



SFA-Popliteal Evidence Development (SPEED): Early OPG results

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Way too very early OPG results

- Cohort included per lesion analysis of patients having only one procedure
- Primary outcome of Target Lesion Revascularization (TLR) analyzed first
- Understand what we have and how to refine for subsequent analysis



		PTA N= 9018 %	Stent N= 10932 %	Atherectomy +/- PTA N= 3081 %	Atherectomy + stent N= 969 %	Other N= 931 %
Age (mean)		70	69	69	70	70
BMI (mean)		28	28	28	28	28
Gender (female)		46	38	41	36	42
Ethnicity Hispanic/Latino		7	6	5	5	6
Race						
Black		19	16	15	14	17
	White	75	79	79	81	78
	Other	6	5	6	4	5
Discharge status home		86	89	91	91	86
Preop Smoking						
	Never	29	21	24	20	21
	Prior	43	43	43	45	45
	Current	28	36	33	35	34
Hypertension		89	88	90	87	92
Diabetes						
None		42	47	45	50	48
	Diet	5	4	4	3	4
	Non-insulin Meds	18	19	18	19	17
	Insulin	36	30	33	28	31
CAD						
None		71	71	68	68	68
	hx MI but no sx	20	20	22	21	22
	Stable angina	7	7	7	8	8
	Unstable angina or MI < 6 mos	2	2	2	3	3
CHF						
Asymp, hx CHF		12	10	11	12	11
	Mild	5	5	4	5	4
	Moderate/Severe	4	3	3	3	3
COPD		22	23	23	24	27
CREATININE		1.16	1.14	1.13	1.09	1.13
Dialysis		10	7	9	6	8
Living status Nursing home		6	4	4	4	6
Preop ambulation						
Ambulatory		70	76	77	81	74
	Amb w/ Assistance	21	18	16	13	18
	Wheelchair/Bedridden	9	6	7	6	8
ASA Class						
	1-2	19	24	22	25	23
	3	63	63	59	62	62
	4	11	8	11	8	10
Prior Bypass		15	11	10	11	14
Prior PVI		35	32	35	37	44
Prior Major Amp		7	4	4	3	5
Preop Aspirin		69	72	71	71	75
Pre-op P2Y12 Antagonist		35	37	43	45	44
Pre-op Statin		66	67	68	70	73
Pre-op Anticoagulation						
Warfarin		2	2	2	2	2
Dabigatran/Rivaroxaban		2	2	2	2	2

Some Observations

- Females 36-46%
- African American 14-19%
- Smoking: prior ~ 43% current 28-36%
- IDDM 28-36%
- CAD ~ 30%
- Dialysis 6-10%
- 35-44% prior PVI





SFA lesion characteristics by treatment type

	PTA only		Stent +/- PTA		Atherectomy +/- PTA		Stent + Atherectomy		Other	
	N= 6889		N= 9847		N= 2376		N= 871		N= 807	
	n	%	n	%	n	%	n	%	n	%
Indication on same side										
claudication	3066	45	5051	51	1378	58	495	57	372	46
rest pain	922	13	1365	14	300	13	136	16	123	15
tissue loss	2900	42	3427	35	697	29	240	28	311	39
Inflow Bypass on same side	201	2.9	221	2.2	56	2.4	24	2.8	17	2.1
Inflow PTA Stent on same side	609	8.8	820	8.3	190	8.0	76	8.7	88	10.9
Leg Bypass on same side	353	5.1	306	3.1	74	3.1	31	3.6	44	5.5
Leg PTA Stent on same side	1481	21.5	1508	15.3	494	20.8	162	18.6	232	28.7
Major Amputation on same side	27	0.4	10	0.1	7	0.3	0	0.0	0	0.0
Minor Amputation on same side	506	7.3	502	5.1	119	5.0	36	4.1	37	4.6
TASC										
A	2382	34.6	2283	23.2	548	23.1	150	17.2	132	16.4
B	1680	24.4	2417	24.5	612	25.8	213	24.5	171	21.2
C	1041	15.1	1975	20.1	410	17.3	175	20.1	163	20.2
D	553	8.0	1645	16.7	275	11.6	175	20.1	218	27.0
Total treated length (cm)	5766	11	8583	15	1857	13	721	16	555	16
Total occlusion length (cm)	5742	6	8421	10	1911	7	710	11	569	10
Preop ABI	5221	0.72	7401	0.68	1795	0.70	656	0.67	604	0.70
Preop TBI	1778	0.40	2285	0.38	415	0.44	135	0.44	171	0.39

