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Atherectomy-Associated Complications in the Southern California Vascular Outcomes Improvement Collaborative

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Abstract

Introduction—Atherectomy has become an increasingly utilized modality for the endovascular treatment of peripheral arterial occlusive disease. The objective of this study is to determine the incidence and risk factors for atherectomy-associated complications.

Methods—A retrospective review was performed of all atherectomy procedures performed between January 2011 and December 2015 in the Southern California Vascular Outcomes Improvement Collaborative. Atherectomy was defined as laser, orbital or excisional atherectomy. Complications were dissection, perforation and distal embolization.

Results—729 atherectomy procedures were performed at seven institutions by 27 practitioners. Mean age was 73 with 415 (57%) male. 419 (57%) were diabetic, 673 (92%) hypertensive, 457 (63%) smokers and 244 (34%) had coronary artery disease. Dissection occurred in 51 (7%) procedures, embolization in 23 (3.1%) and perforation in 12 (1.6%). The mean number of lesions treated per artery was the same at 1.6 in patients with any complication and no complication ($P=0.77$). The total occluded length was 7.4 cm for complications vs 7.2 cm for no complication ($P=0.73$). The total treated length was 12.9 cm for complications vs 11.3 cm for no complication ($P=0.03$). The incidence of complications for TASC C/D lesions were 13% compared to 10% for TASC A/B lesions ($P=0.05$). The incidence of complications in superficial femoral/popliteal lesions was 12.9% vs 10.4% in tibial lesions ($P=0.13$). On multivariable analysis, treatment length was associated with a small increased risk of complication (OR 1.02, 95% CI 1.0–1.04).

Conclusions—Increased treatment length is associated with an increased risk of atherectomy-associated complications. Demographic factors and co-morbidities were not predictors of complications.

Introduction

Endovascular interventions have become much more common than bypass surgery in the treatment of lower extremity peripheral arterial disease. Specifically, in recent years, there

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has been a dramatic increase in the utilization of atherectomy for endovascular procedures. One study of Medicare claims data demonstrated that the annual rate of peripheral vascular interventions remained relatively stable from 2006 to 2011, however, the rate of atherectomy increased significantly from 96.4 per 100,000 Medicare beneficiaries in 2006 to 125.9 per 100,000 in 2011.[1]

Despite the increasing use of atherectomy, the existing data regarding atherectomy-associated complications and other clinically relevant outcome measures is limited. One study using the Nationwide Inpatient Sample from 2012 demonstrated a 10.9% complication rate of peripheral atherectomy.[2] No analysis was performed of factors that increased the risk of an atherectomy-associated complication. In addition, by virtue of the administrative data used, the study only included hospitalized patients and utilized billing codes as surrogates for complications. The objective of this study is to determine the practice patterns of atherectomy for peripheral vascular intervention in the Southern California Vascular Outcomes Improvement Collaborative (SoCal VOICE) and the incidence of and risk factors for atherectomy-associated complications.

Methods

A retrospective review was conducted of all procedures in the peripheral vascular intervention (PVI) registry of the So Cal VOICE performed between January 2011 through December 2015. The So Cal VOICE is one of 17 regional quality groups of the Vascular Quality Initiative, a quality improvement project of the Society for Vascular Surgery designed to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.

Inclusion criteria was occlusive disease with procedural indication of claudication or critical limb ischemia. Atherectomy was defined as laser, excision or orbital atherectomy. Atherectomy-associated complications recorded in the VQI are dissection, perforation, embolization, complication requiring treatment and complication requiring admission. Dissection and perforation are defined as yes/no outcomes. Embolization is defined as no, minor, requiring percutaneous intervention or requiring operation. The composite outcome of any complication was met if any of those complications occurred. Of note, peri-procedural amputation as a result of procedural complications is not recorded by the VQI. Tibial arteries were defined as tibioperoneal trunk, anterior tibial, posterior tibial and peroneal. For the center-level analysis, centers performing less than 10 PVI procedures during the study period were excluded.

Statistical analysis was conducted using SAS, version 9.4 (SAS Institute Inc, Cary, NC) Two group comparisons of continuous variables were assessed by a t-test of equality of means. Two group comparisons for categorical variables were assessed by chi-squared tests. Logistic regression of atherectomy-associated complications was performed by putting factors significant at the $P=0.05$ level on univariate analysis into the model and applying backward selection with a significance level to stay of 0.05.

