Five-Year Clinical Outcomes for Resolute Zotarolimus-Eluting Stents in Total Occlusions

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BACKGROUND

- Long-term outcomes of patients with drug-eluting stents (DES) in total occlusions (TO) are not well known.
- The current analysis compares 5-year clinical outcomes for patients implanted with Resolute DES in chronic or non-chronic TO lesions versus those who were treated for lesions without a total occlusion.

METHODS

- Data for this analysis was pooled from

RESOLUTE All-Comers[1,2]

RCT 1:1 vs. Xience V™ EES (R=1140; X=1152) — 5 yr

RESOLUTE International[3,4]

Non-RCT Observational (R=2349) — 3 yr

RESOLUTE China RCT[5]

RCT 1:1 vs. Taxus™ PES (R=198; T=202) — 5 yr

RESOLUTE China Registry[6]

Non-RCT Observational (R=1800) — 5 yr

- Three groups of patients[#] were compared in Kaplan-Meier cumulative curves to 5 years:
  1. **CTO: chronic TO patients** (N=436)
  2. **Non-chronic TO patients** (N=467)
  3. **Patients without TO** (N=4584)

[#]Because R-AC study did not differentiate between CTO and TO, the following definitions were used to assign to groups:
- CTO group: all CTO patients from R-INT, R-China RCT and R-China Reg (investigator reported by history) plus total occlusion (TIMI 0) patients from R-AC *excluding* those with AMI.
- TO group: all remaining TO patients from R-INT, R-China RCT and R-China Reg.
- No occlusion: consists of the remaining patients without a TO or CTO

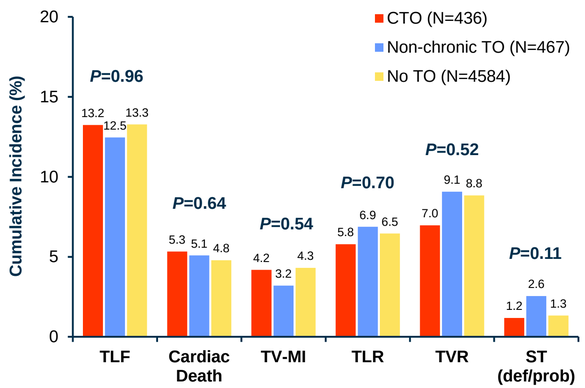
1 Serruys PW, et al. *N Engl J Med*. 2010;363:136-46
2 Iqbal J, et al. *Circ Cardiovasc Interv*. 2015;8:e002230
3 Neumann FJ, et al. *EuroIntervention*. 2012;7(10):1181-8
4 Belardi JA, et al. *J Interv Cardiol*. 2013;26(5):515-23
5 Xu B, et al. *JACC Cardiovasc Interv*. 2013;6(7):664-70
6 Qiao S, et al. *Am J Cardiol*. 2014;113(4):613-20

RESULTS

Baseline and Angiographic Characteristics

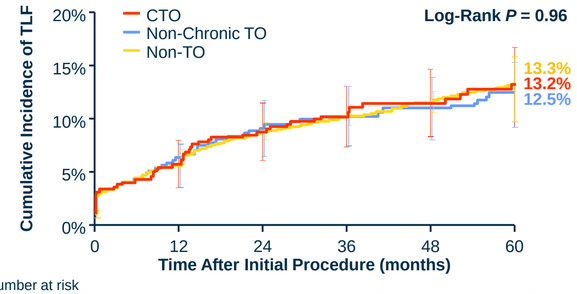
(% or mean ± SD)	CTO group (N = 436)	TO group (N = 467)	No Occlusion (N = 4584)	P (CTO vs NO)	P (TO vs NO)
Age (years)	60.8 ± 11.2	60.0 ± 11.6	63.3 ± 10.9	<0.001	<0.001
Female gender	17.2	24.6	23.6	0.002	0.61
Diabetes mellitus	26.1	26.6	28.9	0.22	0.28
Insulin dependent	4.6	4.9	6.2	0.19	0.29
Hypertension	64.7	57.6	68.5	0.10	<0.001
Hyperlipidemia	52.1	48.6	56.5	0.08	0.001
Current smoker	30.3	45.8	27.2	0.16	<0.001
Prior MI	37.7	33.5	29.4	<0.001	0.06
Prior PCI	20.9	10.3	25.7	0.03	<0.001
ACS	47.0	78.4	53.3	0.01	<0.001
Acute MI (within 72 hrs)	16.1	70.4	13.2	0.09	**<0.001**
Vessel location (pt level)					
LAD	51.6	48.2	56.2	0.06	<0.001
LCX	27.1	26.6	27.5	0.86	0.67
RCA	50.7	45.0	30.8	**<0.001**	**<0.001**
Left main	0.9	1.5	2.6	0.03	0.15
RVD (mm)	2.9 ± 0.5	2.9 ± 0.5	2.9 ± 0.5	0.19	0.15
Number of lesions treated/pt	1.6 ± 0.8	1.5 ± 0.8	1.4 ± 0.7	<0.001	0.01
Total stent length/pt	53.9 ± 35.9	41.3 ± 28.2	33.4 ± 22.1	<0.001	<0.001

Clinical Outcomes to 5 Years



Cumulative Incidence of events calculated by Kaplan Meier method with Log-Rank *P*-value.

