Potential conflicts of interest

Speaker's name: Pieter C Smits

I have the following potential conflicts of interest to report:

* Research contracts: Institutional with Abbott Vascular, Boston Scientific and Terumo
* Consulting : Blue Medical

COMPARE II trial

Pieter Smits

On behalf of all principal COMPARE II investigators:

Ad van Boven, Jean-Jaques Goy, Peter den Heyer, Antonio Serra, Ton Slagboom, Mario Togni, Ramiro Trillo Nouche, Mariano Valdés, Andre Vuillomenet, Jose Vázquez, Vassilis Voudris

Introduction

First generation drug eluting stents (DES) have shown to be superior in preventing re-stenosis compared to bare metal stents, however, at an increased risk of late stent thrombosis due to delayed re-endothelialisation and healing, specifically when used in a real life /off-label setting.

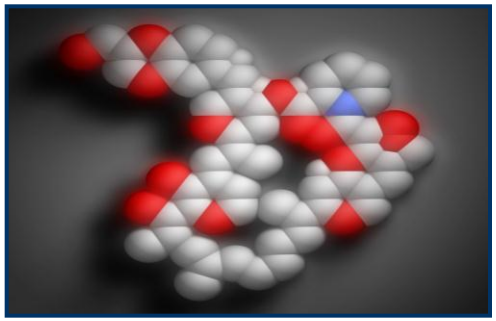
In an attempt to overcome these unwanted late effects of DES, new generation DES with other limus analogues and more biocompatible durable polymers or biodegradable polymers have been developed.

Purpose

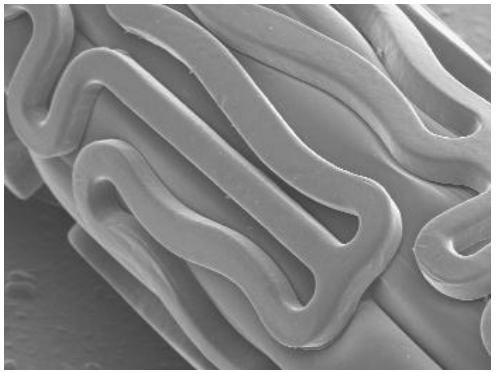
The main objective of the COMPARE II trial is
a head to head comparison of
the everolimus eluting XIENCE-V/PRIME/ PROMUS®(EES)
with
the biolimus eluting NOBORI® stent (BES)
to assess:
whether there is a difference in clinical outcome between both stent types
in a real life situation

euro PCR

Xience / Promus



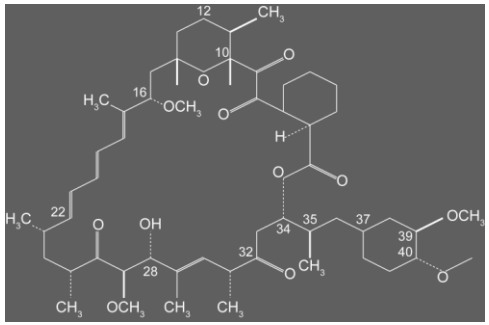
Everolimus 1.0 µg/mm²



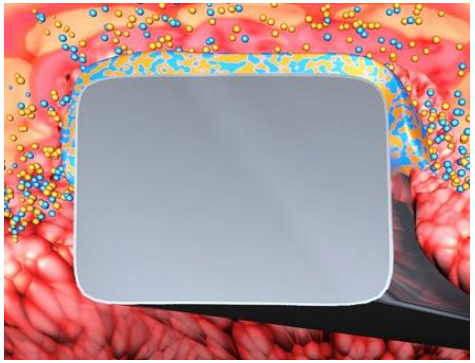
Fluoropolymer

Vision multilink™
CoCr, strut 81 µm

Nobori



Biolimus 15,6 µg/mm



Poly-lactic acid

S-Stent™
Stainless Steel, 120 µm

Methodology

- Patients eligible for PCI were prospectively randomized (1:2) between EES or BES in 12 sites across Europe
- There were minimal in- and exclusion criteria
- The trial was physician initiated
- Design: non inferiority