Results

During the study period, 2,048 PVI procedures meeting the inclusion criteria were performed at 10 institutions by 62 practitioners. Of those, 729 (35.6%) of the procedures utilized atherectomy, either alone or in conjunction with angioplasty and/or stenting. The atherectomy procedures were performed at 7 of the 10 institutions by 27 practitioners. Three of the 27 providers performed 66.5% of the atherectomy procedures. The two providers who performed the most atherectomy procedures (29.4% and 21.7%) performed the procedures at the same institution. The third provider, who performed 15.5% of the atherectomy procedures, performed them at a different institution.

Overall, the mean age of all patients undergoing PVI was 71.4 years, with the majority being male, diabetic, hypertensive and current or prior smokers; one third had history of coronary artery disease. (Table 1) The patients who underwent atherectomy were slightly older than the patients who did not undergo atherectomy, and there were fewer smokers in the atherectomy group. (Table 1) Otherwise, there was no difference between the two groups with respect to male sex, diabetes, hypertension or coronary artery disease. The majority of PVI procedures were performed for claudication and there was no significant difference in indication between the atherectomy and no atherectomy group. (Table 1)

The prevalence of atherectomy varied widely by institution from 0 to 83% of all PVI procedures performed at the institutions reviewed. (Figure 1) PVI was performed on a total of 4,059 arteries. Of those, 1,497 (37%) arteries underwent atherectomy. The prevalence of atherectomy varied by anatomic location of the intervention. The arteries most likely to undergo atherectomy were the superficial femoral, popliteal and tibial arteries. (Figure 2) The most common atherectomy type used was excisional atherectomy in 1298 (86.9%) arteries, followed by orbital atherectomy in 159 (10.6%) and laser atherectomy in 41 (2.7%).

The majority of atherectomies were performed in conjunction with other procedures; 122 (8%) arteries underwent atherectomy alone without another procedure. 1126 (75%) arteries underwent atherectomy in conjunction with balloon angioplasty. 218 (15%) arteries underwent atherectomy in conjunction with a bare metal stent, 6 (0.4%) with a stent graft and 6 (0.4%) with a cutting balloon. Embolic protection devices were used in 166 (11%) of arteries that underwent atherectomy and 21 (0.8%) of arteries that did not undergo atherectomy

The overall rate of composite complications in the atherectomy group was higher than the no atherectomy group, although this difference in composite endpoint was driven primarily by the higher rate of dissections in the atherectomy group. (Table 2) There were significantly more arterial dissections and complications requiring treatment in patients who underwent atherectomy compared to those who did not. (Table 2) Otherwise, there was no significant difference between the two groups in the incidence of perforation, embolization or complication requiring admission. (Table 2)

Within the atherectomy group, there was no association of age, male sex, diabetes, hypertension coronary artery disease or smoking with the risk of complication. (Table 3) Within the atherectomy group, there was no significant difference between the incidence of

complication in the superficial femoral/popliteal distribution and the tibial distribution (111 (12.8%) vs 59 (10.2%), $P=0.13$). There was no significant difference in the mean number of lesions treated per artery in cases with and without a complication (1.6 vs 1.6, $P=0.55$). There was no difference in the total arterial occlusion length in atherectomy procedures with a complication compared to procedures without a complication (7.4cm vs 7.2 cm, $P=0.73$). The total treated length was slightly longer in atherectomy procedures with a complication (12.9cm vs 11.3cm, $P=0.03$). The incidence of complications was lower for TASC A/B lesions at 10% vs TASC C/D lesions at 13%, $P=0.05$.

On multivariable analysis, TASC classification became no longer significantly associated with risk of complication (OR 1.35, 95% CI 0.94–1.94). Increasing treatment length was independently associated with a very small per centimeter increased risk of atherectomy-associated complication (OR 1.02, 95% CI 1.0–1.04).

