Predictors of Provisional Stenting in Patients Undergoing Lower Extremity Arterial Interventions

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ABSTRACT

Predictors of provisional stenting in patients undergoing lower extremity arterial interventions remain unclear. We performed an ad hoc analysis on the predictors of provisional stenting during infrainguinal arterial percutaneous interventions using data from the Percutaneous Lower Extremity Arterial Interventions Using Primary Balloon Angioplasty versus Silverhawk Atherectomy (SA) and Adjunctive Balloon Angioplasty trial. In the above trial, SA of infrainguinal de novo arterial lesions was shown to reduce significantly provisional stenting compared with primary percutaneous transluminal angioplasty (PTA). In this ad hoc analysis, patients were divided into two groups based on whether provisional stenting has occurred. Univariate analysis was conducted between the stent versus the no-stent group. Logistic regression (LR) analysis was performed to model for the predictors of provisional stenting. Variables included were diabetes, presence of moderate calcification (versus none to little), age, gender, hypercholesterolemia, Transatlantic Intersociety Consensus (TASC) D lesion (vs. TASC A to C), and treatment method (primary PTA vs. SA with adjunctive PTA). By LR analysis, predictors of stenting were as follows: moderate calcification (odds ratio [OR] 6.56, 95% confidence interval [CI] 1.21 to 35.56, $p = 0.029$), primary PTA (vs. SA) (OR 0.19, 95% CI 0.04 to 0.93, $p = 0.04$), and TASC D lesions (vs. A to C) (OR 0.10, 95% CI 0.01 to 0.87, $p = 0.037$). Provisional stenting in infrainguinal interventions is predicted by the use of primary PTA, presence of moderate calcification, and TASC D lesions after controlling for gender, age, hypercholesterolemia, and diabetes.

KEYWORDS: Peripheral angioplasty, predictors of stenting, atherectomy, vessel calcification, long occlusions

Predictors of stenting in lower extremity arterial interventions have not been well defined. Balloon angioplasty has been associated with a higher rate of provisional stenting ranging from 10 to 43%.¹⁻⁴ Atherectomy with the SilverHawk device showed a stenting rate ranging from 0 to 6.3% in various studies.⁵⁻⁷ Although stenting has been shown to reduce restenosis

when compared with percutaneous transluminal angioplasty (PTA),³ stenting carries its own set of problems including a continued high rate of restenosis, thrombotic occlusions, stent fractures, and may potentially limit future therapies in the femoropopliteal artery.⁸⁻¹⁰

In the Percutaneous Lower Extremity Arterial Interventions Using Primary Balloon Angioplasty versus

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Silverhawk Atherectomy and Adjunctive Balloon Angioplasty trial, Silverhawk atherectomy (SA) of infringuinal de novo arterial lesions was shown to reduce significantly bailout stenting compared with primary PTA.¹¹ Provisional stenting was a predefined end point in this study with prespecified conditions for stenting including a residual of $>30\%$ or type C dissection and higher. We present an ad hoc analysis of this trial analyzing the clinical, angiographic, and procedural predictors of provisional stenting.

METHODS

In this two-center, prospective randomized trial in treating infrainguinal de novo lesions using PTA versus SA with adjunctive balloon angioplasty, patients were included if they were referred for percutaneous lower extremity intervention because of claudication (Rutherford Becker I to III) or chronic limb ischemia (Rutherford Becker IV to V). They were excluded if they had one or more of the following: (1) heavily calcified vessels or total occlusions longer than 10 cm or any total occlusion with suspicion of subintimal wire recanalization, (2) inability to take antiplatelet drugs or a history of coagulopathy, (3) chronic renal failure with creatinine over 2.5 mg/dL, and (4) decompensated congestive heart failure or acute coronary syndrome. The study was approved by the institutional board of each institution where the study was conducted. Informed consent was obtained on all patients. Target lesion revascularization (TLR) at 1 year was the primary end point of the study. Provisional stenting because of suboptimal acute angiographic results defined as a residual stenosis of $>30\%$ or the presence of type C or higher dissection was a secondary end point.

Randomization was done after crossing total occlusions if the wire was intraluminal. For patients enrolled in the SA arm, the SilverHawk atherectomy device (ev3 Endovascular, Plymouth, MN) was used before adjunctive PTA. Procedural success was defined as residual stenosis of $\leq 30\%$ and/or no higher than a type B dissection. The same balloon angioplasty protocol was used in both arms:

1. balloon inflation time was 90 seconds, with two inflations each for every lesion treated;
2. balloon inflation pressure was started at 2 atm and was increased gradually (1-atm increments) until no waist was seen on the balloon.

