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Resolute

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

RESOLUTE International Trial

12-month results from TCT 2010

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Strong New Data from TCT 2010

RESOLUTE International 12-month summary

- **Strength in numbers**
  - RESOLUTE International is a large, high quality all-comer trial
    - 2349 real world patients enrolled in 88 International sites
    - 97.4% patient follow-up at 12 months
    - Excellent clinical outcomes at 12 months
      - Cardiac death/TVMI (Primary Endpoint): 4.1%
      - ARC definite/probable stent thrombosis (Secondary Endpoint): 0.87%

- **Strength in consistency**
  - Total of 3489 real world Resolute DES patients in RESOLUTE All Comers and RESOLUTE International trials
  - Clinical outcomes are consistent between the trials at 12 months

- **Strength in complexity**
  - Resolute DES continues to show strong results in complex patients
    - Almost 70% of patients enrolled were defined as complex
    - Consistent outcomes are seen across patient subgroups

RESOLUTE All Comers and RESOLUTE International were not specifically designed or powered for complex patient subset analysis.

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RESOLUTE International Trial Design

Strength in numbers: large, all-comer trial

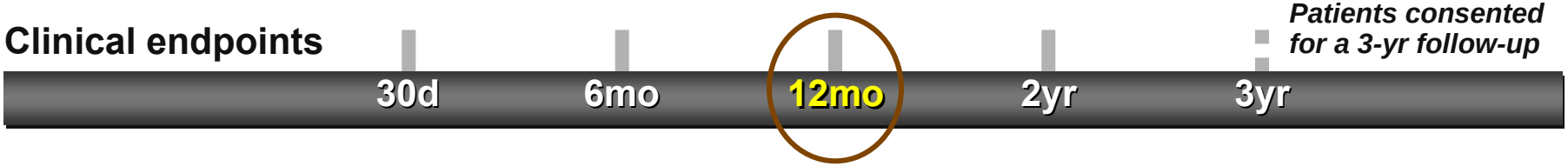
PI: J. Belardi, F–J. Neumann, P. Widimský

Real World (Open Label)
All patients with symptomatic coronary artery disease eligible for DES implantation (no lesion/vessel limitations)

Resolute Stent
n = 2200

88 international sites (Europe, Asia, Africa and South America)
No angiographic follow-up
100% Independent clinical event adjudication
25% randomly assigned to 100% monitoring

Clinical endpoints



Primary endpoint: Composite of cardiac death and target vessel MI at 12 mo
Key secondary endpoint: ARC definite/probable stent thrombosis at 12 mo
Drug therapy: ASA and clopidogrel/ticlopidine ≥6 mo (per guidelines)

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Enrollment Reflects Real-World Practice

Baseline characteristics similar to RESOLUTE All Comers

	RESOLUTE International	*RESOLUTE All Comers*	
	Resolute DES (n = 2349)	***Resolute DES (n = 1140)***	***Xience V DES (n = 1152)***
Age (yr)	63.5 ±11.2	64.4 ± 10.9	64.2 ± 10.8
Men (%)	77.8	76.7	77.2
Diabetes mellitus (%)	30.5	23.5	23.4
Insulin Dependent (%)	9	8.4	7.1
Prior MI (%)	27	28.9	30.4
Unstable Angina (%)	26.1	19.4	18.9
AMI (within 12 hr) (%)	9.7	15.4	17.8
AMI (within 72 hr) (%)	20	28.9	28.8
Lesions treated per patient	1.3 ± 0.7	1.5 ± 0.7	1.5 ± 0.8
Multi vessel treated (%)	14.0	25	25
Small vessel (RVD ≤2.75 mm)	45.4	67.8	67.4
Long lesion (length >18 mm)	46.1	18.2	21.2
In-stent restenosis (%)	7.6	8.1	8.0
Bifurcation/trifurcation (%)	18.2	16.9	17.7
Total occlusion (%)	6.3	16.3	17.2
Complex Patients[1] (%)	**67.5**	**67.0**	**65.6**

[1]Complex patient definition: bifurcation, bypass graft, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0).

With the exception of small vessels and long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved for the patient subsets noted above.

