Table. Association with statin use duration and MACEEs

Statin Duration	Univariate			Multivariate*		
	P value	OR	95% CI	P value	OR	95% CI
30 days	0.100	0.646	0.384-1.087	0.204	0.703	0.408-1.211
90 days	0.098	0.656	0.398-1.081	0.241	0.732	0.435-1.233
180 days	0.003	0.464	0.279-0.773	0.033	0.559	0.328-0.953
360 days	0.003	0.446	0.263-0.756	0.047	0.567	0.324-0.991

* adjusted by age, gender, hypertension, diabetes, cerebrovascular accident, and chronic renal failure
MACEE; major adverse cardiovascular and extremity events (composite of repeat PTA, amputation, cardiac death, and myocardial infarction)

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Intravascular Ultrasound Assessment of the Optimal Number of Runs Using the JetStream Navitus Device to Achieve Maximum Tissue Debulking in Femoral Artery in-Stent Restenosis Porcine Model

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BACKGROUND The JetStream Navitus (JS) atherectomy device (Boston Scientific) is a rotational cutter with aspiration capability to treat infrainguinal arterial obstructive disease. Intravascular ultrasound (IVUS) assessment of the number of blades up (BU) runs needed to achieve optimal tissue debulking in in-stent restenosis (ISR) using the JS is unknown.

METHOD 4 pigs (8 limbs) were implanted with overlapping SMART (Cordis) nitinol self-expanding stents using an overstretch balloon/stent model. In-stent restenosis (ISR) was treated 1 month after stent implantation with an initial 2 blades down (BD) runs followed by 4 BU runs. A run was defined as a single proximal to distal pass of the device within the stent at a speed of approximately 1-2 mm per sec. IVUS quantitative measurements were performed at baseline, after 2 BD runs, and after each BU run (BU1, BU2, BU3, BU4) on a total of 24 lesions. Minimal luminal area (MLA, mm2) and plaque surface area (PSA, %) were obtained in each of the proximal, mid, and distal segments of the lesion. Wilcoxon signed-rank test and paired t-test (1-tail) were performed to compare baseline, BD and BU 1 to 4 runs.

RESULTS The mean baseline MLA was 7.8 ± 2.7 mm2. Following 2BD and 1 BU runs the mean MLAs were 8.1 ± 2.5 mm2 ($p<0.044$) and 8.7 ± 2.0 mm2 ($p=0.007$) when compared to baseline MLA respectively. There was also a significant increase in MLA between 2BD runs and BU1 run ($p=0.033$) and between BU1 and BU2 runs (9.4 ± 2.4, $p=0.007$). No statistical difference in MLA was seen between BU 2 to 3 runs ($P>0.05$). Similarly, PSA was significantly reduced between baseline (65.2 ± 11.7) and 2 BD (63.0 ± 10.5, $p=0.015$) and BU1 (60.7 ± 9.2, $p=0.011$) runs, and between BU1 and BU2 runs (57.5 ± 7.5, $p=0.025$). No differences in PSA was seen between the BU2, BU3 and BU4 runs ($p=0.12$). Vessel area at site of treatment remained unchanged between baseline and BU4 run (23.3 ± 5.8 vs. 22.5 ± 4.9 mm2 respectively, $p=0.73$) indicating that the increase in MLA and reduction in PSA is a true plaque cutting rather than a dottering effect by the JS. There were no IVUS stent strut disruption following JS treatment which was later confirmed by high resolution radiographs.

CONCLUSION JS achieved optimal and true tissue debulking after 2 BD and 2 BU runs. Based on these IVUS observations, performing more than 2 BU runs in a femoral artery ISR model is unlikely to yield further tissue debulking.

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Optimal Number of Runs Using the JetStream Navitus Device to Achieve Maximum Tissue Debulking of in-Stent Restenosis in a Porcine Stent/Balloon Injury Overstretch Model

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BACKGROUND The JetStream Navitus (JS) (Boston Scientific) is an atherectomy device that uses rotational cutting and aspiration to treat infringuinal arterial obstructive disease. The number of blades up (BU) runs needed to achieve safe and maximum tissue debulking using the JS is unknown.

METHOD In this swine model, 4 animals (8 limbs) were implanted with overlapping SMART (Cordis) nitinol self-expanding stents 1 month prior to JS treatment. In-stent restenosis (ISR) was treated with an initial 2 blades down (BD) runs followed by 4 BU runs. A run was defined as a single proximal to distal pass of the device within the stent at a speed of approximately 1-2 mm per sec. Quantitative vascular angiography using edge detection technique (QVA) was performed at baseline, after 2 BD runs, and after each BU run (BU1, BU2, BU3, BU4). Minimal luminal diameter (MLD), plaque surface area (PSA) and percent stenosis (PS) within the treated stented segment (n=8) were measured by QVA. Descriptive analysis was performed on all angiographic variables. Wilcoxon signed-rank test and paired t-test (1-tail) were performed to compare baseline, BD and BU 1 to 4 runs.