Provisional stenting was performed in patients with procedural failure with nitinol self-expanding stents (LifeStent, Bard Peripheral Vascular, Tempe, AZ; and Protégé, ev3 Endovascular, Plymouth, MN). Stents were sized at 1 to 2 mm above the estimated vessel diameter. Stenting was not permitted for procedural success.

Statistical Analysis

Patients were divided into those who underwent provisional stenting versus those who did not get a stent. Univariate analysis was conducted between the two groups. Continuous variables were analyzed with *t*-testing and dichotomous variables with chi-square or Fisher's exact test. Logistic regression (LR) analysis was performed to model for the predictors of provisional stenting. A *p* value of <0.05 was considered significant.

RESULTS

A total of 58 patients were included in the study. Of these, 29 patients (36 vessels) were included in the SA arm and 29 patients (48 vessels) in the PTA arm. Approximately 80% of patients were claudicants, and the rest had chronic limb ischemia. There were 46 of 58 (79.3%) patients with only femoropopliteal vessels treated. The mean number of tibial runoffs was 1.9 ± 0.9 . Total occlusions were present in 12 of 84 (14.3%) vessels treated.

Table 1 shows the differences in the demographic, clinical, and angiographic variables between the provisional stent and no-stent groups.

There was a higher prevalence of moderate calcification in the stent group and a lower residual narrowing poststenting. Also, stent deployment was performed at a statistically higher pressure than balloon angioplasty alone, although this difference is clinically small (delta 1.27 mm Hg).

At 1 month, both groups had the same TLR and target vessel revascularization (TVR) although TLR trended in favor of the no-stent group compared with the stent group (Table 2). There were no differences in death and amputation in either group. Approximately 40% of patients in both groups were in a Rutherford Becker class II to IV.

LR analysis (Table 3) was performed to model for the predictors of provisional stenting. Variables included were diabetes, presence of moderate calcification (versus none to little), age, gender, hypercholesterolemia, Transatlantic Intersociety Consensus (TASC) D lesion (vs. TASC A to C), and treatment method (primary PTA vs. SA with adjunctive PTA). By LR analysis, predictors of stenting were as follows: moderate calcification (odds ratio [OR] 6.56, 95% confidence interval [CI] 1.21 to 35.56, $p=0.029$), primary PTA (vs. SA) (OR 0.19, 95% CI 0.04 to 0.93, $p=0.04$), and TASC D lesions (vs. A to C) (OR 0.10, 95% CI 0.01 to 0.87, $p=0.037$).

DISCUSSION

In this ad hoc analysis of the Percutaneous Lower Extremity Arterial Interventions Using Primary Balloon

Table 1 Univariate Analysis Comparing Baseline Demographic, Clinical, and Angiographic Variables of Provisional Stent Group Versus the No-Stent Group

Parameter	No Provisional Stent	Provisional Stent	p Value
Age (years)	67.17 ± 10.38	72.23 ± 13.32	NS
BMI	29.26 ± 5.76	27.31 ± 5.64	NS
Male (%)	60	69.6	NS
Smoking (current)	31.4	27.3	NS
ABI: treated leg at baseline	0.76 ± 0.25	0.72 ± 0.19	NS
hs-CRP at baseline (mg/L)	9.48 ± 11.03	8.98 ± 20.86	NS
Prestenosis (%)	82.77 ± 12.86	86.03 ± 13.36	NS
Poststenosis (%)	12.22 ± 8.30	4.22 ± 7.52	0.001
Post TIMI flow	2.98 ± 0.14	2.91 ± 0.53	NS
Runoff treated leg	2.03 ± 0.98	1.68 ± 0.89	NS
Lesion length (mm)	81.63 ± 84.99	98.59 ± 84.95	NS
Balloon pressure (atm)	8.92 ± 2.37	10.19 ± 2.16	0.016
Hypertension (%)	80	81.8	NS
Hypercholesterolemia (%)	80	68.2	NS
Diabetes (%)	51.4	36.4	NS
Presence of angiographic thrombus (%)	5.7	4.3	NS
hs-CRP at 48 hours posttreatment (mg/L)	24.81 ± 23.05	37.02 ± 29.12	NS
Rutherford class II to V (%)	100	100	NA
Segment treated			NS
Femoral	65.4	78.1	
Tibial	34.6	21.9	
TASC lesions (%)			NS
TASC D	9.6	22.6	
TASC A, B, C	90.4	77.4	
Calcium (%)			0.008
None to little	86.5	59.4	
Moderate	13.5	40.6	

ABI, ankle brachial index; BMI, body mass index; hs-CRP, high sensitivity C-reactive protein; NS, not significant; TASC, Transatlantic Intersociety Consensus 2002; TIMI, thrombolysis in myocardial infarction.

