %) had 3 patent BTK vessels. Minor complications occurred in 2/16 patients (12.5 %) including one hematoma and vasospasm at the pedal access site in the other patient, both of which were treated conservatively. At completion angiography, all retrogradely accessed vessels were intact and showed no stenosis or occlusion at the point of access. Major complications were not observed. The rate of freedom from major amputation (limb salvage) at 6 and 12 months was 87.5 % and 72.9 %, respectively (two major amputations on day 167 and 240). These two major amputations were not thought to be related to the transpedal access maneuvers but to a deterioration of ulcerations. One of these two patients with a major amputation had a failed BTK revascularization from antegrade as well as retrograde via the transpedal access. Both patients were in Rutherford-Becker class 6 at the time of revascularization. The survival rate at 6 and 12 months was 100 % with one death due to pneumonia 18 months after revascularization (Fig. 4A, B). Minor amputation after revascularization was observed in 1/16 patients (6.3 %).

Discussion

Critical limb ischemia is associated with significant morbidity and mortality, particularly in patients with end-stage renal disease, who are undergoing dialysis or are diabetic [1, 2]. One major goal of treatment is to prevent (major) amputation in these pa-

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Fig. 4 Kaplan-Meier survival analysis of A major amputation-free survival and B overall survival.

Abb. 4 Kaplan-Meier-Analyse des A amputationsfreien und B Gesamtüberleben.
tion. Furthermore, radiation exposure of patients and staff is reduced. Even more importantly, in patients with often encountered end-stage renal disease the amount of contrast medium can be reduced by using ultrasound instead of angiography. However, in some patients it might be possible to visualize heavily calcified arteries and steer the puncture needle by use of fluoroscopy and without using contrast. In our experience a very low amount of subcutaneous tissue with a superficially located dorsal pedal artery or massive subcutaneous edema may be challenging scenarios and one option in such patients may be to relocate the puncture site more proximally if the distal extension of the target lesion allows for this.

There are three reasons why the retrograde passage of a BTK CTO might be successful where the antegrade has not been. First, the distal cap of the CTO is often softer and therefore easier to enter, especially if concave-shaped [8]. Second, from below the distance to the target lesion is shorter, and together with a smaller-sized access vessel, may give more support for the CTO wire and other equipment used. Third, collaterals do not misguide the wire as easily if coming from below owing to the angle and caliber of collaterals at the proximal end of the occlusion [1]. In fact, in selected cases careful analysis of the proximal (flat or convex) and distal cap (concave) of a CTO as well as existing collaterals may one day direct interventionalists to a retrograde-first approach. More data on the configuration of CTOs and how to tackle them best would be helpful. Regarding crossing the occlusion with a balloon, the second access at the pedal site allows for a pull-and-pull maneuver, thereby increasing the stability of the wire and enabling forward movement of the balloon which might have not been possible by an antegrade approach only.

Besides the technique of ultrasound-guided puncture, we altered the reported techniques for retrograde pedal interventions described by others in such a way that we remove the pedal access sheath as soon as we have converted to an antegrade maneuver, the target lesion has been crossed with an adequately sized balloon from above and the balloon has been inflated. In this way, antegrade blood flow to the pedal puncture site is reduced (“internal compression”) and additional manual compression is hardly necessary. This may save time and increase the patients’ comfort. As an alternative to cross a BTK occlusion from above after conventional CTO guidewires have failed, dedicated crossing and re-entry devices have become available. These devices may be used during the same session immediately after an antegrade wire passage of a lesion has failed and without any preparation for an alternative pedal access. Therefore, utilization of these devices might save time and be more comfortable for the patient compared to pedal puncture. As these devices add considerable costs to the procedure and are not reimbursed in the authors’ country, we do not use these devices. Furthermore, reported procedural success rates for these devices are in the range of 70% [16], and therefore do not guarantee lesion crossing.