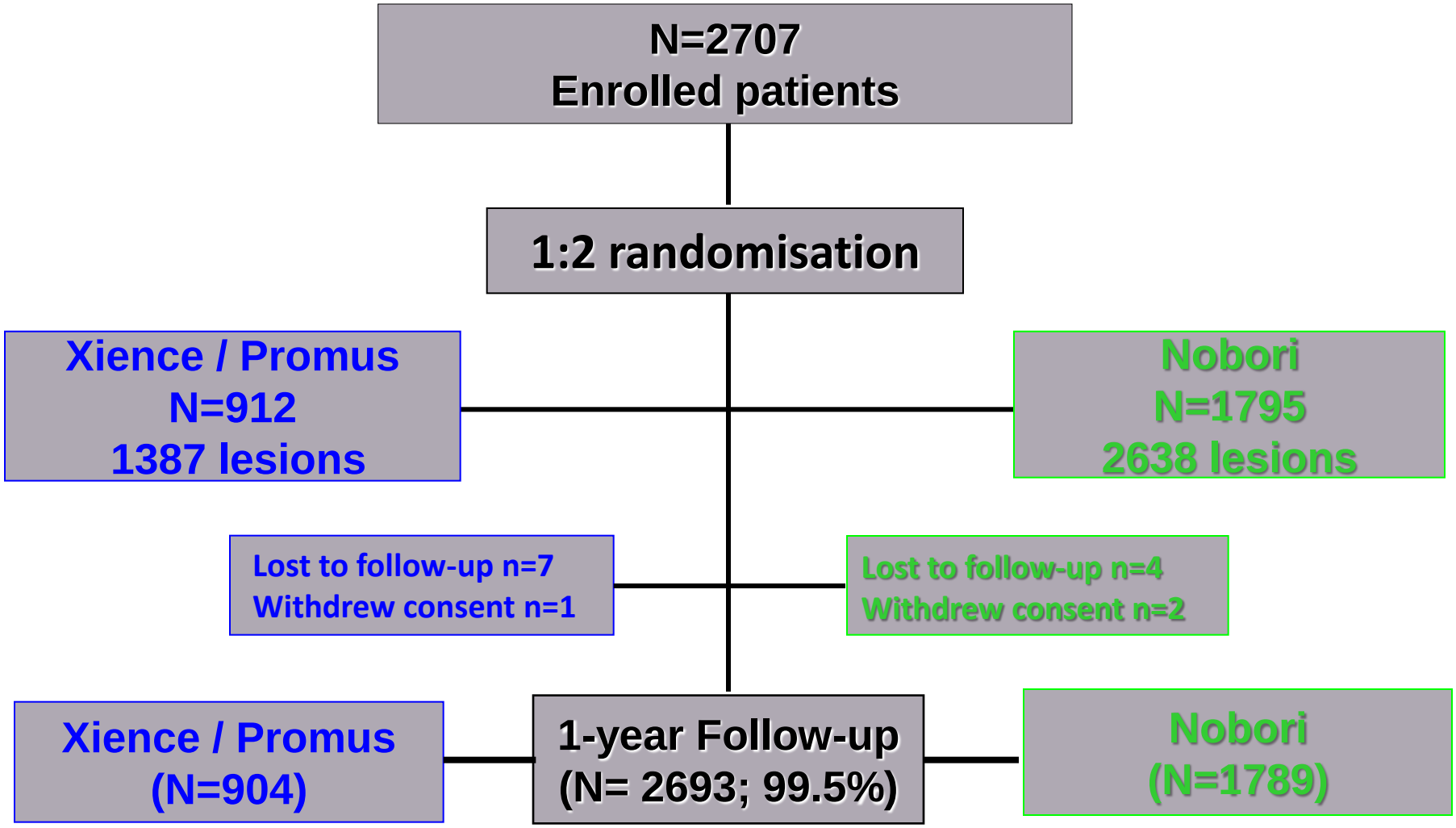
Methodology (2)

- With an assumed difference of 0%, a non-inferiority margin of 4.0% and a one-sided type 1 error of 0.05%, 2700 patients were calculated to provide a power of more then 90% to detect non-inferiority

- All sites and events were independently monitored and events adjudicated by an independent core-lab and clinical event committee at a clinical research organisation (Cardialysis, Rotterdam, The Netherlands)