Angioplasty versus Silverhawk Atherectomy and Adjunctive Balloon Angioplasty trial, provisional stenting was performed under strict predefined end points.¹¹ Patients could get a stent only if they had a residual narrowing of more than 30% or a type C and higher dissection. In the initial trial, patients who received primary angioplasty had more provisional stenting than those who were treated with initial atherectomy (62.1 vs.

27.6%, $p = 0.017$). Clinical, angiographic, and procedural predictors of stenting in infrainguinal interventions remain, however, unclear. In this ad hoc analysis, moderate calcification was a strong predictor of stenting (OR 6.56, $p = 0.029$). In contrast, the use of atherectomy as a primary therapy and treating type A to C lesions were associated with reduced odds of stenting (OR 0.19, $p = 0.04$ and 0.10, $p = 0.037$ respectively).

Table 2 Outcomes of Patients with Provisional Stenting Versus No Provisional Stenting

Parameter	No Provisional Stent	Provisional Stent	p Value
Follow-up duration (months)	9.79 ± 3.59	10.02 ± 3.41	NS
ABI: treated leg at 30 days	0.98 ± 0.17	0.91 ± 0.14	NS
ABI: treated leg at 1 year	0.94 ± 0.16	0.78 ± 0.22	0.031
Rutherford class II to IV at 30 days	44.1	30	NS
Rutherford class II to IV at 1 year	41.4	38.9	NS
Death at 1 year (%)	12.1	10	NS
Amputation at 1 year (%)	0	5.3	NS
TLR cumulative at 1 year (%)	9.6	15.6	NS
TVR cumulative at 1 year (%)	13.5	15.6	NS

ABI, ankle brachial index; NS, not significant; TLR, target lesion revascularization; TVR, target vessel revascularization.

Table 3 Predictors of Provisional Stenting by LR Analysis

Parameter	<i>p</i> Value		Odds Ratio	95% Confidence Interval
	Lower	Upper		
Atherectomy versus PTA	0.04	0.189	0.038	0.928
Calcium				
Moderate versus none to little	0.029	6.562	1.211	35.561
TASC A, B, C lesions versus TASC D	0.037	0.104	0.012	0.872
Control variables				
Gender	0.261	2.359	0.528	10.533
Age	0.437	1.024	0.964	1.088
Hypercholesterolemia	0.882	0.888	0.185	4.265
Diabetes	0.072	0.255	0.057	1.131

LR, logistic regression; PTA, percutaneous transluminal angioplasty; TASC, Transatlantic Intersociety Consensus.

Reducing provisional stenting has several advantages when treating femoropopliteal or tibial disease. Although stenting is promising to reduce restenosis compared with balloon angioplasty by reducing acute recoil, dissections, and negative remodeling, the rate of restenosis remains substantially high with stenting alone,¹⁻³ and no randomized data are available on stenting versus atherectomy. Furthermore self-expanding nitinol stents continue to have a high rate of fractures that have been linked to an increase in restenosis rate.^{8-10,12} Finally, stents may limit future pharmacologic or surgical targets for peripheral bypass preventing a viable revascularization alternative to patients. Reducing stenting therefore might have its advantages when treating infrainguinal disease.

In this study, the rate of amputation and death were similar in both arms. Also, there were no statistical differences in the TLR and TVR in both groups. The study, however, was likely to be underpowered to determine the differences in TLR or TVR between stenting and no stenting.

Limitations of the Study

This study is an ad hoc analysis and therefore is not powered to compare the differences in the two groups. Also, the overall number of patients is small. However, provisional stenting was not random and was done under predefined conditions, reducing the bias in the analysis.

CONCLUSION

In summary, provisional stenting in infrainguinal interventions appears to be predicted by the use of primary PTA, presence of moderate calcification, and TASC D lesions after controlling for gender, age, hypercholesterolemia, and diabetes. A large prospective trial testing this hypothesis is warranted.

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