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# Standards of Practice for Superficial Femoral and Popliteal Artery Angioplasty and Stenting

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**Abstract** This is a Standards of Practice document endorsed by CIRSE. The authors performed a literature review and provide recommendations and quality improvement guidelines based on the most recent and highest level of evidence available to date on the field of Superficial Femoral and Popliteal Artery Angioplasty and Stenting. Standards for the use of basic and more advanced endovascular techniques in the femoropopliteal arteries are reported and relevant aspects of case selection, imaging, follow-up, and overall patient management are presented to guide endovascular practice in Europe.

**Keywords** Imaging · Angioplasty · Stenting · Arteriosclerosis · Superficial femoral artery · Popliteal artery

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## Introduction

The femoropopliteal arteries are very common sites of involvement in patients with atherosclerotic peripheral arterial disease (PAD) [1]. A minority of those will require treatment for intermittent claudication (IC) or critical limb ischemia (CLI). PAD often is multilevel and femoropopliteal lesions may be combined either with more proximal aortoiliac disease or with distal infrapopliteal lesions, particularly in patients presenting with limb-threatening CLI. Patients may be elderly with multiple comorbidities, such as diabetes, coronary artery disease, carotid stenosis, renal dialysis, and chronic obstructive pulmonary disease, which put them at increased perioperative risk [2–4]. Percutaneous angioplasty and stenting of the superficial femoral and popliteal artery is the proposed treatment of choice in the majority of patients with IC or CLI on the basis of its reduced perioperative morbidity and mortality, and reduced in-hospital stay [5, 6]. To date, several new technologies, such as bare metal stents made from nitinol, drug-eluting stents (DES), covered stents, and drug-coated balloons (DCB), have emerged with the aim to improve long-term patency outcomes following angioplasty of the femoral and popliteal arteries [7–11]. A literature review was performed and recommendations and quality improvement guidelines provided in the present document are based on the highest level of evidence available to date with particular focus on the field of angioplasty of the superficial femoral and popliteal arteries. For more detailed information about the strength and level of the relevant evidence, the reader is urged to refer to other collaborative standards of practice and multidisciplinary recommendations as well [2–5, 12–14].

## Clinical Assessment

Peripheral arterial disease affects almost 12 % of the general population and is responsible for substantial healthcare costs. PAD primarily results in a decreased functional capacity and deterioration in quality of life and is associated with an increased risk of limb amputation, myocardial infarction, stroke, and death [4, 5, 15]. Two-thirds to three-fourths of patients initially presenting with IC symptoms will remain stable for several years after the initial diagnosis, whereas the remaining one-third to one-fourth will show progressive disease, but only 1–5 % of the PAD population will eventually undergo amputation [14]. The prevalence of comorbid coronary and cerebrovascular disease in the PAD population exceeds 50 %. The risk of cardiovascular mortality in PAD patients is >5 times higher compared with normal individuals and up to 10 times higher in case of symptomatic patients with more advanced disease [16]. Patients suffering from PAD typically present with symptoms of IC or CLI. IC is defined as an intermittent cramping pain during walking caused by an inadequate supply of blood to the musculature of the lower limb. IC typically develops on exertion and is relieved at resting conditions. CLI is the final clinical manifestation of PAD and is typically characterized by either chronic ischemic rest pain and/or ischemic tissue loss of the limb (ulcers or gangrene) attributable to objectively proven arterial occlusive disease [2, 3]. CLI is defined by an ankle systolic pressure of 50 mmHg or less. In case of incompressible arteries at the ankle, a toe systolic pressure of 30 mmHg or less can be used [17]. Acute limb ischemia has been addressed by a previous Standards of Practice CIRSE document [18].

Clinical assessment of patients with suspected or documented PAD (exertion leg symptoms, nonhealing wounds or tissue loss, history of smoking or diabetes) must take place in an organised outpatient setting with appropriate facilities. Physical examination must include assessment of the extremities' colour and temperature, skin, hair, and nail trophic changes and muscle findings. In the diabetic population, any ulcers must be identified and classified into neuropathic, ischemic, or mixed neuroischemic on the basis of their clinical features. Location and quality of pulses on both upper arms and lower legs must be documented on dedicated vascular mapping schemas. Resting Ankle-Brachial Index (ABI) measurements are taken to establish firmly the diagnosis and assess the anatomical extent of the disease. Resting ABI measurements are to be classified and reported as >1.4 (noncompressible values), 1.0–1.4 (normal), 0.90–0.99 (borderline), and <0.9 (abnormal) according to the Ankle Brachial Index Collaboration [19]. An ABI <0.9 is considered as highly sensitive (95 %) and specific (100 %) for the diagnosis of PAD [20]. In case of noncompressible vessels, the Toe-Brachial Index (TBI) may be used instead (critical level <50 mmHg) [4]. Measurements of $TcPO_2$ (critical level <30 mmHg) are suggested in case of diabetic patients with ulcers both for baseline evaluation and for assessment of response to revascularization [21, 22]. Examination for carotid bruits, cardiac murmurs, gallops, or arrhythmias and palpation for the presence of an abdominal aortic aneurysm also is recommended [3]. The accepted Fontaine and Rutherford-Becker classification system of PAD is outlined in Table 1.

