Establishing the Optimal Duration of DAPT After PCI in High-Risk TWILIGHT-like patients with Acute Coronary Syndrome

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Background & Objective

- Current practice guidelines recommend treatment of ACS patients include more aggressive risk factor modification and prolonged antiplatelet therapy, and recommend DAPT for a minimum of 12 months following an ACS, regardless of whether or not PCI is performed.
- With the improvement of stent device technology, several studies evaluating the safety and efficacy of shortening DAPT to <12-month in patients with ACS undergoing PCI reported conflicting results. The SMART-DATE trial found a significant risk of spontaneous MI in patients who stopped DAPT at 6 months versus those receiving 12-month or longer DAPT.
- Recent emphasis on diminished need for long-term antiplatelet therapy may fail to account for the a possibly heightened risk of de novo atherothrombotic lesions in the entire coronary arterial bed in the “vulnerable” post-ACS patient.
- The TWILIGHT study inclusion required the presence of at least 1 additional clinical *and* angiographic feature associated with a high risk of ischemic or bleeding events.
- This study sought to investigate the benefits and risks of extended-term (>12-month) DAPT as compared with short-term DAPT in high-risk "TWILIGHT-like" ACS patients undergoing PCI.

Clinical criteria

Age ≥65 years

Female gender

Troponin positive ACS

Established vascular disease (previous MI, documented PAD or CAD/PAD revasc)

DM treated with medications or insulin

CKD (eGFR <60ml/min/1.73m^2 or CrCl <60ml/min)