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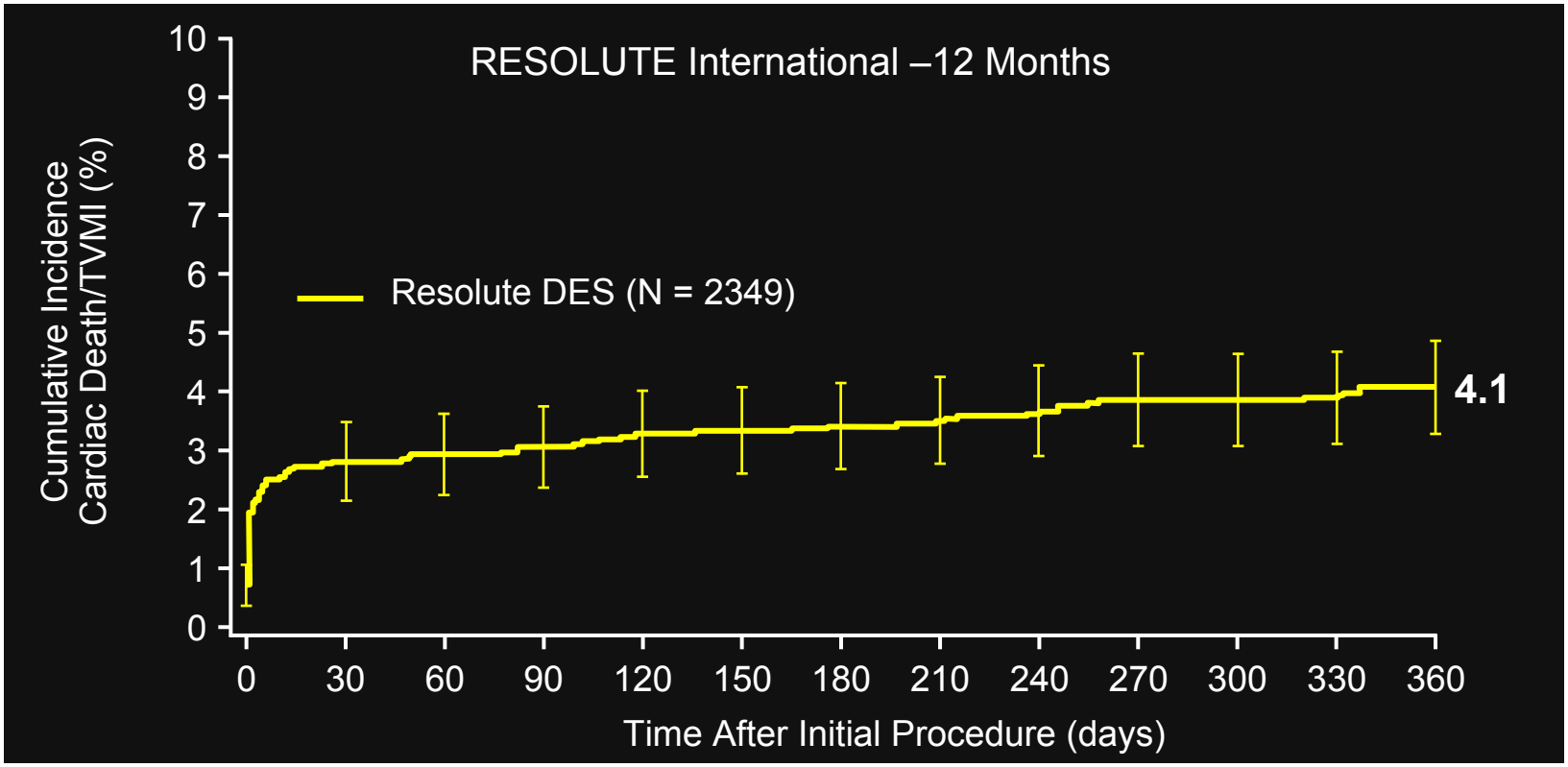
Low Cardiac Death/Target Vessel MI Rate

RESOLUTE International primary endpoint



RESOLUTE All Comers 12 months	*Resolute DES n = 1119*	*Xience V DES n = 1126*	*p-Value*
Cardiac death/TVMI	5.3%	5.4%	0.96

RESOLUTE All Comers was not specifically designed or powered to individually compare cardiac death/TVMI.