**Table 1** Rutherford-Becker and Fontaine classification

| Rutherford stage | Fontaine stage | Description/definition |
|---|---|---|
| 0 | I | Asymptomatic |
| 1 | IIa | Mild claudication |
| 2 | IIb | Moderate claudication |
| 3 | IIb | Severe claudication |
| 4 | III | Rest pain |
| 5 | IV | Ischemic ulcers of the digits of the foot (minor tissue loss) |
| 6 | IV | Severe ischemic ulcers or gangrene (major tissue loss) |

## Conservative Therapy

Smoking cessation and aggressive control of diabetes are the cornerstones of risk-factor modification for PAD treatment [3–5]. Updated guidelines also recommend to help active smokers with behavioural (counselling, smoking cessation program) and/or pharmacological treatment (varenicline, bupropion, nicotine replacement) [4]. Smoking cessation aims to reduce the risk of adverse cardiovascular events and the risk of progression to amputation, but patients should be informed not to expect any symptomatic improvement [3]. Supervised exercise therapy has been shown to increase walking distance in claudicants and is recommended as first management of claudicants in combination with best medical therapy [3, 23, 24]. Pharmacotherapy with daily cilostazol, naftidrofuryl, or pentoxyfilline has also been shown to increase walking distance in claudicants [3, 20]. Patients who are obese (BMI >30) or overweight (BMI >25) should be counselled to restrict calorie intake and increase exercise to lose weight. The Heart Protection Study (HPS) has demonstrated the value of statins to reduce LDL cholesterol levels and thereby reduce cardiovascular events in the PAD population [25]. Apart from statins, fibrates can be used to control hypertriglyceridemia and niacin to raise HDL levels.

**Table 2** Best medical therapy

| Therapy | Regimen |
|---|---|
| Supervised exercise | 30–45 min 3 times/week for 3 months |
| Cilostazol | 100 mg b.d. |
| Pentoxyfilline | 400 mg t.d.s. |
| Aspirin | 75-325 mg o.d. |
| Clopidogrel | 75 mg o.d. |
| Blood pressure | Aim for BP <140/90 mmHg (<130/90 mmHg if diabetes or renal disease) |
| Diabetes | Aim for $HbA_{1c}$ <7 % (ideally 6 %) |
| Cholesterol | Aim for LDL <100 mg/dl (<70 mg/dl if high-risk) |
| Smoking | Cessation therapy |
| Obesity | Aim for BMI <25 |

Antiplatelet therapy is indicated for reduction of the risk of myocardial infarction, stroke, and death in all patients with symptomatic atherosclerotic disease of the lower extremities), including patients who have undergone open surgical or percutaneous revascularization or even major amputation [3, 4]. All patients with symptomatic PAD must receive at least single antiplatelet therapy with aspirin, 75–325 mg daily. Clopidogrel, 75 mg daily, is a safe and effective alternative [26]. Use of aspirin will realize a 25 % odds reduction in subsequent adverse cardiovascular events [27]. The CAPRIE trial has shown a further 24 % relative risk reduction of future adverse events with the use of clopidogrel versus aspirin in the symptomatic PAD population [28]. Dual antiplatelet treatment for PAD patients remains controversial and may depend on local practice, other cardiovascular comorbidities, severity of leg symptoms, and anatomical extent of the disease. Emerging evidence from the CHARISMA clinical trial suggests that a combination of aspirin and clopidogrel is more beneficial in reducing adverse vascular events and may be offered to high-risk PAD patients who are at low risk for bleeding [29, 30]. Recommended best medical therapy for PAD is summarized in Table 2 [20, 23, 24, 31, 32].

## Imaging

Imaging interrogation of the peripheral arteries must extend from the level of the infrarenal abdominal aorta to the feet in order to provide a global view of potential approach, access vessels for treatment, identify anatomical variants, exclude aneurysmal disease, assess any inflow and outflow disease, and assess the suitability of vessels for revascularization in line with the angiosome concept [33, 34]. Digital subtraction angiography (DSA) is invasive with attendant risks of haemorrhage, vessel injury, and embolization and therefore must be reserved for cases where noninvasive imaging is inadequate. Noninvasive imaging modalities for investigation of symptoms and/or preoperative treatment planning includes color Doppler ultrasonography (Duplex or Triplex Sonography), computed tomography angiography (CTA), and magnetic resonance angiography (MRA) (Table 3). Each imaging modality has its own advantages and disadvantages. Duplex is proposed first, because it is inexpensive, radiation-free, versatile, and provides both anatomic and hemodynamic information about the degree of a stenosis [35, 36]. In candidates for revascularization of complex and multilevel infrainguinal disease, CTA or MRA may then allow for more detailed preoperative arterial mapping [37]. Recent guidelines suggest that MRA is the most accurate noninvasive technique, but CTA is also a reasonable alternative [38]. CTA or MRA imaging may be limited by impaired renal function (because of the risk of contrast-induced nephropathy and acute kidney injury or nephrogenic systemic fibrosis, respectively) or allergy to iodinated/gadolinium contrast agents. Alternatively, novel noncontrast MRA techniques employing rapid steady state free-precession (SSFP) sequences are already commercially available from large vendors [39]. Noncontrast MRA techniques may reduce risk and produce significant cost savings. In general, evaluation of both axial and coronal or multiplanar reformatted images is necessary for more accurate estimation of stenoses that are borderline significant (50–70 %). The presence of heavy or cylindrical calcifications must be noted due to their association with increased failure of recanalization in case of chronic total occlusions (CTO) and with increased residual stenosis and early restenosis following angioplasty.

