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Twelve-month Outcomes of Stenting versus Standard Balloon Angioplasty for the Below-the-Knee Arterial Disease Patients underwent Percutaneous Transluminal Angioplasty

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Background

Although percutaneous transluminal angioplasty (PTA) is considered as an effective treatment strategy in patients (pts) with critical limb ischemia (CLI), PTA for below-the-knee (BTK) lesions with CLI is particularly challenging.

Purpose

The aim of this study was to analyze to compare the 12-month outcomes following stenting versus standard plain old balloon angioplasty (POBA) alone in BTK lesions.

Method

1. Study Population

1) This study consisted of 339 consecutive lower extremity arterial disease pts (394 limbs, 1026 lesions included 716 BTK lesions) with BTK lesions from Sep 2004 to Dec 2013.

2) All the enrolled pts were treated either by stenting (bare metal stents, primary or provisional, 78 limbs in 73 pts) or POBA (316 limbs in 266 pts) with PTA.

2. Antiplatelet Regimen

1) All pts received Aspirin; 100 mg orally.

2) All pts received Clopidogrel (Plavix®) preloaded 300-600 mg before PCI, followed by daily administration of 75 mg and encouraged to continue at least for 1 year.

3) Usage of adjunctive Cilostazol to dual antiplatelet regimen (aspirin + clopidogrel) was depending on physician's discretion. Cilostazol was administered by 200mg post-loading and then 100mg bid for at least one month

3. Antithrombotic therapy used for PCI

1) Enoxaparin (Clexane®); 60mg bid before PCI and after PCI during the hospital stay (within 7 days).

2) Unfractionated Heparin; a bolus of 50 U/kg prior to PCI for 1st one hour

3) GP IIb/IIIa blocker (Reopro®); depend on physician's discretion.

4. PTA Procedure

1) For the stenotic lesion; simple balloon angioplasty with/without stenting (provisional stenting if balloon results are not satisfactory)

2) For the CTO lesion; Mostly subintimal angioplasty for longer CTO lesion was done with provisional spot stenting and true lumen wiring was done for shorter CTO lesion.

5. Study Endpoints

Procedural success, complications and clinical outcomes were compared between the two groups up to 12 months.

Statistics

1. All statistical analyses were performed using SPSS 20.0.

2. Continuous variables were expressed as means ± standard deviation and were compared using Student's t-test.

3. Categorical data were expressed as percentages and were compared using chi-square statistics or Fisher's exact test.

4. A P-value of 0.05 was considered statistically significant.

5. To adjust potential confounders, a propensity score matched (PSM) analysis was performed using the logistic regression model.

