Original communication

# Clinical outcomes of a balloon-expandable stent for symptomatic obstructions of the subclavian or innominate arteries

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**Summary:** *Background:* Upper-extremity peripheral arterial disease (PAD) may present with a broad spectrum of signs and symptoms. If an endovascular treatment is planned, percutaneous angioplasty and stent placement may lead to a better patency compared to percutaneous angioplasty alone. We assessed the characteristics and clinical course of patients with upper-extremity PAD who received angioplasty and a balloon-expandable stent. *Patients and methods:* We analyzed data from consecutive patients treated with angioplasty and placement of a balloon-expandable BeSmooth Peripheral Stent System® (Bentley, Germany) at the Angiology Department (University Hospital Zurich) between 2018 and 2022. The primary outcome was re-intervention at the target lesion within 6 months from index angioplasty and during available follow-up. The study was approved by the local ethical commission. *Results:* A total of 27 patients were treated. The median age was 70 (Q1–Q3: 60–74) years and 59% were men. The subclavian artery (74%) represented the most frequently treated target lesion, followed by the innominate artery (26%). The mean improvement in blood pressure in the treated arm was 21 (95%CI 7 to 35) mmHg at 24 hours and 29 (95%CI 15 to 43) mmHg at 6 months. At 6 months, 2 (8%) patients required a target lesion re-intervention. During the remaining follow-up period up to 24 months, one of these two patients required additional intervention and a total of 3 (11%) patients died due to sepsis, cancer, and unknown causes, respectively. *Conclusions:* Percutaneous catheter-based treatment with a balloon-expandable stent for symptomatic upper extremity PAD appeared to be effective and safe.

**Keywords:** Angioplasty, cohort study, peripheral arterial disease, stent, upper extremity

## Introduction

Peripheral arterial disease (PAD) is a leading cause of global morbidity and mortality [1, 2]. The prevalence of PAD ranges between 7 and 28% in different European countries and 12% in Switzerland [3]. Despite these statistics, however, global awareness of the disease is still low [4]. PAD can lead to disease-specific complications, notably ischemia and sepsis, and is a marker of overall cardiovascular risk. Although there is a growing number of medical and interventional treatment options, PAD is still under-recognized and under-treated [5]. This is particularly the case for those rarer manifestations of the disease involving the upper limb, for which accurate diagnosis and management can be even more challenging due to sparse or absent evidence [6].

Upper extremity PAD most frequently affects the subclavian and innominate arteries and its manifestations may range from an asymptomatic course to acute ischemia of the limb, with or without concomitant vertebro-basilar insufficiency or subclavian steal syndrome [7]. In the presence of such symptoms, catheter-based revascularization may be preferable to open surgical treatment, even though there are no ad hoc randomized controlled trials (RCTs) comparing the two procedures to date [6]. If opting for an endovascular approach, previous observational studies have described a superiority of stent placement to percutaneous angioplasty (PTA) alone both in terms of one-year patency [8, 9] and technical success rate. Furthermore, other retrospective observational studies have reported a low rate of complications, such as death and stroke, and a high rate of freedom from symptoms after catheter-based revascularization. Based on such evidence, an endovascular approach currently seems to be the treatment of choice for patients requiring an intervention.

However, the retrospective nature of available studies, their small data size, and the heterogeneity of interventions described limit their interpretation. Moreover, several studies covered an older timeframe belonging to an era when evidence on antithrombotic therapies and the

development of endovascular materials were still in their infancy.

In this single-center retrospective study, we evaluate the characteristics and clinical course of patients with symptomatic upper-extremity PAD treated with a single endovascular technique, specifically with angioplasty in combination with balloon expandable stents.