- Analyses were done on intention-to-treat principle

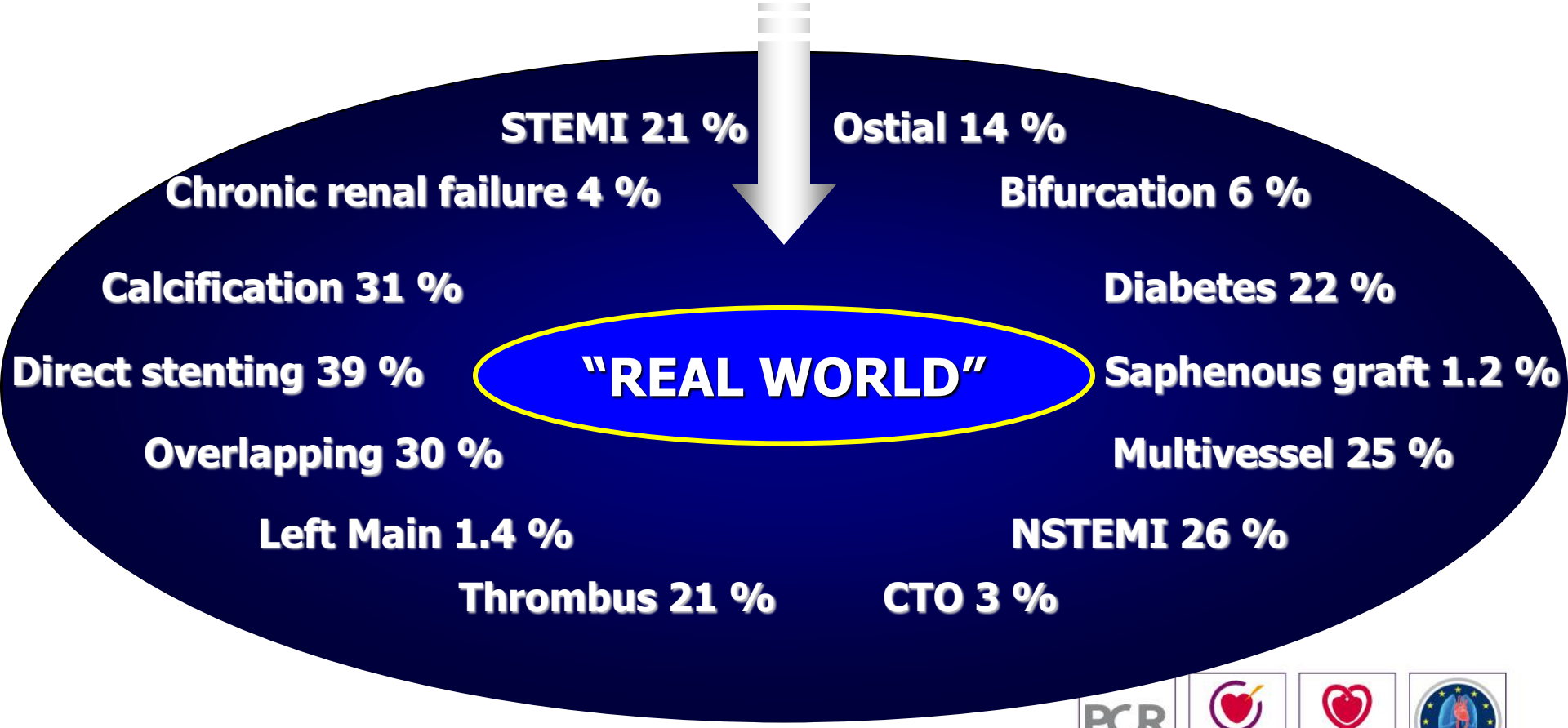
Results


N=2707
Enrolled patients
1:2 randomisation
Xience / Promus
N=912
1387 lesions
Nobori
N=1795
2638 lesions
Lost to follow-up n=7
Withdrew consent n=1
Lost to follow-up n=4
Withdrew consent n=2
Xience / Promus
(N=904)
1-year Follow-up
(N= 2693; 99.5%)
Nobori
(N=1789)

