Thieme

Pain Reduction in the Recanalization of Chronic Iliofemoral Venous Occlusion with a New Scoring Balloon: A Retrospective Series in 10 Consecutive Patients

Schmerzreduktion bei der Rekanalisation chronischer Venenverschlüsse mit einem neuen Scoring-Ballon: eine Retrospektive Auswertung von 10 Patienten

Abstract

Purpose To study the capabilities of a novel scoring balloon concept in the recanalization of chronic iliofemoral venous occlusions and the impact on the periprocedural pain management concept.

Materials and Methods A novel scoring balloon designed for problematic arterio-venous access stenosis was utilized for the recanalization of chronic iliofemoral occlusions. Severe pain during dilatation of occluded iliofemoral veins is difficult to control and often necessitates general anesthesia. The goal of this study was to avoid general anesthesia by taking advantage of the capabilities of a scoring balloon. Iliofemoral recanalization was performed in 10 consecutive patients under local anesthesia utilizing the scoring balloon. The inflation pressure and subjective sensation of pain during dilatation were recorded on a scale of 0 – 10.

Results In all 10 patients, the whole intervention could be performed under local anesthesia without any additional pain medication. Due to the unique balloon design, an inflation pressure of 5 bar or less was sufficient to reopen the occluded veins. No severe pain was reported by the patients (mean pain score: 3.1 +/- 1.1).

Conclusion In the reported patients, scoring balloon angioplasty allowed recanalization of chronic iliofemoral vein occlusion without the need for general anesthesia or any specific pain management.

Key Points

- Recanalization of chronic occluded iliofemoral veins with the use of a scoring balloon is technically feasible.
- Pain during dilation with the scoring balloon was tolerated well without further pain medication.
- With the use of the scoring balloon, the required inflation pressure for recanalization of chronic occluded iliofemoral veins was 5 bar or less.

Zusammenfassung

Ziel Ziel dieser Serie war die Verwendung eines neuartigen Scoring Ballons bei der Rekanalisation chronischer iliofemoraler Venenverschlüsse zu testen mit besonderem Blick auf die Schmerzkontrolle.

Material und Methoden Ein neuartiger Scoring Ballon, der für den Einsatz bei problematischen Hämodialyseshunt-Stenose entwickelt wurde, wurde zur Rekanalisation von chronischen iliofemoralen Venenverschlüssen verwendet. Die ausgeprägte Schmerzhaftigkeit der Dilatation chronischer Venenverschlüsse stellt ein schwer zu kontrollierendes Problem dar, das häufig eine Vollnarkose nötig macht. Die Idee dieser Fallserie war, durch die Verwendung des Scoring Ballons auf eine Vollnarkose oder hochdosierte Analgesie verzichten zu können. Bei 10 aufeinanderfolgenden Patienten wurden chronische iliofemorale Venenverschlüsse mit dem Scoring Ballon in Lokalanästhesie rekanalisiert. Der Inflationsdruck und das subjektive Schmerzempfinden (Skala von 0 – 10) wurden dabei erfasst.

Ergebnisse Bei allen 10 Patienten konnte die Intervention in Lokalanästhesie ohne zusätzliche Schmerzmedikation oder Narkose durchgeführt werden. Aufgrund des Ballondesigns war ein maximaler Inflationsdruck von 5 bar bei allen Patienten ausreichend. Die Intervention wurde gut toleriert (mittlerer Schmerzwert 3,1 +/– 1,1).

Schlussfolgerung Bei 10 aufeinanderfolgenden Patienten konnten chronische iliofemorale Venenverschlüsse mithilfe des untersuchten neuen Scoring Ballons technisch erfolgreich rekanalisiert werden ohne das eine Vollnarkose oder spezifische Schmerzmedikation nötig gewesen wäre.

Kernaussagen

- Die Verwendung eines Scoring-Ballons zur Rekanalisation von chronischen iliofemoralen Venenverschlüssen ist technisch möglich.
- Die Schmerzen während der Dilatation mit dem Scoring-Ballon sind ohne weitere Schmerzmedikation gut durch die Patienten toleriert worden.
- Die zur Rekanalisation chronischer iliofemoraler Venenverschlüsse notwendigen Inflationsdrücke lagen mit der Verwendung des Scoring-Ballons bei 5 bar oder weniger.