## Treatment Decision Making

Indications and contraindications for femoropopliteal procedures are outlined in detail in Table 4. The original and revised Trans-Atlantic Intersociety Consensus (TASC) documents address the issue of choice between endovascular therapy and surgery for specific types of lesions in terms of length and complexity. This is based on the grounds that these parameters are important determinants of short- and long-term clinical outcomes of the revascularization procedure. Femoropopliteal lesions are anatomically classified into four major categories (TASC A–D). Endovascular therapy is recommended for TASC A–C lesions of the superficial femoral and popliteal artery and vein bypass surgery for TASC D lesions in relatively young and fit patients [2, 3]. In general, the latest TASC document recommends that an endovascular-first strategy should be offered for the majority of symptomatic patients with

**Table 3** Imaging modalities

| Modality | Sensitivity | Specificity | Pros | Cons |
|---|---|---|---|---|
| Duplex Ultrasound (DUS) | 88 % | 95 % | Inexpensive, widely available, no risks of allergy, CIN, NSF | Operator-dependent, anatomical limitations (adductor canal, calcifications, tibial arteries) |
| Computed tomography angiography (CTA) | 95–97 % | 91–98 % | Multiplanar reformats, quantitative vessel analysis, calcium mapping | Risks of CIN, allergy, radiation metal implants, calcifications |
| Magnetic resonance angiography (MRA) | >90 % | >90 % | Multiplanar reformats, quantitative vessel analysis, noncontrast SSFP sequences | Time-consuming, expensive, risk of NSF, metal implants |
| Digital subtraction angiography (DSA) | Imaging standard of reference | | High SNR and CNR, detailed morphological analysis | Invasive, CIN, allergy, radiation, vessel injury |

Sensitivity and specificity values of detecting a significant stenosis (>50 %) or occlusion at the femoropopliteal level in comparison to DSA as the "gold standard" [79]

*CIN* contrast-induced nephropathy, *SNR* signal-to-noise ratio, *CNR* contrast-to-noise ratio, *NSF* nephrogenic systemic fibrosis

superficial femoral and popliteal artery disease based on the rationale that when two therapies (transluminal angioplasty and bypass surgery) achieve equivalent clinical benefits, the approach with the least morbidity and mortality should be pursued first [2, 3].

Multidisciplinary decision-making for treatment must take into account the patient's clinical symptoms, the anticipated life-expectancy, morphological classification of the femoropopliteal atherosclerosis, anatomical challenges, renal failure, contrast allergy, and the availability of vein conduits. In patients with limb-threatening ischemia and a life-expectancy of <2 years or in the absence of a suitable vein conduit, percutaneous transluminal angioplasty is recommended as the first-line treatment regardless of the anatomical extent of disease. Patients with TASC D and/or heavily calcified femoropopliteal lesions and a life-expectancy of >2 years may be first considered for vein bypass surgery [4].

## Patient Preparation

Routine laboratory examinations, including a baseline full blood count, clotting profile, and renal function, are usually reviewed pre-procedure. Warfarin is usually interrupted a few days before the procedure and bridged to low-molecular weighted heparin (LMWH) or intravenous unfractionated heparin (UFH) according to underlying comorbidities and local trust policies. In case of baseline coagulopathy, appropriate measures should be taken to correct it, e.g., administration of vitamin K, fresh-frozen plasma, or platelet transfusions. Consensus guidelines on periprocedural management of coagulation status have been published elsewhere [40]. Assessment of baseline renal function is imperative because of the increased risk of CIN, especially in the diabetic population. In case of impaired renal function (eGFR <60 ml/min/1.73 $m^2$), patients should be treated according to the ESUR (European Society of Urogenital Radiology) international guidelines (prophylactic intravenous hydration with saline infusion at a dosage of 1.0–1.5 ml/kg/h, 6 h before, during, and for another 6 h after the procedure). Hydration with intravenous sodium bicarbonate also is proposed [41]. However, available national guidelines and local policies also will need to be adhered to.