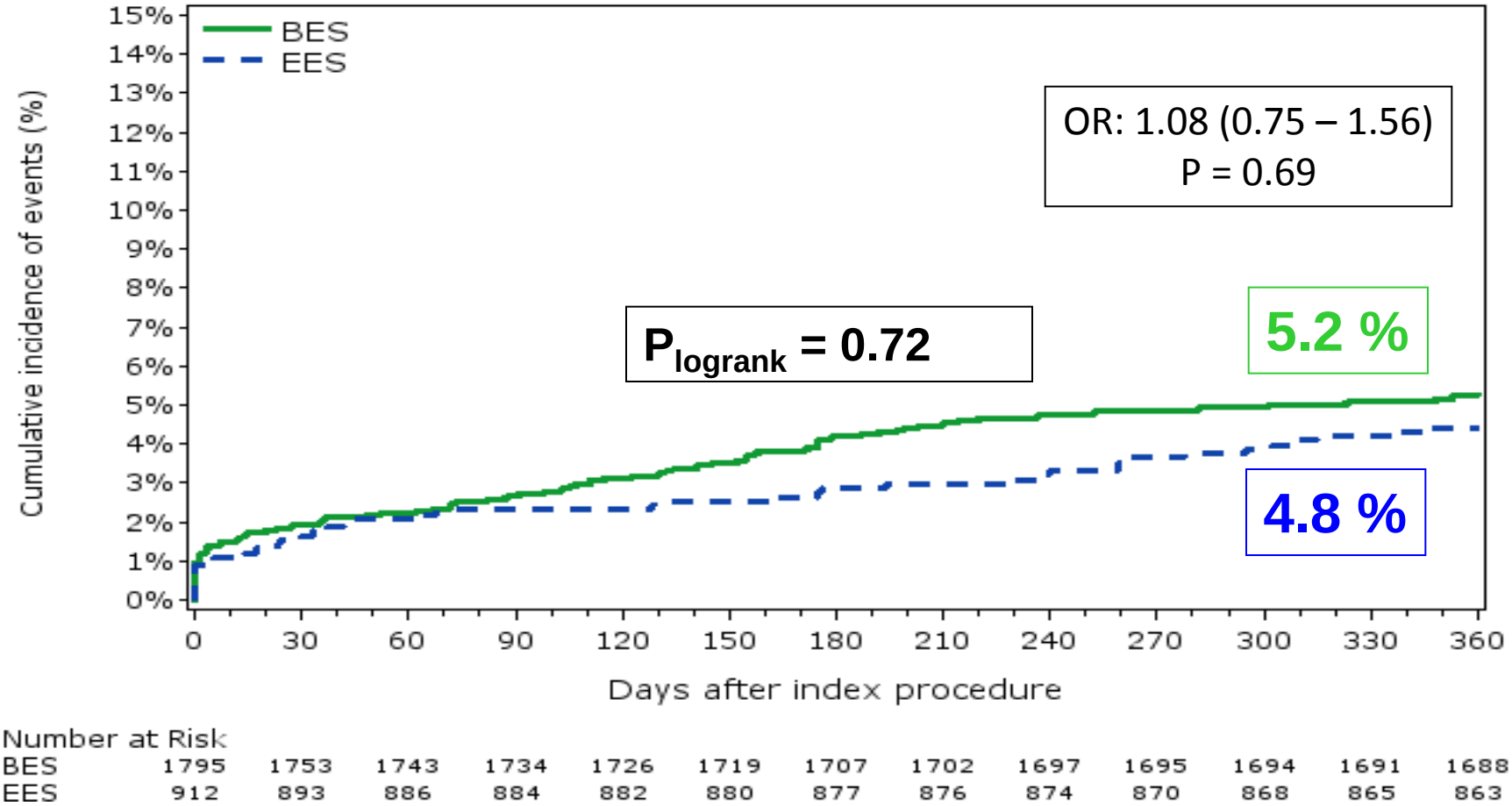
Baseline characteristics

Variable	Nobori	Xience	All Patients	P-values*
Nr of patients	1795	912	2707	.
Age (Years)	62.97±11.05 (1,795)	62.68±11.04 (912)	62.87±11.05 (2,707)	0.3655
Male Gender	74.43% (1,336/1,795)	74.34% (678/912)	74.40% (2,014/2,707)	0.9629
Diabetes	21.78% (391/1,795)	21.60% (197/912)	21.72% (588/2,707)	0.9215
Hypertension	54.76% (983/1,795)	56.25% (513/912)	55.26% (1,496/2,707)	0.487
Current Smoker	30.82% (553/1,794)	27.41% (250/912)	29.67% (803/2,706)	0.0681
Renal Failure	4.28% (76/1,775)	4.44% (40/901)	4.33% (116/2,676)	0.8414
Previous Stroke (CVA/TIA/RIND)	5.25% (94/1,792)	5.27% (48/910)	5.26% (142/2,702)	1
Peripheral Vascular Disease	7.55% (135/1,788)	5.61% (51/909)	6.90% (186/2,697)	0.0645
Previous myocardial infarction (MI)	20.28% (362/1,785)	18.76% (170/906)	19.77% (532/2,691)	0.3571
Previous PTCA	17.83% (320/1,795)	17.00% (155/912)	17.55% (475/2,707)	0.6305
Previous CABG	5.85% (105/1,795)	5.70% (52/912)	5.80% (157/2,707)	0.9308
Stable Angina	38.94% (699/1,795)	38.93% (355/912)	38.94% (1,054/2,707)	1
Silent Ischemia	3.18% (57/1,795)	3.29% (30/912)	3.21% (87/2,707)	0.9083
Acute coronary syndrome	57.88% (1,039/1,795)	57.79% (527/912)	57.85% (1,566/2,707)	0.9672
Unstable Angina	10.81% (194/1,795)	9.65% (88/912)	10.42% (282/2,707)	0.3869
ST-segment elevation Myocardial Infarction	20.67% (371/1,795)	21.60% (197/912)	20.98% (568/2,707)	0.583
Non-ST-segment elevation Myocardial Infarction	26.41% (474/1,795)	26.54% (242/912)	26.45% (716/2,707)	0.9632
GP IIb/IIIa inhibitor (stage 0)	19.63% (332/1,691)	20.23% (173/855)	19.84% (505/2,546)	0.713
Multivessel Treatment	25.24% (453/1,795)	25.22% (230/912)	25.23% (683/2,707)	1
Total Nr of lesions treated per patient	1.47±0.77 (1,795)	1.52±0.86 (912)	1.49±0.80 (2,707)	0.3647
RVD	2.88±0.44 (1,355)	2.88±0.48 (680)	2.88±0.46 (2,035)	0.6269
At least 1 RVD <2.75mm	37.86% (513/1,355)	37.21% (253/680)	37.64% (766/2,035)	0.8084
Lesion length	18.78±10.65 (1,373)	19.85±11.69 (686)	19.14±11.02 (2,059)	0.0778

