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Original Article

Incidence of Distal Embolization during Peripheral Intervention using the NAV-6 Embolic Protection System

Abstract

Purpose: To compare the rates of embolic debris (ED) generation during lower extremity arterial interventions and evaluate the safety and efficacy of the using an embolic protection device (EPD). **Methods:** This was a single-center retrospective review of 111 patients (114 vessels) having undergone peripheral arterial intervention with the use of an EPD (Emboshield NAV-6 device). A database was created through review of the electronic health record and images in PACS. The presence of ED was determined through visual inspection after retrieval of the device or from filling defects identified during digital subtraction angiography with the device deployed. Descriptive statistics were used to report the demographic and clinical information. Relative frequencies of debris generation were determined for vessel type, trans-atlantic inter-society consensus (TASC) classification, and type of intervention. Differences in frequencies between groups weer evaluated with the Chi-square test, and associations were examined using the logistic regression analysis. **Results:** Of the 114 vessels treated, 16 (14%) demonstrated true distal embolization (DE) past the filter basket and 58 (51%) demonstrated generation of ED as determined by filling of the filter basket. This was significantly higher in patients undergoing atherectomy (70%) compared with those undergoing thrombolysis (38%) or angioplasty with or without stenting (29%) ($P < 0.001$). Of those patients undergoing atherectomy, laser atherectomy had the lowest rate of DE (26%) compared with either orbital (67%) or directional atherectomy (57%) ($P < 0.05$). In regression analysis, atherectomy was the only factor with significant association with detection of ED (odds ratio: 4.52, $P < 0.0001$). There was no statistically significant difference in the frequency of debris generated based on vessel type or TASC classification. **Conclusion:** The frequency of ED is higher in patients undergoing atherectomy versus patients undergoing lysis or percutaneous transluminal balloon angioplasty with or without stenting. Laser atherectomy has a lower frequency of debris generation when compared to either orbital or directional atherectomy.

Keywords: *Arterial, atherectomy, distal embolization, peripheral arterial disease (PAD), peripheral*

Timothy C. Huber, Younes Jahangiri Noudeh[1], John F. Angle[2], Daniel Sheeran[2], Megan Tracci[3], Luke Wilkins[2]

Department of Interventional Radiology, Oregon Health and Science University, Portland, Oregon, [1]Dotter Institute of Interventional Radiology, Oregon Health and Science University, Departments of [2]Interventional Radiology and [3]Vascular Surgery, University Of Virginia, Charlottesville, Virginia, USA

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Address for correspondence:
Dr. Timothy C. Huber, Department of Interventional Radiology, Oregon Health and Science University, 3181 SW Sam Jackson Park Road, Portland, OR 97239, USA.
E-mail: timhuber3@gmail.com

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Introduction

Distal embolization (DE) is a risk inherent in peripheral vascular intervention. DE rates have been reported to be higher in patients with TASC D lesions and in patients undergoing thrombolysis or atherectomy.[1,2] Patients undergoing such interventions often have diseased distal vessels as well, placing them at especially high risk of critical ischemia if emboli are propagated downstream.

The showering embolic debris (ED) generated during treatment can be intercepted by embolic protection devices (EPDs) such as the Emboshield NAV-6 EPD (Abbott, Abbott Park Illinois, USA).[3] The use of these devices has been described in carotid, coronary, and renal interventions and is becoming more widely utilized in peripheral arterial interventions.[4] However, the necessity of these devices has been debated in the literature, and indications for use remain unclear.

This study evaluates the safety and efficacy of the NAV-6 EPD by determining the relative frequencies with which ED are subjectively observed after a variety of peripheral arterial interventions in different types of vessels to determine when distal protection would be most appropriate.

Methods

Study design

A retrospective study at a single academic center was performed with the institutional

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review board approval. Using the HI-IQ inventory management system (ConexSys Inc., Lincoln, RI, USA), we identified patients having undergone peripheral intervention during which an EPD was used. Between October 2010 and January 2017, we identified a total of 111 patients (114 vessels) in this manner. Demographic, clinical, and procedural information were obtained from the electronic health record (EPIC, Verona, WI, USA). Images for each case were reviewed in PACS (Carestream, Carestream Health Inc., Rochester, NY, USA). The average age of patients was 62 years (range, 36–93 years).

