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Usefulness of intraopertive ultrasonography during directional atherectomy using SilverHawk/TurboHawk system

Yoong-Seok Park, Seon-Hee Heo, Dong-Ho Hyun[1], Young-Soo Do[1], Hong-Suk Park[1], Kwang-Bo Park[1], Young-Wook Kim, Yang-Jin Park, Chul-Hyung Lee, Dong-Ik Kim

Division of Vascular Surgery, [1]Department of Radiology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

Purpose: Directional atherectomy (DA) was introduced for the management of infrainguinal arterial stenosis or occlusive lesions. The procedure success rate in the DEFINITIVE LE study was determined using radiologic imaging. The aim of our study was to determine the usefulness of intraoperative ultrasonography (USG) during DA for evaluating the early results of this procedure.
Methods: Patients who underwent DA from January to December 2014 were reviewed retrospectively. Twenty lesions from 14 patients with femoral artery stenosis (>70% stenosis) with short segment occlusive lesions (<2 cm in length) were treated. Among 20 lesions, 3 were treated with the TurboHawk system with a protective device due to lesion calcification. The percentage of stenosis during and after DA was determined with USG.
Results: Median follow-up was 5.1 months, and the procedural success rate (<30% stenosis at the end of the procedure) was 100% on angiography, but only 30% on intraoperative USG. On USG, median residual stenosis was 40% (range, 28%–42%) at the end of DA, 40% (range, 30%–55%) at 1 month, 55% (range, 35%–85%) at 6 months, and 64% (range, 60%–100%) at 1 year. There was one dissection, but no cases of perforation, pseudoaneurysm, or thrombosis. Primary patency, which was defined as a peak systolic velocity ratio ≤3.5 with no reintervention at 6 months, was found in 18 lesions (90%), and 11 of 14 patients (78.6%) were free of ischemic symptoms such as claudication at 6 months.
Conclusion: Our results demonstrated that DA with intraoperative USG is an effective treatment option for short segment occlusive lesions of the femoral artery.
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Key Words: Silverhawk, Turbohawk, Atherectomy, Ultrasonography

INTRODUCTION

Endovascular treatment has evolved from Charles Dotter's use of coaxial "pencil-point" dilators to treat superficial femoral artery (SFA) stenosis in 1964 [1]. Revascularization via endovascular treatment is widely used in the cardiovascular field. To correct stenosis or occlusive arterial lesions, new technologies such as excimer laser and rotational and excisional atherectomy have been introduced [2]. Among these debulking technologies, excisional or directional atherectomy (DA) showed better results than other angioplasty methods in the DEFINITIVE LE study [3].

Endovascular treatment via radiologic imaging has weaknesses due to the use of 2-dimensional (2D) image. DA is a tech-

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Corresponding Author: Dong-Ik Kim
Division of Vascular Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul 06351, Korea
Tel: +82-2-3410-3467, **Fax:** +82-2-3410-0040
E-mail: dikim@skku.edu

nology for removing atheroma from within the lumen. Thus, the results of DA are related to 3-dimensional (3D) structures. Optical coherence tomography (OCT) and intravascular ultrasound (IVUS) are good options for analysis of 3D intraluminal vascular structures. However, OCT and IVUS are not yet widely used.

Ultrasonography (USG) is a popular and easy-to-use method that is a good option for visualizing 3D intraluminal vascular structures. The aim of our study was to determine the usefulness of intraoperative USG during DA and to evaluate the early results of DA using the Silverhawk/Turbohawk System.

METHODS

Patients

This retrospective study was designed to determine the usefulness of USG during DA for patients with femoral artery stenosis at our hospital from January to December 2014.

The indications for this procedure were femoral artery stenosis, greater than 70% stenosis, and less than 2-cm lesion length. Stenotic lesions without calcification were treated with a SilverHawk device, and calcified stenotic lesions were treated with a TurboHawk atherectomy device (Covidien, Mansfield, MA, USA). Computed tomography angiography and USG were performed routinely for preinterventional planning.

Retrospective data collection and analysis were approved by the Institutional Review Board of Samsung Medical Center (IRB No. 2015-07-010).