COMPARE II TRIAL



Primary endpoint
C-Death, MI, CI-TVR



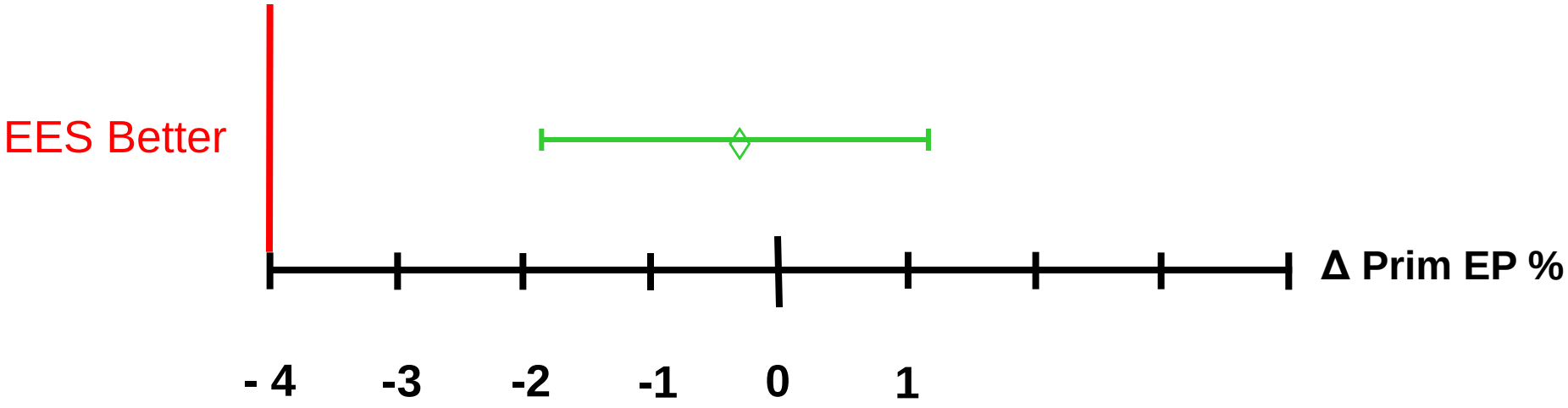
C-Death = Cardiac Death

CI-TVR = Clinically Indicated TVR

Primary endpoint non-inferiority analysis

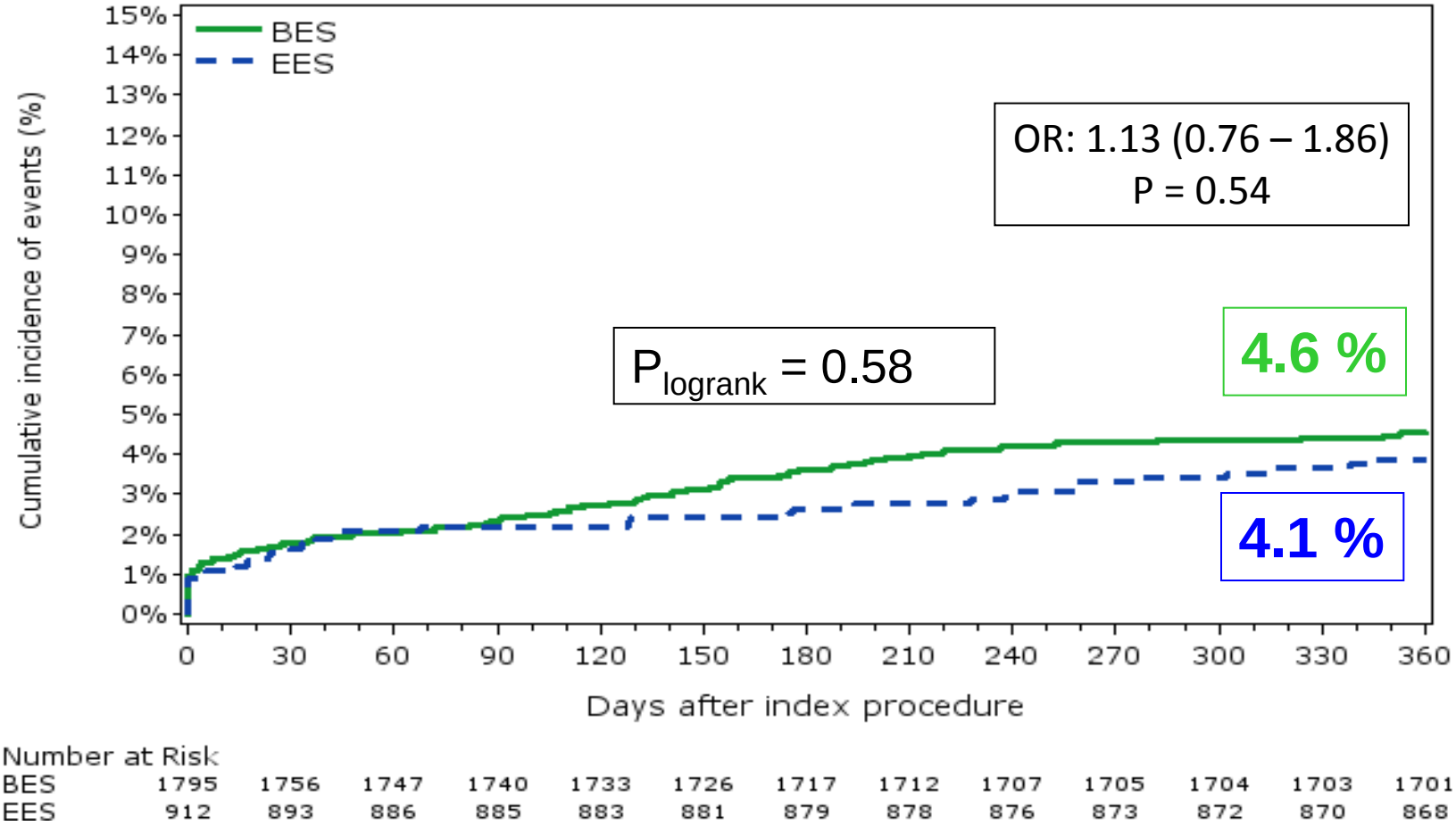
- Assumed difference between EES & BES : 0 %
- Non inferiority margin : 4.0 %

Δ Prim. EP: EES – BES = - 0.36 % (90% CI: -1.75 % ; 1.17 %)