The generation of embolic debris (ED) was identified by visualization of debris within the NAV-6 basket on retrieval or by the presence of filling defects on digital subtraction angiography (DSA). True DE was identified as distal filling defects beyond the filter basket after treatment. Follow-up was performed in either the interventional radiology clinic or the vascular surgery clinic. The target limb revascularization (TLR), major adverse limb event (MALE), and overall survival rates were determined through follow-up visits scheduled at 2 weeks, 1 month, 3 months, 6 months, 12 months, and then yearly.

Technique

Before intervention, either computed tomography angiography or duplex ultrasound was performed to identify and evaluate the lesions for treatment. Using either ipsilateral (antegrade) or contralateral (retrograde) access, DSA was performed to confirm the lesions for treatment. The decision to use distal protection was at the discretion of the operating physician. Three physicians with an average of 6 years of experience performed these interventions. A minimum sheath size of 6 Fr was used in all cases. Intravenous heparin was administered to all patients with a goal activated clotting time >200 s. Through the sheath, an Emboshield NAV-6 EPD (2.5–4.8 or 4.0–7.0 mm with 140 micron pore size, Abbott, Abbott Park, IL, USA) was advanced over a 0.014 inch wire and placed beyond the site of intervention [Figure 1]. The chosen intervention (again at the discretion of the operating physician) was performed over the 0.014 inch wire. DSA was performed before retrieval of the EPD, following retrieval of the EPD, and at completion of the case. Visual inspection of the basket after retrieval was also performed.

Statistical analyses

Demographic, clinical, and procedural data were summarized with descriptive statistics. The relative frequencies of DE were compared using the Chi-square test. Association between the evaluated factors and detection of ED on postprocedure visual evaluation of the basket was evaluated using the univariate logistic regression analysis. Multivariate analysis was planned in case more than two factors had statistically significant associations in the univariate analysis. All analyses were performed using the R 3.3.2 (R core team, Vienna, Austria) and Stata IC version 14.2 (StataCorp LLC, College Station, Texas) statistical packages.

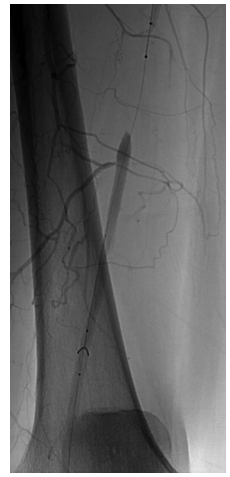

Figure 1: Digital subtraction angiogram demonstrating deployment of the NAV-6 device in the popliteal artery before intervention

Results

Descriptive data are presented in Table 1. Fifty-five native vessels were treated with an ED rate of 54%. Eleven bypass grafts were treated with an ED rate of 45%. Forty-eight vessels with existing stents in place were treated (for in-stent restenosis or thrombosis) with an ED rate of 48%. There was no statistically significant difference among the rates of ED in these groups.

Of the 114 vessels treated, ED were observed in 58 (51%), with true DE in 16 (14%). Of the 25 TASC A lesions, ED were observed in 11 (44%). Of the 27 TASC B lesions, ED were observed in 14 (52%). Of the 22 TASC C lesions, ED were observed in 9 (41%). Of the 11 TASC D lesions, ED were observed in 5 (45%). There was no statistically significant difference in the rates of debris generation based on TASC classification. There were thirty patients treated for total occlusions. Of these, 15 (50%) had filling of the EPD with debris, and 5 (17%) had embolization beyond the EPD.

The EPD was positioned in the popliteal artery in 82 (72%) vessels treated. Of these, the basket was visibly filled in 41 (50%) and there was true embolization beyond the EPD in 9 (11%). The EPD was positioned within the spectral-based fatigue analysis in 14 (13%) vessels treated. Of these, the basket was visibly filled in 10 (71%), and there was true embolization distal to the EPD in 6 (43%). The EPD was positioned in one of the runoff vessels in 7 (6%) of the vessels treated. Of these, the basket was visibly filled in 2 (29%), and there was true embolization beyond the EPD in 3 (43%).

