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Stent thrombosis after primary angioplasty for STEMI in relation to non-adherence to dual antiplatelet therapy over time: results of the HORIZONS-AMI trial

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KEYWORDS

- acute coronary syndromes
- dual antiplatelet therapy
- stent thrombosis

Abstract

Aims: Rates of stent thrombosis (ST) after ST-elevation myocardial infarction (STEMI) may vary over time and the relationship of this complication with non-adherence to dual antiplatelet therapy (DAPT) during long-term follow-up remains unclear.

Methods and results: We analysed 2,997 patients who were treated with at least one stent and in whom a non-target vessel ST did not occur during follow-up from the large-scale Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial of patients with STEMI undergoing primary percutaneous coronary intervention (PCI). Aspirin was prescribed indefinitely, and a thienopyridine for at least six months. DAPT usage was evaluated according to the development of ST in four time periods (<1 month, 1-6 months, 6-12 months and >1 year from index stent implantation). DAPT non-usage was lowest within the first month, but was strongly associated with ST. During the 1-6 month period the relationship remained strong, but was absent in the 6-12 month period. Beyond one year, ST was associated with non-usage of aspirin but was paradoxically more common in patients taking a thienopyridine.

Conclusions: The relationship between stent thrombosis and non-adherence to DAPT varies over time. It is strong within the first month, remains important until six-month follow-up but fades afterwards. Very late ST is associated with both DAPT and aspirin alone but not with thienopyridine non-adherence. Clinical trial registration: HORIZONS-AMI - registered at clinicaltrials.gov #NCT00433966.

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Introduction

Stent thrombosis is a serious complication of percutaneous coronary intervention (PCI) with stent implantation. Dual antiplatelet therapy (DAPT) has been shown to reduce subacute stent thrombosis[1] and prolonged use of DAPT has been shown to reduce major adverse cardiac events after treatment of acute coronary syndromes with or without PCI[2]. Following concerns regarding drug-eluting stent (DES) thrombosis at late and very late time frames, a set of standardised definitions has been applied[3], and current guidelines suggest the use of DAPT for at least one year post-stenting even for non-urgent PCI with stent implantation. The utility of DAPT beyond one year is the subject of a large trial, but smaller scale studies have questioned its efficacy in low-risk groups[4]. Among other risk factors[5,6], non-adherence to DAPT is considered a risk factor of stent thrombosis[7]. However, the relationship between timing of DAPT non-adherence and the risk of stent thrombosis has not been investigated. We sought to analyse this association in the HORIZONS-AMI trial database, which enrolled patients with ST-segment elevation myocardial infarction (STEMI) who fulfil the criteria for prolonged DAPT after PCI with stent implantation.

Methods

The HORIZONS-AMI trial methodology has been published previously[8]. In brief, STEMI patients treated with immediate cardiac catheterisation and primary angioplasty were included. A total of 3,602 patients were primarily randomised 1:1 to treatment with bivalirudin plus a provisional glycoprotein IIb/IIIa inhibitor (GPI) versus unfractionated heparin plus a routinely administered GPI. Subsequently, 3,006 patients eligible for stent implantation underwent a secondary randomisation 3:1 to a paclitaxel-eluting stent (Taxus®; Boston Scientific, Natick, MA, USA) versus an identical bare metal stent (Express®; Boston Scientific, Natick, MA, USA). For the purpose of the present analysis (n=2,997), we only considered patients who were treated with at least one stent (n=3,006) and did not sustain a non-target vessel stent thrombosis (n=9). Stent thrombosis at follow-up was defined as occurring in the original target vessel treated during the STEMI admission and trial enrolment, and was defined as definite or probable according to the Academic Research Consortium criteria[3].

Patients without stent thrombosis were questioned about DAPT adherence at the 1, 6, 12, 24 and 36-month follow-up time points. Patients were then assigned one of three possible classifications: 1) those who were on DAPT during the complete follow-up interval; 2) those who were off DAPT during the complete follow-up interval; or 3) those who were not faithfully compliant to the daily dosage of DAPT or were unclear about what regimen they followed were classified as following "irregular use" of DAPT. In our primary analysis we compared together patients on DAPT with those off DAPT in combination with those reporting irregular use of DAPT. A secondary analysis was performed only on confirmed cases, i.e., after exclusion of the "irregular use" cases. The overall patient population was analysed first, and then the analysis was repeated among patients who received a DES during the index PCI.

Stent underexpansion was defined as a minimum stent area <5.0 mm by intravascular ultrasound imaging (IVUS). Stent malapposition was defined as the presence of blood speckles behind stent struts by IVUS. The presence of residual dissection or residual thrombus adjacent to a stent was assessed by IVUS.

The relationship between DAPT adherence status and the occurrence of definite/probable stent thrombosis was examined in a total of four time frames: up to 30 days, 1-6 months, 6-12 months and beyond one year from the index PCI with stent implantation for STEMI. Within each time frame, patients were grouped according to the occurrence of stent thrombosis. The rate of DAPT adherence was derived and compared between the groups using the Fisher's exact test. The significance level was set at $p<0.05$. Descriptive statistics were used to report the rate of stent thrombosis related events that might have contributed to this event according to the relevant case report form.

Results

The summary of results in the overall population is given in **Table 1** and **Figure 1** and **Figure 2**. With respect to subacute stent thrombosis after index STEMI and primary angioplasty with stent implantation, the rate of discontinuation or irregular aspirin, thienopyridine or combined DAPT therapy was low, but also associated with stent thrombosis. Stent underexpansion, dissection and adjacent thrombus were reported. Although the confirmed DAPT discontinuation cases were rare, a statistical trend was documented towards discontinuation of either aspirin or thienopyridine and subacute thrombosis.