# Patients and methods

## Study setting and patient population

We conducted a retrospective analysis of 27 consecutive patients with symptomatic upper extremity PAD treated with one or more balloon-expandable BeSmooth Peripheral® stents (Bentley InnoMed GmbH, Germany) at the Department of Angiology of the University Hospital Zurich between December 2018 and February 2022. We included adult patients with subclavian artery or innominate artery stenosis or occlusion, irrespective of the etiology, who underwent a percutaneous transluminal angioplasty (PTA) and stenting, provided they have signed a written informed consent for the use of data for scientific purposes. Indication for the procedure was given when the patient presented with at least one symptom typical of upper extremity PAD (such as arm pain during exertion, vertigo, dizziness, syncope, arm weakness or numbness, or acute symptoms indicative of acute ischemia), along with sonographic evidence of arterial stenosis or occlusion. Individual data were retrieved from the personal records of the patients. No additional interviews or surveys took place beyond the clinical routine.

## Procedures

All the patients were treated in a single session with an endovascular approach encompassing angioplasty and stent placement. The three possible access techniques included (1) ipsilateral or contralateral common femoral artery; (2) ipsilateral brachial artery; (3) "pull through" technique with a vascular sheath placed in the common femoral artery and a second vascular sheath from radial (or brachial) access to cross the lesion. In case of particularly narrow lesions, pre-dilatation was first performed with a non-compliant balloon and the stent was placed with "protected positioning", namely protected by the extremity of the sheath in order to avoid the stent sliding out from its balloon. Patients received 5000 IU unfractionated Heparin (UFH) bolus after sheath insertion. In case of acute or acute-on-chronic thrombotic occlusions, human tissue-type plasminogen activator (Alteplase) could have been administered locally as a bolus and/or as a prolonged infusion through a lysis catheter.

We focused on subjects treated with a balloon expandable BeSmooth Peripheral® stent: diameter and size were selected by the operator based on the angiographic characteristic of the lesion. A dual antiplatelet therapy consisting of aspirin 100 mg once daily and a P2Y12 inhibitor was established for a minimum of four weeks after the intervention. In selected cases, patients were discharged with a single antiplatelet therapy with aspirin 100 mg combined with rivaroxaban 2.5 mg twice daily.

**Table I.** Patient and target lesion characteristics

| Number of patients | Total (N=27) |
|---|---|
| Age (years), median (Q1–Q3) | 70 (60–74) |
| Men, n (%) | 16 (59) |
| Body mass index (kg/m$^2$), median (Q1–Q3) | 24 (22–29) |
| Diabetes mellitus, n (%) | 7 (26) |
| Arterial hypertension, n (%) | 22 (81) |
| Dyslipidemia, n (%) | 15 (58) |
| Obesity, n (%) | 8 (30) |
| Current tobacco use, n (%) | 17 (63) |
| Previous tobacco use, n (%) | 24 (89) |
| Chronic kidney disease, n (%) | 5 (18) |
| Coronary artery disease, n (%) | 14 (52) |
| Cerebrovascular disease, n (%) | 14 (52) |
| Lower-extremity peripheral arterial disease, n (%) | 16 (59) |
| Renovascular disease, n (%) | 3 (11) |
| Antiplatelet therapy, n (%) | 23 (85) |
| Acetylsalicylic acid | 14 (52) |
| P2Y12 inhibitor | 1 (4) |
| Dual antiplatelet therapy | 8 (30) |
| Anticoagulation therapy, n (%) | 6 (22) |
| Direct oral anticoagulant | 3 (11) |
| Low-molecular-weight heparin | 2 (7) |
| Fondaparinux | 1 (4) |
| Target lesion location, n (%) | |
| Arteria subclavia | 20 (74) |
| Arteria anonima | 7 (26) |
| Left | 17 (63) |
| Right | 10 (37) |
| Etiology of peripheral arterial disease, n (%) | |
| Atherosclerotic | 25 (93) |
| Radiation therapy | 2 (7) |
| Flow in the ipsilateral vertebral artery, n (%) | |
| Orthograd | 6 (26) |
| Rethrograd | 16 (59) |
| Occluded | 1 (4) |
| Target lesion, n (%) | |
| Intermediate-grade stenosis | 3 (12) |
| High-grade stenosis | 22 (85) |
| Occlusion | 1 (4) |
| Previous revascularization, n (%) | |
| Target lesion | 3 (11) |
| Non-target lesion | 20 (74) |
| Symptoms, n (%) | |
| Arm claudicatio | 10 (37%) |
| Subclavian steal syndrome* | 14 (52%) |
| Arm weakness and/or numbness | 6 (22%) |
| Critical ischemia | 2 (7%) |

*Notes.* *Subclavian steal syndrome symptoms include vertigo, dizziness, and syncope.