Results

Baseline Clinical Characteristics

Variables, N (%)	Overall			Matched		
	Stent, Pts (n=73)	POBA, Pts (n=266)	p Value	Stent, Pts (n=56)	POBA, Pts (n=56)	p Value
Gender (Male)	57 (78.0)	201 (75.5)	0.655	42 (75.0)	43 (76.7)	0.825
Age	67 ± 11	67 ± 10	0.633	67 ± 11	67 ± 11	0.978
Body mass index	23 ± 3	23 ± 3	0.837	22 ± 3	23 ± 3	0.381
Clinical presentations						
Wound	58 (79.4)	220 (82.7)	0.521	45 (80.3)	47 (83.9)	0.622
Diabetic foot	55 (75.3)	198 (74.4)	0.875	43 (76.7)	42 (75.0)	0.825
Berger's disease	2 (2.7)	10 (3.7)	ns	2 (3.5)	4 (7.1)	0.679
History of risk factors						
Hypertension	47 (64.3)	186 (69.9)	0.366	33 (58.9)	32 (57.1)	0.848
Diabetes mellitus	62 (84.9)	236 (88.7)	0.379	48 (85.7)	51 (91.0)	0.376
Insulin	22 (30.1)	119 (44.7)	0.025	19 (33.9)	25 (44.6)	0.246
Duration, year	17 ± 9	16 ± 10	0.823	17 ± 9	15 ± 10	0.379
Dyslipidemia	5 (6.8)	11 (4.1)	0.352	2 (3.5)	3 (5.3)	ns
Stroke	6 (8.2)	50 (18.7)	0.031	5 (8.9)	8 (14.2)	0.376
Chronic renal insufficiency	21 (28.7)	104 (39.0)	0.105	18 (32.1)	17 (30.3)	0.838
Dialysis	13 (17.8)	74 (27.8)	0.083	13 (23.2)	10 (17.8)	0.483
History smokers	36 (49.3)	112 (42.1)	0.271	27 (48.2)	26 (46.4)	0.850
History alcoholics	14 (19.1)	48 (18)	0.824	10 (17.8)	9 (16.0)	0.801
Significantly CAD						
Prior MI	2 (2.7)	14 (5.2)	0.538	1 (1.7)	5 (8.9)	0.206
Prior PTCA	18 (24.6)	73 (27.4)	0.634	11 (19.6)	13 (23.2)	0.645
Prior CABG	3 (4.1)	13 (4.8)	ns	2 (3.5)	2 (3.5)	ns
De novo PCI within 30 day	19 (26.0)	80 (30.0)	0.500	12 (21.4)	14 (25.0)	0.654
Laboratory findings						
Hemoglobin	11 ± 1	11 ± 1	0.025	11 ± 1	11 ± 2	0.304
A1c, %	7.2 ± 1.6	7.4 ± 1.4	0.501	7.2 ± 1.7	7.2 ± 1.4	0.950
Fasting blood glucose	143 ± 71	141 ± 71	0.866	142 ± 78	140 ± 75	0.872
Serum insulin	9.7 ± 7.6	9.5 ± 6.7	0.911	10.1 ± 8.1	7.8 ± 5.0	0.175
Total cholesterol	133 ± 34	145 ± 42	0.023	132 ± 34	140 ± 44	0.265
Triglyceride	136 ± 14	121 ± 76	0.274	139 ± 163	128 ± 103	0.716
HDL cholesterol	35 ± 14	35 ± 11	0.819	34 ± 15	36 ± 12	0.481
LDL cholesterol	75 ± 29	87 ± 34	0.011	72 ± 30	84 ± 29	0.470
High-sensitive CRP	25 ± 28	28 ± 53	0.750	26 ± 26	19 ± 34	0.436
Uric acid	5.4 ± 2.1	5.6 ± 1.8	0.563	5.1 ± 2.0	5.9 ± 1.9	0.087
Creatinine	2.2 ± 2.9	2.8 ± 3.1	0.181	2.6 ± 3.2	2.2 ± 2.5	0.576

Variables, N (%)	Overall			Matched		
	Stent, Limb (n=78)	POBA, Limb (n=316)	p Value	Stent, Limb (n=61)	POBA, Limb (n=61)	p Value
Ankle brachial index	0.8 ± 0.2	0.7 ± 0.4	0.116	0.8 ± 0.2	0.7 ± 0.4	0.364
Rutherford classifications			0.016			0.874
Grade 0	0 (0.0)	2 (0.6)				
Grade 1	19 (24.3)	51 (16.1)		10 (16.3)	12 (19.6)	
Category 1	1 (1.2)	4 (1.2)				
Category 2	3 (3.8)	3 (0.9)		1 (1.6)	2 (3.2)	
Category 3	15 (19.2)	44 (13.9)		9 (14.7)	10 (16.3)	
Grade 2	35 (44.8)	102 (32.2)		31 (50.8)	24 (39.3)	
Category 4	6 (7.6)	18 (5.6)		6 (9.8)	3 (4.9)	
Category 5	29 (37.1)	84 (26.5)		25 (40.9)	21 (34.4)	
Grade 3	24 (30.7)	161 (50.9)		20 (32.7)	25 (40.9)	
Sub-intimal approach	45 (57.6)	134 (42.4)	0.015	34 (55.7)	27 (44.2)	0.205
Lesion location						
Distal aorta a.	1 (1.2)	0 (0.0)	0.198			
Iliac a.	6 (7.6)	14 (4.4)	0.251	4 (6.5)	2 (3.2)	0.680
Femoral a.	31 (39.7)	127 (40.1)	0.943	25 (40.9)	21 (34.4)	0.455
Popliteal a.	13 (16.6)	42 (13.2)	0.441	10 (16.3)	6 (9.8)	0.283
Posterior tibia a.	50 (64.1)	139 (43.9)	0.001	36 (59.0)	40 (65.5)	0.455
Arterial tibia a.	61 (78.2)	235 (74.3)	0.483	47 (77.0)	48 (78.6)	0.827
Peroneal a.	32 (41)	90 (28.4)	0.032	23 (37.7)	26 (42.6)	0.580

