Intravascular Ultrasonography Analysis of the Everolimus-Eluting Stent in Coronary Chronic Total Occlusions

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ABSTRACT

PURPOSE: Chronic total coronary occlusions (CTOs) are challenging to treat in part due to high rates of restenosis after stenting. Drug-eluting stents improve outcomes compared to bare metal stents. The goal of the present study was to evaluate the angiographic, intravascular ultrasonography (IVUS) and clinical outcomes after implantation of the Everolimus-Eluting Stent (EES) in CTOs.

METHODS: One hundred consecutive CTO patients who were successfully treated using EES at the Dallas VAMC between 2009-2012 were enrolled in the AngiographiC Evaluation of the Everolimus-Eluting Stent in Chronic Total Occlusions (ACE-CTO trial: NCT01012869). Patients underwent follow-up angiography and IVUS imaging at 8 months and clinical follow-up at 12 months. The primary endpoint of this study, binary angiographic restenosis, was defined as >50% minimum lumen diameter stenosis at 8-month follow-up quantitative coronary angiography. The primary endpoint of the IVUS analysis was 8-month in-stent neointimal hyperplasia (NIH) volume (stent volume-lumen volume).

RESULTS: Patients had high prevalence of hypertension (91%), hyperlipidemia (90%), diabetes (47%), prior MI (51%), and prior PCI (21%). Of the 89 patients who underwent follow-up angiography, binary in-stent angiographic restenosis occurred in 41 patients (46%). IVUS analysis was performed in 61 patients. IVUS was not performed in 24 patients (8 of whom had occlusive in-stent restenosis), and suboptimal image quality precluded analysis in 4 patients). Mean and median neointimal hyperplasia volume were 68 ±100 and 26 (0, 91) mm3, respectively. This corresponded to a mean and median percent volume obstruction of 12% ± 15% and 5% (0%, 24%), respectively. No NIH could be detected in 33% of patients.

CONCLUSIONS: EES implantation in CTO patients is associated with high rates of angiographic restenosis as well as revascularization, yet most patients derived significant symptomatic improvement despite focal NIH formation.

INTRODUCTION

- Chronic total occlusions (CTOs) are defined as 100% occlusions of ≥ 3 month duration
- 1st generation drug-eluting stents (DES) have been shown to be more effective than bare metal stents (BMS) in reducing restenosis in coronary CTOs
- However, there is limited data on the efficacy of 2nd generation DES in CTO lesions
- The ACE-CTO trial aims to evaluate the efficacy of the 2nd generation Everolimus-eluting stent (EES) in CTO lesions
- This study presents the **intravascular ultrasound (IVUS) findings of the ACE-CTO trial patients**

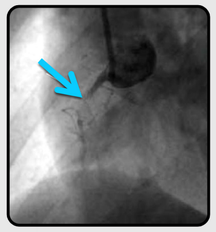
MATERIALS AND METHODS

Study design:

- Single-center, single-arm, non-randomized, open label, prospective that evaluating the 8-month angiographic and 12-month clinical outcomes after implantation of the Everolimus-eluting stent in CTOs
- 100 consecutive patients were enrolled

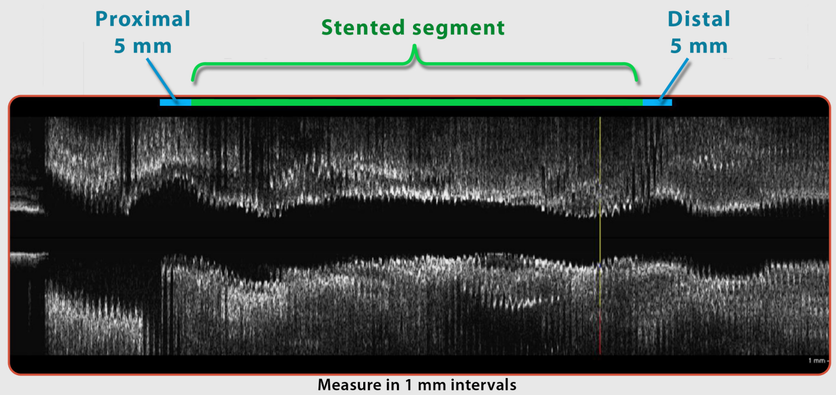
Intravascular Ultrasound:

- Image acquisition: 20 MHz or 40 MHz scanner; motorized transducer pullback at 1.0 mm/second
- Recordings performed at 30 frames/second
- Data analysis: EchoPlaque 4.0 (INDEC Medical Systems, Santa Clara, CA)
- Contours for the lumen, stent, and vessel wall were manually traced at every 1 mm interval over the stented region and 5 mm-length reference segments proximal and distal to the stented region
- **Neointimal hyperplasia (NIH) volume = stent volume - lumen volume**