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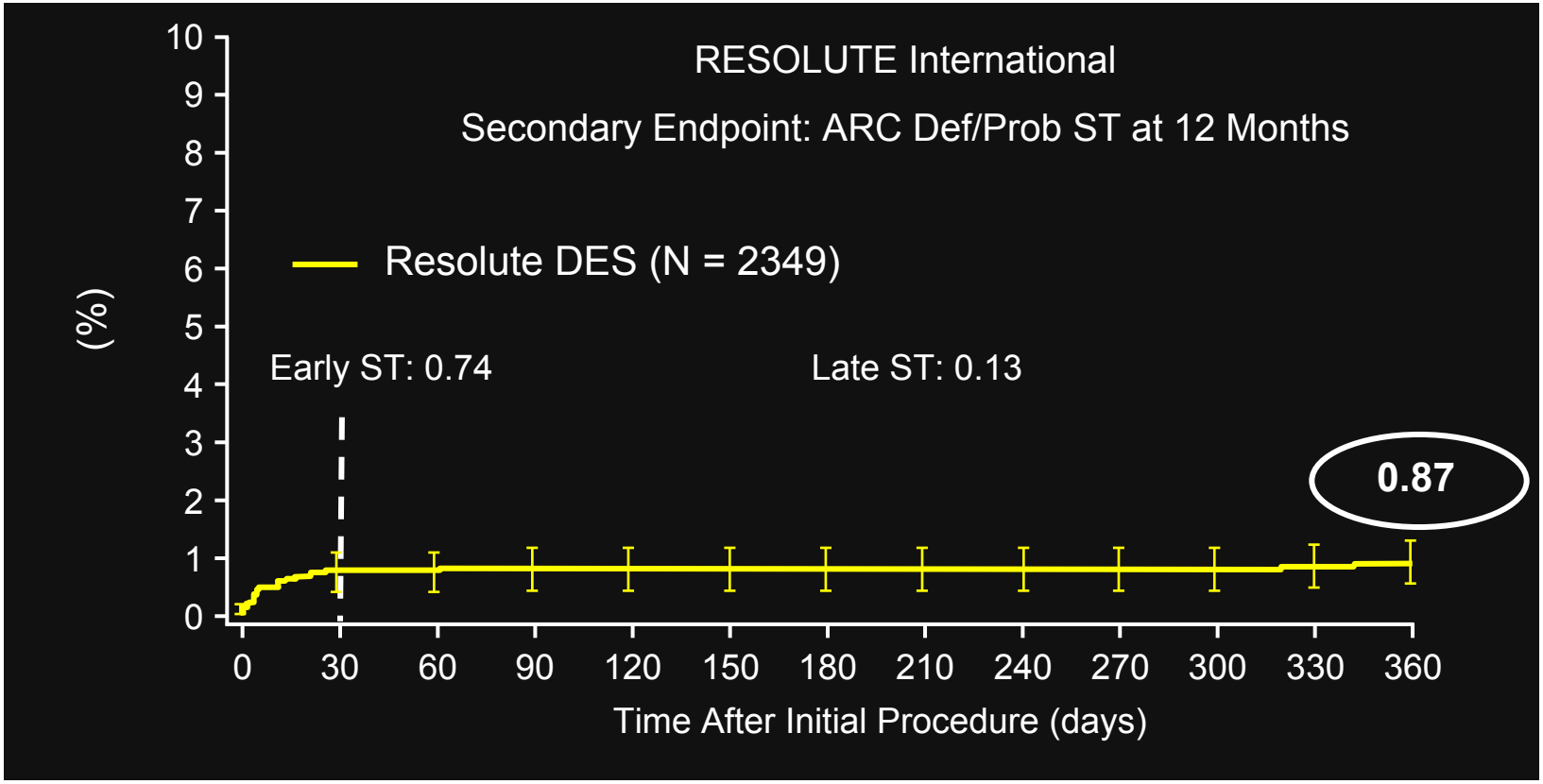
Low Stent Thrombosis Rate for an All-Comer Trial