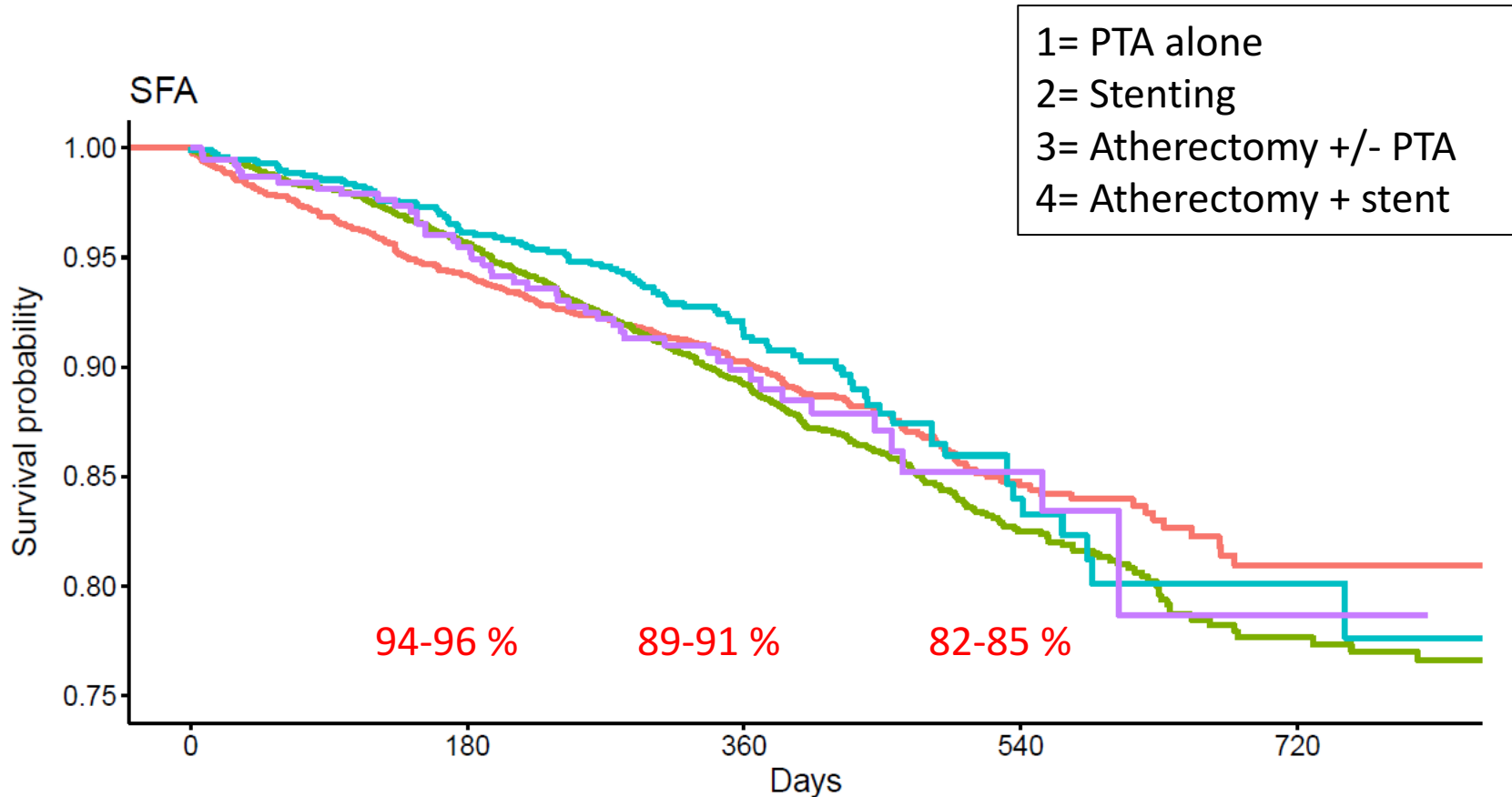
Some Observations

- 42-55% for critical limb ischemia
- PTA appears more common for TASC A
- 15-21 % prior ipsilateral leg PTA
- Mean occlusion 6-11 cm
- Total treatment length mean 11-16 cm
- TASC C= 3,601 and TASC D= 2,648 for total N= 6,249





