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ORIGINAL ARTICLE

Clinical outcomes of high-pressure balloon angioplasty for common femoral artery disease in contemporary practice

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Abstract

In recent years, improvements in endovascular equipment and the technical skills of operators have led to an increasing number of percutaneous common femoral artery (CFA) interventions. However, there are few reports of the detailed treatment strategy for CFA intervention and its subsequent clinical outcomes. We evaluated the safety and efficacy of endovascular therapy (EVT) with a high-pressure balloon for CFA disease. Fifty-five consecutive patients (59 lesions) who underwent EVT with high-pressure ballooning were analyzed retrospectively. The primary endpoint was clinically driven target lesion revascularization (TLR). The median follow-up was 34.0 months. The mean age was 68.0 ± 10.1 years, and 70.1% were men. The procedural success rate was 98.3%. All patients underwent high-pressure balloon angioplasty (mean pressure 17.7 atm). Clinically driven TLR-free rates at 2, 3, and 4 years were 88.7%, 77.9%, and 74.2%, respectively. Endovascular interventions with high-pressure ballooning for CFA showed an acceptable mid-term freedom rate from TLR.

Keywords Endovascular therapy · Common femoral artery · Target lesion · Revascularization

Introduction

Endovascular therapy has emerged as the first-line treatment for most patients with claudication and critical limb ischemia (CLI), and it has gained widespread acceptance among vascular physicians and patients because of its minimal invasiveness [1]. Common femoral artery (CFA) disease remains mainly a surgical domain because of its easy accessibility and favorable long-term outcomes [2, 3]. Primary patency rates of endarterectomy for CFA lesions have been reported to be as high as 96% after up to 7 years, and major complications such as infections, hematoma, seroma, and lymphatic leaks may occur in up to 17.1% of cases [4, 5].

Recently, improvements in endovascular equipment and the technical skills of operators have led to an increasing number of percutaneous CFA interventions [6]. This is primarily the result of a favorable periprocedural risk profile compared with open surgery, and numerous reports have demonstrated less perioperative mortality and morbidity and shorter lengths of hospital stay. However, studies reporting clinical outcomes after endovascular CFA revascularization are limited to a few outdated and small single-center studies. Moreover, there are few reports regarding the detailed treatment strategy for CFA intervention and its subsequent clinical outcomes. Therefore, the purpose of the present study was to evaluate the safety and efficacy of endovascular therapy (EVT) for CFA disease with high-pressure ballooning.

Methods

Study design and patient population

We retrospectively enrolled consecutive patients who underwent percutaneous intervention for de novo CFA lesion between December 2008 and November 2016 at Tokyo Women's Medical University Hospital in Tokyo, Japan. A total of 55 consecutive patients who underwent EVT were examined (Fig. 1). In our hospital, the optimal treatment strategy for CFA lesions is routinely discussed within the heart team, consisting of cardiovascular interventionists and surgeons. EVT is generally selected as the first-line treatment for CFA lesions, if possible; endarterectomy is chosen only when we cannot perform EVT because of problems

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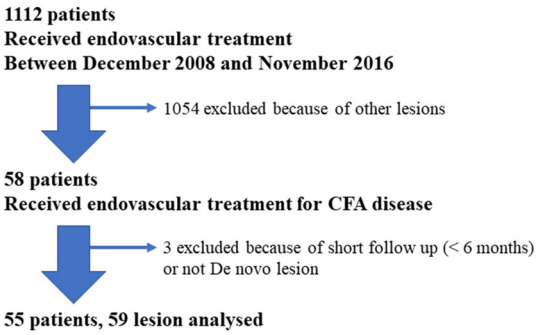

Fig. 1 Participant flow. *CFA* common femoral artery

with vascular access (for example, in cases of bilateral CFA occlusion) or when restenosis occurred repeatedly. Three cases of endarterectomies were performed during the study period. Indications for intervention were the presence of a significant and symptomatic atherosclerotic occlusive lesion (Rutherford category: 2, 3, 4, 5, and 6) of the CFA, angiographic stenosis more than 90%, or more than 50% stenosis with pressure gradient above 20 mmHg. We evaluated pressure gradient using pressure wire or extraction with 4-Fr JR diagnostic catheter in intermediate stenotic cases. Bifurcated lesions of the CFA were classified according to the Medina classification [6]. Patients who were lost to follow-up within 6 months were excluded.