RESOLUTE International secondary endpoint



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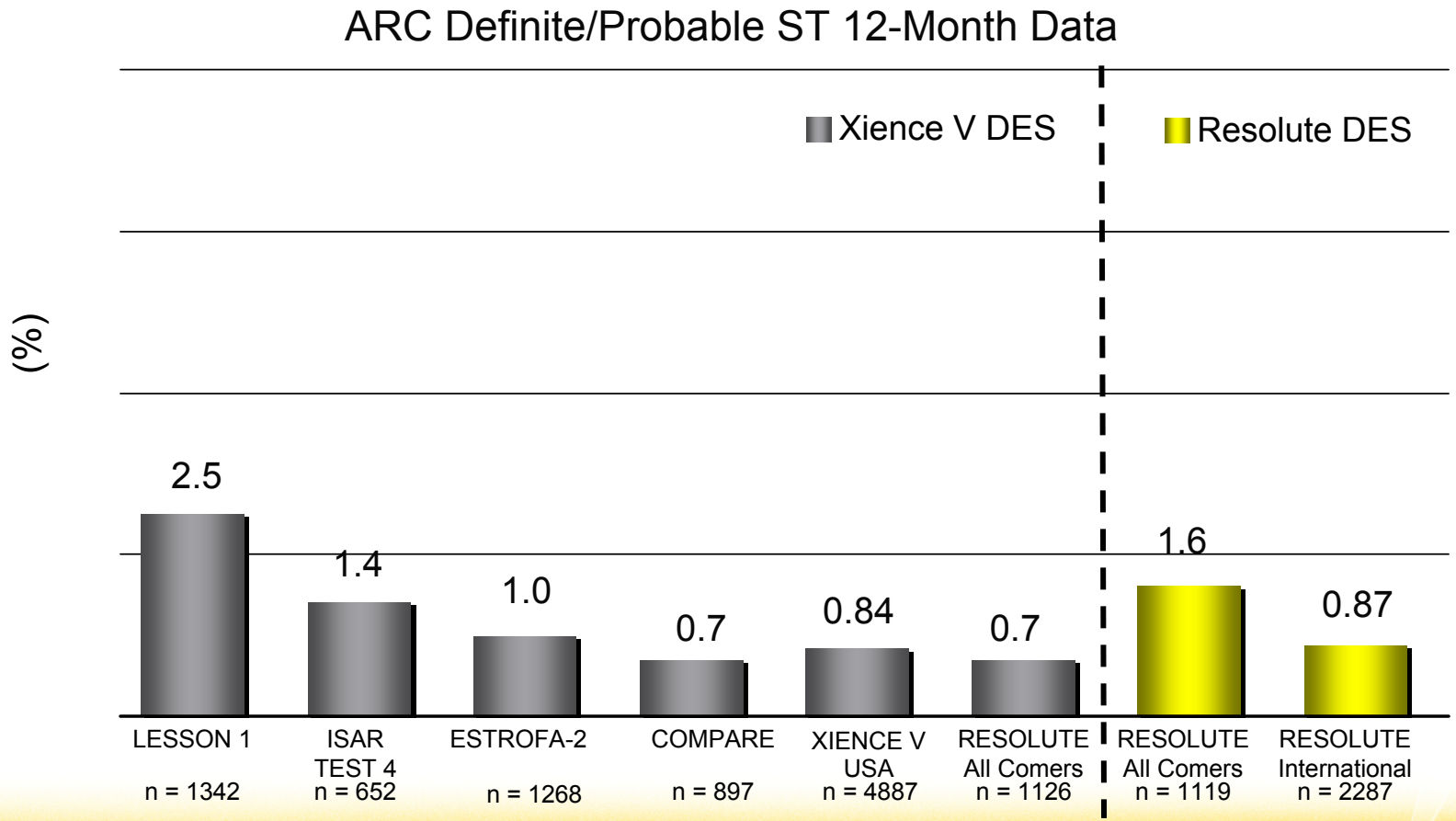
Stent Thrombosis Rates in All-Comer Trials

Studies not powered for this low frequency ST event



Results from clinical trials are not directly comparable. Information is provided for educational purposes only.