Introduction

Post-thrombotic syndrome (PTS) is a common complication of deep venous thrombosis (DVT) with typical symptoms as swelling, pain, ulceration and venous claudication of the lower extremities. Although anticoagulation effectively prevents thrombus extension, pulmonary embolism, and recurrence of DVT, it does not resolve the thrombus itself. The resulting obstruction of the venous inflow leads to venous hypertension in the veins of the leg and impairment of the vein valves, which can finally develop PTS. Despite adequate treatment of the acute event with anticoagulation, up to 44 % of patients develop venous claudication and up to 15 % develop stasis ulcers (Mussa FF et al. Iliac vein stenting for chronic venous insufficiency. Tex Heart Inst J 2007; 34: 60 – 66). Other authors describe a prevalence of PTS despite optimal anticoagulant therapy between 23 – 60 % (Razavi MK et al. Safety and effectiveness of stent placement for iliofemoral outflow obstruction. Circ Cardiovasc Interv 2015. DOI: 10.1161/CIRCINTERVENTIONS.115.002 772). Especially the involvement of the iliofemoral veins increases the risk for developing recurrent problems greater than twofold.

It has been shown that PTS may be prevented by providing rapid thrombus elimination. However, in our clinical practice we see many patients with longstanding occlusions of the iliofemoral veins suffering from severe PTS symptoms such as pain, leg swelling, venous claudication

and ulceration. Since dedicated venous stents are available, recanalization of the iliofemoral veins with stent placement has been propagated by many authors.

Recanalization and dilatation of chronically occluded iliac and common femoral veins is painful due to the high pressure needed to open up the strong scar tissue with PTA balloons. Therefore, infusion of potent i. v. analgesics, such as pethidine or piritramide, conscious sedation or even general anesthesia is recommended (Mahnken AH et al. CIRSE standards of practice guidelines on iliocaval stenting. Cardiovasc Intervent Radiol 2014; 37: 889 – 897).

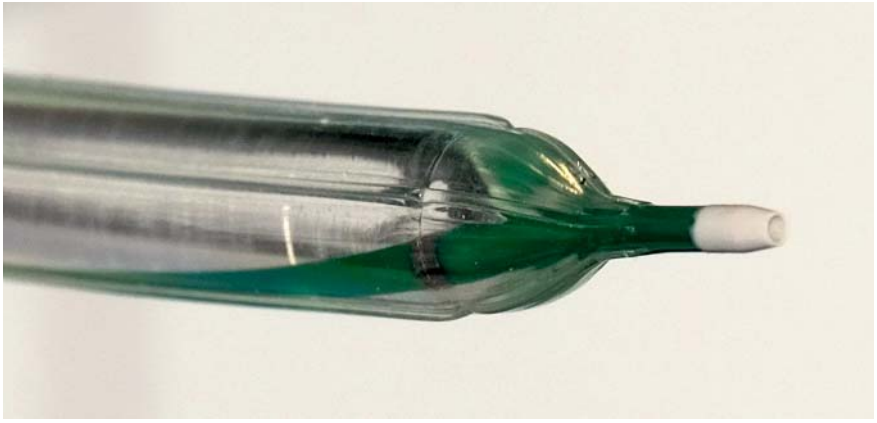
Cutting balloon angioplasty has shown better long term patency with reduced pain during dilatation in the treatment of hemodialysis access stenosis. Cutting balloons were originally designed for arterial interventions. Their use in venous vessels with their thinner vessel walls might lead to an even higher rupture rate compared to the treatment of arterial vessels. Similar issues have been seen in arterialized veins in hemodialysis access. A novel scoring balloon, specially designed for hemodialysis access angioplasty, works in a manner similar to the cutting balloon without the use of microsurgical blades. The forces are distributed across a larger area than conventional cutting balloons and theoretically the incidence of vessel perforation may be reduced. The principle of focal force enables the scoring balloon to open tough venous stenosis at a relatively low pressure.