Regarding costs, the pedal access set and sterile dressing for the ultrasound probe not only need to be taken into account but the utilization of a snare device might also become necessary. To avoid utilization of a cost-adding snare device, we find it useful to first try to navigate the wire from below into a selective diagnostic or balloon catheter inserted from above. We try to place those as close to the lesion as possible to occlude as much as possible of the artery diameter, thereby enabling entry of the wire into the catheter and exit via the femoral sheath. However, as demonstrated in our study, this was technically successful in only one third of cases. Alternatively, the procedure may be finished from the pedal or tibial puncture site. Therefore, either a conventional 4F sheath has to be placed into a small-luminal vessel with the drawbacks of additional costs, risks of bleeding and the potential to induce spasm, or the procedure might be carried out in a retrograde manner using dedicated balloons which can be advanced through the pedal access set sheath. Furthermore, retrograde revascularization may be performed without a sheath by pushing the balloon through the arteriotomy with the risk of damage to the puncture site, especially during removal of the (partially) deflated balloon. We have limited experience with these alternatives and so far, for safety reasons, try to switch to an antegrade approach whenever possible.

The main reason for procedural failure in our study was inability to achieve re-entry after retrograde passage of the CTO. In this context one may hypothesize that the crossing and procedural success rates could be improved by use of additional techniques like the dual-balloon technique (balloons with antegrade and retrograde placement in the subintimal space with simultaneous inflation to interrupt the intimal wall) or by utilization of angulated (support) catheters [15]. However, during the study period...
we did not use these techniques and did not have support catheters available. In contrast to our experience, Mustapha et al. reported the main reason for failure as access site calcification and consecutive inability to puncture the crural or pedal vessel [20]. Sabri et al. reported both an inability to access the pedal vessel and failure to achieve re-entry following retrograde subintimal passing of the lesion as the main reasons for procedural failure [19].

So far, the literature regarding retrograde transpedal revascularization procedures is limited and to some degree inhomogeneous. Walker et al. [11] reported the largest series of patients. They too found a high technical success rate of 95%. However, in their cohort also patients with femoral and/or popliteal occlusions were treated by a retrograde approach, making it difficult to compare it with our group with BTK occlusions only. Furthermore, their definition of procedural success was “antegrade flow” in the target lesion, while we chose a more rigorous endpoint for the definition of procedural success with residual stenosis < 30%. This might explain the higher success rate in their study (99% vs. 69%). Unfortunately, they did not report on limb salvage rates. Other groups, however, reported limb salvage rates at 12 months between 64% and 82.3% after retrograde pedal access interventions [1, 5, 19]. Although femoral and popliteal occlusions were included in these studies, the reported limb salvage of 72.9% in our study compares favorably with these results.

Compared to the results reported by Bazan et al. [1], we noted with interest that although the lesions in our study appear to be more complex (only CTOs, longer lesions), the results for procedural success and limb salvage are similar. From this we conclude that the complexity of a lesion may play a minor role regarding outcome as long as it can be passed with a guidewire from the retrograde approach.

Possible drawbacks of the retrograde access maneuver include secondary changes like hematoma, scar formation and vascular injuries at the pedal access site which may complicate a pedal or tibial bypass. However, regarding complications our results are comparable to those reported by others and underline the fact that the retrograde pedal or tibial access is safe. Walker et al. [11] reported one pedal occlusion at the access site (0.4%), of note after use of a 6F sheath. Therefore, one may anticipate that a retrograde puncture does not preclude a pedal bypass. Other reported complications relate mainly to ones observed at the femoral access (hematoma) and myocardial infarction. Major complications have been reported in up to 8% of cases, and minor complications in up to 2% [1, 19]. We observed no major complications and found a minor complication rate of 12.5%. Taking into account that major complications are mainly associated with the femoral access, maybe more procedures should be performed solely from the retrograde access. However, in such cases careful, high-quality, noninvasive imaging is mandatory to evaluate inflow lesions and plan the retrograde approach. On the other hand, in our experience two or even all crural vessels often need to be treated during the intervention and an exclusively retrograde approach may be time-consuming or even impossible in such a scenario but may be a good option if only one vessel has to be treated. There are some limitations to this study. First, the number of patients is small, which prevents us from generalizing our data. Second, the presented series is retrospective and lacks randomization. Therefore, patient selection bias may have influenced the results. Furthermore, no rigorous imaging follow-up was available in the analyzed patients. Therefore, no data on patency or target lesion revascularization of the lesions with retrograde revascularization are available.

In conclusion, the retrograde transpedal or transtibial access utilizing a dedicated pedal access set is safe and offers high technical and acceptable clinical success rates. BTK occlusions that could not be addressed by an antegrade transfemoral approach should be tackled by a retrograde approach whenever possible. Further data are needed to answer the question as to whether this could be the first-line approach in selected patients as compared to the antegrade transfemoral route.

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments. The ethics approval number for this study is 15 – 285A.

References
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