BES is non-inferior compared to EES

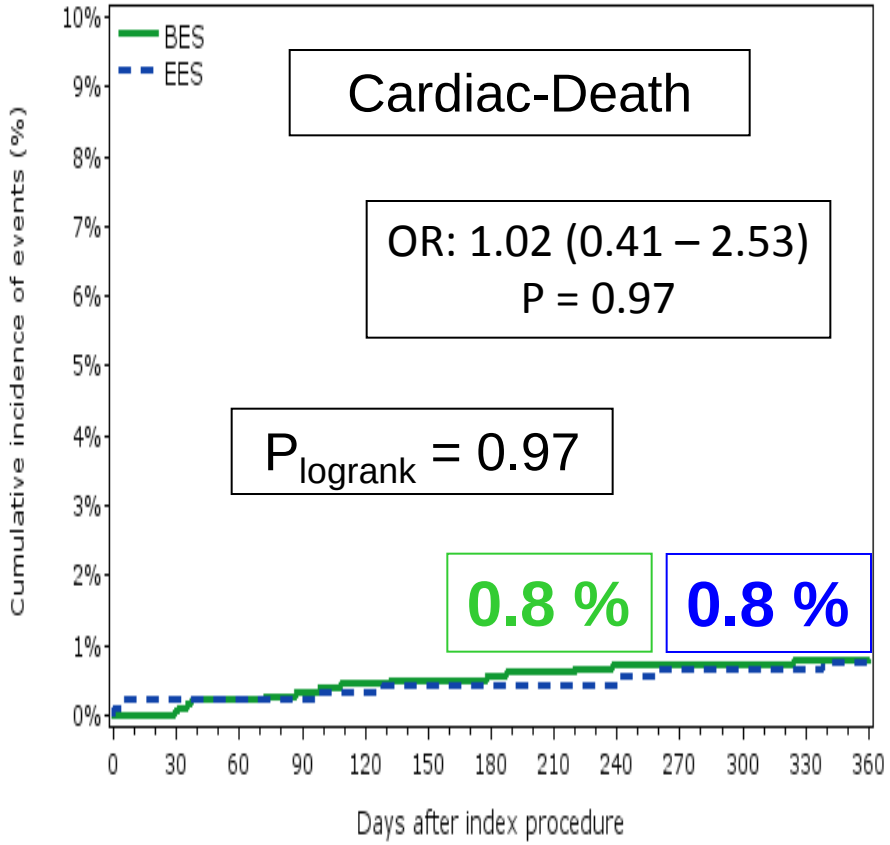
Secondary endpoint
C-Death, MI, CI-TLR

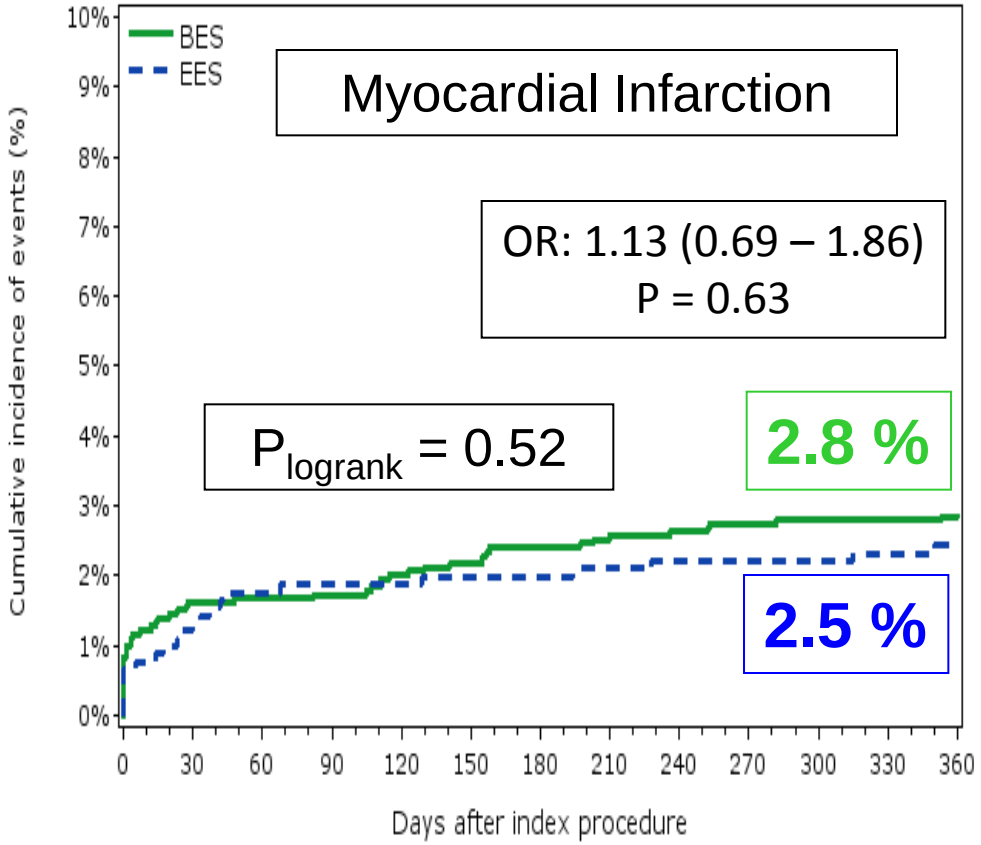


C-Death = Cardiac Death

CI-TLR = Clinically Indicated TLR

Safety





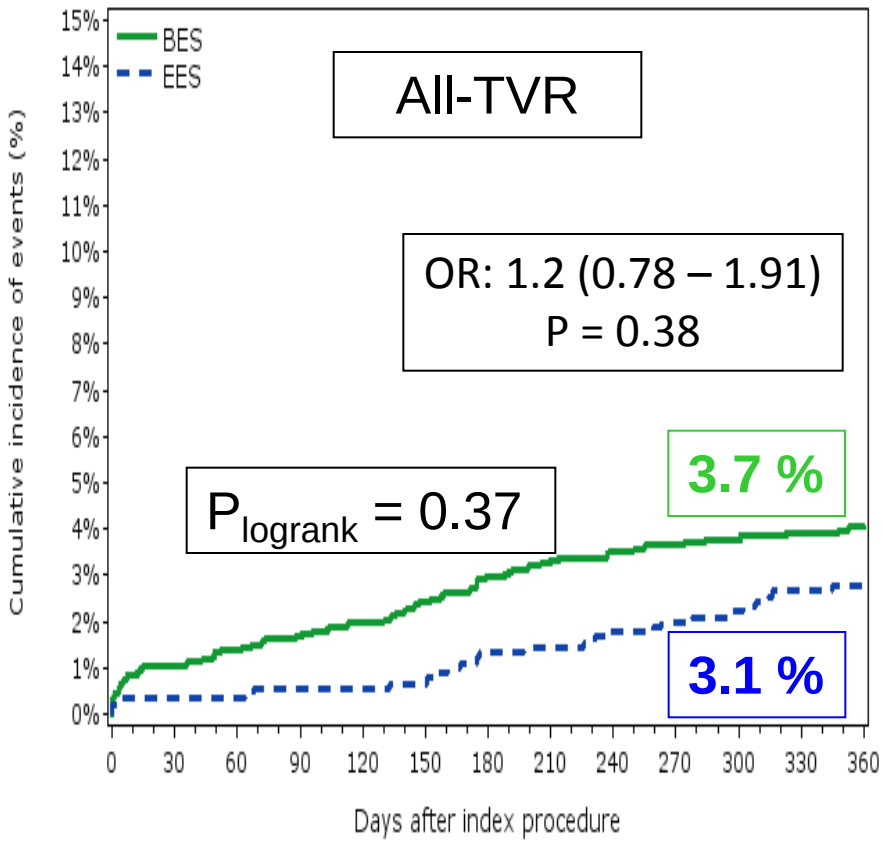
Number at Risk

BES	1795	1787	1779	1776	1774	1773	1772	1771	1769	1769	1769	1768	1768