Diabetes, renal disease, heart disease, and advanced age (>70 years) are associated with an increased risk of CIN [42]. The role of *N*-acetylcysteine (NAC) in preventing CIN remains controversial but may be prescribed at 600 mg b.d. per os 1 day before and continued for a couple of days after the procedure. In diabetic patients receiving metformin treatment and with normal creatinine clearance (eGFR ≥60 ml/min/1.73 $m^2$), metformin can be continued normally. If the renal function is impaired (eGFR is 30–59 ml/min/1.73 $m^2$), metformin treatment has to be withheld 48 h before the procedure and should be recommenced 48 h after the procedure only if the renal function has not deteriorated to reduce risk of lactic acidosis. Patients with known allergic reactions to contrast material should be prepared according to the same ESUR guidelines [41].

A standard functioning peripheral intravenous access must be obtained, and the urinary bladder should be emptied before the procedure. In critically ill patients, patients who are unable to cooperate, or have suffered recent myocardial infarction, if there is history of contrast anaphylactoid reaction and in the presence of arrhythmias or electrolyte imbalances, treatment may be undertaken in the presence of anaesthetic cover. Percutaneous femoropopliteal interventions are generally performed under local anaesthetic and/or light conscious sedation. General anaesthesia also may be considered in cases of uncooperative elderly patients who are unable to stay flat and still.

## Equipment Specifications

Endovascular procedures of the peripheral arteries must be performed in a well-organized hospital that provides essential internal services, such as a blood bank, a

**Table 4** Indications and contraindications for revascularization

| Indications |
|---|
| Lifestyle-limiting claudication (Fontaine stage IIb, Rutherford category 2–3) |
| Critical limb ischemia (CLI); rest pain (Fontaine stage 3, Rutherford category 4) or non-healing ulcer/gangrene (Fontaine stage 4, Rutherford category 5–6) |
| Hemodynamically significant proximal or distal juxta-anastomotic stenosis in failing below- or above-knee bypass grafts |
| *Absolute contraindications* |
| Medically unstable patients (may require anaesthetic support) |
| Life-threatening infected (wet) gangrene or/and life-threatening osteomyelitis (indicated only to allow for a more limited extent of amputation) |
| Uncorrectable coagulopathy |
| *Relative contraindications* |
| Pregnancy |
| Uncooperative patients |
| Critically ill elderly patients |
| Dementia, impaired mobility and limited life-expectancy |
| Impaired renal function (eGFR <30 ml/min/1.73 $m^2$) |
| Iodinated contrast allergy or anaphylaxis |
| Contra-indication to antiplatelet or heparin treatment |

high-dependency unit, and an intensive care unit and maintains high standards of tertiary surgical care. Coverage by an anaesthesiologist and a vascular surgeon should be readily available if and when necessary. The basic equipment is a state-of-the-art DSA angiography unit (monoplane or biplane) ideally equipped with a modern flat panel detector system that provides larger anatomical coverage than traditional image intensifiers (larger field of view) and produces higher CNR with good anatomical detail. A portable ultrasound machine with a high-frequency linear probe also is useful for routine ultrasound-guided vascular access. Basic monitoring and resuscitation equipment is mandatory and must be regularly inspected to ensure proper function. All medical and nursing personnel must be adequately trained in basic and intermediate life-support measures and familiar with the local department policies and code of practice. Advanced life-support training also is encouraged.

In case of a femoropopliteal intervention, the endovascular toolkit includes a wide variety of guidewires, catheters, balloons, stents, and perhaps some more specialized endovascular devices for bailout situations. Standard soft-tipped, straight or curved, hydrophilic or exchange, or soft or stiff guidewires are generally used with variable diameter (0.014–0.035-inch) and length (180–300 cm) depending on the point of access, operator preference, stenosis versus occlusions, extent of calcium, and the need for adjunctive tibial recanalization. Vascular sheaths up to 8Fr and with variable length (up to 60 cm or even 90 cm) and standard or hydrophilic 4-5Fr catheters with various tip configurations and 0.035-inch compatible will suffice for most of the procedures. Balloons are available on 0.018–0.035-inch over-the-wire (OTW) and rapid-exchange (RX or monorail) platforms and in variable lengths and diameters. Low-profile 0.018-inch systems that are compatible with 4Fr sheath access are generally advocated to minimize the risk of bleeding, especially in a day-case setting. Self-expanding nitinol stents with a diameter of 4–7 mm and length of 4–20 cm will generally cover the majority of clinical scenarios. Further consumables depending on local practice may include one or more of the following: covered stents for treating fistulae, pseudoaneurysms or de-novo atherosclerosis, thrombectomy devices and thrombolytic drugs to treat acute thrombosis, suction catheters >5FR for aspiration in case of distal thromboembolism, and micropuncture access kits for retrograde pedal punctures. Special note should be made of arterial closure devices (intravascular or extravascular, plug-, suture-, or clip-based) that permit rapid patient ambulation. More specialized equipment may include true-lumen reentry devices that allow successful completion of a subintimal recanalization technique, snares and microforceps for endovascular foreign body removal, distal protection filters to protect against distal trashing in acute occlusions or long-segment CTOs, and intravascular ultrasound (IVUS) or optical coherence tomography (OCT) imaging that may provide valuable insights of de novo disease and help guide the need for stent placement.

