coronary and peripheral arteries, to simulate the properties of a calcific chronic partial occlusion (CPO) lesion for the evaluation of catheter based technologies.

Forty-one pigs were prepped sterilely for creation of the CPO. An introducer sheath was placed in the carotid artery for vascular access. Angiograms of the left anterior descending (LAD) coronary artery and the iliac tree were obtained. A section of artery measuring 2.8 - 3.0mm in diameter was identified and targeted for implantation with the plug. A cylinder of bone marrow measuring 3mm in outer diameter by 10mm in length was obtained from the rib of a donor animal and a lumen measuring approximately 1.6mm in diameter was created. The bone plug was loaded into a 9Fr guide catheter, tracked to the targeted location within the artery and deployed. Angiography immediately post deployment demonstrated an average lesion lumen diameter of 1.32mm (1.08 - 2.35mm).

Twenty-nine of forty-one pigs (implanted with a total of thirty-five bone plugs) survived to the scheduled follow-up procedure (between 4 and 14 days). Thirty of the thirty-five surviving implanted bone plugs were patent, with follow-up angiography demonstrating reduced blood flow through the lesion, with an average lesion lumen diameter of 1.20mm (0 - 2.59mm).

We can reliably create a porcine coronary model simulating a calcific partial occlusion, which can be used for the evaluation of interventional technologies and platforms used to treat coronary and peripheral artery disease. The results of previous studies have demonstrated successful deployment of a chronic total occlusion (CTO) version of the bone plug in the coronary and peripheral vasculature. Additionally, we have successfully implanted larger bone marrow plugs (measuring 3.0 - 5.5mm in outer diameter) and demonstrated the ability to reduce the calcium content of the bone marrow plug prior to deployment, thereby decreasing the hardness of the lesion.

## CRT-114

### Correlation Between Carotid Ultrasonographic Parameters And Syntax Score According To The Extent Of Coronary Artery Disease

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**Background:** Carotid ultrasonography is a good non-invasive modality to evaluate atherosclerotic changes. Intima-media thickness (IMT) is a well-established surrogate marker of coronary atherosclerosis. But, the role of other carotid parameters for predicting coronary artery disease (CAD) is still lack of evidence. Therefore, we evaluated the correlation between carotid parameters and SYNTAX score (SS) representing the severity and extent of CAD. We also investigated whether carotid parameters predict the presence of CAD or not.

**Methods:** Total 663 of 1698 patients (408 men, mean age: 64.1 ± 11.9 years) who performed both carotid ultrasonography and coronary angiography during admission from Sep 2011 to Aug 2012 were studied. The patients were divided into three groups: normal or minimal CAD, 1 vessel disease (VD) and ≥2VD. Plaque score (PS) was defined as a numerical summation of the presence of plaque in 4 different locations of both carotid arteries. Maximum % diameter stenosis (DS) and area stenosis (AS) were measured at the narrowest portion in longitudinal and short axis view.

**Results:** The old age, male gender, diabetes mellitus and smoking were significantly related to the extent of CAD. All carotid parameters showed significant relationship with the extent of CAD. Mean carotid IMT, maximum carotid IMT, PS, %AS and %DS were weakly but significantly correlated with SS (r=0.226, 0.162, 0.336, 0.361, 0.318, respectively, all p value < 0.001). After adjusted for classic risk factors, PS was the best predictor for CAD (Odds ratio 1.576, 95% confidence interval 1.365-1.820, p<0.001). The diagnostic accuracy of PS for the detection of CAD by the area under the receiver operating characteristics curve was 0.702 (95% confidence interval 0.661-0.743, p<0.001).

**Conclusion:** All carotid parameters were weakly but significantly correlated with SYNTAX score. PS was a good predictor for coronary artery disease. Long-term follow-up is warranted to discriminate clinical outcomes using carotid ultrasonographic parameters.

## Other

## CRT-115

### Demographics Of Study Participants In Clinical Trials For Cardiovascular Drugs Approved By FDA From 2010 To 2011

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**Objectives:** Historically, women and minorities have been underrepresented in clinical trials of drugs to treat cardiovascular disease (CVD). To accurately assess the safety and efficacy of CVD drugs, the U.S. Food and Drug Administration (FDA) has made a conscious effort to ensure adequate representation of women and minorities in clinical drug trials through guidance documents and regulations. The purpose of this study is to assess the participation of women and racial/ethnic minorities in FDA-reviewed CVD drug trials that were included in New Drug Applications (NDAs) approved between 2010 and 2011.

**Methods:** The sex and race/ethnicity of subjects in all CVD drug clinical trials submitted to FDA in support of NDAs approved between January 2010 and December 2011 were assessed from final clinical study reports. The reports were accessed via internal FDA databases.

**Results:** Four drugs (1 per NDA) indicated for hypertension (HTN), acute coronary syndrome (ACS), non-valvular atrial fibrillation (NAF) and deep vein thrombosis/pulmonary embolism (DVT/PE) after joint replacement surgery were approved during the period studied. A total of 231 clinical trials classified as phase 1, 2, or 3 studies were submitted to the NDAs. There were 107,156 subjects included in these studies. Demographic analysis (shown in Table 1) indicated that the mean participation of women in these trials was 41% and the majority of the trial subjects were Caucasians (79%). When analyzed by the phase of the trials, mean female participation was 21%, 43% and 42% for Phase 1, 2 and 3 respectively.

**Table 1. Subject Demographics in CVD drug trials of NDAs approved by FDA from 2010 to 2011.**

| | Overall N=107156 | HTN N=10558 | ACS N=21127 | NAF N=33662 | DVT/PE N=41809 |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Females N (%) | 44169 (41) | 4643 (44) | 5960 (28) | 13960 (41) | 19606 (47) |
| Males N (%) | 62987 (59) | 5915 (56) | 15167 (72) | 19702 (59) | 22203 (53) |
| **Race** | | | | | |
| Caucasian N (%) | 84587 (79) | 7201 (68) | 18942 (90) | 26291 (78) | 32153 (77) |
| Black N (%) | 2571 (2.4) | 1254 (12) | 462 (2.0) | 228 (6.8) | 627 (1.5) |
| Asian N (%) | 9077 (8.5) | 1058 (10) | 1321 (6.3) | 1085 (3.2) | 5613 (13) |
| Hispanic* N (%) | 1969 (1.8) | 1119 (11) | 66 (3.1) | 0 | 784 (1.9) |
| Other** N (%) | 2242 (2.1) | 1027 (9.7) | 343 (1.6) | 159 (0.5) | 713 (1.7) |
| Unknown^ N (%) | 2111 (2.0) | 0 | 0 | 466 (1.4) | 1645 (3.9) |

*Depending on the study, Hispanic subjects were counted either as Caucasian or a separate race/ethnicity category. **Includes those classified as American Indian/Alaska Native, Hawaiian/Pacific Islander, Multiracial or Other. ^Any participants whose race is listed as missing or who participated in studies where there were legal concerns about collecting race data (applied in some European trials).

**Conclusions:** The overall inclusion of women in these CVD drug trials is comparable to the overall female CVD population (51%) in the US. However, women are largely underrepresented in the Phase 1 trials, during which much of the pharmacokinetics and pharmacodynamics of new drugs are evaluated.