EES	912	905	903	903	900	899	899	899	899	897	897	897	896

Number at Risk

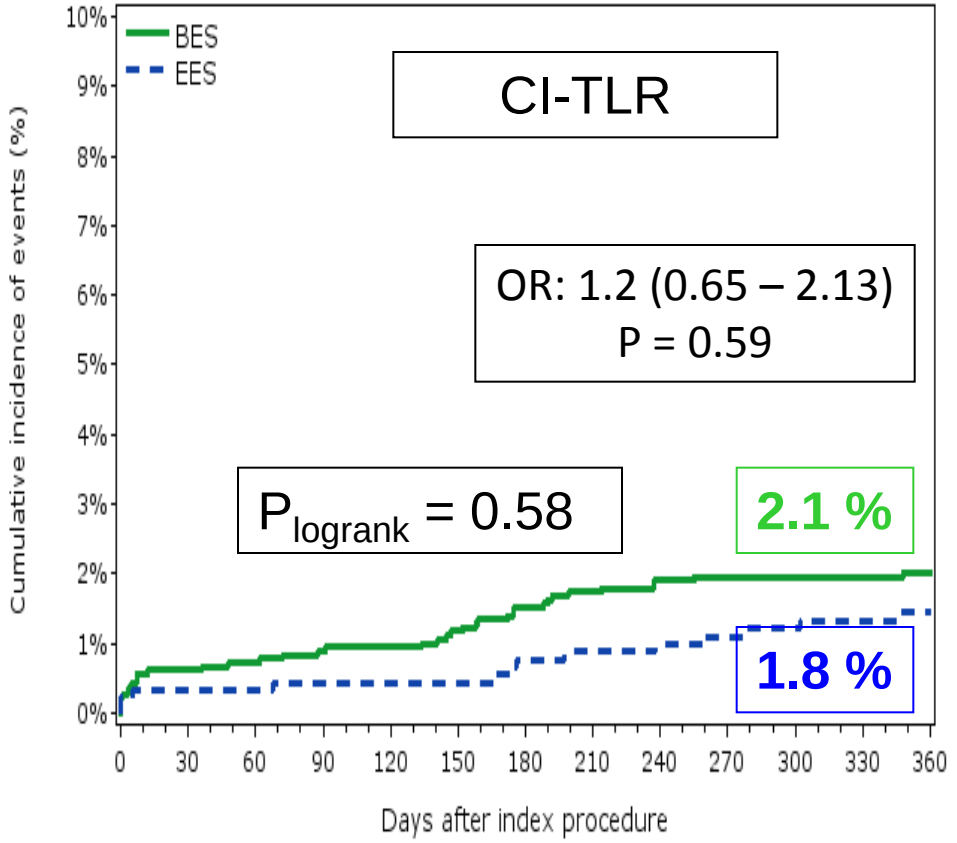
BES	1795	1759	1751	1748	1743	1740	1736	1734	1732	1730	1729	1729	1728
EES	912	894	887	886	884	883	883	882	881	881	881	880	879

Efficacy



Number at Risk

BES	1795	1768	1756	1749	1744	1736	1726	1721	1716	1714	1712	1709	1707
EES	912	902	900	898	896	895	889	888	885	883	881	877	876