Discussion

Despite the increasing prevalence of atherectomy utilization in the endovascular treatment of peripheral arterial disease, there is little published data on the risk factors for atherectomy-associated complications. Our study demonstrated no association between demographics and co-morbidities and risk of atherectomy-associated complication. In contrast, analysis of the CONFIRM registries (US multicenter, nonrandomized, all-comers registries of peripheral arterial disease patients treated with orbital atherectomy) demonstrated that females had a higher rate of all types of dissection than men.[3] However, both genders had equal rates of flow-limiting dissections, perforation, slow flow, vessel closure, spasm, embolism and thrombus formation. It is possible that this gender distinction is limited to orbital atherectomy and dissection, whereas in our study three types of atherectomy were pooled and complications were pooled. Due to the overwhelming predilection for directional atherectomy in our study, a subgroup analysis of each type of atherectomy could not be performed for statistical reasons. Similarly, due to low rates of complications and small sample sizes, no sub-analysis was performed in our study of factors associated with individual complications for statistical reasons.

Likewise, our study found that age was not associated with risk of atherectomy-associated complications. This is in keeping with the findings of another analysis of the CONFIRM registries stratifying age by elderly ≥ 75 years and younger <75 years.[4] The composite of adverse events in their study included dissection, perforation, slow flow, vessel closure, spasm, embolism and thrombus formation. While the composite rate was equal between younger and elderly patients, elderly patients had a lower rate of thrombus formation and a higher perforation rate.

Diabetes was also not found to be associated with risk of atherectomy-associated complications in our study. An analysis of diabetics in the CONFIRM registries also found that diabetics and non-diabetic patients had the same composite rate of atherectomy-associated complications, despite diabetics having more severe Rutherford categories, longer lesions, more infrapopliteal lesions and more lesions with severe and moderate calcium.[5]

Again, due to sample size limitations, we could not perform a sub-analysis of the diabetics in our study.

Treatment length was associated with a two percent increased risk of atherectomy-associated complications per centimeter of increased treatment length. While this is a very small per centimeter increased risk, a five centimeter increase in treatment length would be associated with a ten percent increase in atherectomy-associated complications. Despite this result, it is outside the scope of this study to make a recommendation that only short lesions should undergo atherectomy. The decision to perform atherectomy should be multifactorial and not based on only one anatomic characteristic.

Distal embolization rates in endovascular interventions of all types has been shown to be low; in one study using the Vascular Study Group of New England (VSGNE) database, the overall incidence of distal embolization for all types of interventions was 1.73%. [6] These rates of embolization are comparable to the rates of embolization in our study. However, the VSGNE study also demonstrated that compared to atherectomy and balloon angioplasty, the risk of distal embolization was significantly lower with stenting alone, balloon angioplasty alone and combined stenting and balloon angioplasty. In contrast, our study demonstrated no difference in the risk of embolization between procedures that utilized atherectomy and those that did not. The difference in outcomes may be related to the fact that in the VSGNE study, the overall incidence of atherectomy use was much lower than in our study and the majority of atherectomy type utilized was orbital.

In our study, a relatively small minority of arteries that underwent atherectomy had a distal embolic protection device placed. Recommendations for the use of distal embolic protection are limited. One single institution study of 508 patients with peripheral arterial disease treated with atherectomy and distal embolic protection analyzed their results and the material recovered from the embolic protection devices and developed an algorithm based on their findings. In their algorithm, if the lesion is calcified and over 4cm in length, a filter is indicated. Other indications for filter are chronic total occlusion, in stent restenosis, thrombus, single-vessel runoff, and lesion length greater than 14cm. [7] This is consistent with our finding that longer treated length increases the risk of complication.

The large variation in atherectomy use across centers within the So Cal VOICE suggests that indications for atherectomy use vary widely among So Cal VOICE participants. High quality data to support the use of atherectomy is lacking. A Cochrane review of all randomized controlled trials (RCT) comparing atherectomy and other established treatments revealed only four RCT performed prior to 2014. [8] All of those studies compared atherectomy with plain balloon angioplasty. The Cochrane review demonstrated no evidence for superiority of atherectomy over angioplasty on any outcome. Since then, a small randomized study has been performed comparing treatment with balloon angioplasty followed by paclitaxel-eluting balloon angioplasty and stenting, stenting alone and directional atherectomy with bailout stenting. [9] This study found that paclitaxel-eluting balloon angioplasty and stenting had the lowest risk for target lesion revascularization at 24 months. It is clear that further investigation is required regarding the indications and outcomes of atherectomy for peripheral arterial disease.