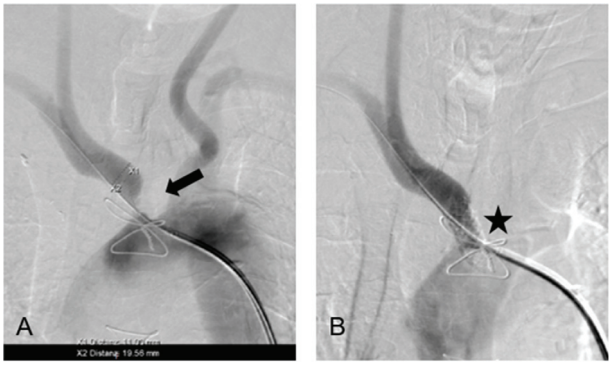


**Figure 1.** Revascularization of the innominate artery. A: Proximal stenosis of the innominate artery (arrow). B: Successful primary stenting of the target lesion with a 9x28mm balloon expandable BeSmooth Peripheral stent (star).

## Follow up

After the procedure, a duplex ultrasound examination of the target lesion was performed on all the patients to ensure the success of the intervention and to estimate any residual stenosis. Standard follow-up visits were planned at three, six and twelve months after index procedure and in selected cases at one month. These included routine clinical visit with the evaluation of ongoing medications, onset of novel cardiovascular complications, bilateral systolic pressure difference, oscillometric measurement of blood pressure, and duplex ultrasound.

## Outcomes

The primary outcome included novel restenosis or occlusion of the target lesion requiring re-intervention. Restenosis and occlusion were diagnosed using duplex ultrasound and confirmed during the angiography. Secondary outcomes included all-cause death, stenosis at the target lesion not requiring re-intervention, persisting symptoms (arm claudicatio and subclavian steal symptoms), or persisting brachial blood pressure difference between upper limbs and pathological brachial pulse oscillometry, and periprocedural success. The latter was defined as the technical success in crossing the lesion, deploying the stent, and the absence of a hemodynamically significant stenosis within 24 hours after the intervention. Outcomes were assessed within 6 months from index angioplasty and during available follow-up.

For all the patients, baseline demographic information (age, sex, body mass index), cardiovascular comorbidities, smoking habit, previous interventions at target and non-target lesion, baseline antithrombotic medications, signs and symptoms of upper extremity PAD, bilateral systolic pressure difference and oscillometric measurement of blood pressure of the upper limbs were recorded. A duplex ultrasound assessing the characteristics of the vascular lesion (target lesion), including an evaluation of patency, flow profile as well as flow direction in the arteria vertebralis, was also performed. A trained specialist in vascular medicine assessed the oscillometric measurement of blood pressure and graded them semi-quantitative as the following: normal, mildly-, and severely-pathological.

