Superficial Femoral Artery Endovascular Therapy: 12-Month Primary Patency Rates of Contemporary Endovascular Devices from 25,051 Patients

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Abstract

Background. Approximately 5.8 million people experience peripheral arterial disease (PAD) in the United States today. Superficial femoral artery (SFA) disease is the most common cause of symptomatic PAD. New-generation nitinol stents, drug-coated stents, drug-coated balloons (DCB), covered stents, and directional or orbital atherectomy devices have shown promising results. However, clinical equipoise persists regarding the optimal selection of devices, largely attributable to the different inclusion criteria, study populations, length of lesions treated, definitions of "patency" and "restenosis," and follow-up methods in the up-to-date pivotal trials. **Methods.** A prospective protocol was developed. We performed a literature search using PubMed from January 2011 to July 2021. All published articles including endovascular interventions in the SFA with reported 12-month "primary patency" rates as endpoints were included. **Results.** We identified 25,051 patients in 124 studies reporting 12-month primary patency rates in patients with SFA disease. Primary patency rates were (weighted average) 82.6% for drug-eluting stents, 77.2% for drug-coated balloons, 75.2% for covered stents, 73.9% for nitinol self-expanding stents, 66.1% for atherectomy, and 44.5% for bare balloon angioplasty. **Conclusion.** The most frequently used endovascular devices yielded various 12-month primary patency rates ranging from 44.5% to 82.6%. The increased variation in inclusion criteria, lesion length, and complexity of lesions between studies does not allow direct comparison between the individual devices. Larger randomized trials in specific patient populations comparing these modalities are needed well before we can make proper recommendations on the superiority of one device over the other.

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Peripheral arterial disease (PAD) affects 5.8%-10.7% of the population 40 years and older. Approximately 5.8 million people today experience PAD, defined as an ankle-brachial index (ABI) <0.9 in the United States.[1] Despite advancements in medical therapies, identification and control of risk factors, and percutaneous and surgical revascularization techniques, the rate of non-traumatic lower-extremity amputation has increased by 50% between 2009 and 2015 in adults with diabetes.[1] The average healthcare costs over 2 years for vascular-related hospitalizations in patients with PAD ranges from $7000 to $11,693, while in patients with critical limb ischemia (CLI), the average annual healthcare cost ranged from $49,200 to $55,700. Superficial femoral artery (SFA) disease is the most common cause of symptomatic PAD, and may progress to lifestyle-limiting claudication, CLI, or limb amputation.[2]

With optimal use of new technologies, endovascular revascularization has been feasible even in patients with complex SFA lesions. Chronic total occlusion (CTO) devices, orbital or rotational atherectomy, new-generation stents, drug-eluting stents, drug-coated balloons, and covered stents have all been studied with varying success rates in different patient groups.

Data comparing each of those modalities with plain old balloon angioplasty or medical therapy are available; however, head-to-head comparisons between advanced endovascular treatment modalities have been scarce. Moreover, accurate conclusions comparing published data are difficult due to important differences in included samples. Variations in patient risk factors (diabetes, kidney disease, and smoking), clinical presentation (claudication, acute, or CLI), lesion characteristics (CTO, extent of calcification,

multisegmental disease, and long segments), studied outcomes (primary or secondary patency, length of follow up, target-lesion revascularization, target-vessel revascularization), and follow-up methods (clinical, ultrasound, ABI, or angiography) make such comparisons imprecise.

In 2018, the Society of Cardiovascular Angiography and Interventions (SCAI) published a consensus guidelines document for device selection in femoropopliteal arterial interventions.[3] A quantitative evaluation and synthesis of the data is hence essential and timely in helping to define and quantify the durability of various endovascular devices (other than balloon angioplasty). In this study, we attempted to investigate the 12-month primary patency rates of various endovascular therapies in patients with femoropopliteal PAD using published registries, case reports, and trials.

Methods

A prospective protocol using a detailed literature search using PubMed from January 2011 to July 2021 was performed. Randomized trials and outcome registries with the following characteristics were included: (1) evaluation of endovascular intervention; (2) report of 12-month primary patency; (3) sample >30 patients; and (4) published in English. The primary outcome of interest was primary patency at 12 months. The medical subject heading (MeSH) terms ("superficial femoral artery" OR "sfa" OR "superficial femoral") OR ("superficial femoral and popliteal" OR "femoropopliteal") AND ("primary patency" OR "binary restenosis") AND ("atherectomy" OR "angioplasty" OR "DCB" OR "drug coated balloon" OR "stent" OR "balloon angioplasty" OR "cryoplasty" OR "lithotripsy" OR "cutting balloon") were used.

