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Percutaneous common femoral artery interventions using angioplasty, atherectomy, and stenting

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Background: **This study evaluated the feasibility, safety, and effectiveness of endovascular interventions for common femoral artery (CFA) occlusive disease.**
Methods: **Using a prospectively maintained multicenter database, we analyzed outcomes in 167 consecutive patients who underwent percutaneous CFA interventions for Rutherford class 3 to class 6 (R3-R6) disease. The standardized treatment approach included primary percutaneous transluminal angioplasty (PTA) only, atherectomy + PTA, and provisional stenting. Outcomes included technical failure rate, recurrence, complications, and major or minor amputation rate. Data were analyzed using multivariate regression analysis.**
Results: **During a 7-year period, 167 patients with R3 (n = 91 [54.5%]) and R4 to R6 (n = 76 [45.5%]) disease underwent CFA interventions that included PTA only (n = 114 [68.2%]), atherectomy ± PTA (n = 38 [22.8%]), and provisional stenting (n = 15 [9.0%]) for failed atherectomy ± PTA. Procedure-related complications included pseudoaneurysm (n = 1 [0.6%]), thrombosis (n = 1 [0.6%]), distal embolization (n = 1 [0.6%]), and death (R6, n = 1 [0.06%]). CFA restenosis was observed in 34 (20.4%) patents; these underwent further percutaneous (n = 18 [10.8%]) or surgical (n = 17 [10.2%]) revascularization that included CFA endarterectomy ± femoral distal bypass. Major or minor amputations were observed in none of the R3 patients and in only three (3.9%) and five (6.5%) of the R4 to R6 patients, respectively. Compared with the atherectomy + PTA group, patients in the PTA-only group had a significantly lower patency. Furthermore, during long-term mean follow-up of 42.5 months, the CFA provisional stent group had a 100% primary patency, which was significantly better than the primary patency in the CFA nonstent groups combined (77.0%; *P* = .0424).**
Conclusions: **Data from this study to date would suggest that percutaneous CFA interventions in select patients are relatively safe and effective. In the long term, CFA stenting has significantly better primary patency than CFA atherectomy and PTA combined. CFA atherectomy + PTA has significantly better primary patency than CFA PTA-only at midterm, especially in patients with claudication. Future randomized controlled trials are warranted. (J Vasc Surg 2016;64:369-79.)**

The "gold standard" for common femoral artery (CFA) occlusive disease remains surgical endarterectomy with or without patch angioplasty. Although data are limited, several studies indicate that common femoral endarterectomy with or without patch angioplasty has a 5-year patency >90%, with an incidence of postoperative complications, including wound infection, hematoma, and lymph leaks, of approximately 17%.[1-7]

The perceived benefits of an endovascular approach are lower procedure-related morbidity and mortality. This has prompted us to investigate its role in symptomatic CFA occlusive lesions. Emerging literature has described endovascular treatments of CFA occlusive disease with variable results that suggest the patency of CFA angioplasty with provisional stenting to range between 60% and 90% at 1 to 2 years.[8-15] As new techniques and devices are introduced, their safety and validity also need to be evaluated. Although atherectomy has been well studied in the superficial femoral, popliteal, and tibial territories, its role in managing CFA occlusive disease remains poorly defined. Our initial endovascular CFA intervention experience started in only high-risk patients with morbid obesity, multiple prior CFA open interventions, or severe cardiac or pulmonary risk. With initial success, our experience increased gradually to include appropriately selected lower risk patients.

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The purpose of this study was to evaluate the feasibility, safety, and effectiveness of percutaneous transluminal angioplasty (PTA) with provisional stenting vs atherectomy for CFA occlusive disease.

METHODS

Between July 1, 2006, and December 31, 2013, there were 167 consecutive patients who underwent percutaneous CFA interventions for Rutherford class 3 to class 6 (R3-R6) disease, either as an isolated procedure or as part of endovascular treatments in series for additional ipsilateral limb lesions. This was a longitudinal intention-to-treat study; all data were prospectively collected and maintained and retrospectively evaluated. Initially, CFA interventions were performed only in high-risk patients. As our experience grew, the procedure was used in a preferential fashion by experienced providers. Common femoral angioplasty was performed since 2006. Atherectomy was introduced as a treatment option in 2010.