**Table II.** Characteristics of angioplasty and medical therapy

| Procedural data | Patients N=27 |
|---|---|
| Stent size, n (%) | |
| 10 mm×28 mm | 3 (11) |
| 6 mm×58 mm | 1 (4) |
| 7 mm×27 mm | 5 (18) |
| 7 mm×38 mm | 5 (18) |
| 8 mm×27 mm | 8 (30) |
| 8 mm×37 mm | 2 (7) |
| 9 mm×28 mm | 4 (15) |
| Number of stents used per patient, n (%) | |
| 1 | 26 (94) |
| 2 | 1 (4) |
| Contrast medium (mL), median (Q1–Q3) | 75 (52–97) |
| Transfemoral access, n (%) | 19 (70) |
| Brachial access, n (%) | 2 (7) |
| Pull-through technique (bidirectional approach), n (%) | 6 (22) |
| Intraoperative complications, n (%) | |
| Hematoma at access site | 2 (7) |
| Pseudoaneurysma at access site | 1 (4) |
| Stroke | 0 |
| Distal embolism | 0 |
| Hospitalization days, median (Q1–Q3) | 2 (2–2) |
| **Medical therapy after angioplasty and stent placement** | |
| Aspirin, n (%) | 3 (11) |
| P2Y12 inhibitor, n (%) | 2 (8) |
| Dual antiplatelet therapy – long term | 4 (15) |
| Dual antiplatelet therapy – 3 months | 5 (19) |
| Dual antiplatelet therapy – 1 month | 11 (42) |
| No antiplatelet therapy | 1 |
| Direct oral anticoagulant, n (%) | 3 (11) |
| Rivaroxaban 2.5 mg twice daily | 2 (8) |
| Edoxaban | 1 (4) |

## Statistical analysis

Continuous data were presented as mean (± standard deviation) or median (interquartile range) based on the type of data distribution, while categorical variables were presented as count (percentage). Mean difference (95% confidence interval) was calculated for the systolic pressure values at every follow up visit (24 hours within the intervention, after 3 months, and after 6 months) with reference to pre-procedural values. All the statistical analyses were conducted with R-based software Jamovi. The study was conducted in accordance with the local ethics committee.

# Results

We included 27 patients with a median age of 70 (Q1–Q3: 60–74) years. As shown in Table I, 16 (59%) patients were

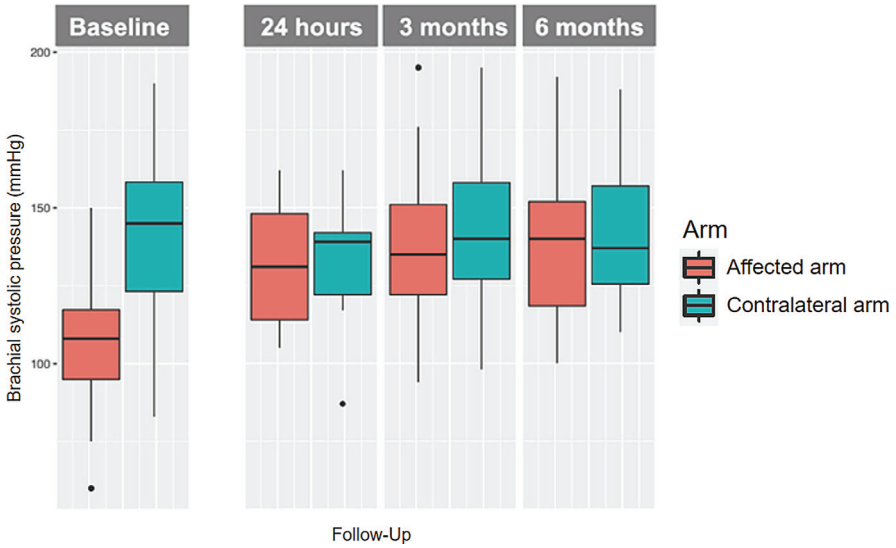


**Figure 2.** Brachial systolic blood pressure in the treated and contralateral arm before and after endovascular intervention. Median (Q1–Q3, min–max) values are expressed in mmHg.

men, the median body mass index was 24 (Q1–Q3: 22–29), and the prevalence of tobacco use was 89%. Hypertension, dyslipidemia, and obesity were the most prevalent comorbidities in our cohort and affected 22 (81%), 15 (58%), and 8 (30%) patients, respectively. A total of 3 (11%) patients had prior angioplasty and stenting of the target lesion. Concomitant lower extremity PAD was present in 16 (59%) patients, cerebrovascular disease in 14 (52%), and coronary artery disease in 14 (52%).

Atherosclerosis was the etiological agent in all but 2 (4%) patients, who had been previously exposed to radiation therapy. Overall, the subclavian artery was affected in 20 (74%) patients and the innominate artery (Figure 1) in 7 (26%). Prevalence and type of symptoms, as well as baseline hemodynamic and sonographic parameters at presentation, are depicted in Table I. Two (7%) patients experienced critical limb ischemia at baseline. The left side was more often involved than the right one (17 vs 10 patients, respectively).