Fifty-three vessels were treated with atherectomy. Of these, ED was observed in 53 (70%). Twenty-nine vessels were treated with tissue plasminogen activator lysis. Of these, ED was observed in 11 (38%). Forty-one vessels

Table 1: Results demonstrating the rates of debris generation based on Trans-Atlantic Inter-Society Consensus classification of the lesion, treated vessel type, and treatment

	Number of vessels	Debris observed	No debris observed	Percentage debris generated
TASC	114	58	56	51%
A	25	11	14	44%
B	27	14	13	52%
C	22	9	13	41%
D	11	5	6	45%
Other (in-stent stenosis, occlusion, and bypass graft)	29	19	10	66%
Vessel type				
Native vessel	55	30	25	55%
Bypass graft	11	5	6	45%
Prior stenting	48	23	28	48%
Treatment	**Total**	**Debris observed**	**No debris observed**	**Percentage debris generated**
tPA	29	11	18	38%
Atherectomy	53	37	16	70%
Laser	19	5	14	26%
Directional	7	4	3	57%
Orbital	27	18	9	67%
PTA/stenting	41	12	29	29%
PTA alone	24	7	17	29%

TASC: Trans-Atlantic Inter-Society Consensus classification, tPA: Tissue plasminogen activator, PTA: Percutaneous transluminal balloon angioplasty

were treated with percutaneous transluminal balloon angioplasty (PTA) with or without stenting. Of these, ED was observed in 12 (29%).

A Chi-square test of independence was performed to assess the relationship between type of treatment and generation of debris. There was a statistically significant difference in the rate of ED generation between the treatment groups, X^2 (2, n = 114) = 17, $P < 0.001$. ED were generated more frequently during atherectomy than during thrombolysis or angioplasty with or without stenting. Furthermore, in univariate regression analysis, atherectomy, among the evaluated factors, was the only factor that was significantly associated with detection of ED on postprocedure visual evaluation of the basket (odds ratio: 4.52; $P < 0.0001$) [Table 2].

Of the patients treated with atherectomy, 19 were treated with laser (ED rate of 26%), 7 were treated with directional atherectomy (ED rate of 57%), and 27 were treated with orbital atherectomy (ED rate of 67%). Again, a Chi-square test of independence was performed to assess the relationship between the type of atherectomy performed and generation of ED. There was a statistically significant difference in the rate of embolic generation between the treatment groups, X^2 (2, n = 53) = 7.4, $P < 0.05$. There was a lower rate of ED after laser atherectomy compared to directional or orbital atherectomy.

The mean follow-up period was 41 months (range of 1–81 months). The TLR, MALE, and overall survival are

Table 2: Results of univariate logistic regression analysis evaluating associations between assessed factors and detection of embolic debris on postprocedure visual evaluation of the basket

Factor	OR (95% CI)	*P*
Age at intervention (years)	1.01 (0.98-1.04)	0.533
TASC (>B versus A/B)	1.23 (0.59-2.58)	0.574
Preprocedure vessel occlusion	0.83 (0.37-1.84)	0.651
Treated stented or grafted versus native vessel	0.81 (0.39-1.68)	0.565
tPA infusion	0.62 (0.26-1.47)	0.280
Atherectomy	**4.82 (2.17-10.71)**	**<0.0001**
Thrombectomy	1.20 (0.44-3.30)	0.725
Stent placement	0.66 (0.30-1.43)	0.290
Basket location (popliteal versus other)	1.10 (0.49-2.50)	0.815

Factors with statistically significant association are shown in bold. CI: Confidence interval, OR: Odds ratio, TASC: Trans-Atlantic Inter-Society Consensus classification, tPA: Tissue plasminogen activator

summarized in Table 3. Following the procedure, a total of 7 Society of Interventional Radiology (SIR) Class A complications, 1 SIR Class B complications, 2 SIR Class C complications, and 3 SIR Class D complications were noted. No complications were related to the use of the EPD. The total complication rate was 11%. Of the SIR Class A complications, there were two cases of re-occlusion, two cases of in-stent restenosis, one case of symptomatic DE, one case of recurrent stenosis of a native vessel,