RESULTS The mean baseline (n=8) MLD was 1.73 ± 0.84 mm. Following 2BD and 1 BU runs the mean MLDs were 2.56 ± 0.7 mm ($p=0.025$) and 3.12 ± 0.39 mm ($p=0.005$) when compared to baseline MLD respectively. There was also a significant increase in MLD between 2BD runs and BU1 run ($p=0.005$). No statistical difference in MLD was seen between BU runs ($P > 0.05$). Similarly, PSA was significantly reduced between baseline (83.9 ± 14.8) and 2 BD (67.7 ± 17.0, $p=0.005$) and BU1 (55.4 ± 9.0, $p=0.005$) runs and between BU1 and BU2 runs (50.7 ± 9.7, $p < 0.05$). No differences in PSA was seen between the BU2, BU3 and BU4 runs ($p>0.05$). Finally, PS was reduced from a mean of 63.13 ± 16.91 to 44.97 ± 15.08 ($p=0.005$) with BD runs and to 33.51 ± 6.73 ($p=0.005$) with BU1 run. There was also a significant reduction in PS between 2 BD runs and BU1 run ($p=0.01$) and between BU1 and BU2 runs (30.1 ± 7.0, $p=0.05$). No difference between PS was seen between BU 2 to 4 runs ($p=0.10$). There were no angiographic complications or stent strut discontinuities on high resolution radiographs following JS treatment.

CONCLUSION JS achieved optimal tissue debulking after 2 BU runs with no further gain in debulking after the second BU run. Based on these observations, operators treating ISR with the JS device may need to limit their debulking to 2 BD and 2 BU runs performed at 1 to 2 mm per second speed to achieve optimal debulking and minimize the chance of complications from additional BU runs.

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Procedural Success and In-hospital Outcomes in Treating Femoropopliteal Arteries with the Jetstream Navitus System in The Post-market Jet Registry

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BACKGROUND The Jetstream NAVITUS™ System (JS) (Boston Scientific) is a rotating and aspirating atherectomy catheter approved for active removal of atherosclerotic disease and thrombus in infrainguinal arteries. The post market JET registry is a multicenter, prospective study that is currently evaluating femoropopliteal artery (FP) patency at 1 year, acute procedural success and major adverse events (MAE) in denovo and non-stent restenotic lesions following treatment with the JS device. We present preliminary acute procedural success and in-hospital outcomes from currently enrolled patients in JET.

METHOD The JET has a target enrollment of 500 patients with Rutherford category 1-3 denovo or non stent restenotic FP lesions, > 4 cm in length and > 70% in severity. Lesions with in-stent restenosis, or crossed via a subintimal approach or treated within 1 month prior to index procedure are excluded. There were no prespecified criteria for stenting post JS which was left to operator's discretion. Procedural success is defined as ≤ 30% residual diameter stenosis following atherectomy ± adjunctive therapy. In-hospital major adverse events (MAE) included amputation, death, and distal embolization (DE) requiring separate intervention or hospitalization. Calcium was graded from 0 to 4 by the operator (0=none, 1= < 25% of treated segment length (TSL), 2= 25-50% of TSL, 3=>50% of TSL and 4=dense calcium of entire TSL).

RESULTS Preliminary results from the first 155 patients enrolled in the JET registry are as follows: mean age 66 ± 11 yrs., males 68.0%, diabetics 42%, smoking history 51.0%, hypertension 80.0%, de novo lesions 90.0%, lesion length 220 ± 290 mm, reference diameter 6.0 ± 4 mm, pretreatment stenosis 91 ± 10%, post JS residual stenosis 47 ± 21% and post JS + adjunctive treatment 9 ± 8%. Adjunctive stenting was 33.0%. Distal embolic protection was used in 19% of patients. Distal embolization requiring treatment was 2%. There were no other in-hospital device-related complications reported. Calcium scoring (0 to 4 respectively) were as follows: Preprocedure: 7, 15, 25, 31 and 22%; post procedure: 15, 28, 26, 22 and 8%

CONCLUSION Preliminary data from the JET registry shows a high procedural success and low rate of acute complications in treating denovo and non-stent restenotic lesions with low rate of DE despite a relatively low use of embolic filter protection and a trend toward improvement in calcium grade.

RENAL INTERVENTION

CRT-313

Feasibility of Robotic Percutaneous Renal Artery Revascularization

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BACKGROUND The safety and precision of PCI performed with the CorPath robotic system been demonstrated. Percutaneous treatment of ostial renal artery stenosis requires precise stent positioning. We examined the feasibility of robot assisted renal artery stent implantation.