The purpose of this study was to retrospectively assess the feasibility, safety and the potential influence on periprocedural pain management using a novel scoring balloon for the recanalization of chronically occluded iliofemoral veins.

Materials and Methods

Personal data was managed in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written consent to the usage of anonymized patient data was given.

We studied 10 consecutive patients (6 females and 4 males) with chronic occlusion of the iliofemoral veins between February and December 2015. The mean patient age was 47.6 years, the mean duration of symptoms was 106.7 months (9 – 468 months). The reason for intervention was venous claudication and swelling of the leg in 6 patients, venous ulceration in 3 patients and phlegmasia cerulea dolens due to tumor compression of the iliac vein in 1 patient.

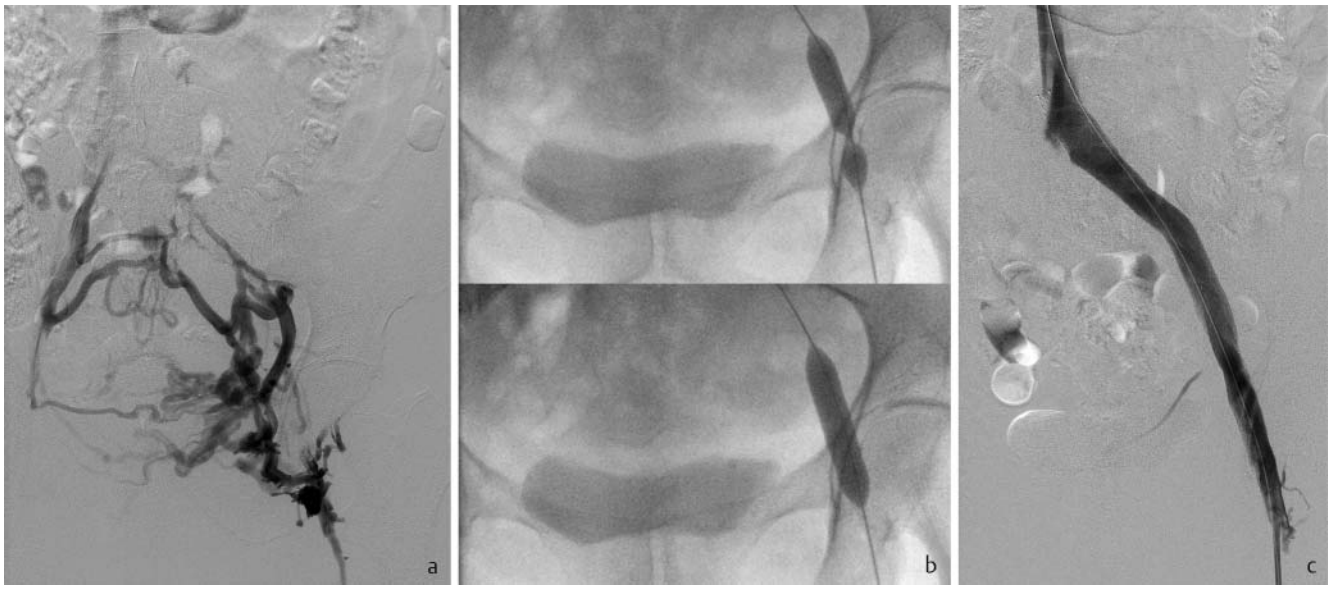


▶ **Fig. 1** Image of the scoring balloon. The four elements providing the focal force are clearly visible.
Abb. 1 Nahaufnahme des verwendeten Scoring-Ballons. Gut zu erkennen sind die Elemente auf der Ballonoberfläche.

The diagnosis of chronic iliofemoral vein occlusion was established by clinical examination and duplex sonography. After discussion of the case in our interdisciplinary board, CT venography was performed in all patients. When the diagnosis could be confirmed by CT venography, each patient was informed in detail and written informed consent was obtained from the patient.

The scoring balloons utilized in this study have four rigid polymer elements integrated into the balloon material (▶ **Fig. 1**) providing focal force to the vessel wall resulting in an up to 450 %+ increased force focused on the elements compared to the average of standard and high-pressure balloons. In comparison to most other scoring balloons, this one also didn't contain any metal making it more flexible during usage. The balloon has a CE-mark. According to the instructions for use, the balloon is intended for percutaneous transluminal angioplasty of lesions in peripheral arteries, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. At the moment, the balloon is available in sizes with a diameter between 6 and 12 mm.

