

A Novel Thin-strut Cobalt-chromium Stent For Inhibition Of Neointimal Formation In A Porcine Coronary Artery Model

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Abstract

Background:

Cobalt chromium is being increasingly used in coronary stents due to its superior mechanical properties with higher radial strength, radio opacity and good biocompatible properties compared with stainless steel. The present study was designed to evaluate a novel thin-strut cobalt-chromium bare metal stent (BMS) (COBRA®, 71µm strut) in comparison with commercially available paclitaxel-eluting stent (PES, 97µm strut) and BMS (Driver, 91µm strut) in porcine coronary artery model.

Methods:

COBRA (n = 19), TAXUS (n = 8), and Driver (n = 10) were implanted in 13 juvenile pigs. Animals were terminated at 28 days post-implant for angiographic restudy and complete histopathologic and histomorphometric analyses.

Results:

There was a difference in angiographic late loss among the groups (COBRA: 0.45±0.36, TAXUS: 0.51±0.64, Driver: 0.98±0.74mm, P=0.018, COBRA versus Driver). Histomorphometric neointima area was decreased for COBRA (1.54±0.45cm²) and TAXUS (1.32±0.64cm²) compared to Driver (2.51±1.74cm², P<0.05 respectively).

Re-endothelialization was complete in all three groups. However, intramural thrombi and inflammation score were higher in TAXUS compared to COBRA and Driver (P<0.05 respectively)

Conclusion:

A novel thin-strut cobalt-chromium BMS (COBRA) demonstrated effective inhibition of neointimal growth to the levels comparable to PES, without toxicity to the vessel wall in porcine coronary artery model.

Objective

The present study was designed to evaluate a novel thin-strut cobalt-chromium bare metal stent (BMS)(COBRA®) in comparison with commercially available paclitaxel-eluting stent (TAXUS®) and BMS (Driver®) in porcine coronary artery model.

Methods

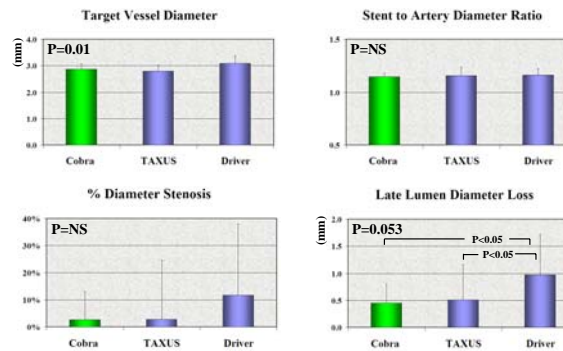
- Animal Model: Juvenile domestic Yorkshire hybrid pigs (N=13) body weight 33.2±2.3 Kg
- Interventional Procedure: Sterilized stents (N=37) of three different types (Cobra (n=19), Taxus (n=8) and Driver (n=10)) sized ~15% larger than target site diameter were implanted using standard techniques
- Angiographic Restudy and Termination
 - Animals were terminated at one month post-implant
 - Hearts were excised and fixed *ex vivo* by intravascular perfusion at physiologic pressure
- Quantitative Coronary Angiography (QCA)
 - At implant, target vessel diameter and stent-to-artery ratio
 - At follow-up, %diameter stenosis and late lumen loss
- Histomorphometry
 - Luminal area; 2) Internal elastic lamina (IEL) area;
 - External elastic lamina (EEL) area, 4) Neointimal thickness, 5) Area of Tunica Medial (EEL area - IEL area) and 6) Histologic %area stenosis ((1-(luminal area/IEL area)) X 100)

Histopathology

- inflammation; 2) mural/luminal thrombus; 3) intramural hemorrhage; and 4) medial necrosis scored whereby 0=none; 1=mild; 2=moderate; and 3=severe, where 0 represented the least response and 3 represented the greatest response
- Luminal surface coverage with flattened, confluent cells scored whereby 0=0-25% coverage of circumference; 1=25-50% coverage; 2=50-75% coverage; and 3=75-100% coverage

Results

QCA Results

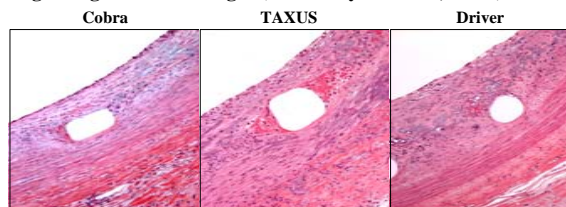


Low Magnification Images (Movat pentachrome, 20X)



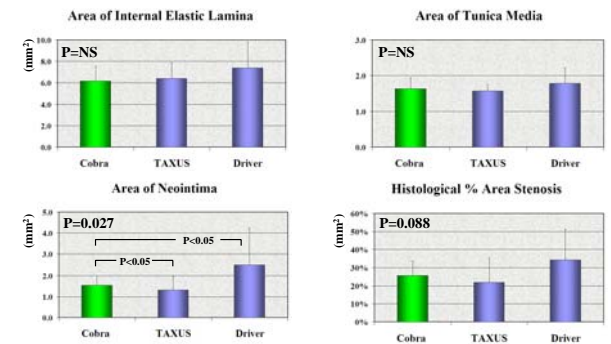
Low magnification light microscopic images of Movat pentachrome stained sections, demonstrating overall vessel morphologies. Suppression of neointimal formation was observed in Taxus and Cobra compared to Driver. Strut-associated compression and thinning but not laceration of the tunica media, and minimal concentric neointima formation. Movat, 20X

High Magnification Images (Hematoxylin-Eosin, 200X)

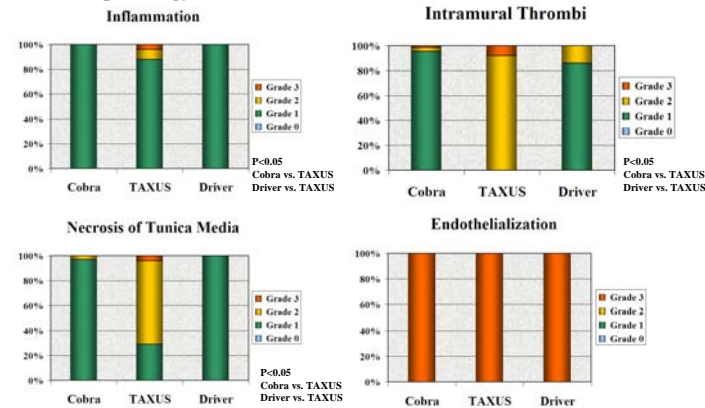


High magnification image of stent implant displayed a wide range of healing responses from mild to moderate neointimal formation, mild inflammatory reaction, no luminal thrombi formation and complete endothelialization. Most of the Cobra and Driver stent implants had the expected mild compression injury to the tunica media with thin to moderate, concentric fibrocellular neointima and little adventitial reaction. In TAXUS stent, peri-stent intramural thrombi are seen frequently and in excess. Foam cell infiltrates adjacent to the stent strut. Stent strut is attached to IEL border, while compressed media shows moderate necrosis. H&E, 200X

Histomorphometry



Histopathology



Summary

- Cobra stent suppressed neointimal formation compared to Driver stent, which was comparable to TAXUS stent in a porcine coronary model.
- Cobra stent showed less inflammation, intramural thrombi and necrosis of tunica media compared to TAXUS stent.

Conclusions

- A novel thin-strut cobalt-chromium BMS (Cobra) demonstrated effective inhibition of neointimal growth to the levels comparable to PES, without toxicity to the vessel wall in a porcine coronary artery model.