The study protocol was based on the regulations of the hospital's ethics committee. All participating patients provided written informed consent. Patient enrollment was performed according to the principles of the Declaration of Helsinki.

Endovascular procedures

Our EVT strategy for CFA lesions had four steps. First, we expanded the lesions with "high-pressure" as much as possible, up to the rated pressure or highest pressure when patients claimed severe vascular pain, using a noncompliant balloon. Second, if the CFA lesion was heavily calcified, we used the Crosser system, a recanalization device for high-frequency mechanical vibration, for cases after 2013. Until then, we used only non-compliant balloons and did not use either cutting balloons or scoring balloons. Third, we chose an adequate intraplaque route, not subintimal tracking, for occlusive CFA lesions with biplane cine angiography. Fourth, we set the clear endpoint of EVT as less than 5 mmHg of the pressure gradient after angioplasty. The residual pressure gradient was evaluated by measuring the extraction with 4-Fr JR diagnostic catheter in all cases. When there were suboptimal angiographic results, repeated inflations were performed at the discretion of the attending physician to achieve residual stenosis less than 50% and an optimized residual pressure gradient less than 5 mmHg. We used a stent only when flow-limiting dissection occurred after balloon angioplasty. We treated patients involving the deep femoral artery (DFA) simultaneously with the kissing balloon technique only when CFA lesions occurred within DFA lesions, except for cases involving occlusive DFA. After the procedures, we evaluated the presence of distal embolization by angiography in all cases. All procedures were performed in the catheter laboratory using local anesthesia.

Endpoint and definitions

Technical success was defined as successful vascular access, completion of the endovascular procedure, and immediate morphologic success with less than 50% residual diameter reduction and less than 5 mmHg residual pressure gradient of the treated lesion according to angiography. Procedural success was defined as a combination of technical success and the absence of procedural complications during the 30 days after the procedure.

The primary endpoint was clinically driven target lesion revascularization (TLR) for CFA, either percutaneous or surgical. We also examined the ankle–brachial index (ABI) and Rutherford category class before and after the procedures. The timing of evaluation of ABI and Rutherford category after the procedure was at the patients' first visit (1 month after the procedure) to our hospital. In cases where the patients were hospitalized for more than a month, evaluation was performed at 1 month after EVT.

Statistical analysis

The cumulative incidence rate of TLR was analyzed based on time to the first adverse event and estimated using the Kaplan–Meier method with the log-rank test. A two-sided $p < 0.05$ was considered statistically significant. Statistical analyses were performed by an independent physician using statistical software (JMP 11; SAS Institute Inc., Cary, NC, USA).

Results

During the study period, 61 consecutive patients underwent 65 percutaneous CFA interventions. A total of six patients (six lesions) were excluded from the analysis because the follow-up period was less than 6 months. Of the remaining 55 patients with a significant (> 70%) CFA lesion, 3 (5.5%) presented with bilateral CFA stenosis (59 total 59). Baseline patient characteristics, lesion characteristics, and procedural parameters and techniques are reported in Tables 1 and 2. The 55 patients who underwent EVT were aged between 43

Table 1 Baseline characteristics of patients

Covariates	CFA interventions ($N=55$) No. (%) or mean ± SD
Age (year)	68 ± 10.8
Male (%)	39 (70.9)
BMI	23 ± 3.6
Prior PCI (%)	17 (30.9)
Prior CABG (%)	9 (16.3)
Prior any EVT (%)	16 (29)
Prior MI (%)	11 (22)
Prior CVD (%)	6 (10.9)
CKD stage ≤ 3 (%)	32 (58.2)
Hemodialysis (%)	28 (50.9)
Diabetes mellitus (%)	31 (56.4)
Insulin-treated (%)	14 (25.5)
Hypertension (%)	47 (85.5)
Hyperlipidemia (%)	30 (54.5)
ABI	0.66 ± 0.2
Smoking	
Current smoker (%)	28 (9.1)
Ex-smoker (%)	28 (50.9)
Rutherford	
2 (%)	16 (29.1)
3 (%)	25 (25.5)
4 (%)	4 (7.3)
5 (%)	14 (25.5)
6 (%)	0

Values are shown as mean ± SD or number (%)

CFA common femoral artery, *BMI* body mass index, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass grafting, *EVT* endovascular therapy, *MI* myocardial infarction, *CVD* cerebrovascular disease, *CKD* chronic kidney disease, *ABI* ankle–brachial index

and 90 years (mean age 68.0 ± 10.8 years). The prevalence of diabetes mellitus was 56.4%, and 50.9% of all patients underwent dialysis.