K-M of TLR for SFA by 4 treatment types

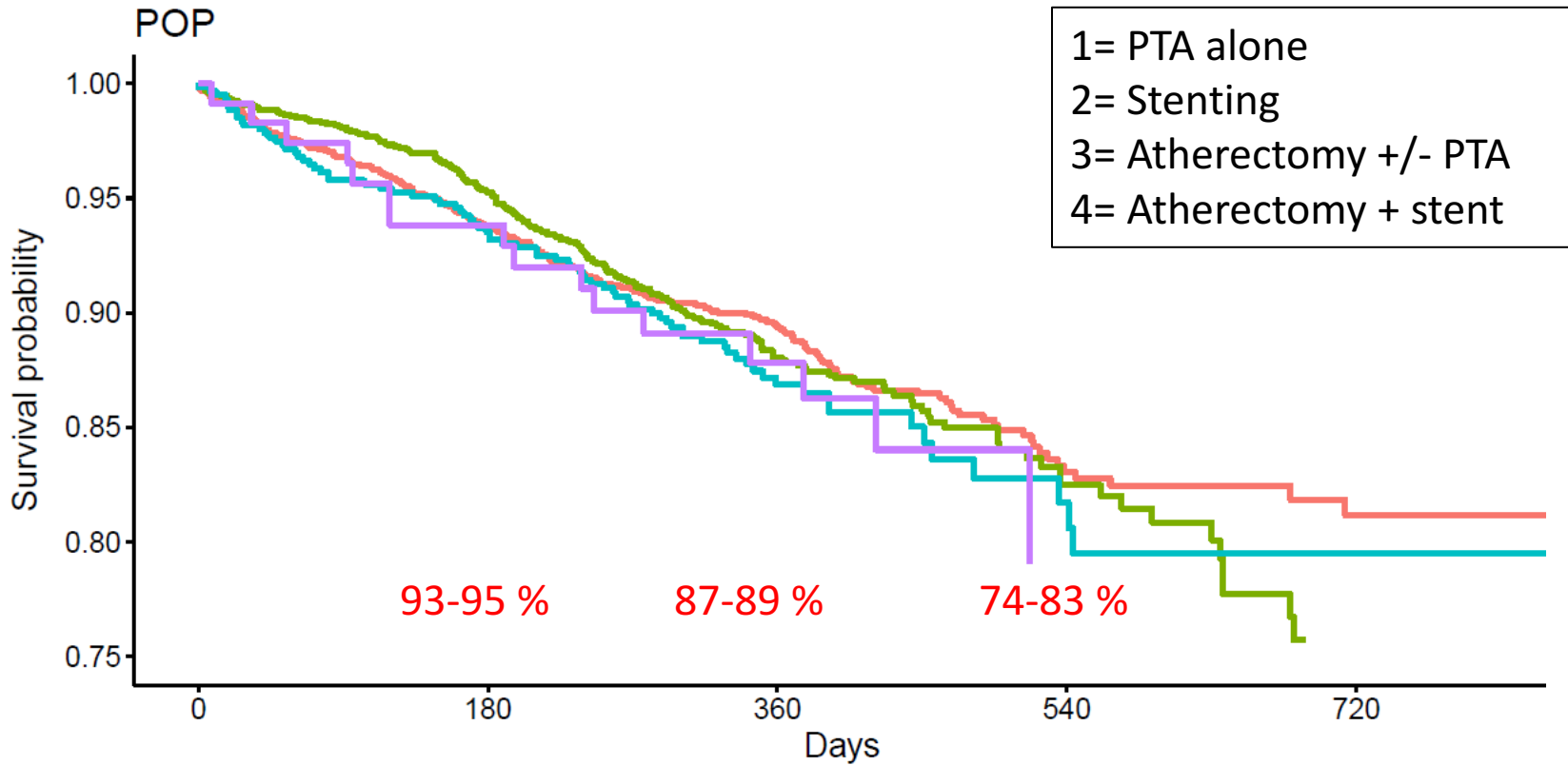


at risk, KM estimate (95% C.I.)

strata	trt=1	trt=2	trt=3	trt=4
0	3171	5094	980	384
180	2786, 94.17% (93.35%, 95.01%)	4603, 95.64% (95.07%, 96.22%)	906, 96.12% (94.90%, 97.35%)	354, 95.47% (93.39%, 97.60%)
360	1723, 90.24% (89.16%, 91.34%)	2797, 89.22% (88.32%, 90.13%)	499, 91.37% (89.47%, 93.31%)	217, 89.87% (86.77%, 93.09%)
540	438, 84.60% (82.76%, 86.48%)	757, 82.48% (80.97%, 84.02%)	119, 83.98% (80.20%, 87.93%)	52, 85.20% (80.67%, 89.97%)
720	159, 80.95% (78.17%, 83.82%)	250, 77.64% (75.32%, 80.04%)	37, 80.13% (75.04%, 85.55%)	16, 78.65% (70.71%, 87.49%)