Data were entered in a prospectively maintained database. Risk factors including hypertension, American Society of Anesthesiologists class, vessel lesion length, diabetes, coronary artery disease, tobacco abuse, chronic obstructive pulmonary disease, renal insufficiency, and dyslipidemia were analyzed. The standardized treatment choices included primary PTA only, atherectomy + PTA, and provisional stenting. The treatment modality was at the discretion of the vascular surgeon or interventionist. In general, if the initial CFA lumen was assessed to be >5 mm, patients primarily underwent PTA with provisional stenting, and atherectomy was reserved as a plaque debulking procedure for select patients with critical CFA stenosis or occlusion. Institutional Review Board expedited review category 5 with waiver from the requirement to obtain informed consent (CRF 45.46.116 (d)) request was submitted and approval obtained.

Procedure steps. Access was obtained from the contralateral femoral artery. After diagnostic arteriography, a 5F to 7F sheath was advanced from the contralateral iliac artery across the aortic bifurcation and then in an antegrade fashion into the ipsilateral external iliac artery. In treating isolated CFA lesions, wire access was obtained across the CFA and into the superficial femoral artery (SFA); whereas in patients with SFA occlusion, wire access was obtained across the CFA and into the profunda femoris artery (PFA). In patients with complex CFA disease that extended into the SFA and PFA, a buddy wire system was used across the CFA with distal wire placement into the SFA and PFA; in such cases, kissing balloon angioplasty of CFA, SFA, and PFA was performed with balloons appropriately sized to match the caliber of the nondiseased SFA and PFA. Balloons used for PTA were not drug coated and were inflated to reach nominal pressures.

In patients with 50% to 79% CFA stenosis, the initial treatment included balloon angioplasty with provisional stenting; whereas in patients with 80% to 99% CFA stenosis and complete occlusion, the preferred treatment was atherectomy and balloon angioplasty. All lesion characteristics were defined by arteriography, and any lesion with >30% residual stenosis was identified as procedure-related technical failure. The bare-metal stent diameters ranged between 3 and 4 cm in length; they were self-expanding, appropriately sized to the CFA, and placed from distalmost external iliac artery to distalmost CFA.

When atherectomy was performed, Jetstream/Pathway atherectomy (Boston Scientific, Marlborough, Mass) devices were used. Multiple passes of the device were used to achieve a residual diameter stenosis of <30%. Disease extending into the proximal SFA or PFA was also treated at the time of the intervention. Distal embolic protection devices were not used in any of the cases. All patients were systemically anticoagulated during the procedure with intravenous heparin to achieve activated clotting times >275 seconds. After the procedure, patients were discharged home on a 3-month course of antiplatelet agents (aspirin ± clopidogrel).

Patients were divided into two major groups, a claudication group (R3) and a critical limb ischemia (CLI) group (R4-R6). Patients were routinely followed up at 2 weeks after the procedure and subsequently at 6-month intervals. Postprocedure follow-up included clinical examination, pulse volume recordings, and duplex ultrasound. The end point of the study included primary patency, procedure-related complications, and major or minor amputations. Loss of primary patency was defined as peak systolic velocity ratio of >2.0, indicating a >50% vessel restenosis, or recurrence of symptoms. Multivariate regression analysis was used in statistical analysis comparing different treatments within respective groups.

Kaplan-Meier analysis was used to illustrate intervention patency between PTA-only and atherectomy + PTA treatments and intervention patency between claudication and CLI treatments. A log-rank test was used to calculate statistical significance between treatment arms. The one-way analysis of variance test was used to calculate statistical significance of runoff status and lesion stenosis, followed by Tukey test to compare specific arms of the study. *Z* test and Fisher exact test were used to compare proportional differences of patients undergoing concurrent SFA and PFA lesion treatment.

RESULTS

There were 167 patients who underwent percutaneous endovascular CFA interventions. Patient demographics were consistent with what is expected in peripheral arterial disease patients and are shown in Table I. There were 11 providers performing procedures in 7 facilities. More than 75% (127/167) of the procedures were performed by two surgeons.

Within the entire cohort, 55% (91/167) presented with claudication (R3), and the remaining 45% (76/167) had CLI (R4-R6). Of all patients, 114 (68%) patients underwent PTA only, 38 (23%) patients underwent atherectomy + PTA, and 15 (9%) patients had provisional stenting. A breakdown of Rutherford stages in patients and their corresponding interventions is shown in Table II.