Procedural data are depicted in Table II: 19 (70%) patients had an retrograde femoral access, 2 (7%) a retrograde brachial access, and 6 (22%) a combined femoral and brachial access. Stent diameters and length ranged from 6 to 10 mm and 27 to 58 mm respectively. In one case, two BeSmooth Peripheral® stents were implanted during the same procedure due to the target lesion length. The average amount of contrast agent used during the procedure was 80 (SD 34) mL. Procedural success rate was 100% as confirmed by ultrasound in all patients within 24 hours. Two (7%) patients had a residual stenosis estimated to not exceed 50% by sonography. In 2 (7%) cases, the procedure was complicated by a hematoma or pseudoaneurysm at the arterial access site. Those represented only minor complications that did not lead to an escalation of the treatment and resolved by themselves. After the intervention, a dual antiplatelet therapy (DAPT) was prescribed to 20 (74%) patients for at least one month. Single antiplatelet therapy was prescribed to 5 (19%) patients. Initial treatment with rivaroxaban 2.5mg twice daily on top of aspirin was used in 2 (8%) patients. One patient received edoxaban for atrial fibrillation.

Post-interventional improvement of brachial systolic pressure of the target limb is displayed in Figure 2. The mean improvement was of 21 (95%CI 7 to 35) mmHg at 24 hours, of 28 (95%CI 13 to 43) mmHg at 3 months, and of 29 (95%CI 15 to 43) mmHg at 6 months. In the contralateral arm, no change was observed over time: −8 (95%CI −22 to 8), 0 (95%CI −15 to 15), and −2 (95%CI −16 to 12) mmHg, respectively. Oscillometric measurement were consistent with the pressure recordings.

At 6-month follow-up, 24 (89%) patients were free from hemodynamically relevant stenosis or revascularization at the target lesion (Table III). A total of two (4%) patients necessitated a revascularization at the target lesion. The first was needed to treat an acute thrombotic occlusion at the stent distal end occurring one month after the index procedure in a patient on xarelto 2.5 mg bid on top of aspirin 100 mg, whereas a second patient was treated because of a hemodynamically relevant restenosis occurring 7 months after the index procedure. All these patients were free from claudication or subclavian steal syndrome symptoms at six months. Non-target lesion interventions were performed in 10 (37%) patients and all of them involved the low-extremity arteries, the carotid artery, or the renal artery. No stroke or other systemic embolism events were recorded during follow-up.

Two-year follow-up was available for 17 (65%) patients: one (4%) new revascularization at the target lesion for a symptomatic occlusion of the proximal subclavian artery occurred in the patient who had already had prior revascularization for a thrombotic occlusion of the distal stent (Figure 3).

One (4%) death was recorded in the early follow-up phase: this occurred in a patient presenting with acute critical ischemia due to acute thrombotic occlusion of the subclavian artery occurred in the setting of a crush syndrome