There is increasing early evidence for the benefit in improving immediate and medium-term outcomes with the use of nitinol stents, DCB and DES and they may be considered for complex femoropopliteal lesions, pending more long-term data. Most of current DES platforms slowly release cytostatic sirolimus or cytotoxic paclitaxel [9, 43]. DCB are balloon catheters that are engineered for acute release of cytotoxic paclitaxel upon immediate contact with the vessel wall using an appropriate excipient, i.e., a drug carrier (contrast, urea, sorbitol) [7]. Stent-grafts consist of a stent platform covered with fabric (Dacron) or polytetrafluoroethylene (PTFE) that act as a barrier against NIH that encroaches the vessel lumen [44]. Only self-expanding covered nitinol stents are indicated for femoropopliteal interventions [10].

## Procedural Features

Strict asepsis and sterile draping of both groins is mandatory. The choice between antegrade and contralateral retrograde access will depend on body habitus and the presence of concomitant inflow iliac disease. Any

significant inflow disease must be treated before treating SFA and popliteal lesions. The contralateral crossover approach may be negated in cases of tortuous iliac arteries, hostile aortic bifurcations, Y-prosthesis, or abdominal aortic stent grafts. The ipsilateral approach offers superior purchase, pushability, and trackability of devices for femoropopliteal interventions. The ipsilateral retrograde transpopliteal access may be employed in case of a failed antegrade approach or a flush superficial femoral artery occlusion [45]. Combined antegrade and retrograde approaches may be required for challenging long-segment femoropopliteal occlusions or flush occlusions [46]. The left brachial access is reserved for exceptional cases of proximal common and superficial femoral lesions in the presence of bilateral iliac artery occlusion and entails the risk of vertebrobasilar stroke.

Ideally, common femoral artery access is gained under ultrasound guidance to ensure fast and safe access with a single anterior wall puncture of a relatively disease-free vessel segment. Alternatively the SFA can be accessed under ultrasound guidance to get quick and safe antegrade access especially in obese patients [47]. Typically, a 5-6Fr introducer sheath is placed. Long and/or curved up-and-over sheaths can be used across the aortic bifurcation to allow for uncomplicated advancement of devices and regular angiographic control. Depending on the grade of stenosis and/or the estimated age of an occlusion (based on symptom history), a variety of standard or hydrophilic guidewires may be used for lesion crossing. A straight or angled catheter may support, direct, and facilitate advancement of the guidewire. Stiff straight or angled hydrophilic guidewires are generally reserved for CTO. Soft or stiff (or the half-stiff version) angled guidewires are recommended for subintimal recanalization with the Bolia technique [48, 49]. Operators should be vigilant of subacute or thrombus or acute-on-chronic occlusions that may produce distal thromboembolism (trashing) if the lesions appear to be too soft and the wire crosses easily without any resistance. Reentry devices may allow true lumen reentry (technical success >95 %) at the planned distal landing zone and limit inadvertent distal extension of the subintimal dissection plane [50].

Over-the-wire as well as RX balloon catheters are recommended for balloon angioplasty of the femoropopliteal artery. They are characterized by high pushability and trackability in order to cross tight and calcified occlusions. Presence of cylindrical or high-grade eccentric calcifications is related to increased risk of balloon rupture during inflation. The size and length of the balloon may be chosen on the basis of quantitative vessel analysis or usually by visual estimate in relation to a radiopaque ruler aligned in parallel with the target limb. Use of an inflation device is recommended for correct inflation to the nominal balloon pressure. Inflation times are highly variable and may be up to 1 min. Prolonged inflation up to 3–5 min may be applied in an effort to treat postangioplasty dissection to avoid stenting. If prolonged inflation fails to treat elastic recoil or a flow limiting dissection then bailout self-expanding stent placement is recommended.

Typical indications for stent use include postangioplasty elastic recoil or residual stenosis (>30 %) or flow-limiting dissection with the aim to maximize acute luminal gain. Stenting also may have a role in the treatment of anatomically complex lesions (eccentric calcified plaques, long-segment stenosis, and CTO) [6]. Although balloon angioplasty with provisional stent placement remains the standard of endovascular care, primary nitinol stent placement in the femoropopliteal arteries may reduce vessel restenosis and thereby decrease the need for repeat procedures in the mid-term according to several recent randomized, controlled trials [11, 51–53]. Nonetheless, primary stent placement in the femoropopliteal arteries remains controversial according to recent meta-analyses [54, 55].