Table 3: Results demonstrating freedom from target limb revascularization, major adverse limb events, and overall survival at 6, 12, and 60 months postprocedure

	Freedom from TLR (%)	Freedom from MALE (%)	Overall survival (%)
6 months	79	96	97
1 year	70	96	93
5 years	57	93	76

TLR: Target limb revascularization, MALE: Major adverse limb event

and one case of brachial hematoma. The brachial access hematoma was used during another procedure during the same hospitalization and was unrelated to the peripheral intervention. The SIR Class B complication was a groin site infection that required antibiotics as an outpatient. Of the SIR Class C complications, there was one case of occlusion of a femoral to anterior tibial bypass graft that required reintervention and a case of in-stent restenosis that required reintervention. Of the SIR Class D complications, two patients required toe amputations after intervention and one patient required fasciotomies for compartment syndrome.

Discussion

The use of EPDs was originally utilized in arteries supplying end organs including the brain, heart, and kidneys because these organs are sensitive to ischemia and vital for survival.[5-7] Calcific debris pose increased risk to patients with poor distal runoff.[3] Larger emboli can be aspirated, but doing so places patients at risk of further vessel injury and increased procedure time. Smaller, angiographically occult emboli cannot be readily detected or treated. Because of this, EPDs have been gaining wider use in peripheral intervention as well. However, indications and guidelines for the use of EPDs in peripheral intervention are still unclear.

Some proceduralists argue that EPDs are unnecessary and introduce additional risk to the procedure. In the current study population, ED were generated in 51% of the procedures. Without distal protection, this debris would have traveled distally and embolized. DE rates have been reported in the literature ranging from 50% to 98%.[8-11] The rate of ED in the current study was highest during atherectomy at 70%, which is consistent with the published literature. The PROTECT registry reported a 31-fold increase in DE with directional atherectomy (SilverHawk device) compared to PTA with or without stenting.[12] The DEFINITIVE Ca++ trial demonstrated an 88.4% rate of DE when using the TurboHawk device and the SpiderFX EPD.[13] While the frequency with which ED were generated was highest in atherectomy patients, the rates of 38% during thrombolysis and 29% during angioplasty are not clinically trivial. Chronic ischemia, as seen in patients with CLI, results in a decreased ability of the arterioles to compensate for acute hypoxia.[14] For patients with CLI, reducing the amount of ED propagated distally during atherectomy will in turn reduce hypoxic stress for already compromised vasculature.

Laser atherectomy had a significantly lower frequency of ED than either orbital or directional atherectomy in our population. Shirkhande *et al*. also described lower rates of DE with laser atherectomy compared to atherectomy.[2] Given the ablative nature of laser atherectomy and its lower rate of DE, it may be better tolerated patients with CLI.

There was no statistically significant difference in the frequency of ED based on vessel type or TASC classification in this cohort. Shammas *et al*. reported that TASC D lesions were 3.7 times more likely to embolize than TASC A-C lesions.[15] Shrikhande *et al*. also reported higher rates of DE with TASC C/D lesions (2.2% compared to 0.9% in TASC A/B lesions).[2] Both of these studies contained large numbers of lesions (1183 in Shammas *et al*. and 2137 in Shrikande *et al*.), giving these studies the statistical power to detect significance in such a small difference. This study has the following limitations. Due to the retrospective nature of the study, both the generation of distal ED and true DE were of a qualitative nature and relied on DSA images or reported observations in the procedural dictation. In addition, the small number of patients limited the statistical power of subgroup analysis. Finally, further prospective randomized studies will be necessary to identify which patients and lesions benefit most significantly from embolic protection and for which patient populations EPDs are most cost-effective.

Conclusion

The high frequency with which ED are generated during atherectomy, especially orbital or rotational atherectomy, and the lack of device-related complications argue for the use of EPDs during atherectomy.

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Conflicts of interest

There are no conflicts of interest.

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