Procedure

Percutaneous femoral arterial puncture was performed with a retrograde or antegrade approach for the DA procedure. A 7-F or 8-F sheath was introduced depending on the size of the DA device. Lesions of the stenotic artery were passed using a 0.035-inch angled hydrophilic and 0.014-inch guidewire. The Silverhawk atherectomy device is composed of a monorail-guided catheter using a high-speed cutting blade. The cutting blade was placed in close apposition to the atherosclerotic plaque using a hinge system and was advanced through the lesion to excise the plaque. The device can be rotated 360 degrees to position the cutting blade toward the plaque within the artery. The hinged nose cone located distal to the cutting blade acts as a container for collecting atherosclerotic debris. If a calcified lesion was present, the SpiderFX embolic protection device (Covidien) was used to prevent distal embolization.

Residual luminal stenosis was determined at the end of the DA procedure using digital subtraction angiography and USG (Fig. 1). We did not use any closure devices at the arterial puncture site. All patients were heparinized during the procedure using intravenous injection of unfractionated heparin (50 IU/kg of body weight), and all patients were medicated with an antiplatelet agent during the follow-up period.

Evaluation of outcome

Technical success was defined as less than 30% residual stenosis according to angiographic findings and USG. Primary patency was defined as no restenosis and a peak systolic velocity ratio (PSVR) less than 3.5 on USG. USG was performed 1 day, 1 month, 6 months, and 1 year after DA.

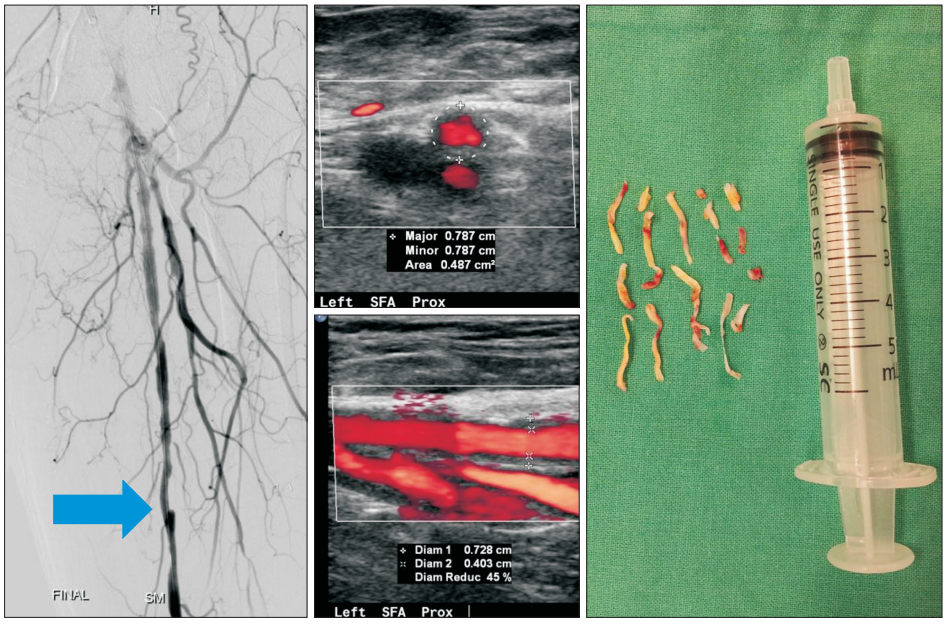

Fig. 1. Evaluation of residual luminal stenosis at the end of procedure and specimen of directional atherectomy. Arrow indicated the lesion of directional atherectomy.

RESULTS

There were 20 lesions from 14 patients who were treated with DA using the SilverHawk or TurboHawk atherectomy devices. All of the patients were male, and the median age was 68.5 years (range, 56–86 years). There were 2 patients with a history of balloon angioplasty in the femoral artery (Table 1). Seventeen cases of noncalcified stenosis were treated with the SilverHawk device, and three calcified lesions were treated with the TurboHawk atherectomy device. There were 18 *de novo* stenosis lesions and two restenotic lesions (Table 2).

