Comparison of Clinical Outcome between Patient with and without Hemodialysis after Endovascular Treatment with Heparin-Bonded Covered Stent

Shonan Kamakura General Hospital Department of Cardiology Hirokazu Miyashita, Kazuki Tobita, Takahiro Hayashi, Shohei Yokota, Yuka Mashimo, Hiroaki Yokoyama
Takashi Nishimoto, Tomoki Ochiai, Noriaki Moriyama, Koki Shishido, Shingo Mizuno, Futoshi Yamanaka, Yutaka Tanaka, Masato Murakami, Saeko Takahashi, Shigeru Saito

Study Background

Previously several studies reported good outcomes of VIABAHN for femoro-popriteal lesion, and randomized study showed comparable patency rate compared to bare nitinol stent or surgical treatment. However, little is known about clinical outcome for patients with hemodialysis.
Main objective in this study is to investigate mid-term outcome of heparin-bonded covered-stent in daily practice in our hospital.

Methods

・Retrospective analysis.
・Jan,2017 ～ Apr,2018 in our institution.
・Consecutive cases undergoing EVT for femoro-popliteal lesion with VIABAHN.
・Index procedure and medical treatment were at discretion of attending physician.
・Patients were divided into two groups; those with hemodialysis and without hemodialysis .
・Primary endpoint: Primary patency (defined as no evidence of significant restenosis), Assisted Primary Patency (defined as stent graft that had not occluded at any time) and Clinical Driven-Target Lesion Revascularization(CD-TLR).
・Secondary endpoint: MACE (composite of all cause death, stroke, and myocardial infarction), MALE (composite of all re-intervention, and major amputation), device infection and graft thrombosis.

Results

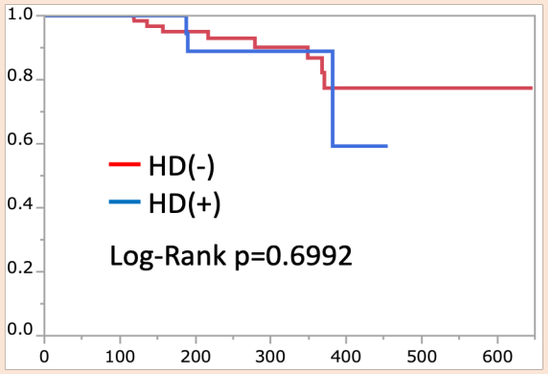
Baseline Characteristics	non-HD	on-HD	p
Patient Number	54	19	
Male	26 (47.3%)	15 (78.9%)	NS
Age, y	76.9±10.3	76.8±9.6	NS
Risk factor			
Diabetes Mellitus	32 (58.2%)	12 (63.2%)	NS
Hypertension	47 (85.5%)	15 (78.9%)	NS
Dyslipidemia	36 (65.5%)	8 (42.1%)	NS
Smoking			
Current	5 (9.1%)	0 (0%)	NS
CKD	23 (41.8%)	19 (100%)	NS
Past interventional data			
CAD	33 (60.0%)	11 (57.9%)	NS
post EVT	24 (43.6%)	11 (57.9%)	NS
Medication			
Statin use	49 (89.1%)	14 (73.7%)	NS
DAPT use	51 (92.7%)	18 (94.7%)	NS
Anticoagulant use	5 (9.1%)	1 (5.3%)	NS
Cilostazol use	43 (78.2%)	12 (63.2%)	NS

Results

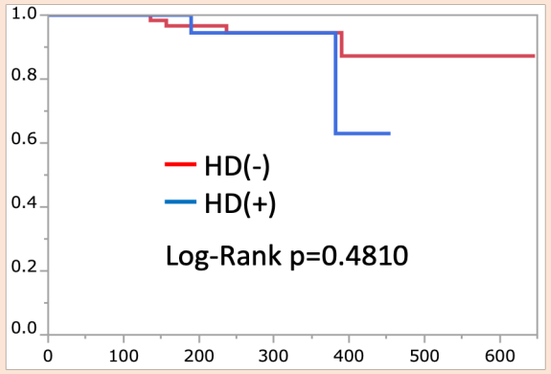
Lesion Characteristics	non-HD	on-HD	p
Lesion Number	72	23	
Right	38 (52.8%)	13 (56.5%)	NS
ABI	0.66 ± 0.16	0.62±0.20	NS
CLI	19 (26.4%)	9 (39.1%)	NS
TASC C/D	63 (87.5%)	21 (91.3%)	NS
Occlusion	42 (59.2%)	10 (43.4%)	NS
Lesion length	274 ± 80mm	268 ± 86mm	NS
Severe calc	**24 (33.3%)**	**17 (73.9%)**	**p=0.0006**
ISR	14 (19.4%)	4 (17.4%)	NS
Distal runoff	1.46 ± 0.75	1.43 ± 0.66	NS
RVD proximal	6.0 ± 0.49mm	6.17 ± 0.41mm	NS
RVD distal	5.7 ± 0.63mm	5.80 ± 0.62mm	NS