After completion of this electronic search, 2 reviewers screened all titles and abstracts to assess the eligibility of each article and studies that fulfilled the inclusion criteria were retrieved in full text for further evaluation. Only studies with a minimum sample size of 30 patients and with a follow-up of at least 12 months were included in this report. Studies evaluating common femoral artery, deep femoral artery, and aortoiliac arteries were excluded. The search was limited to human studies and restricted to articles in English. Abstracts and presentations were also excluded. The outcome of interest was primary patency at 12 months.

Data extraction. Studies were selected and data were extracted independently by 2 reviewers (IDK and MA) and disagreements were resolved by consensus. The studies were evaluated carefully for duplicate or overlapping data. We reported the type of endovascular device, sample size, and 12-month primary patency rates.

Results

A total of 124 studies (25,051 patients) met the selection criteria and were included in our study. The results involving

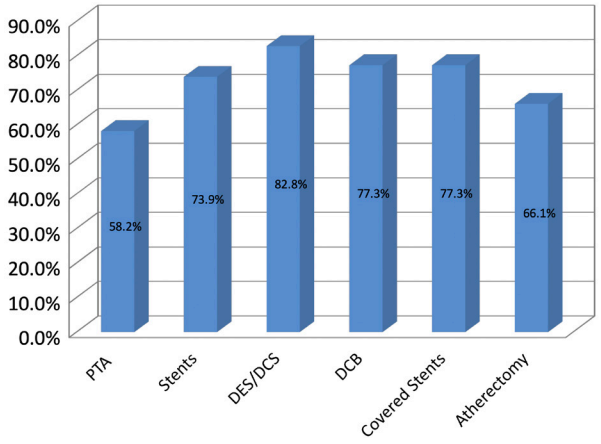

FIGURE 1. Superficial femoral artery endovascular modalities with 12-month patency rates. DCB = drug-coated balloon; DCS = drug-coated stent; DES = drug-eluting stent; PTA = percutaneous transluminal angioplasty;

TABLE 1. Balloon angioplasty (percutaneous transluminal angioplasty.

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Schroeder et al[7]	72	60.6%
Tsuchiya et al[8]	572	77.2%
Jia et al[9]	100	33.7%
Tepe et al[10]	111	52.4%
Armstrong et al[11]	75	66%
Armstrong et al[11]	31	34%
Chalmers et al[12]	76	39.3%
Bosiers et al[13]	44	28%
Dake et al[14]	238	32.8%
Rastan et al[15]	127	44.9%
Rosenfield et al[16]	160	52.6%
Kinster et al[17]	39	13.4%
Total	**1606**	**44.5%**

Studies listed twice indicate values stratified by study subgroup (stent type, lesion length, TASC score, etc).

stent studies and alternative endovascular devices are listed in the tables. Weighted average 12-month patency rates and length of femoropoliteal lesions treated with each endovascular modality are described in **Figure 1**. In the balloon angioplasty group, 12 studies including 1606 patients formed the data.[4-14] The mean 12-month patency rate was 44.5% (**Table 1**). In the stent group, 68 studies with 17,829 patients were evaluated.[15-69] The mean 12-month patency rate was 73.9% (**Table 2**). In the drug-eluting stent group, we included 12 studies with 2501

TABLE 2. Stenting.

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Mori et al[18]	279	84%
Vent et al[19]	58	66.7%
Powell et al[20]	299	69.5%
Elmahdy et al[21]	213	81.4%
Stavroulakis et al[22]	89	73%
Brouillet et al[23]	203	67%
Myint et al[24]	97	78.9%
Matsumi et al[25]	269	87.7%
Tsuchiya et al[8]	2029	84.2%
Suzuki et al[26]	1265	62.5%
Suzuki et al[26]	240	42.9%
Nishibe et al[27]	82	76%
Ohki et al[28]	261	82.9%
Fujihara et al[29]	161	60.2%
Fujihara et al[29]	323	70.1%
Guo et al[30]	53	63%
Matsumi et al[31]	68	77.9%
Nasser et al[32]	83	76.1%
Soga et al[33]	1047	63.3%
Brescia et al[34]	53	79.6%
Dumantepe et al[35]	36	88.5%
Rocha-Singh et al[36]	287	77.9%
Gabrielli et al[37]	30	43.3%
Gabrielli et al[37]	41	81.5%
Sarkadi et al[38]	102	80%
Gray et al[39]	250	81.1%
Stone et al[40]	151	58%
Iida et al[41]	1356	80%
Iida et al[41]	553	69%
Iida et al[42]	234	72%
Iida et al[42]	234	90%
Gillgren et al[43]	112	63%
Lichtenberg et al[44]	118	79.5%
George et al[45]	80	96.8%
Laird et al[46]	196	72.9%
Armstrong et al[11]	84	49%
Armstrong et al[11]	64	63%
Chan et al[47]	78	78.6%
Wu et al[48]	76	58%
Lichtenberg et al[49]	36	85.4%
Bosiers et al[50]	120	81.4%
Werner et al[51]	100	45%
Matsumura et al[52]	287	77.2%
Yin et al[53]	126	95%
Sakamoto et al[54]	352	79%
Soga et al[55]	90	75.5%
Scheniert et al[56]	101	87.7%
Schulte et al[57]	744	87.6%
Chalmers et al[12]	74	51.8%
Diehl et al[58]	53	71.7%
Bosiers et al[59]	100	64.8%
Gabrielli et al[60]	51	78.4%
Gabrielli et al[60]	44	59.1%
Stavroulakis et al[61]	517	86.2%
Hong et al[62]	129	87%
Hong et al[62]	67	56%
Werner et al[63]	470	83.3%
Iida et al[64]	861	77.4%
Scheinert et al[65]	107	84.7%
Iida et al[66]	119	85.2%
Iida et al[66]	119	72.8%
Lin et al[67]	171	49.8%
Rastan et al[68]	119	67.4%
Lammer et al[69]	69	55.1%
Garcia et al[70]	264	78.9%
Matsumi et al[31]	107	84.6%
Matsumi et al[31]	325	86.3%
San norberto et al[71]	46	89.6%
Soga et al[72]	807	76.3%
Total	**17,829**	**73.9%**