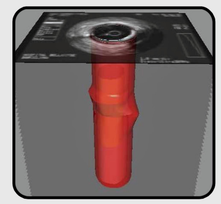


CTO lesion on angio-graphy, illustrated by complete chronic lumen occlusion

INTRAVASCULAR ULTRASOUND IMAGE ANALYSIS



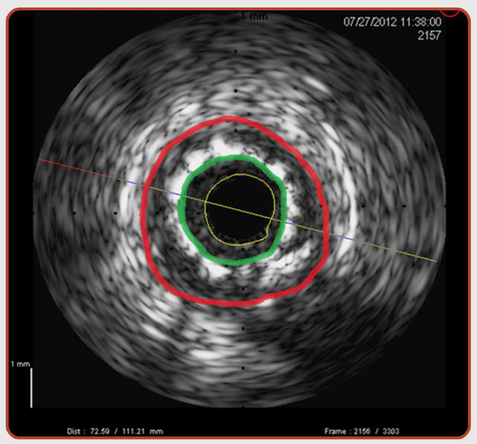
Measure in 1 mm intervals



Transverse vessel imaging visualizes plaque burden

Figure 1. Intravascular ultrasonography was analyzed using EchoPlaque software. At each 1 mm interval of the longitudinal stented region, as well as the proximal and distal 5 mm segments, the transverse lumen, stent, and vessel contours were manually traced as shown in **Figure 2.**

INTRAVASCULAR ULTRASOUND DATA



Vessel Wall

Stent

Lumen

Figure 2. Transverse IVUS image demonstrating in-stent neointimal hyperplasia formation between the lumen and stent boundaries at 8 month follow-up.

Baseline Data (n = 49)

	In-stent segment	Proximal segment (5 mm)	Distal segment (5 mm)
Luminal Volume (mm^3)	489.5 (277.8-650.7)	27.5 (21.4-43.5)	21.9 (17.9-30.3)
Stent Volume (mm^3)	489.1 (278.1-650.6)	N/A	N/A
Mean lumen area (mm^2)	5.8 (5-6.8)	5.5 (4.3-8.7)	4.4 (3.6-6)
Minimum lumen area (mm^2)	4.2 (3.6-5)	4.1 (3.6-6.2)	3.7 (2.9-5)
NIH Volume	0	N/A	N/A

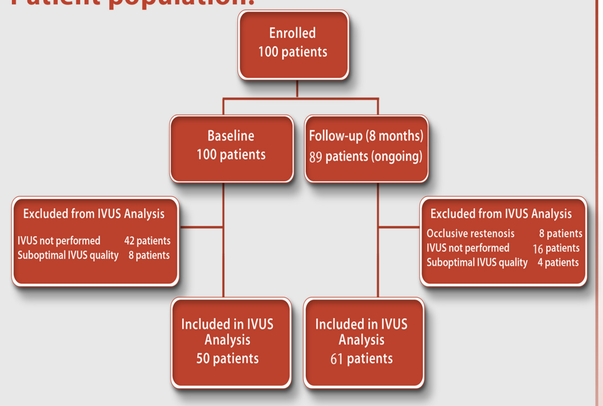
Follow-up Data (n = 61)

	In-stent segment	Proximal segment (5 mm)	Distal segment (5 mm)
Luminal Volume (mm^3)	392 (283-687)	38 (26-51)	26 (20-35)
Stent Volume (mm^3)	495 (298-762)	N/A	N/A
Mean lumen area (mm^2)	5.3 (4.4-6.6)	7.6 (5.2-10.1)	5.3 (4.1-7.1)
Minimum lumen area (mm^2)	3.5 (2.6-4.1)	5.9 (4.1-7.6)	4.5 (3.3-5.9)
NIH Volume	26 (0-91)	N/A	N/A
% Volume Obstruction	5.1 (0-23.7)	N/A	N/A

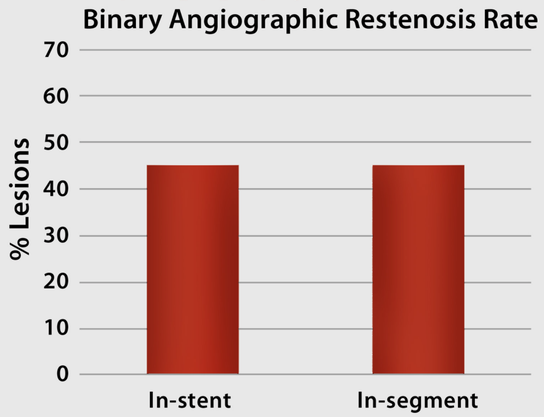
Table 1. Follow-up IVUS findings for in-stent, proximal, and distal segments of CTO lesions treated with EES; data presented as median (interquartile range).

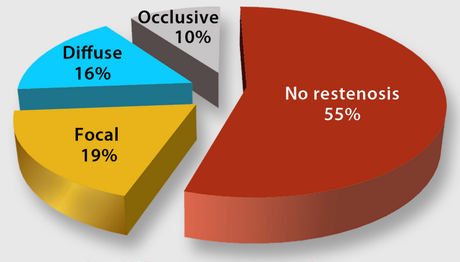
RESULTS

Patient population:



Follow-up Angiography:





Intravascular Ultrasonography:

At follow-up, the CTO lesions treated with everolimus-eluting stents had high rates of angiographic restenosis, but given the high proportion of focal lesions, the median NIH volume over the in-stent segment (26 mm3) and luminal volume obstruction (5%) were low – **Table 1**

CONCLUSIONS

Everolimus-eluting stent implantation in long, complex CTOs is associated with high rates of focal angiographic restenosis

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