Limitations of this study involve the variability in reporting practices between institutions involved in VQI, lack of standardized definitions regarding the relevant measured complications, and limitations on the data elements allowed within the VQI database. The higher complication rate in patients treated with atherectomy compared to those treated with other modalities was driven primarily by higher dissection rates. This fact may appear surprising to regular users of atherectomy, as this modality is often used for the purpose of achieving revascularization without the high rate of bailout stenting seen with a strategy of angioplasty and selective stenting. The complications reported in the VQI dataset are site-reported by the surgeon interventionalist or by data abstractors from the medical record, and thus the inclusion of a dissection in the “complications” field of the VQI dataset is dependent on the report of a residual dissection at the conclusion of the procedure in the operative note. In some patients treated with balloon angioplasty with selective stenting, it is likely that flow-limiting dissections were not reported as complications as these dissections instead led to the common practice of selective stent implantation. On the contrary, residual non-flow limiting dissections are commonly seen and considered to be an acceptable result following atherectomy, and it is possible that these dissections are recorded as complications in the VQI dataset. For the complications that required treatment, VQI does not collect details on the treatment. Similarly, for the complications that required hospitalization, VQI does not collect details on the indication for hospitalization.

The PVI data entry form also limits the type of treatment per artery to only two types of treatment. Users are instructed to input the “primary” two types of treatment. It is possible that atherectomy procedures were not recorded due to this limitation. Although atherosclerotic vessels are often heavily calcified, and calcium can influence the success of the procedure, the VQI does not record the degree of calcification of the artery or the lesion. Primary atherosclerotic lesion composition also may differ from the composition of a re-stenotic lesion. This difference in composition may influence outcomes. However, the VQI does not record whether the lesion is de-novo or re-stenotic. The VQI does not record the experience level of the provider with the procedure in question. Thus no determinations can be made regarding the association of provider experience with incidence of complications.

Conclusion

In the Southern California Vascular Outcomes Improvement Collaborative, increased treatment length is associated with an increase in the risk of atherectomy-associated complications. Demographics, co-morbidities, TASC classification and occlusion length are not associated with the risk of atherectomy-associated complications. Wide variation exists in the utilization of atherectomy in the So Cal VOICe, suggesting that indications for use vary significantly among participants. Future efforts of the So Cal VOICe will focus on determining the drivers of this variation and possible standardization of practices in the region.

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Figure 1.

Incidence of Atherectomy by institution*

*only institutions with at least 10 PVI procedures are included

Figure 2.
Atherectomy prevalence by artery

Table 1

Demographics and Indications of all PVI, by atherectomy

	Overall (%)	Atherectomy (%) n=729	No Atherectomy (%) n=1319	P-value*
Demographics				
Mean age (years)	71.4	73.2	70.4	<0.001
Male	1184 (58)	415 (57)	769 (58)	0.55
Diabetes	1130 (55)	419 (57)	711 (54)	0.13
Hypertension	1863 (91)	673 (92)	1190 (90)	0.11
Coronary Artery Disease	682 (33)	244 (34)	438 (33)	0.91
Smoking	1382 (67)	457 (63)	925 (70)	0.007
Indication				
Claudication	938 (46)	335 (46)	603 (46)	0.25
Rest Pain	299 (15)	120 (16)	179 (14)	
Tissue Loss	787 (38)	267 (37)	520 (40)	

* atherectomy compared to no atherectomy

Table 2

Complications by atherectomy vs no atherectomy

	Atherectomy (%)	No atherectomy (%)	P-value
Composite complication	90 (12)	119 (9)	0.01
Dissection	51 (7)	56 (4)	0.007
Perforation	14 (2)	25 (2)	1.0
Embolization	21 (3)	22 (2)	0.67
Complication requiring treatment	79 (11)	81 (6)	0.0001
Endovascular	77 (97)	80 (99)	
Open surgery	1 (1)	0	
Both	1(1)	1 (1)	
Complication requiring admission	10 (1)	32 (2)	0.11

Table 3

Demographics and Co-morbidities by complication outcome in atherectomy group

	Complication (%) n=83	No Complication (%) n=646	P-value
Mean Age (years)	74	73.1	0.51
Male	46 (55)	369 (57)	0.77
DM	43 (52)	376 (58)	0.27
HTN	80 (96)	593 (92)	0.14
CAD	24 (29)	220 (34)	0.35
Smoking	52 (63)	405 (63)	0.98