Two retrograde and 12 antegrade approaches were used for the procedure. Distal embolic protection (SpiderFX Embolic Protection Device, Covidien) was used for three lesions. There were no cases of pre- or postprocedural ballooning or stenting of stenotic lesions. Concomitant common femoral artery (CFA) endarterectomy was conducted in 1 patient (7.1%) during DA. There was one intima dissection that did not require adjuvant intervention, and there were no cases of perforation, pseudoaneurysm, distal embolization, or thrombotic occlusion during the DA procedure. Procedural success (<30% stenosis at the end of the procedure) was 100% according to angiographic findings, but only 30% based on USG findings (Table 3).

We analyzed the change in ankle brachial index (ABI) after the procedure. Preoperative ABI increased from 0.70 (range, 0.54–1.10) to 0.88 (range, 0.43–1.05) after the procedure. Claudication as an ischemic symptom disappeared after the procedure (Table 4).

We analyzed the change in restenosis during the follow-up period (Fig. 2). According to USG evaluation, median residual stenosis was 40% (range, 28%–42%) at the end of the DA procedure, 40% (range, 30%–55%) at 1 month, 55% (range, 35%–85%) at 6 months, and 64% (range, 60%–100%) at 1 year. One lesion showed total occlusion 10 months after DA. One lesion

Table 1. Patient demographic characteristics

Characteristic	Value
Age (yr), median (range)	68.5 (56–86)
Male sex	14 (100)
Diabetes mellitus	8 (57.1)
Hypertension	9 (64.3)
Hyperlipidemia	3 (21.4)
CAD	4 (28.6)
CABG or PCI	3/4 (75.0)
Smoking	7 (50.0)
CVA	2 (14.3)
Renal insufficiency (creatinine > 2 mg/dL)	1 (7.1)
Rutherford clinical category	
2	8 (57.2)
3	5 (35.7)
4	1 (7.1)
History of major amputation	0 (0)
History of peripheral intervention	2 (14.3)

Values are presented as number of patients (%) unless otherwise indicated.
CAD, coronary artery disease; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; CVA, cerebrovascular accident.

Table 2. Target lesion characteristics

Characteristics	No. of lesions (%)
Treated artery	
SFA	20 (100)
Calcification	
None	17 (85.0)
Present	3 (15.0)
Type of lesion	
De novo	18 (90.0)
Restenotic	2 (10.0)

SFA, superficial femoral artery.

Table 3. Procedure characteristics

Procedure	No. of patients (%)
Type of device	
SilverHawk	11 (78.6)
TurboHawk	3 (21.4)
Route	
Antegrade	12 (85.7)
Retrograde	2 (14.3)
Protection device	3 (21.4)
Preballooning	0 (0)
Postballooning	0 (0)
Poststenting	0 (0)
Adjunctive procedure	
CFA endarterectomy	1 (7.1)
Complications	
Intimal dissection	1 (7.1)
Perforation	0 (0)
Psuedoaneurysm	0 (0)
Distal embolization	0 (0)
Procedure success (<30% stenosis at end of procedure)	
According to angiography	20 (100)
According to ultrasonography	6 (30)

CFA, common femoral artery.

Table 4. ABI change with claudication

	Preoperative	Postoperative	P-value
ABI, median (range)	0.70 (0.54–1.10)	0.88 (0.43–1.05)	0.310[a]
Claudication (%)	100	0	

ABI, ankle brachial index.
[a]Wilcoxon signed rank test.