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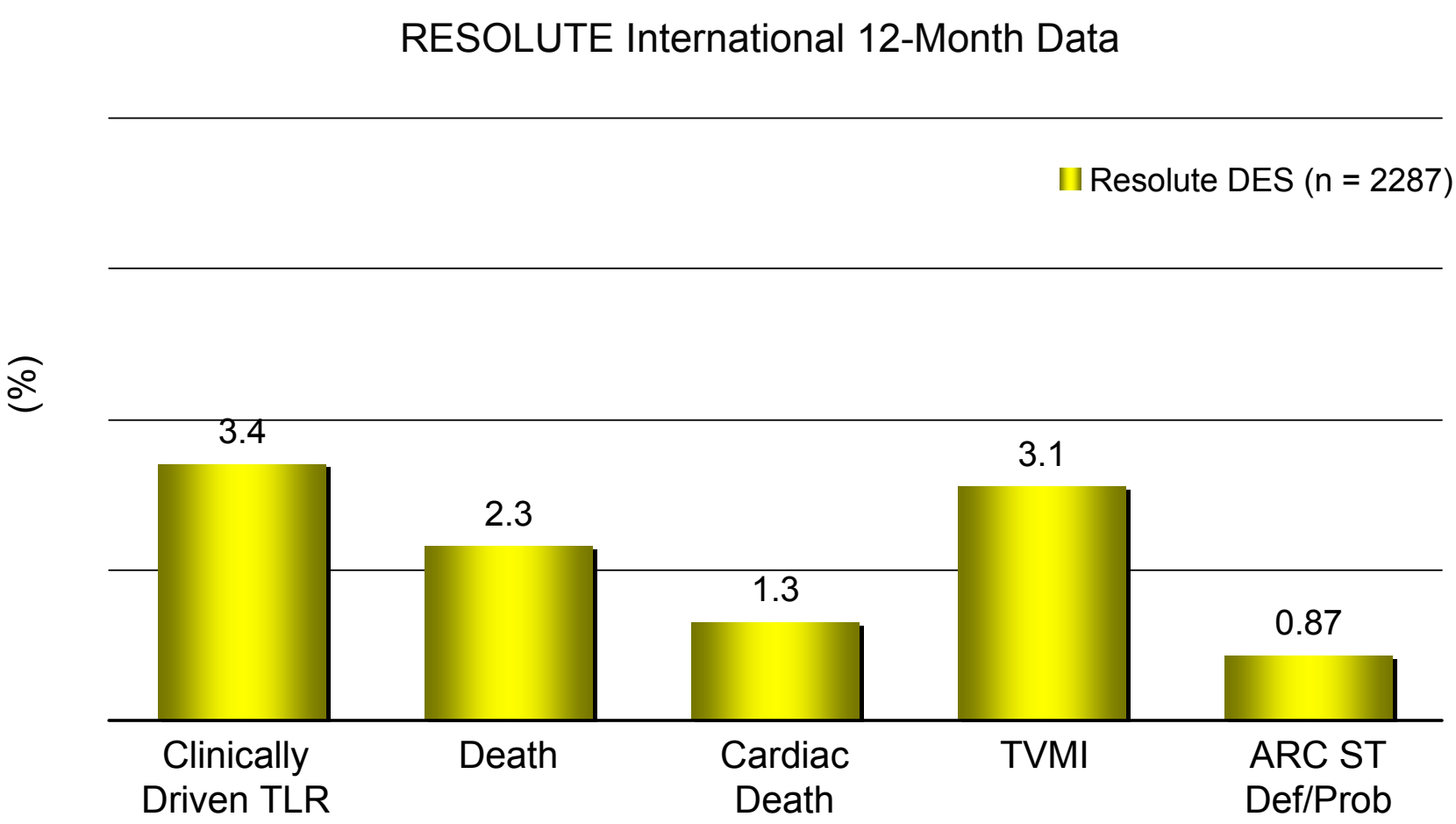
Excellent Safety and Efficacy Clinical Outcomes