Procedural Characteristics	non-HD	on-HD	p
Approach			
Ipsilateral	26 (36.1%)	11 (47.8%)	NS
Cross-Over	46 (63.9%)	12 (52.2%)	NS
Distal puncture	18 (25.0%)	4 (17.4%)	NS
Post-ABI	0.97 ± 0.16	0.99 ± 0.17	NS
IVUS use	72 (100%)	23 (100%)	NS
Stent number	2.15 ± 0.64	1.87 ± 0.46	NS
Min stent diameter	5.69 ± 0.64mm	5.87 ± 0.63	NS
Lesion Success	71 (98.6%)	22 (95.7%)	NS

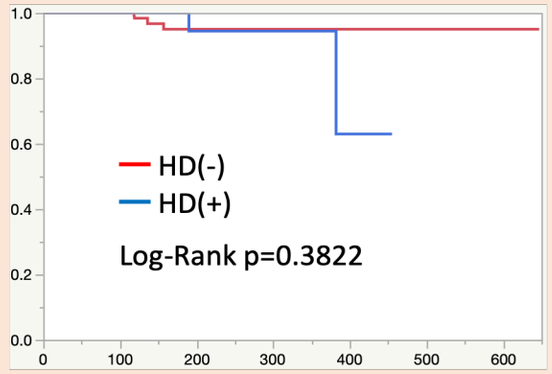
Endpoints	non-HD	on-HD	p
Follow-up period	287days	263days	0.473
Primary Outcome			
Primary Patency	88.9%	88.4%	0.801
Assisted Primary Patency	95.6%	91.3%	0.397
CD-TLR	94.4%	91.3%	0.590
Secondary Outcome			
MACE	**1.4%**	**21.7%**	**<0.001**
all cause death	**1.4%**	**21.7%**	**<0.001**
cardiac death	0%	4.4%	0.08
myocardial infarction	0%	0%	NA
stroke	**0%**	**8.7%**	**0.011**
MALE	6.9%	13.4%	0.359
major amputation	0%	0%	NA
all re-intervetion	6.9%	13.4%	0.359
Device Infection	0%	0%	NA
Graft Thrombosis	2.8%	8.7%	0.219



	day	50	100	150	200	250	300	350	400	450	500
HD+	rate(%)	100	100	100	88.9	88.9	88.9	88.9	59.3	59.3	NA
	at risk	23	23	21	17	14	7	6	2	1	NA
	SE	0	0	0	0.0741	0.0741	0.0741	0.0741	0.247	0.247	NA
HD-	rate(%)	100	100	96.7	95	93	90.1	86.8	77.4	77.4	77.4
	at risk	68	65	59	49	40	31	27	13	8	4
	SE	0	0	0.016	0.028	0.0342	0.0432	0.053	0.0786	0.0786	0.0786



	day	50	100	150	200	250	300	350	400	450	500
HD+	rate(%)	100	100	100	94.4	94.4	94.4	94.4	63	63	NA
	at risk	23	23	21	18	15	8	5	3	2	NA
	SE	0	0	0	0.054	0.054	0.054	0.054	0.2596	0.2596	NA
HD-	rate(%)	100	100	98.3	96.6	94.5	94.5	94.5	87.2	87.2	87.2
	at risk	68	64	61	51	42	32	28	13	9	5
	SE	0	0	0.0165	0.0234	0.0312	0.0312	0.0312	0.0755	0.0755	0.0755



	day	50	100	150	200	250	300	350	400	450	500
HD+	rate(%)	100	100	100	94.4	94.4	94.4	94.4	63	63	NA
	at risk	23	23	21	18	15	8	5	3	2	NA
	SE	0	0	0	0.054	0.054	0.054	0.054	0.2596	0.2596	NA
HD-	rate(%)	100	100	98.4	95.0	95.0	95.0	95.0	95.0	85.0	95.0
	at risk	68	65	59	50	42	32	28	15	10	6
	SE	0	0	0.0160	0.0280	0.0280	0.0280	0.0280	0.0280	0.0280	0.0280

Discussion & Conclusion

Our study suggested no significant differences in terms of efficacy outcome between on-HD and no-HD patient. However, clinical outcome in on-HD patient had worsening trend.
Previous large retrospective study suggests that on-HD patients have an increased risk for loss of primary patency and need for TLR after bare self-expandable nitinol stent implantation to femoro-popriteal lesions. Our result had similar trend.
Twenty percent of On-HD patients had dead during follow-up period, this is consistent with previous report which showed on-HD patient had bad prognosis. We might underestimate primary outcome because on-HD patient could die before they reach to primary endpoint.
Further Follow-up study and larger sample size are needed.