K-M of TLR for Popliteal by 4 treatment types



at risk, KM estimate (95% C.I.)

strata	0	180	360	540	720
trt=1	2212	1935, 93.82% (92.80%, 94.85%)	1166, 89.35% (88.00%, 90.71%)	296, 83.07% (80.76%, 85.45%)	118, 81.16% (78.20%, 84.24%)
trt=2	1492	1332, 95.27% (94.18%, 96.38%)	810, 88.03% (86.29%, 89.81%)	199, 82.47% (79.66%, 85.38%)	65, 74.70% (69.49%, 80.29%)
trt=3	604	541, 93.54% (91.57%, 95.55%)	276, 86.85% (84.00%, 89.81%)	74, 81.71% (77.25%, 86.43%)	18, 79.47% (74.24%, 85.07%)
trt=4	117	103, 93.82% (89.49%, 98.36%)	64, 87.83% (81.78%, 94.32%)	15, 74.13% (60.82%, 90.35%)	6, 67.39% (51.34%, 88.47%)



SFA TLR covariates *

Covariate	DF	Score Test	P Value	Higher Hazard
AGE	1	44.58	0.0000	Younger
INDICATION	2	43.64		2 Rest Pain > 3 Tissue Loss / 1 Claudication
TASC	3	31.36	0.0000	Higher
Ipsilateral LEG PTA/STENT	1	30.39	0.0000	Yes
BMI	1	14.89	0.0001	Lower?
DIABETES	3	14.02	0.0029	Insulin
RACE	2	13.10	0.0014	African American
COPD	1	12.33	0.0004	No COPD?
PREOP SMOKING	2	10.36	0.0056	Current > Prior > NO
PRIOR PT/ASTENT	1	9.44	0.0021	Yes
HTN	1	9.42	0.0021	Hypertension
CHF	3	8.31	0.0401	Severe
PRIOR BYPASS	1	7.96	0.0048	Yes
SURGYEAR	1	7.55	0.0060	Recent ?
CREATININE	1	7.36	0.0067	Lower
Ipsilateral PIN BYPASS	1	6.79	0.0092	Yes
ASA CLASS	2	6.18	0.0455	Higher Class
TOTAL OCC LENGTH	1	4.66	0.0309	Longer
DIALYSIS	1	4.63	0.0315	Dialysis
PREOP ANTICOAG	3	3.67	0.2995	
GENDER	1	3.53	0.0604	Female

* results are based on Cox PH models with covariates including total_num_sites, TOT_TREATED_LENGTH and the covariate of interest



Popliteal TLR covariates *

Covariate	DF	Score Test	P Value	Higher Hazard
TASC	3	25.17	0.0000	Higher
INDICATION	2	23.27	0.0000	2 Rest Pain > 3 Tissue Loss / 1 Claudication
PRIOR BYPASS	1	19.03	0.0000	Yes
PRIOR MAJOR AMP	3	16.12	0.0011	1
RACE	2	15.14	0.0005	AfricanAm
Ipsi_PLEGPTASTENT	1	14.66	0.0001	Yes
AGE	1	12.61	0.0004	Younger
Ipsi_PINPTASTENT	1	8.62	0.0033	Yes
Ipsi_PLEGBYPASS	1	8.54	0.0035	Yes
BMI	1	8.21	0.0042	Lower?
PREOP SMOKING	2	8.17	0.0168	Current > Prior > NO
CAD	3	4.58	0.2051	
PRIOR PTA/STENT	1	4.15	0.0417	Yes

*results are based on Cox PH models with covariates including total_num_sites, TOT_TREATED_LENGTH and the covariate of interest

SFA TLR covariates (all)



