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Anatomic and clinical predictors of reintervention after subclavian artery stenting

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Objective: **This study was conducted to determine long-term predictors of target lesion reintervention (TLR) after subclavian artery stenting (SAS).**

Methods: **This was a single-center retrospective review of patients with symptomatic atherosclerotic subclavian artery disease who underwent SAS between January 1999 and December 2013. Repeat intervention was only performed in patients with recurrent symptoms and ≥70% in-stent restenosis (ISR). TLR was defined as need for a repeat percutaneous intervention involving a previously stented area. Freedom from events (ISR and TLR) was analyzed using Kaplan-Meier curves. Cox regression analysis was used to determine the significant predictors of TLR and ISR.**

Results: **Index procedures were performed on 139 arteries in 138 patients (69.6% female). Patients were an average age of 64.5 years, with major comorbidities of hypertension (80.4%), hyperlipidemia (72.5%), and tobacco use (60.1%). Also performed during the study period were 24 TLR procedures, resulting 166 SAS interventions attempted for patients with subclavian atherosclerotic disease during a 15-year span. Of 166 procedures, 163 (98.2%) were treated successfully. Stents were placed in all but two index arteries. The main indications for SAS were subclavian steal syndrome (48.9%), arm claudication (21.6%), and coronary steal syndrome (28.8%). The average preprocedure stenosis was 87.2% ± 11.2%. For index procedures (139 arteries), duplex follow-up was available for 134 arteries (96.4%), with an overall ISR rate of 18.7% (25 of 134). Primary patency for the index procedures was 84.7% at 10 years. The overall TLR rate for the index procedures was 12.7% (17 cases). Seven patients required more than one secondary procedure. For all cases, the freedom from ISR was 91%, 77%, and 68% at 1, 5, and 10 years, respectively, and freedom from TLR was 94%, 85%, and 82% at 1, 5, and 10 years, respectively. Multivariate analysis showed the significant predictors of ISR were smoking/chronic obstructive pulmonary disease (hazard ratio [HR], 3.2; $P = .001$), age by decade (HR, 0.5; $P < .001$), discharged with statin therapy (HR, 0.3; $P = .001$), vessel diameter ≤7 mm (HR, 2.3; $P = .028$), and right-sided intervention (HR, 0.3; $P = .040$). The sole significant predictor of TLR was age by decade (HR, 0.6; $P = .008$).**

Conclusions: **SAS has a high primary success and durability with satisfactory outcomes well beyond 10 years. ISR was more likely to develop in patients who were smokers with chronic obstructive disease or had a baseline vessel size of ≤7 mm. Younger age could be an independent risk factor for secondary intervention. (J Vasc Surg 2015;62:106-14.)**

Atherosclerotic subclavian artery disease (ASAD) is not an uncommon finding in patients with severe systemic atherosclerosis, and many retrospective studies have shown higher prevalence in patients requiring coronary angiography. The prevalence of ASAD may be as high as 3.5% in the general population based on angiographic screening, and peripheral vascular disease has been shown to be a predictor of ASAD.[1] Most ASAD patients are asymptomatic, and the diagnosis is confirmed with a proper physical examination and a documented blood pressure difference between both arms of ≥20 mm Hg, with or without a supraclavicular bruit. If symptoms develop, they include arm claudication, vertebrobasilar insufficiency, and embolization. Claudication is often mild, and in the absence of an internal mammary graft, the need for treatment is relatively uncommon.

During the past three decades, percutaneous balloon angioplasty and stenting has emerged as a minimally invasive option for treating patients with symptomatic ASAD[2] and has contributed to a shift in treatment patterns from surgery to this less invasive alternative. A significant decrease in perioperative complications has led some authors to advocate subclavian artery stenting (SAS) as the procedure of choice for subclavian artery revascularization[3-7]; others have suggested a more selective approach where open bypass may be offered to good-risk surgical candidates seeking a more durable procedure.[6,8] In the current study, we set out to evaluate long-term outcomes of subclavian artery angioplasty at our tertiary teaching center with an emphasis on factors that may contribute to the need for target lesion reintervention (TLR).

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METHODS

This was a retrospective review of all consecutive symptomatic ASAD patients who underwent SAS in a large tertiary care center between January 1999 and December 2013. The study was approved by our governing Institutional Review Board and conducted in accordance with the Health Insurance Portability and Accountability Act requirements and the prevailing ethical principles governing research. The Institutional Review Board waived informed consent due to the retrospective study design.