Angiographic criteria

Multivessel CAD

Target lesion requiring total stent length >30mm

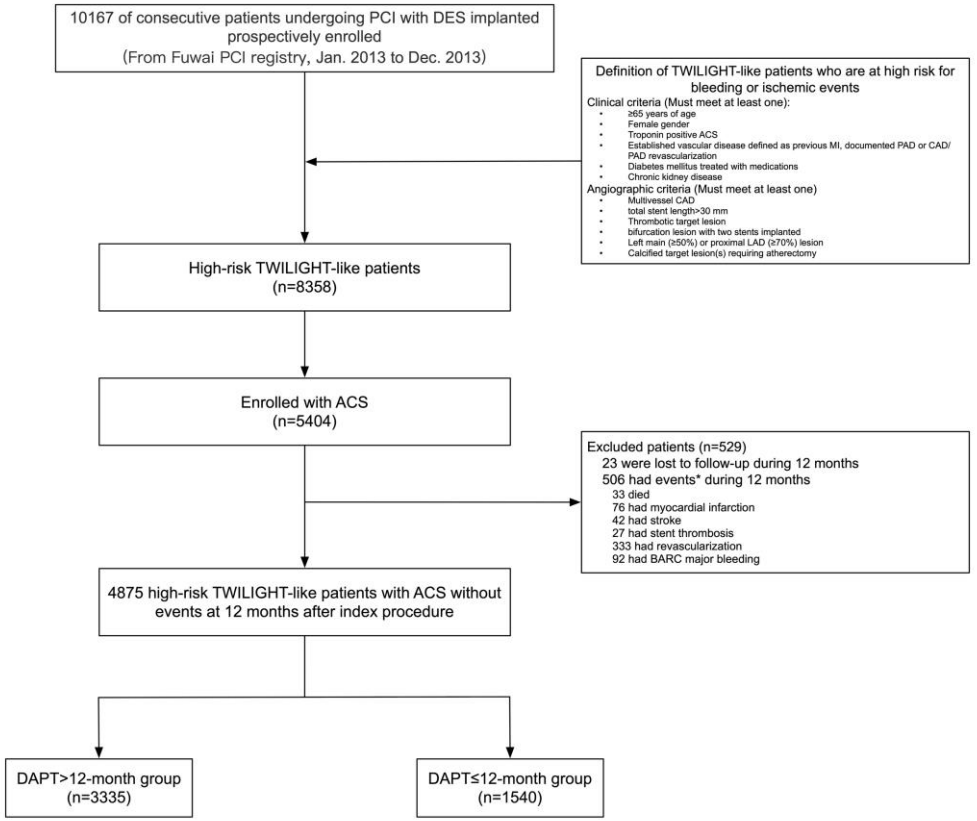
Thrombotic target lesion

Bifurcation lesion(s) with Medina X,1,1 classification requiring ≥2 stents

Left main (≥50%) or proximal LAD (≥70%) lesions

Calcified target lesion(s) requiring atherectomy

Study flow



Baseline, Angiographic, Procedural Characteristics

Baseline feature	DAPT>12-month (n=3335)	DAPT≤12-month (n=1540)	P value
Age, yrs	58.31 ± 10.22	58.51±10.46	0.526
Male	2581 (77.4)	1191 (77.3)	0.967
Hypertension	2118 (63.5)	990 (64.3)	0.600
Diabetes mellitus	1382 (41.4)	636 (41.3)	0.926
Diabetes mellitus requiring medication	892 (26.7)	409 (26.6)	0.890
Current smoking	1977 (59.3)	912 (59.2)	0.969
Prior MI	451 (13.5)	196 (12.7)	0.446
Prior PCI	730 (21.9)	314 (20.4)	0.235
STEMI	721 (21.6)	356 (23.1)	0.241
Multivessel disease	2733 (81.9)	1222 (79.4)	0.031
Target vessel location			
Left main	99 (3.0)	37 (2.4)	0.265
Left anterior descending artery	2982 (89.4)	1388 (90.1)	0.447
Left circumflex coronary artery	671 (20.1)	293 (19.0)	0.373
Right coronary artery	679 (20.4)	304 (19.7)	0.616
Bypass graft	9 (0.3)	3 (0.2)	0.763
Number of vessels treated	1.30 ± 0.51	1.29 ± 0.50	0.492
Total lesion length, mm	40.49 ± 27.04	39.18 ± 25.51	0.110
Number of stents implanted	1.98 ± 1.06	1.93 ± 1.02	0.089
Total stent length, mm	44.19 ± 26.93	43.28 ± 25.77	0.268
Bifurcation lesion	524 (15.7)	261 (16.9)	0.275
Chronic total occlusion	276 (8.3)	93 (6.0)	0.006
In-stent restenosis	150 (4.5)	61 (4.0)	0.392
Heavy calcification	117 (3.5)	35 (2.3)	0.021
Thrombus-containing lesion	188 (5.6)	94 (6.1)	0.516
SYNTAX score	12.03 ± 7.83	11.92 ± 7.70	0.667
Second-generation DES	2961 (88.8)	1386 (90.0)	0.205
Radial artery access	3032 (90.9)	1417 (92.0)	0.207
Use of intravascular ultrasound	170 (5.1)	98 (6.4)	0.071
Glycoprotein IIb/IIIa use	526 (15.8)	262 (17.0)	0.274