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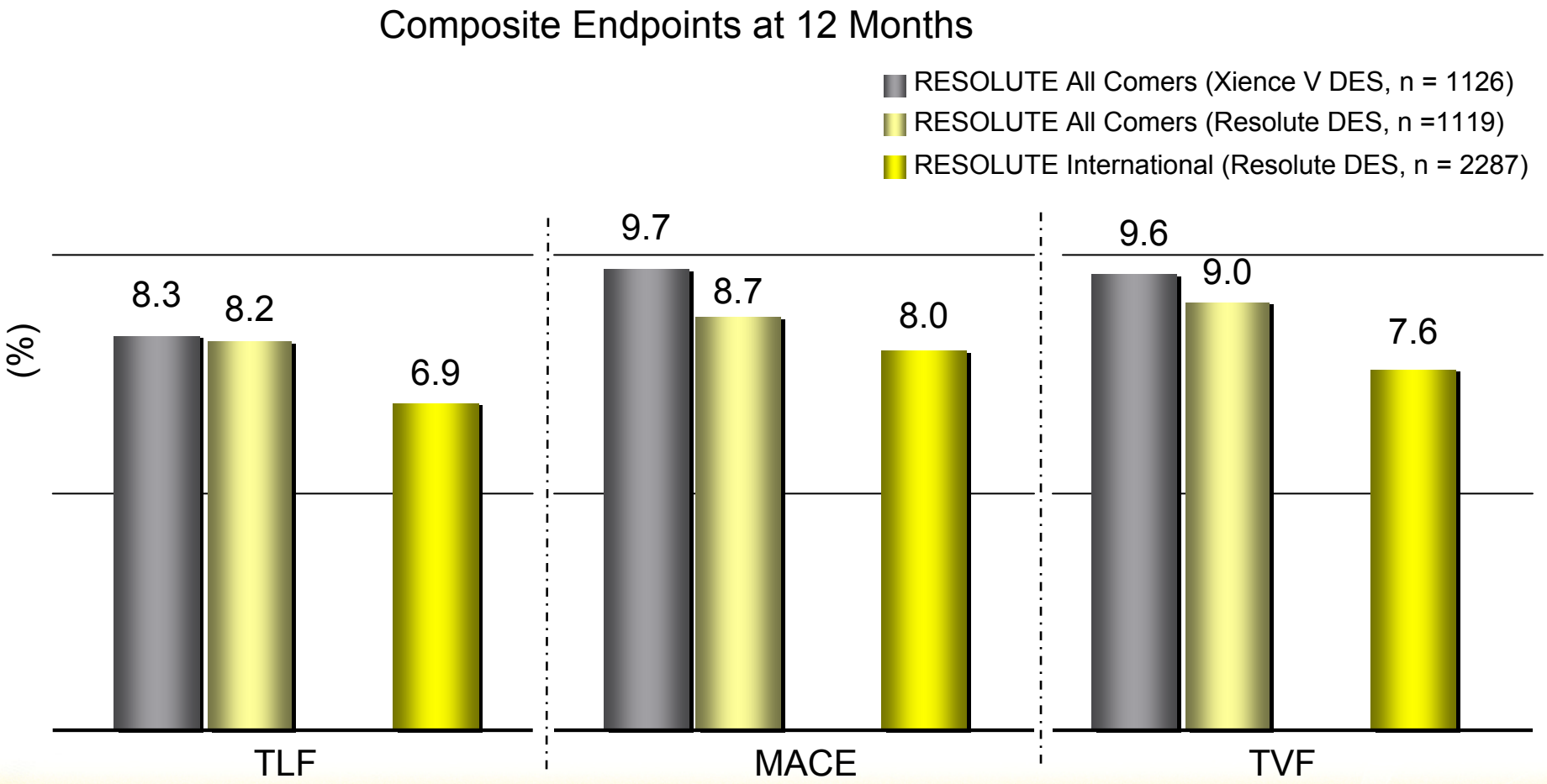
Results are Consistent with RESOLUTE All Comers

Strength in consistency: total of 3489 Resolute patients enrolled



TLF: cardiac death, TVMI, clinically driven TLR

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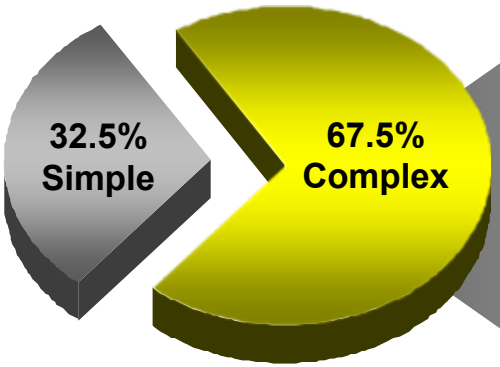
RESOLUTE International – A Truly Real-World Trial

Strength in complexity: almost 70% of patients are complex



- Bifurcation
- Bypass grafts
- ISR
- AMI <72 hr
- LVEF <30%
- Unprotected LM
- >2 vessels stented
- Renal insufficiency or failure (creatinine >140 µmol/L)
- Lesion length >27 mm
- >1 lesion per vessel
- Lesion with thrombus
- Total occlusion (preprocedure TIMI = 0)

With the exception of long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved for the patient subsets noted above.