Studies listed twice indicate values stratified by study subgroup (stent type, lesion length, TASC score, etc).

TABLE 3. Drug-eluting stenting.

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Tran et al[73]	46	81.6%
Mori et al[18]	27	77%
Vent et al[19]	45	52.5%
Müller-Hülsbeck et al[74]	57	96%
Yokoi et al[75]	907	86.4%
Kang et al[76]	63	66.7%
Oberto et al[77]	67	88%
Fujihara et al[78]	60	50.2%
Zeller et al[79]	97	69.6%
Dake et al[80]	787	86.2%
Dake et al[14]	241	83.1%
Lammer et al[81]	104	68.4%
Total	**2501**	**82.6%**

TABLE 4. Drug-coated balloon.

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Schroeder et al[7]	222	83.9%
Schroeder et al[7]	50	89.5%
Bague et al[82]	53	83.7%
Foley et al[83]	61	81%
Stavroulakis et al[84]	31	65%
Micari et al[85]	105	83.7%
Schmidt et al[86]	260	79.2%
Jank et al[87]	87	77.5%
Jia et al[9]	100	76.1%
Tepe et al[10]	220	82.2%
Zeller et al[79]	131	76.1%
Stabile et al[88]	39	92.1%
Micari et al[85]	105	83.7%
Herten et al[89]	61	68%
Herten et al[89]	39	85%
Rosenfield et al[16]	316	65.2%
Kinstner et al[17]	35	40.7%
Total	**1915**	**77.2%**

Studies listed twice indicate values stratified by study subgroup (stent type, lesion length, TASC score, etc).

TABLE 5. Covered stent

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Ohki et al[90]	103	88.1%
Sibe et al[91]	215	82%
Mohr et al[92]	41	74.8%
Parthipun et al[93]	48	69.5%
Kruse et al[94]	315	72.2%
Piorkowski et al[95]	32	85.5%
Saxon et al[96]	113	74%
Bosiers et al[13]	39	74.8%
Ullery et al[97]	61	60%
Lensvelt et al[98]	53	76.2%
Lammer et al[69]	72	70.9%
Total	**1092**	**75.2%**

patients.[11,15,16,70-78] The mean 12-month patency rate was 82.6% (**Table 3**). The drug-coated balloon group was formed with 17 studies and 1915 patients.[4,6,7,13,14,79-86] The mean 12-month patency rate was 77.2% (**Table 4**). The covered stent group included 12 studies and 1092 patients. The mean 12-month patency rate was 75.2% (**Table 5**). Finally, the atherectomy group comprised 3 studies and 108 patients (**Table 6**). The mean 12-month patency rate was 66.1%.

A small group of 2 studies and 104 patients that evaluated biodegradable stents demonstrated a 12-month patency rate of 50.5%. One study evaluated the combination of orbital atherectomy with drug-coated balloon and showed a 12-month patency 77.0%.

Discussion

SFA endovascular interventions are subject to restenosis, which often appears within the first 12 months after the initial procedure. Despite advances in device optimization to achieve successful recanalization for the majority of arterial lesions, long-term primary patency rates remain relatively low in these patients. In contrast to the coronary circulation, PAD of the SFA includes longer segments, often at many levels, high prevalence of calcification, decreased flow rates and mechanical compression from adjacent anatomy with various range of motion, triggering restenosis, stent fracture, or occlusion even after highly satisfactory initial angiographic results.