The complete intervention was carried out under only local anesthesia without conscious sedation. No additional pain medication was necessary. Vascular access was established via ultrasonography-guided puncture of the ipsilateral femoral vein (n = 9) or popliteal vein (n = 1). In one patient additional puncture of the contralateral femoral vein was performed. A vascular sheath was introduced into each vein and venography was obtained. Recanalization of the occluded iliofemoral vein was conducted with an 0.035" hydrophilic guidewire and a 4F support catheter. After confirmation of correct intraluminal catheter position in the inferior vena cava, a stiff Amplatz wire was introduced. Then the occluded segment was predilated with a 12 × 40 mm scoring balloon (Advance Enforcer 35, Cook Medical, Bloomington (IN), USA). After predilation with full expansion of the balloon, stenting was performed with 14 mm or 16 mm dedicated venous stents (Zilver Vena, Cook Medical, Bloomington (IN), USA). Then the stents were post-dilated with a standard 14 mm or 16 mm PTA balloon. After post-dilation control venography was performed in orthogonal views to ensure complete deployment of the stents. All patients received 5000 IU heparin during the intervention and were placed under subsequent vitamin K antagonist anticoagulation treatment.



▶ **Fig. 2** **a** Venography after contrast injection over the left femoral vein. **b** 12 × 40 mm scoring balloon opening up at 4 bar. **c** Venography performed after stent implantation and angioplasty revealed complete resolution of collateral filling with good flow through the femoral and iliac system into the IVC.
Abb. 2 **a** Phlebographie nach Kontrastmittelinjektion über die linke V. femoralis. **b** Wiedereröffnung der Stenose mit dem Scoring-Ballon bei einem Druck von 4 bar. **c** Die Abschlussphlebografie nach Angioplastie und Stentimplantation zeigt eine komplette Rekanalisation der Beckenvenen links. Die Kollateralvenen kontrastieren sich nicht mehr.

The pressure needed for full effacement of the scoring balloon during predilation was measured with the inflation device. After the intervention, the patients were asked to rank the pain during dilation on a scale of 0 – 10 (0 = no pain, 10 = extremely painful).

Results

Venography performed during endovascular treatment revealed total occlusion of the common iliac vein (CIV) with additional occlusion of the external iliac vein (EIV) in 8 patients (7 patients on the left side, 1 patient on the right side). In one patient, we found isolated occlusion of the left CIV and in one patient of the left EIV. Extensive cross-pelvic and hypogastric collateralization was visible in all patients. The technical success rate was 100 %. A total of 22 stents were placed in 10 patients. The mean stent diameter was 15 ± 1 mm (range: 14 – 16 mm) and the mean stent length was 114 ± 35 mm (range: 60 – 160 mm). 8 patients were treated with two stents, and 2 with three stents. After each procedure, venography revealed good common iliac vein patency and flow of contrast material without collateral flow (▶ **Fig. 2**).

The intervention was well tolerated by all patients. The mean inflation pressure needed to completely open up the scoring balloon was 5.2 ± 1.9 atm (range: 3 – 9 atm). The mean pain score during dilation was 3.1 ± 1.1 (range: 1 – 5).

During post-dilation of the stents with a standard semicompliant 14 mm or 16 mm PTA balloon, the patients reported pain that was tolerable but more severe than the pain during predilation with the scoring balloon.

No procedure-related mortality or major complication was noted. One patient developed a minor complication at the vein access site due to local infection.

Discussion

Iliofemoral vein recanalization and stenting is a well-accepted treatment for patients suffering from PTS. Recanalization of an occluded segment has varying degrees of difficulty. With some experience, most occluded iliofemoral veins can be recanalized in 30 to 40 minutes. The technical success is reported to be quite good with rates between 91.3 % and 100 % (Bozkaya H et al. Endovascular Treatment of Iliac Vein Compression (May-Thurner) Syndrome: Angioplasty and Stenting with or without Manual Aspiration Thrombectomy and Catheter-Directed Thrombolysis. Ann Vasc Dis 2015; 8: 21 – 28). Compared to other interventional procedures, major complications are rare. In a meta-analysis of 37 studies including 2869 patients, the complication rates ranged between 0.3 % and 1.1 % for major bleeding and 0.2 % and 0.9 % for pulmonary embolism. The periprocedural mortality was reported as 0.1 – 0.7 %.