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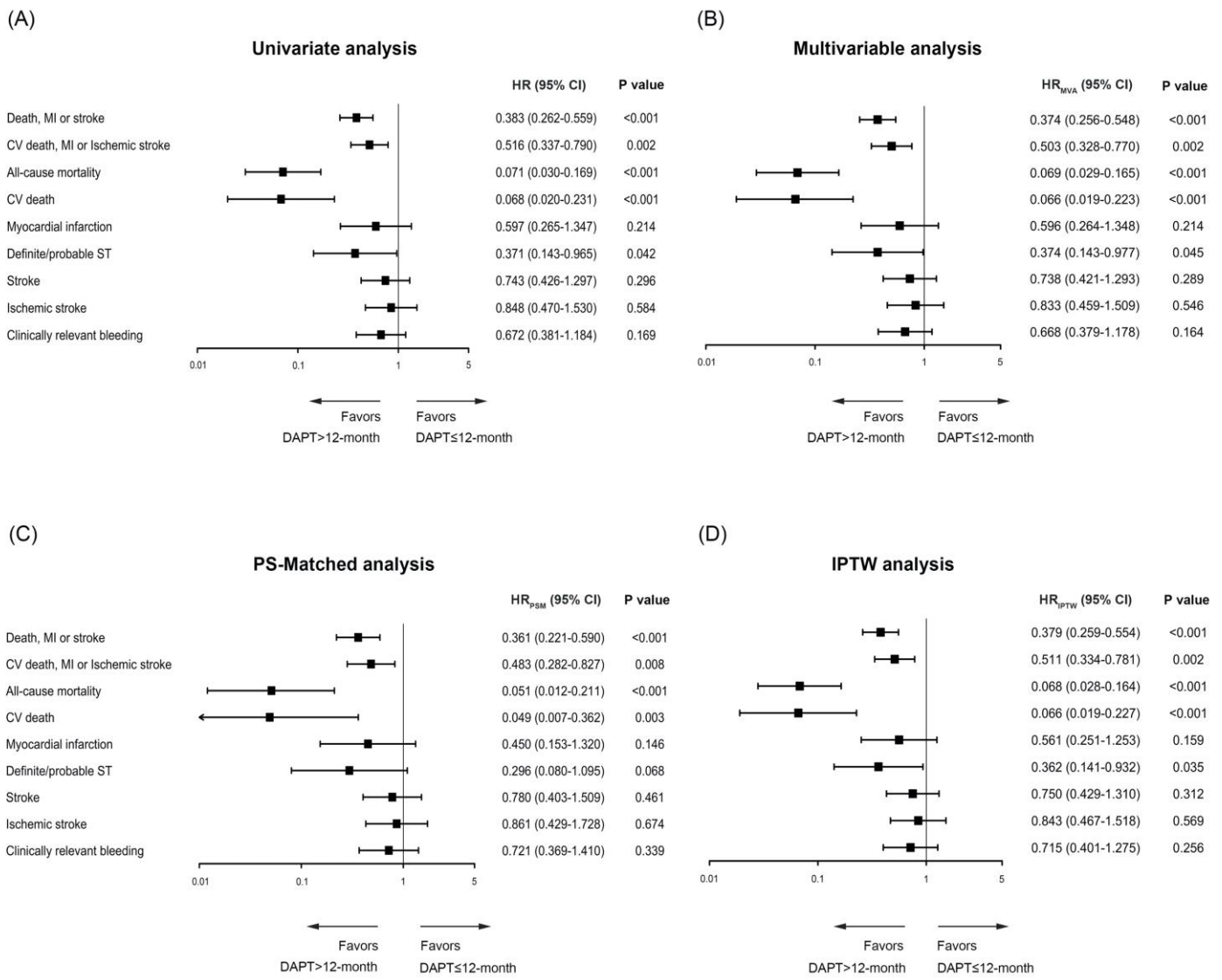
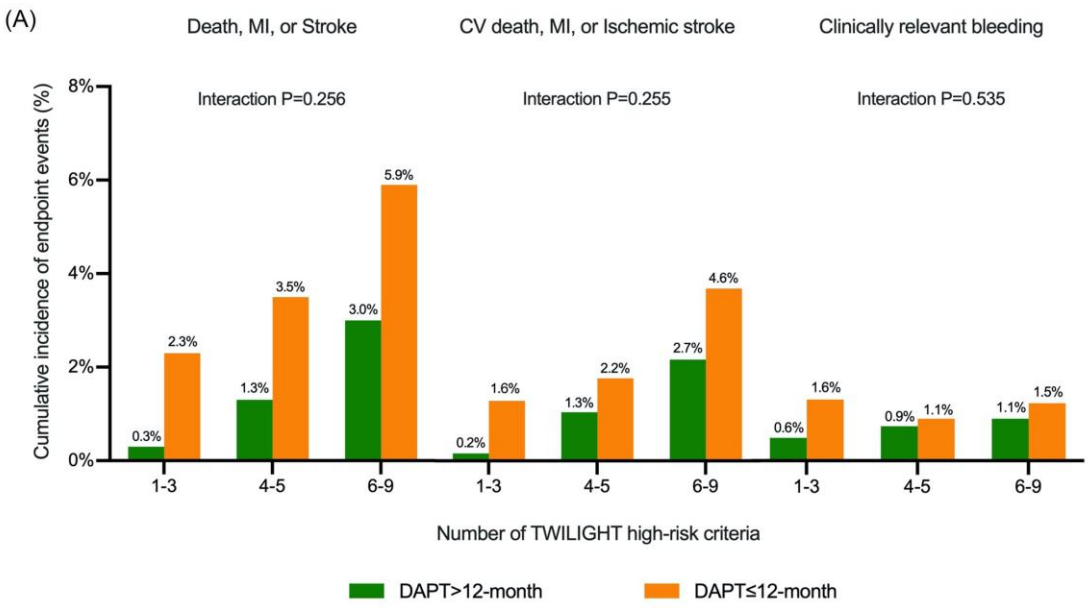
Results