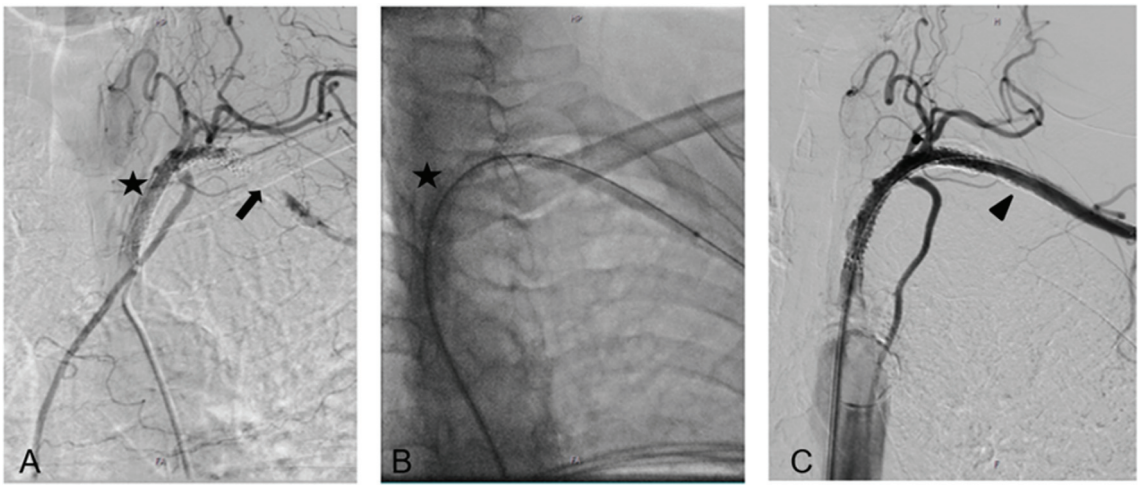


**Figure 3.** New revascularization of target lesion in the left subclavian artery. A: BeSmooth Peripheral stent (star) with distal thrombotic occlusion (arrow) of the left subclavian artery requiring new revascularization of target lesion in a patient on rivaroxaban 2.5 mg twice daily on top of aspirin. B: Pre-dilatation with a 5x60 mm semi-compliant balloon. C: Final angiography after the successful implantation of a 6x60 mm self-expandable stent (triangle) at the distal edge of the BeSmooth Peripheral stent. The patient was discharged with a DAPT for 3 months.

**Table III.** Study outcomes

| Follow-up visit | 0–24 hours | 24 hours–3 months | 3–6 months | 6–24 months | Overall period |
|---|---|---|---|---|---|
| Occlusion/restenosis needing new revascularization of target lesion | 0 | 1/27 (4%) | 1/26 (4%) | 1/26 (4%) | 3/26 (11%)* |
| Stenosis not requiring new revascularization of target lesion, n (%) | 0 | 1/27 (4%) | 2/26 (8%) | 0 | 3/26 (11%) |
| Arm claudicatio, n (%) | Not assessed | 1/27 (4%) | 1/26 (4%) | 0 | 1/26 (4%) |
| Steal syndrome symptoms, n (%) | Not assessed | 0 | 0 | 0 | 0 |
| All-cause death | 0 | 1/27 (4%) | 0 | 2/26 (8%) | 3/26 (11%) |

*Notes.* *Two restenosis and one occlusion requiring new revascularization of target lesion.

following alcohol intoxication. This patient, initially classified in the Rutherford IIb group, was the only one necessitating the placement of two stents as well as an additional administration of recombinant tissue plasminogen activator (rtPa-alteplase). Two days after intervention, the patient ultimately died because of the consequences of a septic shock due to a pre-existing urinary infection. Over long-term follow-up, two (8%) additional deaths were recorded: these included advanced pharyngeal cancer and unknown reason, respectively (Table III).

## Discussion

The overall low prevalence of upper-extremity PAD in the general population explains the paucity of evidence concerning all aspects of its management, including secondary preventive measures [10] and, in case of a symptomatic course, interventional strategies [6] Our study provides reassurance that a fixed, homogeneous endovascular therapy including percutaneous angioplasty and placement of a balloon-expandable stent represents a feasible, effective, and safe therapeutic approach to treat symptomatic upper-extremity PAD. Based on this preliminary data, an endovascular approach to subclavian and brachiocephalic lesions may be reasonably preferred over an open surgical approach in light of its minimally invasive nature and favorable and durable risk-benefit ratio [7]. However, the lack of ad hoc randomized clinical trials prevents drawing final conclusions: these results may serve to quantify the expected risks and benefits related to a similar treatment to design future studies but also to inform patients before planned procedures.