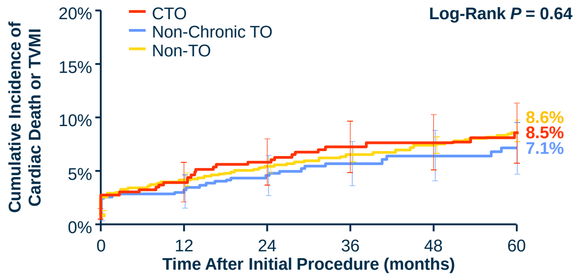
Target Lesion Failure



Number at risk

CTO	436	433	403	384	351	207
Non-Chronic TO	467	464	434	410	355	240
Non-TO	4584	4537	4213	4040	3612	2180

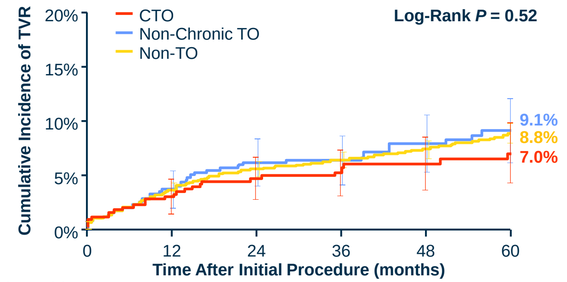
Cardiac Death or MI



Number at risk

CTO	436	433	411	397	363	215
Non-Chronic TO	467	465	445	430	373	254
Non-TO	4584	4540	4315	4188	3749	2263

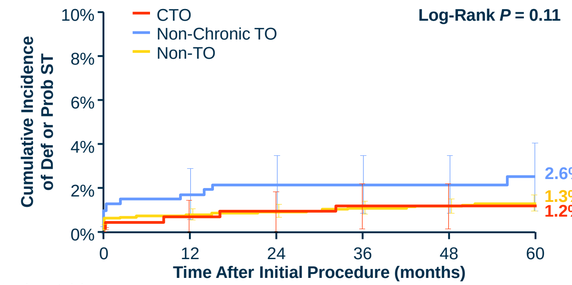
Target Vessel Revascularization



Number at risk

CTO	436	436	410	390	354	211
Non-Chronic TO	467	466	440	416	360	237
Non-TO	4584	4577	4286	4094	3655	2202

Stent Thrombosis



Number at risk

CTO	436	436	421	407	371	220
Non-Chronic TO	467	466	452	437	379	256
Non-TO	4584	4577	4422	4302	3855	2322

LIMITATIONS

- Despite differences in demographic data, which represent differences in their clinical status, patients with CTO, TO and non-occluded lesions had similar outcomes.
- The (C)TO lesions included in this post-hoc analysis seemed to be relatively short and simple, so that outcomes in more complex CTO lesions may be different.

CONCLUSIONS

- The current analysis of 903 patients with totally occluded lesions treated in Europe and China within the RESOLUTE Global Clinical Program supports the safety and efficacy of Resolute DES in complex coronary artery disease.
- These data suggest that patients treated with Resolute DES after recanalization of totally occluded coronary lesions have long term results that are comparable to those with non-occlusive disease.

DISCLOSURES

Robert Yeh has received grant support/research contract from Abbott Vascular, Abiomed, Boston Scientific Corporation and has received consultant fee/honoraria/speaker's bureau from Abbott Vascular, Boston Scientific Corporation, Medtronic, Asahi Intecc and Teleflex. **Franz-Josef Neumann** has received grant support/research contract from Boston Scientific Corporation, Biotronik, Edwards Lifesciences and Medtronic and has received consultant fee/honoraria/speaker's bureau from Boston Scientific Corporation, Biotronik, Medtronic, and Edwards Lifesciences. **Patrick Serruys** has received consultant fee/honoraria/speaker's bureau from Abbott Vascular. **Stephan Windecker** has received grant support/research contract from Boston Scientific Corporation, St. Jude Medical (now Abbott), Abbott Vascular, Biotronik, Terum Medical Corporation, Symetis SA, Amgen Inc, Edwards Life Sciences and Bayer AG. **Minglei Liu** is an employee of Medtronic. **Sigmund Silber, Henning Kelbaek, Jorge Belardi, Bo Xu, Shubin Qiao** have nothing to disclose.