The primary ischemic endpoint occurred in 1.5% of patients with continued DAPT beyond 12 months and in 3.8% patients with short-term (≤12-month) DAPT. Rates of BARC type 2, 3, or 5 bleeding were similar between the two groups (0.9% vs. 1.3%).

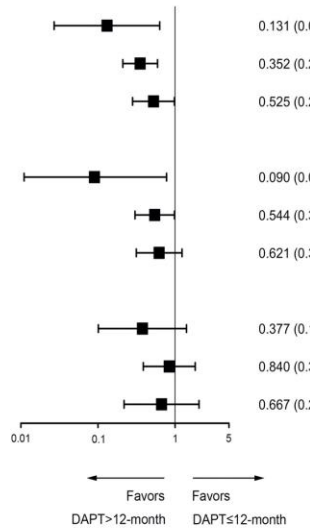
Results

(A)



(B)

Number of TWILIGHT high-risk criteria	DAPT>12-month (n=3335)	DAPT≤12-month (n=1540)	HR (95% CI)	P for interaction
Death, MI, or Stroke				
1-3 (n=962)	2/652 (0.3%)	7/310 (2.3%)	0.131 (0.027-0.632)	
4-5 (n=2858)	26/1952 (1.3%)	32/906 (3.5%)	0.352 (0.210-0.592)	0.256
6-9 (n=1055)	22/731 (3.0%)	19/324 (5.9%)	0.525 (0.281-0.980)	
CV death, MI, or Ischemic stroke				
1-3 (n=962)	1/652 (0.2%)	5/310 (1.6%)	0.090 (0.011-0.775)	
4-5 (n=2858)	25/1952 (1.3%)	20/906 (2.2%)	0.544 (0.302-0.981)	0.255
6-9 (n=1055)	20/731 (2.7%)	15/324 (4.6%)	0.621 (0.314-1.230)	
Clinically relevant bleeding				
1-3 (n=962)	4/652 (0.6%)	5/310 (1.6%)	0.377 (0.101-1.406)	
4-5 (n=2858)	18/1952 (0.9%)	10/906 (1.1%)	0.840 (0.387-1.823)	0.535
6-9 (n=1055)	8/731 (1.1%)	5/324 (1.5%)	0.667 (0.218-2.044)	



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Conclusion

- To the best of our knowledge, this is the first report investigating the feasibility and safety long-term DAPT for high-risk "TWILIGHT-like" patients with ACS treated with DES. There are several notable findings from this study.
- First, high-risk patients with ACS had higher rates of physician-guided continuation of DAPT beyond 12 months.
- Second, long-term DAPT (>12-month) was associated with a lower risk for major cardiovascular composite endpoints without any measurable increase in clinically relevant bleeding events compared with shorter DAPT duration than 12 months.
- Third, we observed a significant reduction in all-cause mortality among patients receiving extended-term DAPT duration, driven mostly by a reduction of cardiovascular death, that requires a cautious interpretation in view of the similar rates of MI and stroke.
- In aggregate, these results suggested that prolonged DAPT in ACS patients who present with a particularly higher risk for thrombotic complications without excessive risk of bleeding could remain the standard of care.