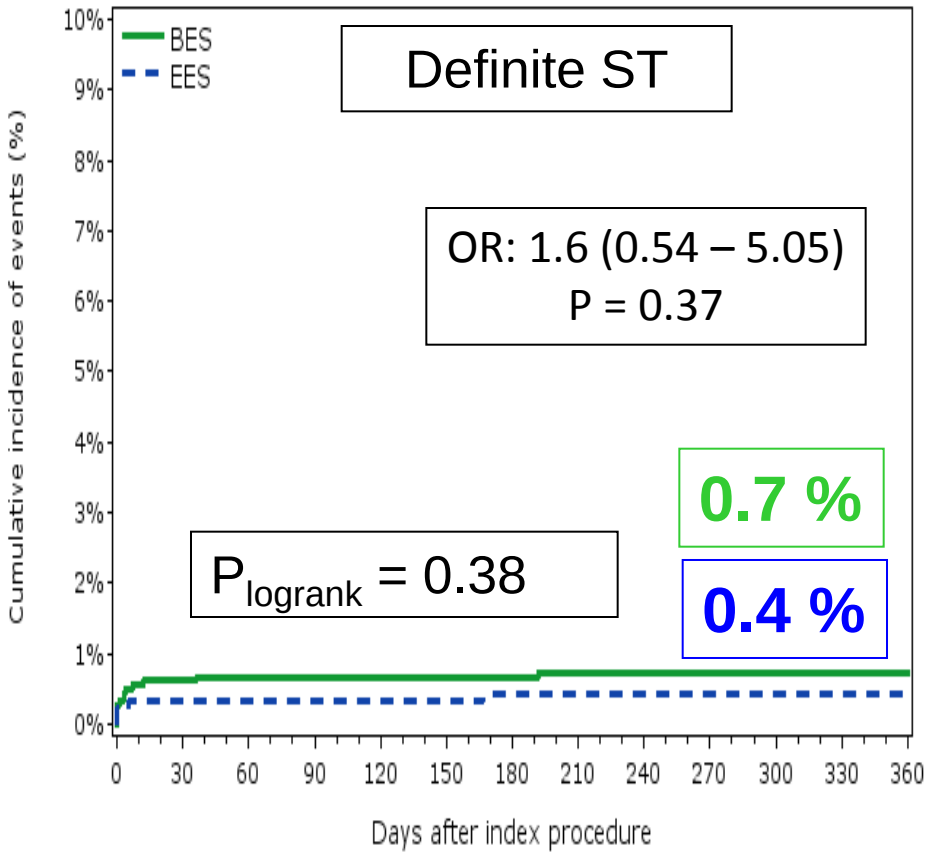


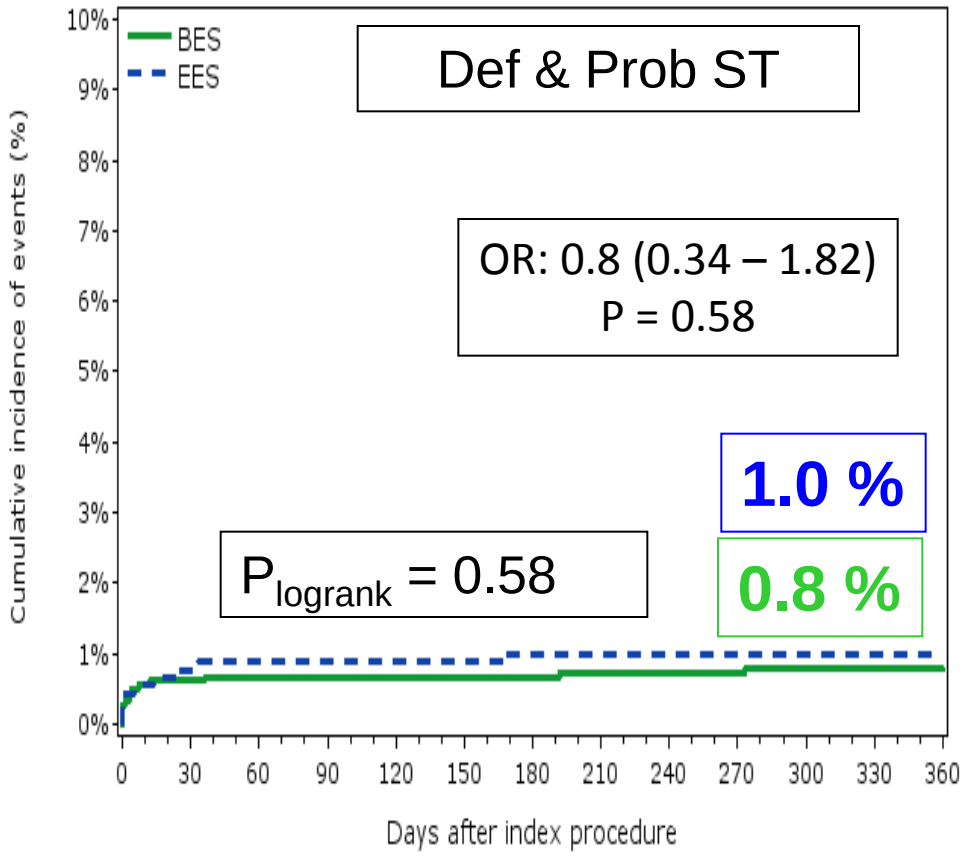
Number at Risk

BES	1795	1776	1768	1763	1762	1758	1752	1748	1745	1744	1744	1744	1743
EES	912	902	900	899	897	897	894	893	892	891	890	889	888

CI-TLR = Clinically Indicated TLR

Stent Thrombosis (ARC)





Conclusions COMPARE II

- In the largest prospective randomised all-comer trial, the Biolimus eluting Nobori stent is non-inferior compared to the current Everolimus eluting Xience/Promus stent

- Primary and secondary endpoints were not significant different between both stent groups and similar cardiac death and similar low ST rates were observed in this real life patient population

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