In our cohort of 27 patients, two (7.7%) required a further endovascular intervention due to restenosis or occlusion of the target lesion within 6 months of follow-up with no additional patients undergoing further revascularization related to the index treatment during the available follow-up. This corresponds to an overall primary patency rate of 89% and appears comparable to most previous studies [11, 12, 13, 14, 15]. Notably, this result matches the findings of a recent study, which reported a 3-years primary patency between 81% and 91% after stenting of the subclavian artery [16] and shows a greater patency in comparison to the 2-years results of a previous metanalysis [11]. It also confirms the efficacy and safety of this approach to treat lesions located in the subclavian and innominate arteries. Consistently, the patients experienced a complete resolution of claudication and steal syndrome typical symptoms over time with a sustained normalization of oscillometric measurement of blood pressure and systolic pressure values.

In our experience, the periprocedural success rate of percutaneous angioplasty and BeSmooth® stenting was 100% with a low periprocedural bleeding complication rate related to arterial access. The low periprocedural complication rate may be directly linked to the prevalent use of femoral or femoro-radial access rather than brachial access, which allows better compression of the puncture site and thus a lower incidence of bleeding. The only periprocedural death observed in our cohort was unrelated to PAD treatment. The overall early death rate of 4% is comparable with that from a previous retrospective study on 110 patients (3.6%) [13]. It is thought that some of the advantages of the balloon-expandable BeSmooth Peripheral® stent (vs. self-expanding stent) for this novel application include stronger support to the treated vessel due to high radial force and a high precision in positioning. This may have also led to the very low rate of observed systemic embolism events. Indeed, we did not record other major complications typical of this procedure, such as transient ischemic attack (TIA), myocardial infarction, or stroke, even though no embolic protection device (EPD) in the right internal carotid or in the vertebral artery was used. The "protected placement" technique used during positioning and the pre-dilatation performed in the case of occlusive lesions may also explain the high procedural success rate.

These results are in line with those of previous studies and reports [12, 17, 18] and are likely directly influenced by implantation of a stent rather than angioplasty alone. Stent implantation has been linked to significantly higher procedural success rates in comparison to that of angioplasty alone [11, 16]. Currently, there is no evidence from randomized clinical trials that stenting is superior to angioplasty alone for subclavian and innominate artery stenosis or occlusion and less is known about the difference in efficacy between different types of stent [7, 11]. Although a previous study reported that the type of stent used does not affect the outcomes of the procedure [19], some authors favor balloon expandable stents for their higher radial expansion force and higher accuracy in placement [13, 16, 20]. Nevertheless, one retrospective study with 36 patients affected by upper extremity PAD reported a higher rate of restenosis in patients treated with a balloon-expandable stent in comparison to a self-expanding stent [12] and in a randomized trial with patients receiving stenting for iliac artery occlusive disease, the use of balloon expandable stent resulted in a significant higher rate of new revascularization of target lesion [21].

## Limitations

These results are subject to certain limitations, such as the retrospective design and the small sample size. Follow-up was also limited to two years and we could not retrieve information for all patients. Furthermore, enrolling both patients with upper extremity PAD determined by atherosclerotic disease and patients with PAD secondary to radiotherapy can represent a possible confounding factor. Lastly, we cannot exclude that other etiologies, such as collagen disease, played a role in determining the upper extremity PAD in our cohort.

## Conclusions

In conclusion, percutaneous catheter-based treatment and stenting with BeSmooth Peripheral Stent System® appears a suitable strategy to treat symptomatic upper-extremity PAD. Data from randomized controlled trials comparing different revascularization approaches and techniques is urgently needed.

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**Conflict of Interest**
RF, KS, AG, EH, MM, and WP have nothing to disclose. SB has received congress and travel payments from Daiichi-Sankyo and Bayer Health-Care; honoraria from BTG Pharmaceuticals, Bayer Health Care, and Leo Pharma; and institutional research support from Sanofi. NK reports institutional research grants from Concept Medical, Bard, Bentley, Boston Scientific, INARI, Sanofi, and Bayer; and personal fees from Concept Medical, Bayer, Boston Scientific, and INARI.

**Publication ethics**
The study was performed according to the declaration of Helsinki, and a written informed consent was obtained from all the patients. The local ethic committee approved the study (BASEC Nr. 2022-00917).

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