Table 1

	Men (n=320)	Women (n=230)	p-value
Age (years)	69.9 [62.25-78.0]	73.33 [66.0-80.25]	0.35
Race (%)			<0.001
White	70.3	46.4	
Black	7.2	23.0	
Hispanic	19.7	26.3	
Asian	0.6	1.4	
Other	2.2	2.9	
Body mass index (kg/m^2)	28.2 [25.0-27.4]	28.4 [27.4-30.5]	0.89
Medical history (%)			
Diabetes mellitus	51.6	53.3	0.64
Hypertension	83.7	89.0	0.004
Hyperlipidemia	80.0	84.3	0.16
Coronary artery disease	64.0	50.0	0.002
Prior peripheral artery revascularization	24.1	24.3	1.00
Tobacco use	27.4	11.8	<0.001
Medication use (%)			
Aspirin	57.5	49.5	0.60
Clopidogrel	51.9	45.7	0.84
Cilostazol	11.6	5.7	0.06
Statin	63.4	53.8	0.43
Insulin	17.8	12.9	0.81
Laboratory data			
White blood cell count (x 10^3 cells/mL)	7.7 [6.2-8.9]	10.3 [6.0-9.1]	0.99
Neutrophil/lymphocyte ratio	2.86 [1.65-3.50]	1.97 [1.65-3.53]	0.70
Platelet count (x 10^3 cells/uL)	214 [170-250]	259 [192-309]	<0.001
Creatinine (mg/dL)	1.38 [0.90-1.30]	1.17 [0.71-1.60]	<0.001
LDL-cholesterol (mg/dL)	86 [62-104]	92 [64-116]	0.14
HDL-cholesterol (mg/dL)	46 [36-53]	55 [44-78]	<0.001
Triglycerides (mg/dL)	149 [92-187]	130 [81-200]	0.015
Glucose (mg/dL)	132 [90-149]	129 [89-149]	0.99
Resting ankle-brachial index (ABI)			
Right	0.75 [0.69-0.98]	0.67 [0.41-0.97]	0.10
Left	0.79 [0.65-1.03]	0.56 [0.59-0.99]	0.07
Critical limb ischemia with ABI ≤0.4 (%)	42.8	42.4	0.93
Continuous data are presented as median [interquartile range]			

Table 2

	Men (n=320)	Women (n=230)	p-value
Extent of disease (%)			0.74
Mild or moderate disease	12.5	10.5	
Isolated severe suprapopliteal disease	31.3	32.4	
Isolated severe infrapopliteal disease	15.6	13.3	
Severe multilevel disease	40.6	43.8	
	Men (n=243)	Women (n=168)	
Type of procedural intervention (%)			
Stent placement	59.3	54.8	0.42
Use of adjunctive device therapy (e.g. atherectomy, re-entry device)	33.3	36.9	0.46
Target vessel revascularization (%)	11.9	16.3	0.16

CRT-308

Minimal Plaque Surface Area and Minimal Luminal Area Needed for Effective Atherectomy using the JetStream Navitus in Treating In-Stent Restenosis of Femoral Artery in a Porcine Model

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BACKGROUND The JetStream Navitus (JS) atherectomy device is a rotational cutter with aspiration capability designed to treat infrainguinal arterial obstructive disease. JS XC can be operated with blades down (BD) (2.1 or 2.4 mm perimeter) or blades up (BU) (3.0 or 3.4 mm perimeter) to treat femoropopliteal obstructive disease. It is unclear whether an orbital effect is present while operating the JS leading to a larger minimal luminal area (MLA) than predicted based on device size. Also, the minimum MLA and plaque surface area (PSA) needed in a typical size femoral artery (5-6 mm) for the device to be effective has not been defined. Using an in-stent restenosis (ISR) porcine model and intravascular ultrasound (IVUS) assessment of lesions these questions were addressed.

METHOD 4 pigs (8 limbs) were implanted with overlapping SMART (Cordis) nitinol self-expanding stents using an overstretch balloon/stent model. ISR was treated 1 month after stent implantation with an initial 2 blades down (BD) runs followed by 4 BU runs. IVUS measurements were performed at baseline, after 2 BD runs, and after each BU run on a total of 24 lesions. Minimal luminal area (MLA, mm2) and plaque surface area (PSA, %) were obtained. 1-sample Wilcoxon signed-rank test was performed between MLA obtained after BU runs and theoretical maximal MLA of the XC 2.4-3.4 cutter with BU. MLA and PSA at baseline were plotted against net MLA and PSA gain (BU - baseline) respectively. The minimum MLA and PSA at baseline needed for a positive increase in MLA and reduction in PSA were determined.

RESULTS The femoral artery mean diameter was 4.7 mm. A strong correlation was present between MLA at baseline and after BU runs (Pearson correlation p=0.006) and between PSA at baseline and after BU runs (p<0.0001). An approximate MLA ≤ 9.0 mm2 or PSA ≥ 60% were needed to see a positive effect of atherectomy on treated lesion (i.e. increase in MLA or reduction in PSA). Theoretical MLA achievable from the XC BU 2.4-3.4 device is 9.08 mm2 (A = πr2 using r=3.4/2=1.7mm). No difference is seen between this calculated MLA and the IVUS measured MLAs after BU runs using 1-sample Wilcoxon test indicating no orbital effect of the device on tissue cutting.

CONCLUSION JS XC 2.4-3.4 BU achieved positive cutting of ISR tissue inside a 4.7 mm femoral artery when the baseline lesion MLA was ≤ 9.0 mm2 or PSA ≥ 60% on IVUS. No orbital cutting was seen with the JS BU as MLA obtained after treatment was not different from theoretical MLA.

CRT-309

Impact of Duration of Statin Medication on Clinical Outcomes in Patients Undergoing Percutaneous Transluminal Angioplasty for Atherosclerotic Peripheral Arterial Disease

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BACKGROUND Recently, it was reported that statins are associated with lower rates of major adverse cardiovascular events and amputations in critical limb ischemia (CLI) patients (pts). However, the impact of statin administration duration on clinical outcomes for pts undergoing percutaneous transluminal angioplasty (PTA) due to peripheral arterial disease (PAD) is uncertain.

METHODS A total 286 pts underwent PTA for PAD from Oct 2004 to Feb 2013 from prospective PTA registry was enrolled. Major adverse cardiovascular and extremity events (MACEEs) were defined as the composite end-point consisted of cardiac death, myocardial infarction, repeat PTA, and amputation. The incidence of MACEEs according to statin duration up to 1-year was evaluated.

RESULTS The incidences of total MACEEs was in 33.2% (95/286 pts); cardiac death 7 (2.4%), myocardial infarction 3 (1.0%), major and minor amputation 56 (19.6%), repeat PTA 46 (16.1%). Not only the univariate logistic regression analysis, but also in multivariate logistic regression adjusted by age, gender, hypertension, diabetes, cerebrovascular accident, and chronic renal failure, there was significant risk reduction for MACEES in statin use duration 180 and 360 days group, not in statin use duration 30 and 90 days (Table).

CONCLUSIONS In our study, prolonged statin duration at least longer than 6 months was associated with reduced risk of MACEES compared with shorter statin duration in pts undergoing PTA for PAD.