Balloon-expandable metal stents are no longer used in the femoropopliteal segment because of the risk of external compression and longitudinal axis deformation. New generation stents are made from a nickel–titanium alloy (nitinol). Self-expanding nitinol stents have elastic and thermal memory properties and may resist torsion, flexion, extension, contraction, and compression of the femoropopliteal artery [53]. Stent diameter is slightly oversized (maximum 1 mm) compared with reference vessel size. In a bailout setting, the practice of spot stenting to deal with residual disease or dissections is proposed, whereas in case of primary stenting the stent length is chosen to achieve full lesion coverage of the baseline target vessel segment. Moderate vessel wall calcifications and TASC D lesions have been found to be positive predictors for increased need of provisional femoropopliteal stenting [56]. Overlap of nitinol stents must be minimized, because it relates to increased risk of fracture and site-specific restenosis [57, 58]. Nitinol stent expansion may be suboptimal in case of heavily calcified eccentric or ring-like concentric plaques. Adequate predilation or even postdilation with a high-pressure balloon is advisable to improve acute angiographic outcomes [6].

Neointimal hyperplasia (NIH) leading to vascular restenosis remains the Achilles heel of femoropopliteal interventions. Vascular injury following balloon angioplasty and/or stent placement triggers the release of multiple proinflammatory mediators and a cascade of downstream biological events at the cellular level leading to early and/or late restenosis [16]. The femoral and popliteal arteries are characterized by the highest incidence of postangioplasty vessel restenosis across the various

vascular beds of the human body and NIH is detected more often in long-segment occlusions or stenosis and after placement of multiple stents [3, 6]. NIH is believed to be primarily driven by the acute vessel wall barotrauma and endothelial denudation caused by balloon angioplasty and the chronic constant pressure exerted by metal stents on the vessel wall. Disruption of normal laminar flow by the presence of atherosclerotic plaques and the stent mesh and local flow disturbances at the vessel lumen-wall interface promote platelet aggregation, thrombus formation, and further NIH development [59–62].

Use of DES, DCB, and covered stents has been proposed for inhibition of restenosis and improvement of patency outcomes. Animal studies have provided strong proof of concept and several multicentre, randomized, controlled trials have shown a discernible difference in respect to vessel restenosis with all three strategies compared with standard old balloon angioplasty as described later [7–10, 63]. On the other hand, laser and directional atherectomy have no proven benefit compared with standard balloon angioplasty and stenting [64, 65].

Upon completion of the procedure, haemostasis is usually obtained with manual compression; routine time interval is 10–20 min, but it will vary depending on periprocedural anticoagulation and the size of the sheath used. Vascular closure devices may be used to accelerate haemostasis and patient ambulation [66, 67].

## Medication and Periprocedural Care

Patients may be treated as day-case procedures, but they also can be admitted overnight in case of complex interventions or if large sheaths are used. Best medical therapy including statins and antiplatelet cover as outlined previously are advocated to stabilize the plaques and protect against any adverse vascular events [26]. Although there is no convincing evidence for routine pre-procedure medication with antiplatelet agents, such as aspirin and clopidogrel, the majority of the patients are already receiving at least single antiplatelet therapy. However, there is no widespread consensus with regard to preloading with antiplatelet agents for femoropopliteal interventions [68]. A nonweighted regimen of heparin is routinely administered during the procedure. The usual dosage of heparin is 70 U per kg body weight and the intravenous route is the on-label route (intra-arterial heparin remains off-label use in several countries). Additional heparin is given during a lengthy procedure in order to maintain an activated clotting time (ACT) within the 200–250 s range. The vascular sheath and all devices and wires are regularly flushed with heparinized saline per local practice. Nitroglycerine may be give intra-arterially during the procedure to prevent or to resolve guidewire-induced spasm of the tibial vessels and while monitoring systemic blood pressure.

## Postprocedural Follow-Up Care

Best medical therapy must be continued after a successful femoropopliteal angioplasty or stenting and antiplatelet cover is critical to avoid early vessel failure. For secondary prevention of adverse vascular events at least single-antiplatelet therapy (aspirin or clopidogrel) is recommended following a successful percutaneous infrainguinal revascularization procedure [12, 31]. Dual antiplatelet therapy is used empirically and on an individual basis following stent placement of complex femoropopliteal stenosis or after drug-coated devices because of the presumed increased risk of acute stent thrombosis [26, 68]. There is however emerging evidence that for tailored antiplatelet therapy following screening for clopidogrel high on treatment platelet reactivity (HTPR) (by doubling the dose or switching to alternative antiplatelet agents) may be the next step in antiplatelet management of PAD patients [69, 70]. Regular outpatient visits at 6 weeks, 6 months, and yearly thereafter are recommended for routine clinical assessment and early identification of any recurrent symptoms suggesting target vessel failure. Risk factor modification and best medical therapy must be continued as outlined previously and patients should be encouraged to avoid a sedentary lifestyle and embrace a regular walking training program. Duplex surveillance following peripheral endovascular procedures is proposed to identify early restenosis that may lead to vessel reocclusion and recurrent PAD symptoms. MRA or CTA may be reasonable alternatives. However, there is no current evidence for the benefit of early intervention in these patients [35, 36].