Indications included 41 limbs (69.5%) with claudication and 18 with critical limb ischemia (CLI) (30.5%). There were 56 de novo lesions (94.9%) and 3 cases of restenosis (5.1%). There were 14 occlusions (23.7%). The mean balloon pressure was 17.7 ± 4.1 mmHg. The mean balloon size was 6.7 ± 1.1 mm. We polished calcifications with a crosser in eight cases (13.6%). Stenting was performed in two cases when large dissection occurred after balloon angioplasty. In these two cases, we used self-expanding stents.

The technical success rate was 100%, and the procedural success rate was 98.3%. For one case, we placed the stent the day after performing EVT with balloon dilatation for subacute occlusion. In that case, the superficial femoral artery was occluded and there was poor runoff. The final follow-up was performed in January 2017, and the median follow-up period was 34 months (interquartile range 25th percentile = 18 months; 75th percentile = 56 months). Table 3 shows clinical and procedural outcomes as well as

Table 2 Lesion characteristics and procedural details

Covariates	CFA interventions ($N=59$) No. (%) or mean ± SD
Chronic total occlusion (%)	14 (23.7)
Bifurcation lesion (%)	22 (40)
Medina	
1–0–0	37 (62.7)
1–0–1	7 (11.9)
1–1–0	6 (10.2)
1–1–1	9 (15.3)
Isolated CFA lesion (%)	24 (40.6)
CFA + ≥ 1 other vascular intervention	35 (59.3)
CFA + suprainguinal intervention	7 (11.9)
CFA + infrainguinal intervention	21 (35.6)
CFA + supra and infrainguinal intervention	7 (11.9)
Noncompliant balloon use (%)	39 (66.1)
Scoring balloon use (%)	0 (0)
Stent use (%)	2 (0.8)
Vessel diameters of CFA (mm)	8.1 ± 1.4
Balloon size (mm)	6.7 ± 1.1
Balloon pressure (atm)	17.7 ± 4.1

Values are shown by mean ± SD or number (%)

CFA common femoral artery

Table 3 Clinical and procedural outcomes

Covariates	CFA interventions ($N=59$) No. (%) or mean ± SD
Technical success (%)	59 (100)
Procedural success (%)	58 (98.3)
Periprocedural complications (%)	1 (1.7)
TLR	12 (20.3)
Percutaneous (%)	12 (20.3)
Surgical (%)	0 (0)
Postprocedural ABI	0.94 ± 0.18
Unexpected minor amputation (%)	3 (5.1)
Unexpected major amputation (%)	3 (5.1)
All-cause death (%)	6 (10.2)

Values are mean ± SD or number (%)

TLR target lesion revascularization, *ABI* ankle–brachial index

clinically driven TLR rates at follow-up. After EVT, ABI improved from 0.66 ± 0.2 to 0.94 ± 0.18 ($p < 0.0001$) and 49 patients (89.1%) showed improvement of at least one Rutherford category.

Figure 2 shows the Kaplan–Meier curves of freedom from the clinically driven TLR. Rates of freedom from clinically driven TLR at 2, 3, and 4 years were 88.7%, 77.9%, and 74.2%, respectively. Additionally, we analyzed only isolated CFA lesion cases ($n = 24$) to eliminate the effects of other lesions; the rates of freedom from clinically driven TLR at 2, 3, and 4 years were 95.8%, 81.3%, and 81.3%, respectively. For all cases of clinically driven TLR, we performed EVT again. The mortality rate during follow-up was 1.6% ($n = 6$).

Discussion

The primary findings of the present study were that percutaneous CFA intervention with high-pressure balloon dilatation is associated with a high success rate (98.3%) and low complication rate, and that clinically driven TLR rates at 2, 3, and 4 years were 11.3%, 22.1%, and 25.8%, respectively.