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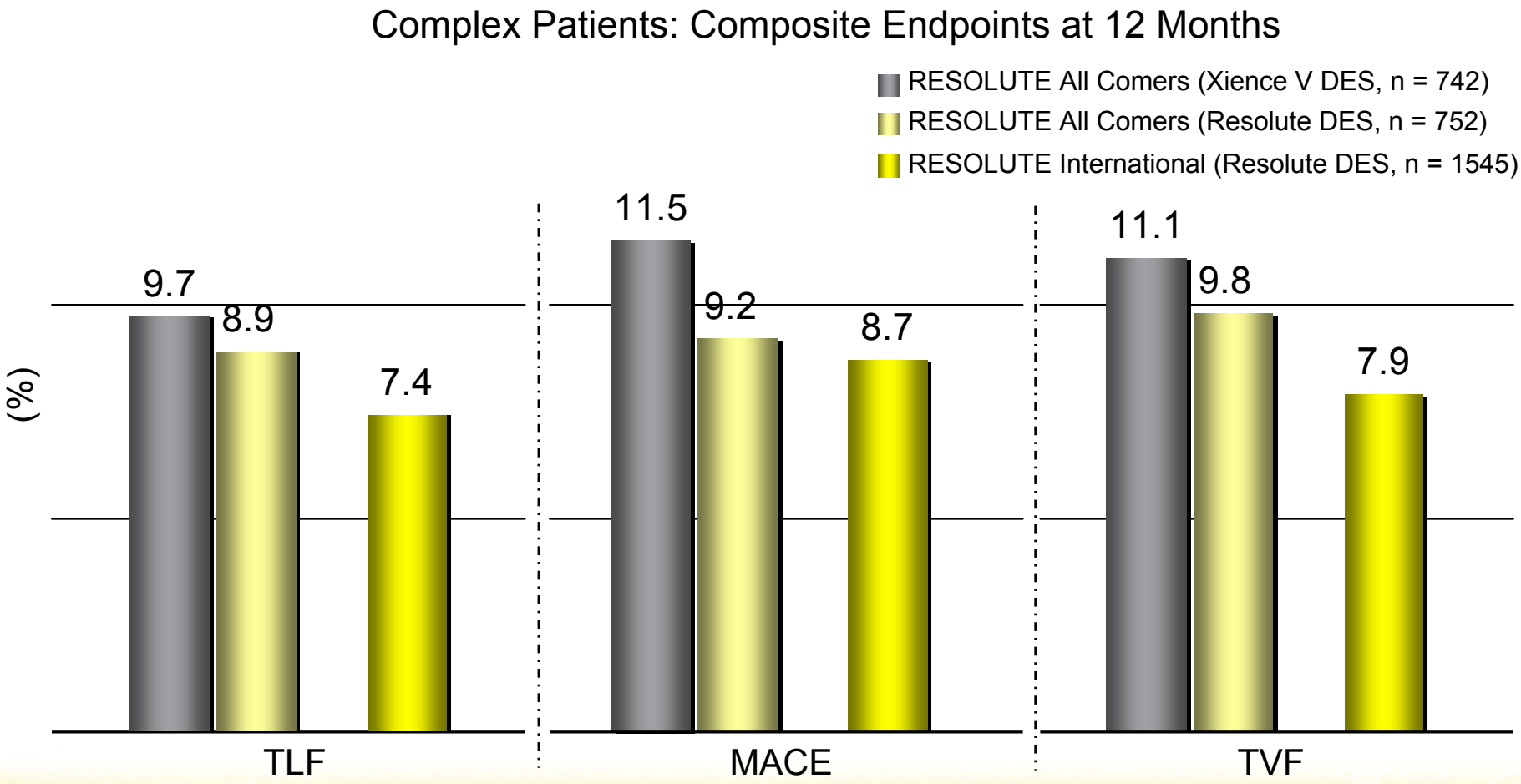
Resolute DES Shows Strong Results in Complex Patient Subgroups



