Impact of Full-Cover Stenting in Femoropopliteal Lesions on Time to Wound Healing in Patients With Critical Limb Ischemia

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Background

In critical limb ischemia (CLI) patients, low BMI and wound infection are reported as the predictors of unhealed wound after EVT[1].
Stenting in femoropopliteal (FP) lesions may have beneficial effects in CLI patients by obtaining larger acute gain than balloon angioplasty alone. However, how much stenting strategy affect the outcomes of FP lesions remains unclear.
We assessed the impact of full-cover stenting (FCS) on time to wound healing in CLI patients.

1) Iida O et al. Circ Cardiovasc Interv. 2013;6:68-76.

Methods

Single-center retrospective analysis
Study period; 1 Nov 2015 to 31 Dec 2017
*Drug-coated balloon was not approved in Japan during the above period.

➢ **Definitions**

Spot stenting was included in non-FCS group.
MALE: major amputation or any revascularization.

➢ **Patient population**

CLI (Rutherford class 5&6) patients undergoing EVT as an initial revascularization therapy for the target limb were included.

106 Consecutive CLI limbs treated by EVT (91 patients)
↓
46 CLI limbs with FP lesions (44 patients)
↓
FCS group: 11 limbs (23.9%) | Non-FCS group: 35 limbs (76.1%)

✓ Median follow up duration was 393.5 (267.8-572.5) days.

Results

➢ Baseline characteristics

	FCS	Non-FCS	p value
Age, y	74.4±11.6	74.2±10.2	0.97
Male, n (%)	9 (81.8)	16 (45.7)	0.045
BMI, kg/m^2	20.8±4.1	22.9±3.5	0.14
BMI<18.5	3 (27.3)	3 (9.1)	0.15
ADL			0.23
Ambulatory	8 (72.7)	19 (54.3)	
Wheel chair user	1 (18.2)	15 (42.9)	
Bed-ridden	1 (9.1)	1 (2.9)	
Diabetes mellitus, n (%)	8 (72.7)	26 (74.3)	> 0.99
Lipidemia, n (%)	5 (45.5)	20 (57.1)	0.73
Hypertension, n (%)	8 (72.7)	28 (80.0)	0.68
Smoking history, n (%)	9 (81.8)	14 (40.0)	0.04
CVD, n (%)	5 (45.5)	5 (14.3)	0.04
CAD, n (%)	6 (54.6)	14 (41.2)	0.49
- PTCA history, n (%)	4 (36.4)	8 (22.9)	0.44
- CABG history, n (%)	3 (27.3)	4(11.4)	0.33
OMI, n (%)	3 (27.3)	9 (25.7)	> 0.99
Heart failure, n (%)	1 (9.1)	9 (25.7)	0.41
EF (%)	56.1±12.3	55.6±8.4	0.91
Hemodialysis, n (%)	6 (54.6)	16 (45.7)	0.73
eGFR	25.1±26.1	30.3±30.9	0.59

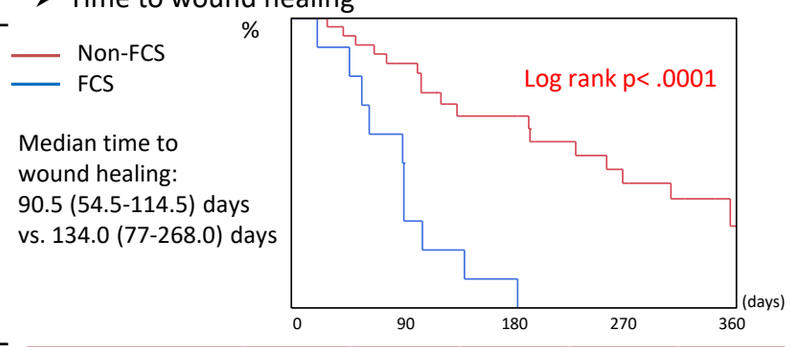
	FCS	Non-FCS	p value
ABI pre	0.50±0.25	0.31±0.28	0.053
ABI post	0.78±0.28	0.68±0.16	0.29
Skin perfusion pressure (SPP)			
Dorsal surface	22.5±2.1	22.7±15.2	0.96
Plantar surface	28.9±15.0	24.6±13.0	0.51
Rutherford classification			> 0.99
R-5	8 (72.7)	26 (74.3)	
R-6	3 (27.3)	9 (25.7)	
- Wound			0.06
1	10 (90.9)	18 (51.4)	
2	1 (9.1)	14 (40.0)	
3	0 (0.0)	3 (8.6)	
- Ischemia			0.12
0	0 (0.0)	1 (2.9)	
1	5 (45.5)	6 (17.1)	
2	4 (36.4)	9 (25.7)	
3	2 (18.2)	19 (54.3)	
- foot Infection			0.27
0	11 (100.0)	28 (80.0)	
1	0 (0.0)	3 (8.6)	
2	0 (0.0)	4 (11.4)	
WIfI stage			0.02
1	4 (36.4)	5 (14.3)	
2	4 (36.4)	4 (11.4)	
3	3 (27.3)	11 (31.4)	
4	0 (0.0)	15 (42.9)	
Foot infection (fI 1 or 2)	0 (0.0)	7 (22.0)	0.17
WIfI Stage 4	0 (0.0)	15 (42.9)	0.009
Planned amputation	0 (0.0)	11 (31.4)	0.04
Regular f/u by plastic surgeon	1 (9.1)	22 (62.9)	0.004