Covariate	DF	Score Test	P Value	Higher Hazard
AGE	1	44.58	0.0000	Younger
Ipsi_INDICATION	2	43.64	0.0000	2 Rest Pain > 3 Tissue Loss / 1 Claudication
TASC	3	31.36	0.0000	Higher
Ipsi_PLEGPTASTENT	1	30.39	0.0000	Yes
BMI	1	14.89	0.0001	Lower?
DIABETES	3	14.02	0.0029	Insulin
RACE_c	2	13.10	0.0014	AfricanAm
COPD_c	1	12.33	0.0004	No COPD?
PREOP_SMOKING	2	10.36	0.0056	Current > Prior > NO
PRIOR_PTASTENT	1	9.44	0.0021	Yes
HTN	1	9.42	0.0021	Hypertension
PRIOR_CHF_c	3	8.31	0.0401	Severe
PRIOR_BYPASS	1	7.96	0.0048	Yes
SURGYEAR	1	7.55	0.0060	Recent?
CREATININE	1	7.36	0.0067	Lower
Ipsi_PINBYPASS	1	6.79	0.0092	Yes
ASACCLASS_c	2	6.18	0.0455	Higher Class
TOT_OCC_LENGTH	1	4.66	0.0309	Longer
DIALYSIS_c	1	4.63	0.0315	Dialysis
PREOP_ANTICOAG_c	3	3.67	0.2995	
GENDER	1	3.53	0.0604	Female
CAD_c	3	3.16	0.3671	
Ipsi_PINPTASTENT	1	2.91	0.0879	Yes
PRIOR_MAJAMP	3	2.89	0.4084	
Ipsi_PLEGBYPASS	1	2.61	0.1064	Yes
treatment_group	3	1.66	0.6468	
Ipsi_PMINAMP	1	1.53	0.2158	
PREOP_AMBUL_c	2	1.05	0.5913	
ETHNICITY	1	0.84	0.3607	
LIVINGSTATUS_c	1	0.68	0.4089	
DC_STATUS_c	1	0.37	0.5446	

Popliteal TLR covariates (all)



Covariate	DF	Score Test	P Value	Higher Hazard
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PRIOR_BYPASS	1	19.03	0.0000	Yes
PRIOR_MAJAMP	3	16.12	0.0011	1
RACE_c	2	15.14	0.0005	AfricanAm
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AGE	1	12.61	0.0004	Younger
Ipsi_PINPTASTENT	1	8.62	0.0033	Yes
Ipsi_PLEGBYPASS	1	8.54	0.0035	Yes
BMI	1	8.21	0.0042	Lower?
PREOP_SMOKING	2	8.17	0.0168	Current > Prior > NO
CAD_c	3	4.58	0.2051	
PRIOR_PTASTENT	1	4.15	0.0417	Yes
ASACCLASS_c	2	4.00	0.1350	Higher Class
PRIOR_CHF_c	3	3.76	0.2883	
DIABETES	3	3.03	0.3877	
PREOP_AMBUL_c	2	2.96	0.2280	
COPD_c	1	2.93	0.0870	No COPD?
Ipsi_PINBYPASS	1	2.91	0.0878	Yes
treatment_group	3	2.87	0.4117	
CREATININE	1	2.59	0.1073	Lower
PREOP_ANTICOAG_c	3	2.41	0.4922	
SURGYEAR	1	1.74	0.1865	Recent?
DC_STATUS_c	1	1.15	0.2840	
ETHNICITY	1	0.74	0.3912	
HTN	1	0.51	0.4734	
DIALYSIS_c	1	0.14	0.7123	
LIVINGSTATUS_c	1	0.11	0.7363	
GENDER	1	0.10	0.7532	
TOT_OCC_LENGTH	1	0.01	0.9118	
Ipsi_PMINAMP	1	0.00	0.9852	

Small Stuff

- Exclude patients w major amputation ipsilateral to PVI
- Categories for BMI by CDC class
- Categories for creatinine
- Calculate Glomerular Filtration Rate (GFR) and categorize by CKD class 1-5
- Add covariate Dual antiplatelet therapy (DAPT) = ASA + P2Y12 inhibitor
- Analyze preop, postop or f/u medications or all 3



Bigger Stuff

- Verify we are analyzing only self-expanding stents?
N=2,879 BES
- Categorical analysis of lesion length
- Categorize occlusion and yes/no
- Patients with >1 procedure
- Next steps: MV analysis of TLR
UV and MV analysis of other OPGs



>1 procedure

- 42,976 procedures meeting inclusion criteria
- Among included procedures, there are 33,727 unique patients
 - 26,749 patients have only one qualifying procedure
 - 5,434 patients have two qualifying procedures
 - 2,572 of these patients had the second procedure on the same leg
 - 2,158 patients had the second procedure on the same artery
 - Of the 2,158, 1801 have at least 1 follow-up recorded
 - Of the 1801, 1682 have at least one follow-up on their first procedure
 - **Of the 1682, 757 had reintervention recorded at follow-up**
 - Of the 757, 661 had percutaneous reinterventions, 80 had surgical reinterventions and 16 had both.
 - 1544 have 3 or more
 - 1,485 patients had more than 1 procedure on the qualifying artery
 - Of the 1,485, 1350 have at least 1 follow-up recorded
 - Of the 1485, 1154 have at least one follow-up on their first procedure
 - **Of the 1154, 506 had reintervention recorded at follow-up**
 - Of the 506, 465 had percutaneous reinterventions, 34 had surgical reinterventions and 7 had both