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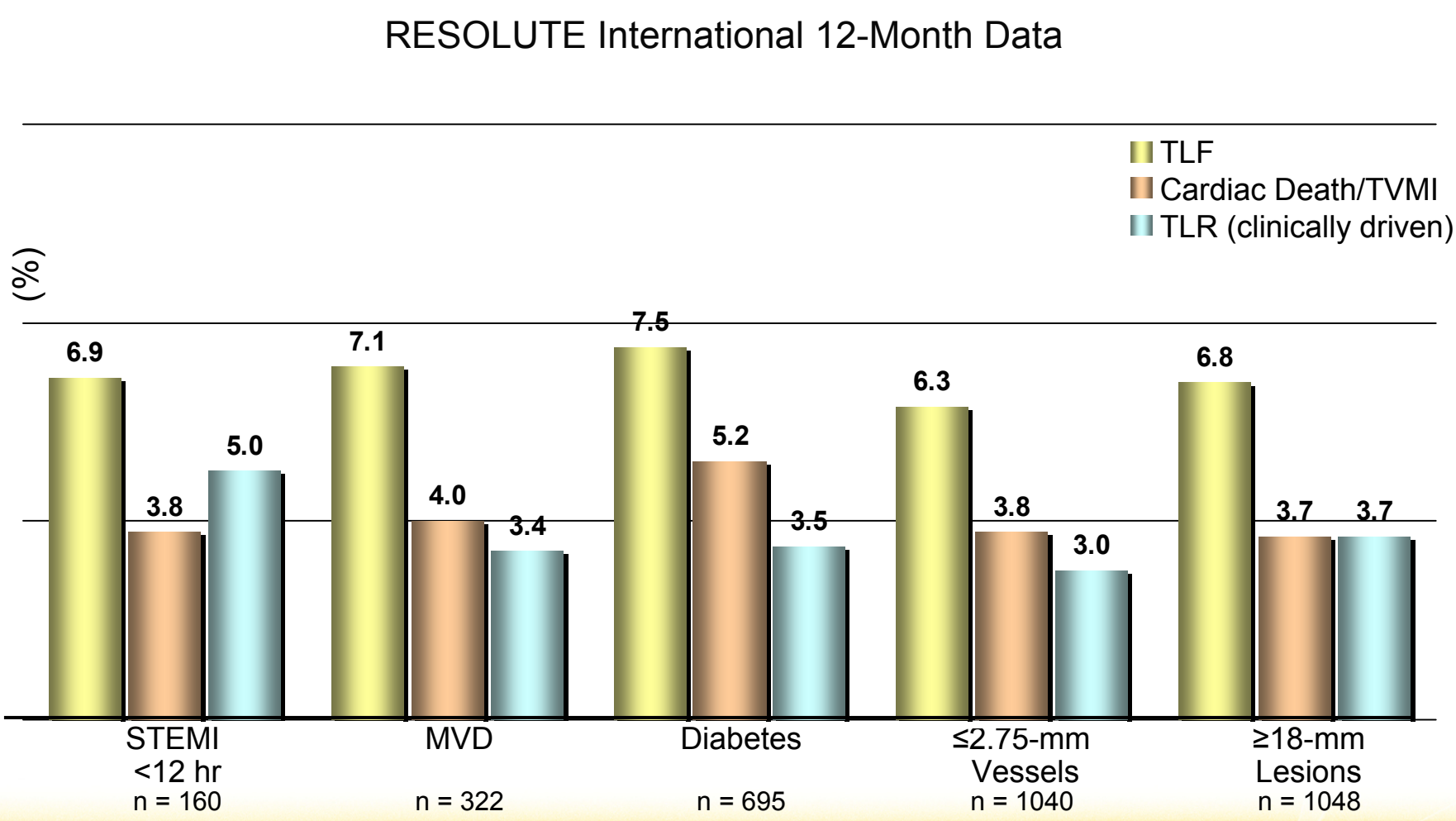
Similar Performance Across Complex Patient Subsets



Resolute DES is not specifically approved for STEMI, multivessel disease and diabetic patient subgroups.

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A Strong Choice For Your Complex Daily Practice

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