Unlike arterial stenosis, the underlying stenosis in iliofemoral veins is often identified as a band-like waist in the balloon that persists even if prolonged dilation with increased pressure is applied. During dilation, this type of stenosis behaves similarly to venous stenosis in hemodialysis fistulas with the presence of dense, fibrous strands incorporated into the venous neointimal layer and scar tissue. The standard approach to overcome the rigid venous stenosis is the use of high pressure balloons but high pressure causes severe pain. Therefore, infusion of potent i. v. analgesics or general anesthesia is recommended during the procedure.

Another approach to overcome rigid venous stenosis is the use of cutting balloons. Cutting balloons were designed primarily for use in coronary artery angioplasty and have been used to control neointimal growth after balloon angioplasty by generating planned dissection to reduce the rate of restenosis. Especially in hemodialysis fistulas and grafts, cutting balloon angioplasty has been successfully studied. Several authors could show that the effect of reduced neointimal proliferation after cutting balloon angioplasty compared to standard angioplasty is also valid for arterialized veins in hemodialysis fistulas. Another positive side effect which was observed in cutting balloon angioplasty of hemodialysis veins was the reduced periprocedural pain (Peregrin JH et al. Results of a peripheral cutting balloon prospective multicenter European registry in hemodialysis vascular access. Cardiovasc Intervent Radiol 2007; 30: 212 – 215).

However, as the blades of the cutting balloon were originally designed for coronary arteries, rupture of the thinner venous wall can occur. Also, the available sizes of the cutting balloon are not appropriate for central venous stenosis in hemodialysis access or for iliofemoral veins. This was the rationale behind the engineering of an alternative approach of a scoring balloon for angioplasty of stenosed veins in hemodialysis access. The promising first results with reduced pain during dilation in hemodialysis access brought us to the idea that this balloon might help us also to reduce pain during other venous interventions.

In the ten patients we studied, the mean pressure needed to open up venous stenosis was 5.2 atm. To date, no reference pressure values have been published for the dilatation of iliofemoral venous occlusions. In our own experience, we can report that in most of the cases with standard balloons pressure above 15 atm is needed for dilation. This corresponds with the recommendation to use dedicated high-pressure balloons. The ability to open up venous stenosis with a low inflation pressure is the most likely explanation for why we could perform our interventions without specific pain medication or general anesthesia.

Although the purpose of this study was not to test patency, the lack of high inflation pressure during dilation may be a way to improve long-term patency due to less vessel wall trauma and less consecutive intimal hyperplasia. This theory should be tested in a larger study with long-term follow-up.

In conclusion, we could show that iliofemoral vein recanalization in patients with chronic occlusion is feasible and safe with the use of the studied scoring balloon. The periprocedural pain could be reduced so far that no specific pain medication or general anesthesia is required. The complete intervention can be carried out under local anesthesia.

Conflict of Interest

C. Hohl: Consulting and honorarium: Cook Medical. A. Bro: Employee: Cook Medical.

The authors

Christian Hohl[1], Anders Bro[2], Ronald Bruce Friedberg[3]

[1] Radiology, Herz- und Gefäßzentrum Südwestfalen am St. Marien-Krankenhaus Siegen, Germany

[2] Peripheral Interventions, Cook Medical, Bjaeverskov, Denmark

[3] Surgery, Herz- und Gefäßzentrum Südwestfalen am St. Marien-Krankenhaus Siegen, Germany

Correspondence

Dr. Christian Hohl
Radiologie, Herz- und Gefäßzentrum Südwestfalen am St. Marien-Krankenhaus Siegen
Kampenstraße 51
57072 Siegen
Germany
Tel.: ++ 49/2 71/2 31 40 00
Fax: ++ 49/2 71/2 31 40 09
chohl@gmx.net

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