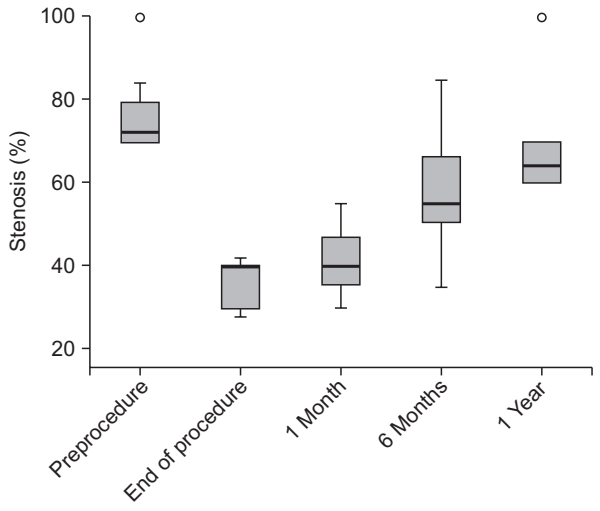

Fig. 2. Box and whisker plot showing distributions of restenosis (%) during the follow-up periods. The boxes represent the 25th to 75th percentiles, and horizontal lines within the box represent median values. The whiskers represent the lowest and highest values of all of the data, respectively. The stenosis was determined using ultrasonography.

was treated with stent insertion due to recurrent claudication related to 70% restenosis six months after DA. Primary patency (defined as PSVR ≤ 3.5 with no reintervention for target lesions at 6 months) was observed in 90.0% of patients (18 of 20), and 78.6% of patients (11 of 14) were free of ischemic symptoms such as claudication at 6 months.

DISCUSSION

DA was the debulking method used in the present study, and the SilverHawk Plaque Excision System was used as the prototype excisional atherectomy device. Zeller et al. [4] reported that 131 lesions from 84 patients with Rutherford category 2 to 5 stenosis were treated using the prototype excisional atherectomy device, and the technical success was 86%, while the primary patency rate was 53% at 12.5 months. Recently, the DEFINITIVE LE trial showed a procedural success rate of 89.1%, a device success rate of 74.9%, and a primary patency of 78% at 12 months. Periprocedural adverse events included embolization (3.8%), perforation (5.3%), dissection causing flow limitation (2.3%), abrupt closure (2.0%), and aneurysm (0.4%), and the bail-out stent rate was 3.2% [3,5].

In our study, the procedure and device success rates were 100% and the 6-month primary patency rate was 90.0% on angiography compared to the 87.6% observed in the DEFINITIVE LE study. There were no perforations, pseudoaneurysms, distal embolizations, or thrombotic occlusions in our study.

The main difference between our protocol and other protocols was the approach for determining residual stenosis at the end of the procedure. In all prior studies, residual stenosis was evaluated at the end of the DA procedure using angiographic findings. In contrast, we determined residual stenosis using both angiography and USG.

The guidelines for the SilverHawk instrument showed passage of the device through each of the 4 quadrants within the atheroma. Also, residual stenosis at the end of the DA procedure was determined based on angiography according to the guidelines. However, not all atheromas were symmetrical in shape, so the direction and number of device passages varied.

Angiography revealed only a planar 2D silhouette of the lumen, which does not provide a precise assessment of luminal narrowing. Intravascular imaging enables direct visualization of the arterial wall. Intravascular imaging modalities show more accurate diagnostic information and evaluation of plaque and vessel remodeling [6]. OCT is an evolving technology that uses near-infrared light to construct an image of the vessel wall. These methods are good tools for planning intervention strategies and angioplasty. However, IVUS is expensive and has a high rate of distal embolization [6]. OCT also requires blood to be cleared from the vessel lumen in order to acquire an image [7].

USG provides more detailed dimensional information compared to angiography. There is a distinct possibility that our good results might be related to the use of USG to determine residual stenosis at the end of the procedure compared to traditional angiography evaluation.

In our study, there was one case of CFA endarterectomy. This patient had right SFA as well as left iliac and CFA stenosis. This patient was treated via left CFA endarterectomy for the approaching vessel, left iliac stenting and right SFA DA. This is a good example of a hybrid operation strategy.

However, our study did have some limitations. First, our results were based on short-term follow-up. Second, this study enrolled only 14 patients, so additional studies with longer follow-up periods and larger populations are needed.

In conclusion, our results demonstrated that DA using the SilverHawk/TurboHawk system with intraoperative USG is an effective treatment option for short segment occlusive lesions of the femoral artery. USG appears to be a good option for evaluating 3D intraluminal vascular structures. Intraoperative USG during DA might increase the rate of procedural success and decrease the number of complications such as perforation.

CONFLICTS OF INTEREST

There are no potential conflicts of interest relevant to this article to report.

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