	FCS	Non-FCS	p value
Reference VD	4.93±0.82	4.32±0.73	0.04
Lesion length	103.6±66.5	137.4±112.9	0.23
Pre MLD	0.96±0.83	0.48±0.69	0.103
Post MLD	4.21±0.68	2.53±0.91	< .0001
Pre %DS	74.0±29.3	85.6±21.8	0.25
Post %DS	11.4±16.1	39.5±19.95	0.0001
CTO	2 (18.2)	17 (48.6)	0.09
Severe calcification	3 (27.3)	11 (31.4)	> 0.99
PACSS			0.21
0	3 (27.3)	11 (31.4)	
1	2 (18.2)	3 (8.6)	
2	1 (9.1)	0 (0.0)	
3	0 (0.0)	6 (17.1)	
4	5 (45.5)	15 (42.9)	
Popliteal	4 (36.4)	24 (68.6)	0.08
P2/P3	0 (0.0)	13 (37.1)	0.02
BK run off	1.5±0.8	1.4±0.9	0.56
AI treatment	0 (0.0)	1 (2.9)	> 0.99
BK treatment	7 (63.6)	16 (45.7)	0.49
Stent use	11 (100.0)	9 (25.7)	< .0001
Max balloon size	4.73±0.65	4.27±0.74	0.06
Max balloon length	61.8±30.3	66.4±59.1	0.74
Total stent length	109.1±59.2	53.9±103.3	0.04
Scoring balloon use	2 (18.2)	24 (68.6)	0.005

➢ Cox proportional hazard model

		HR	95% CI	p value	HR	95% CI	p value
MALE	BMI <18.5	0.74	0.17-2.16	0.61			
	Heart failure	0.87	0.29-2.13	0.77			
	Wound infection	3.30	1.17-8.19	0.03	1.28	0.41-3.70	0.65
	Hemodialysis	1.07	0.49-2.34	0.87			
	R-6	2.10	0.89-4.64	0.09			
	WIfI stage 4	5.40	2.20-13.5	0.003	3.65	1.31-10.3	0.01
	FCS	0.27	0.08-0.73	0.009	0.40	0.11-1.24	0.12
	Post MLD	0.74	0.53-1.03	0.08			
Wound healing	BMI<18.5	2.02	0.67-5.02	0.19			
	Heart failure	0.94	0.31-2.31	0.90			
	Wound infection	0.96	0.32-2.36	0.94			
	Hemodialysis	0.87	0.41-1.85	0.72			
	R-6	1.05	0.43-2.33	0.90			
	WIfI stage 4	0.77	0.33-1.66	0.51			
	FCS	5.53	2.23-13.7	0.0004	4.09	1.16-15.4	0.028
	Post MLD	1.81	1.21-2.74	0.004	1.20	0.68-2.09	0.53

➢ Time to wound healing



Median time to wound healing:
90.5 (54.5-114.5) days
vs. 134.0 (77-268.0) days

Non-FCS					
No. of patients at risk	35	25	16	9	3
No. of events	0	5	10	15	17
Cumulative incidence	0%	15.6%	33.8%	56.9%	71.7%
FCS					
No. of patients at risk	11	5	1	1	1
No. of events	0	5	9	10	10
Cumulative incidence	0%	50.0%	90.0%	100.0%	100.0%

Summary

- Limb status was severer in non-FCS group.
- Postprocedural MLD and %DS were larger in FCS group.
- In a multivariable analysis, MALE was associated with the baseline limb status, whereas time to wound healing was associated with stenting strategies.
- Median time to wound healing was shorter in FCS group (90.5 days vs. 134.0 days, p < .0001).

Limitations

- Small-number, single-center retrospective analysis.
- The baseline patient characteristics were quite different between the two groups.

Conclusion

FCS may be inadequate to avoid MALE; however, it may shorten the time to wound healing in CLI patients with FP lesions.

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