## Outcome

Table 5 outlines the generally accepted terminology for reporting clinical outcomes. The technical success and clinical improvement rates following angioplasty or stenting of the femoropopliteal axis well exceed 95 % (range 98–100 %) in case of stenosis and are around 85 % (range, 81–94 %) in case of CTOs [71]. Primary patency at 1 year is expected to be within the 70–80 % range, at 3 years within 60–70 %, and at 5 years ~50 % [71]. Patency results may vary depending on lesion length, treatment of stenoses versus occlusions, baseline symptoms (IC versus CLI), number and status of run-off vessels, associated comorbidities (diabetes), and patient compliance to smoking cessation and antiplatelet therapy.

**Table 5** Definitions [4, 80]

| Follow-up | |
|---|---|
| Immediate | 1–30 days after the interventional procedure |
| Short-term | 30 days; 12 months after the procedure |
| Long-term | >12 months after the procedure |
| *Success* | |
| Anatomic | <30 % final residual luminal stenosis without flow-limiting dissection |
| Hemodynamic | ABI should be improved by 0.1 or greater above the baseline value and not deteriorated by more than 0.15 from the maximum early postprocedural level |
| Clinical | Immediate improvement by at least one clinical category |
| Technical | In the immediate postprocedural time both anatomic and hemodynamic success should be obtained |
| *Clinical improvement* | |
| +3 | Patient markedly improved: Symptoms gone or markedly improved, ankle/brachial index (ABI) increased to more than 0.90 |
| +2 | Patient moderately improved: still symptomatic, but at least single category improvement. ABI increased by more than 0.10 but not normalized |
| +1 | Patient minimally improved: ABI increased by >0.10 but no categorical improvement in symptoms |
| 0 | No change: no categorical change of symptoms, ABI change <0.10 |
| −1 | Patient mildly worse: either decrease in ABI of >0.10 with no categorical shift or worsening of symptoms with ABI decrease <0.10 |
| −2 | Patient moderately worse: symptomatic deterioration by one category or unexpected minor amputation |
| −3 | Patient markedly worse: symptomatic deterioration by more than one category or major amputation |

Several recent RCTs of primary nitinol stent placement versus standard balloon angioplasty (ABSOLUTE, FAST, RESILIENT & ASTRON trials) have shown significantly reduced risk of vessel restenosis at 12 months [odds ratio (OR) = 3.0] that was translated to numerically less events of repeat procedures (target lesion revascularization) [72]. However, this difference did not reach statistical significance, and therefore, primary nitinol stent placement in the femoropopliteal arteries remains controversial [54, 55, 72]. Published data on femoropopliteal outcomes with DES use is limited to the SIROCCO, STRIDES, and ZILVER-PTX. The SIROCCO trial randomized sirolimus-eluting versus bare nitinol stents in the femoropopliteal artery and failed to show any discernible difference up to 2-year follow-up despite an initial promising early 6-month difference [73]. The ZILVER-PTX trial evaluated paclitaxel-eluting stents for femoropopliteal lesions above-the-knee and demonstrated a significantly improved primary patency and event-free survival at 1 year in favour of the paclitaxel-eluting stent arm on the as-treated data analysis [8].

**Table 6** Systematic review of femoropopliteal outcomes

| Recanalization technology | Lesion length (range, cm) | Technical success [%; (95 % CI)] | Primary patency at 1 year [%; (95 % CI)] |
|---|---|---|---|
| Balloon angioplasty | 5–12 | 69 (59–78) | 57 (42–71) |
| Drug-coated balloons | 5–8 | | 81 (67–91)[a] |
| Nitinol stents | 5–18 | 94 (91–97) | 66 (60–72) |
| Drug-eluting stents | 5–10 | | 83 (77–90) |
| Covered stents | 11–26 | | 68 (60–75) |

Pooled analysis of control and treatment arms of major randomized trials, major single-arm, prospective studies and large ($n > 50$ limbs) cohort studies (ABSOLUTE, FAST, RESILIENT, ASTRON, SIROCCO, STRIDES, ZILVER-PTX, THUNDER, FEMPAC, LEVANT I, PACIFIER, VIABAHN and VIBRANT trials). Pooled proportional outcomes were calculated with a random effects (DerSimonian-Laird) meta-analytic model

[a] Reported primary patency rates are at 1 year with the exception of drug-coated balloons (6-month outcomes) and are based on the 50 or 70 % restenosis threshold evaluable with either Duplex Ultrasound (DU) or Quantitative Vascular Angiography (QVA)