We queried the hospital billing database for International Classification of Diseases, Ninth Revision codes for stenting/angioplasty procedures along with corresponding subclavian steal syndrome diagnosis codes. We then used electronic medical records to construct a more comprehensive data set and extract additional data elements. We subsequently collected data for consecutive SAS patients in the hopes of complementing the data that our group has previously reported.[9]

Statistical analysis. All analyses were performed using SPSS 19.0 software (IBM Corp, Armonk, NY). Descriptive statistics are expressed as frequencies, percentages, or means ± 1 standard deviation. Categoric variables were tested by χ^2 or Fisher exact tests, and continuous variables were tested by the Student *t*-test when deemed appropriate. A *P* value of ≤.05 was considered significant. Kaplan-Meier curves were used to estimate the survival from event for instent restenosis (ISR) and TLR and the results with number at risk for time intervals are demonstrated using life-table graphs. Cox proportional hazards models were used to determine the significant predictors of ISR and TLR. All potential confounding variables (ie, demographics [Table I], lesion characteristics [Table II], and medications prescribed before and after the procedure) of time to event that approached significance ($P < .1$) were entered into a full regression model. Backward stepwise regression was used to reduce the full model to a final model that contained only the significant predictors of time to event.

We have followed our SAS protocol (ie, same as carotid) regarding postoperative care, including medications regimen (acetylsalicylic acid, clopidogrel), and duplex criteria for postoperative surveillance, which has been reported previously.[10] Our standard practice is to follow-up with SAS patients at 1, 6, and 12 months, then annually thereafter or whenever new symptoms appear. Efforts were made during all follow-up visits to obtain a physical examination and a carotid/subclavian duplex assessment, although some patients did not undergo duplex imaging.

Definitions. ISR was defined with a pressure difference between the upper arms of ≥20 mm Hg along with a peak velocity >270 cm/s using duplex ultrasound imaging in an accredited vascular laboratory. This peak velocity has been established and used by other researchers to correlate with ≥70% stenosis.[10,11] All stenosis were confirmed on angiograms.

TLR was defined as the need for reintervention using angioplasty or stenting of clinically significant recurrent disease within the stented segment or contiguous region of the subclavian artery. Our approach for the TLR is to start with balloon angioplasty. We reserve restenting for lesions that are not amenable to balloon angioplasty with residual stenosis ≥30%.

Original ASAD lesions were defined as severe stenosis >270 cm/s along with symptoms, as illustrated above.

Vessel diameter size was based on the reference vessel angiographic diameter measured just distal to the stenosis or occlusion segment of the subclavian artery.

Procedural success was defined as ≤30% residual stenosis at the end of the intervention, along with the absence of a significant pressure difference between the two arms (pressure significance is >20 mm Hg).

Arm claudication was defined as reproducible arm fatigue with exercise.

Subclavian steal syndrome was defined as retrograde blood flow in the vertebral artery associated with proximal ipsilateral subclavian artery stenosis or occlusion at the expense of vertebra-basilar circulation and included, but was not limited to, dizziness, syncope, visual changes, or imbalance.

Table I. Patient demographics

Variable	*Mean ± SD or No. (%) (N = 138)*
Age, years	64.5 ± 11.0
Female gender	96 (69.6)
Tobacco use	83 (60.1)
Acute stroke	3 (2.2)
Diabetes	51 (37.0)
Hypertension	111 (80.4)
Acute myocardial infarction	8 (5.8)
Congestive heart failure history	21 (15.2)
Hyperlipidemia	100 (72.5)
Peripheral vascular disease	39 (28.3)

SD, Standard deviation.

Table II. Lesion characteristics

Variable	*Mean ± SD or No. (%) (N = 139 index lesions)*
Indication	
Arm claudication	30 (21.6)
Coronary steal syndrome	40 (28.8)
Subclavian steal syndrome	68 (48.9)
Prophylactic for arm AVF	1 (0.7)
Location	
Distal to vertebral	17 (12.2)
Proximal to vertebral	122 (87.8)
Lesion	
Preoperative stenosis, %	87.2 ± 11.2
Occluded	36 (25.9)
Severe stenosis ≥70%[a]	132 (95.0)
Vessel diameter, mm	7.4 ± 1.2
Stent length, mm	24.1 ± 8.4
Right-side intervention	22 (15.8)

AVF, Arteriovenous fistula; *SD,* standard deviation.
[a]Includes occluded. Seven arteries were treated for symptoms with ≥50% stenosis.