One Year Cumulative Cardiac Clinical Outcomes

Variables, N (%)	Overall			Matched		
	Stent, Pts (n=73)	POBA, Pts (n=266)	p Value	Stent, Pts (n=56)	POBA, Pts (n=56)	p Value
Clinical outcomes at 30 days						
Total death	0 (0.0)	4 (1.5)	0.581	0 (0.0)	3 (5.3)	0.243
Cardiac death	0 (0.0)	1 (0.3)	ns	0 (0.0)	1 (1.7)	ns
Myocardial infarction	0 (0.0)	1 (0.3)	ns	-	-	-
Cerebral vascular accidents	1 (1.3)	0 (0.0)	0.215	1 (1.7)	0 (0.0)	ns
Clinical outcomes at 1-year						
Follow-up duration, day	362 ± 17	346 ± 69	0.001	362 ± 20	356 ± 44	0.376
Total death	1 (1.3)	19 (7.1)	0.089	1 (1.7)	2 (3.5)	ns
Cardiac death	0 (0.0)	5 (1.8)	0.589	-	-	-
Myocardial infarction	0 (0.0)	2 (0.7)	ns	-	-	-
PCI	2 (2.7)	7 (2.6)	ns	2 (3.5)	1 (1.7)	ns
Cerebral vascular accidents	0 (0.0)	4 (1.5)	0.581			
MACCEs	3 (4.1)	28 (10.5)	0.092	3 (5.3)	3 (5.3)	ns

Six to 9-Month CT-Angiographic and 1-Year Clinical Outcomes

Variables	Matched		Hazard ratio [95% C.I.]	p Value
	Stent, Limb (n=27)	POBA, Limb (n=15)		
Binary restenosis	19 (70.3)	8 (53.3)	2.078 [0.561 - 7.687]	0.270
Total occlusion	12 (44.4)	6 (40.0)	1.200 [0.333 - 4.324]	0.780
Primary patency	7 (25.9)	7 (46.6)	0.400 [0.105 - 1.512]	0.172
Associated primary patency	11 (40.7)	7 (46.6)	0.785 [0.220 - 2.803]	0.710
Secondary patency	19 (70.3)	9 (60.0)	1.583 [0.421 - 5.942]	0.495
Non-occlusive (distal run-off at least 1 artery)	23 (85.1)	13 (86.6)	0.884 [0.142 - 5.506]	ns
Variate, N (%)	Stent, Limb (n=61)	POBA, Limb (n=61)	Hazard ratio [95% C.I.]	p Value
Limb salvage	58 (95.0)	61 (100.0)	-	0.244
Repeat PTA				
Target extremity revascularization; TER	13 (21.3)	2 (3.2)	7.989 [1.718 - 37.14]	0.002
Target lesion revascularization; TLR	12 (19.6)	2 (3.2)	7.224 [1.542 - 33.83]	0.005
Non-TLR TER	5 (8.1)	1 (1.6)	5.357 [0.606 - 47.28]	0.207
Target extremity surgery; amputations	6 (9.8)	6 (9.8)	1.000 [0.303 - 3.292]	ns
Above the knee	1 (1.6)	0 (0.0)	0.495 [0.414 - 0.593]	ns
Above the ankle	3 (4.9)	0 (0.0)	0.487 [0.405 - 0.586]	0.244
Below the ankle	6 (9.8)	6 (9.8)	1.000 [0.303 - 3.292]	ns

Summary

- After PSM analysis, 2 propensity-matched groups (56 pairs in pts, n= 112; 61 pairs in limbs, n=122, C-statistic=0.808) were generated, and the baseline & angiographic characteristics of the two groups were balanced.
- Procedural success, complication incidences were similar between the two groups.
- Six to 9-month CT or angiographic follow-up, there were similar incidence of binary restenosis, primary, and secondary patency.
- At 12 months, there were similar incidence of individual hard endpoints including mortality, myocardial infarction, limb salvage, and any extremity amputations except the target lesion and extremity revascularization.
- Repeat PTA incidence was higher in the stenting group than POBA group (table).

Conclusion

- Although the repeat PTA risk was increased with BTK stenting, other major individual clinical outcomes and limb salvage rates were similar between the POBA and stenting for the BTK lesions.