Studies of PTFE-lined covered stents have demonstrated comparable patency rates with femoropopliteal synthetic bypass surgery (Dacron or PTFE) over 12, 24 months, and 4 years [44]. According to a multicentre RCT comparing covered nitinol stents with standard balloon angioplasty in the superficial femoral artery, primary patency was higher in the VIABAHN group (risk ratio 0.6), but TLR events were similar in the two arms at 1 year [10]. Paclitaxel-coated balloons have shown significant inhibition of NIH as expressed by a marked reduction of late lumen loss at 6-month angiographic follow-up (weighted mean difference −0.75 mm). A meta-analysis of head-to-head RCTs of paclitaxel-coated balloons (THUNDER, FEMPAC, LEVANT I & PACIFIER) with standard uncoated balloon angioplasty have shown a significant reduction of angiographic binary restenosis (OR = 0.26) and target lesion revascularization (OR = 0.22) at 6 months [7]. Balloon cryoplasty seems to have limited effectiveness [74, 75]. Of note, there is limited cost-utility or cost-effectiveness data about any of the previously mentioned techniques in the femoropopliteal artery. Outcomes of different technologies are outlined in Table 6.

## Complications

A prospective audit of more than a thousand peripheral angioplasty procedures on both claudicants and critical

**Table 7** Complications (up to 30 days) [6, 66, 76, 81]

| Type | Incidence (%) | Treatment |
|---|---|---|
| Death | 0–1.0 % | n/a up to 1 % in critical limb ischemia |
| Death or major adverse event or open surgical repair | <3.5 % | Conservative, open surgery, ITU support |
| Major amputation | 0.6–2.2 % | Rehabilitation 2.2 % in case of critical limb ischemia |
| Contrast allergy | <0.1 % | Supportive measures/ advanced life support anaphylaxis protocol |
| Contrast-induced nephropathy | 2–20 % | Pre- and post-hydration, *N*-acetylcysteine |
| Arterial access complications (total) | 2.3–33 % | Conservative or surgical |
| Groin hematoma | 1–10 % | Conservative measures—surgical decompression |
| Retroperitoneal bleeding | <1 % | Transcatheter embolization—covered stent—laparotomy |
| Arteriovenous fistulae | 0–0.7 % | Surgical correction—transcatheter embolization |
| Pseudoaneurysm formation | 0.2–2 % | Manual compression—thrombin injection—covered stent—open surgery |
| Arterial rupture/ perforation | Variable (technique-dependent) | Prolonged balloon inflation—covered stent—bypass surgery |
| Acute thrombosis/ dissection | <1 % | Local thrombolysis—thrombectomy—stent placement—bypass surgery |
| Distal thromboembolism | 1.6–2.4 % (3.8–24 % in case of thrombolysis) | Catheter aspiration—thrombosuction—mechanical thrombectomy—catheter-directed thrombolysis |
| Vessel spasm | <10 % | Intra-arterial nitrates |
| Post-implantation syndrome | Unknown | Conservative measures |
| Stent-related infection | Very rare | Antibiotics—device explantation |
| Device-related allergy or hypersensitivity | Very rare | Conservative measures—device explantation |

ischemic patients reported a major medical morbidity event rate of 2.4 %, an amputation rate of 0.6–2.2 %, and a combined overall risk of death, major adverse event, or open surgical repair of 3.5 % within the peri-procedure 1-month interval [76]. The reported rates of complications and death depend on the baseline symptoms; around 0.5 and 0.2 %, respectively, in the case of claudicants compared with up to 6.7 and 3.2 % in the case of CLI patients [77]. Vessel-related complications in case of femoropopliteal interventions is around the level of 5 % both in case of balloon angioplasty (weighted average 4.3 %, range 2.4–6.3 %) and stenting (weighted average 7.3 %, range 0.0–17.0 %) [6, 78]. Total reported access-related complication rates, including but not limited to groin hematoma, pseudoaneurysm, and fistula formation, are variable; a systematic review of controlled trials on vascular closure devices reported a wide range of 2.3–33 %. Use of vascular closure devices achieved a shorter time to haemostasis but was related to similar total access complication rates, e.g., 3.2–35 % [66]. A detailed list of procedure-related complications relevant to the field of peripheral femoropopliteal interventions is outlined in Table 7.

## Conclusions

An endovascular-first approach is recommended in the majority of femoropopliteal stenoses or occlusions, although vein bypass surgery still has a role in case of long or heavily calcified CTO and in patients with a favourable life-expectancy. Intraluminal or subintimal recanalization techniques may be used based on operator preference and experience. Randomized, controlled trials have also shown marginally increased primary patency rates following primary nitinol stent placement. Evidence about the use of DES has been conflicting, although they do seem to decrease the rate of repeat procedures compared with plain balloon angioplasty. Covered stents inhibit neointimal ingrowth and seem to perform similar to nitinol stents. Paclitaxel-coated balloons have been show to outperform balloon angioplasty in several, randomized, controlled trials, but long-term evidence is still missing. Unmet needs for treatment include in-stent restenosis and the implantable foreign material if stenting is performed. Bioabsorbable vascular scaffolds may address the latter in the future. All patients should receive at least single antiplatelet therapy following a successful endovascular procedure. Overall, this is a rapidly evolving field with several ongoing studies, and operators need to remain up to date with the literature.

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