Newer-generation stents. Currently, nitinol self-expanding stents are widely used in patients with SFA disease. Newer stent platforms are designed to maintain flexibility, radial strength to tolerate vessel bending, torsion, and elongation or shortening, with reduced rates of stent fracture and restenosis.

TABLE 6. Atherectomy.

Authors	Patient Sample (n)	12-Month Primary Patency Rate
Stavroulakis et al[84]	41	82%
Minko et al[99]	38	69%
Wu et al[48]	29	40%
Total	**108**	**66.1%**

Drug-coated balloons. Drug-coated balloons provide significant benefits through local drug delivery to prevent intimal hyperplasia, without the risk of thrombosis from exposed metal struts or stent fracture. They provide a higher patency rate compared with traditional angioplasty balloons. The use of drug-coated balloon significantly decreased in 2019 after concerns about late mortality in patients who received drug-coated balloon treatment of PAD.[4] According to the latest United States Food and Drug Administration recommendations, patients treated with paclitaxel-coated balloons and paclitaxel-coated stents should be carefully monitored. Moreover, "when making treatment recommendations, and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents."

Drug-eluting and drug-coated stents. Drug-eluting therapy has been extensively investigated in patients with coronary artery disease. Based on the success of drug-eluting stents in the coronary circulation, it has been hypothesized that they may provide higher patency rates in PAD patients as well. Early trials demonstrated discrepant outcomes due to the type and quantity of the stent medication used. As with drug-coated balloons, the use of drug-eulting stents has decreased since 2019 due to concerns about potential late mortality.[5]

Covered stents. Covered stents have been commonly used in the peripheral circulation. A covered stent completely "covers" the diseased vessel in long PAD lesions, preventing ingrowth of intimal hyperplasia. Covered stents are made of an expanded polytetrafluoroethylene (ePTFE) liner attached to an external nitinol stent structure, while newer devices have an additional heparin bioactive surface. They are believed to offer higher patency rates by preventing ingrowth from intimal hyperplasia.

Directional and orbital atherectomy. Directional and orbital atherectomy are now widely used to treat calcified femoropopliteal lesions by offering minimal arterial wall stretch injury. These modalities avoid the uncontrolled vascular mechanical damage caused by angioplasty balloons, the exposure of stent struts, or stent fracture. Moreover, no medication remains on the vessel endothelium, which has been a concern with drug-coated balloons and drug-eluting stents. It is important to point out that directional atherectomy has been successfully used in the most complex femoropopliteal lesions, including TransAtlantic InterSociety Consensus (TASC) D and heavily calcified vessels, with excellent results;[6] although, adjunctive percutaneous transluminal angioplasty or drug-coated balloon have been used in 59%-76.5% of the cases and bailout stenting in 6%-23% of the lesions.

Relatively small patient sample size in each study and the lack of uniformly defined endpoints make comparisons between different endovascular treatment modalities very challenging. Furthermore, the number of well-designed randomized controlled trials is limited. Angiographic success, clinical success, ABI, target-lesion revascularization, target-vessel revascularization, Rutherford class, freedom from claudication, and limb-salvage rates are some of the endpoints that have been used to demonstrate the effectiveness of variable endovascular treatment strategies. Primary patency is defined by the TASC document as uninterrupted patency following an endovascular intervention and is the most commonly used endpoint in most of the well-designed clinical trials.

With the existing data, the highest 12-month primary patency rates are achieved with drug-eluting stents (82.6%), followed by drug-coated balloons (77.2%), covered stents (75.2%), nitinol self-expanding stents (73.9%), atherectomy (66.1%), and balloon angioplasty alone (44.5%). These results should be interpreted with caution because of important differences in their use regarding patient demographic and risk factors, clinical presentation, Rutherford class, angiographic severity, and degree of calcification.

Study limitations. The most important limitation of our current review is that the data were obtained from registries, single-center case series, databases, and trials with various inherent biases. As with any quantitative systematic review, the conclusions drawn from such data are subject to the limitations of the original studies. The included studies had significant heterogeneity as well as differences in design, patient selection, and methods. We did not have access to patient-level data, which precluded the possibility of performing meta-regression analysis. However, this is currently the best available information about the long-term patency rates with the currently used endovascular modalities in the treatment of SFA-PAD lesions.

Conclusion

Newer-generation nitinol self-expanding stents, covered stents, drug-eluting stents, drug-coated balloons, and atherectomy devices offer an extensive variety of endovascular options for the treatment of femoropopliteal disease. We present the best available information about the 12-month patency rates with the currently used endovascular modalities. Since the inclusion and exclusion criteria were not uniform among the original studies,

it is impossible to precisely determine the effectiveness of one device compared with others. It is of prime importance to recognize the benefits and shortfalls of each device and choose an appropriate treatment modality. Larger randomized trials in specific patient populations comparing different endovascular treatment options are needed to demonstrate the superiority of one device over another.

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