To date, there were some reports in terms of EVT for CFA lesions. Our results are better than those of these studies with respect to periprocedural and long-term outcomes [6–9]. The lower rate of TLR in our series than in other series might be explained by our use of high-pressure balloon dilatation. In previous studies of CFA intervention, balloon diameter and balloon expansion pressure were not described. In general, physicians performed EVT with a smaller balloon compared with the target vessel diameter and expanded the balloon with relatively low pressure to avoid large dissection, especially in cases in which stent use

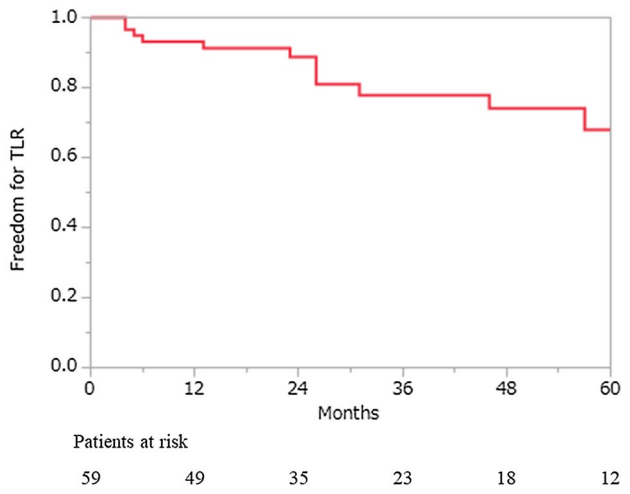

Fig. 2 Kaplan–Meier estimates of freedom from clinically driven TLR over time. Clinically driven TLR-free rates at 2, 3, and 4 years were 88.7%, 77.9%, and 74.2%, respectively

was avoided. In our study, based on our concept of using higher pressure as much as possible, the mean balloon diameter was 6.7 ± 1.1 mm, and the mean expansion pressure was 17.7 ± 4.1 atm.

Previous studies on CFA intervention have reported that the reference vessel diameter for CFA was 6.3 ± 0.7 mm [8] and 6.61 ± 1.21 mm [7]. It seems that these diameters were calculated based on the inner diameter of the reference vessel. In our study, the reference vessel diameter for CFA was 8.1 ± 1.4 mm. This larger diameter size was because we measured the vessel diameter of the CFA with QVA using the shadow of calcification as a marker. Our data were not substantially different from that of previous studies that measured the vessel diameter of the CFA via ultrasonic examination [10]. Because we determined the balloon size based on the vessel diameter of the CFA without concern regarding the creation of large dissections, we used relatively larger balloon sizes than those previously reported. Consequently, we did not experience large dissociations as much. There were no data regarding the relationship between balloon size and patency in the field of EVT. However, our balloon expansion strategy consisting of a large balloon and high-pressure could result in larger luminal diameters during the acute phase and might result in good patency rates.

There were some studies on CFA stenting. Although some studies have reported good results, CFA stenting is still controversial because the number of studies is limited, and stent fracture or puncture site problems were unclear [11, 12]. In our study, stents were used only for two cases as a bailout procedure.

Regarding the surgical treatment for CFA disease, many studies have showed better long-term patency compared with EVT [13]. The patency rates in these studies were better than those of our current study. However, several complications of CFA surgery have been reported. Perioperative minor complications after CFA surgery were reported to occur in 6.6–17.7% of cases [4, 5]. Rates of major complications subsequent to surgical CFA revascularization requiring surgical reintervention have been reported to range from 0 to 1.8% [4, 5].

Endarterectomy of CFA lesions also has some complications, such as lymphatic leakage and local infection. In our study, there were no large hematomas requiring blood transfusions or infections associated with the procedure; these are some of the major advantages of EVT.

Study limitations

Our study had several limitations. First, this study was a retrospective analysis of an observational cohort. Because of the absence of a surgical (endarterectomy) control group, we could not directly compare the safety and efficacy of EVT and endarterectomy. Second, there was no systematically

collected information regarding arterial patency determined by duplex sonography or angiography because those were not mandatory. Third, our study population included only Japanese individuals, which could affect the generalizability of our findings to non-Japanese patients. Fourth, the pressure gradient measured using the 4-Fr diagnostic catheter just before interventions potentially overestimated the lesion severity. Fifth, this study included both isolated CFA lesions and non-isolated CFA lesions. This might have affected the rate of clinical driven TLR, especially in cases including inflow disease. Accordingly, our present results need to be interpreted with caution. Further large scale, prospective study including only isolated CFA lesions would be warranted.

Conclusion

Endovascular interventions with high-pressure ballooning for CFA showed an acceptable mid-term freedom rate from TLR.

Compliance with ethical standards

Conflict of interest This study was not financially supported by any company, grant, or fund. The authors declare that they have no conflict of interest.

Research involving human participants and/or animals The study protocol was based on the regulations of the hospital's ethics committee. Patient enrollment was performed according to the principles of the Declaration of Helsinki.

Informed consent All participating patients provided written informed consent.

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