With respect to late stent thrombosis between one and six months post implantation, we found a strong association between this complication and discontinuation of one or both antiplatelet drugs. These results were unaffected when only the confirmed DAPT discontinuation cases were considered. The only event reported as potentially relating to stent thrombosis was a surgical procedure.

Discontinuation of either aspirin, thienopyridine or both among patients with late stent thrombosis between six and 12 months was considerable (up to 54%), but not significantly different than in patients without stent thrombosis (35.8%, p=0.24). Results were similar when only confirmed DAPT discontinuation cases were considered. The only event reported as potentially relating to stent thrombosis was stent underexpansion.

Very late stent thrombosis was associated with higher discontinuation or irregular use of aspirin and of both DAPT drugs, but less discontinuation of thienopyridine in comparison to patients without very late stent thrombosis. Analysis of only the confirmed cases revealed largely concordant results. Few surgical procedures, a case of trauma and few cases of stent underexpansion were reported in relation to very late stent thrombosis.

The results of the cohort of patients who received a drug-eluting stent during the original index procedure were qualitatively concordant with the above findings in the overall population, and consistent among the four time frames of stent thrombosis occurrence. These findings are summarised in **Online Table 2**.

Table 1. Rates of discontinuation or irregular use of dual antiplatelet therapy during the 3-year follow-up period after primary angioplasty with stent implantation during an ST-elevation myocardial infarction in the HORIZONS-AMI trial; results of the overall patient population. All "confirmed" categories exclude the patients with "irregular use" of antiplatelets.

	Patients with definite or probable stent thrombosis	No stent thrombosis	*p*-value*
Events under 30 days:	**n=74**	**n=2,923**	
Discontinuation/irregular use of thienopyridine	11/74 (14.9%)	183/2,923 (6.26%)	0.007
Discontinuation/irregular use of aspirin	12/74 (16.2%)	193/2,923 (6.60%)	0.004
Discontinuation/irregular use of thienopyridine or aspirin	14/74 (18.9%)	234/2,923 (8.01%)	<0.0001
Discontinuation/irregular use of both aspirin and thienopyridine	9/74 (12.2%)	142/2,923 (4.86%)	0.0107
Confirmed discontinuation of thienopyridine	2/65 (3.08%)	54/2,794 (1.93%)	0.3656
Confirmed discontinuation of aspirin	3/65 (4.62%)	59/2,789 (2.12%)	0.1661
Confirmed discontinuation of thienopyridine or aspirin	5/65 (7.69%)	106/2,795 (3.79%)	0.1055
Confirmed discontinuation of both aspirin and thienoprydine	0/60 (0%)	7/2,696 (0.26%)	1
Factors associated with stent thrombosis events			
Surgical procedure	0 (0%)		
Trauma	1/74 (1.35%)		
Stent underexpansion	6/74 (8.11%)		
Residual dissection adjacent to stent	3/74 (4.05%)		
Residual thrombus adjacent to stent	4/74 (5.41%)		
Stent malapposition	0 (0%)		
Events from 30 days to 6 months:	**n=15**	**n=2,908**	
Discontinuation/irregular use of thienopyridine	7/15 (46.7%)	408/2,908 (14.0%)	0.003
Discontinuation/irregular use of aspirin	7/15 (46.7%)	272/2,908 (9.35%)	<0.001
Discontinuation/irregular use of thienopyridine or aspirin	9/15 (60.0%)	454/2,908 (15.6%)	<0.001
Discontinuation/irregular use of both aspirin and thienopyridine	5/15 (33.3%)	226/2,908 (7.77%)	0.0046
Confirmed discontinuation of thienopyridine	5/13 (38.5%)	204/2,704 (7.54%)	0.002
Confirmed discontinuation of aspirin	5/13 (38.5%)	65/2,701 (2.41%)	<0.0001
Confirmed discontinuation of thienopyridine or aspirin	7/13 (53.8%)	250/2,704 (9.25%)	0.0001
Confirmed discontinuation of both aspirin and thienopyridine	3/9 (33.3%)	19/2,473 (0.77%)	<0.0001
Factors associated with stent thrombosis events			
Surgical procedure	1/15 (6.67%)		
Trauma	0 (0%)		
Stent underexpansion	0 (0%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		
Events from 6 to 12 months:	**n=13**	**n=2,895**	
Discontinuation/irregular use of thienopyridine	7/13 (53.8%)	1,001/2,895 (34.6%)	0.1544
Discontinuation/irregular use of aspirin	2/13 (15.4%)	310/2,895 (10.7%)	0.6422
Discontinuation/irregular use of thienopyridine or aspirin	7/13 (53.8%)	1,036/2,895 (35.8%)	0.2448
Discontinuation/irregular use of both aspirin and thienopyridine	2/13 (15.4%)	275/2,895 (9.50%)	0.3554
Confirmed discontinuation of thienopyridine	6/12 (50.0%)	767/2,661 (28.8%)	0.1174
Confirmed discontinuation of aspirin	0/11 (0%)	75/2,660 (2.82%)	1
Confirmed discontinuation of thienopyridine or aspirin	6/12 (50.0%)	803/2,662 (30.2%)	0.2032
Confirmed discontinuation of both aspirin and thienopyridine	0/6 (0%)	39/1,898 (2.05%)	1
Factors associated with stent thrombosis events			
Surgical procedure	0 (0%)		
Trauma	0 (0%)		
Stent underexpansion	1/13 (7.69%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		

Table 1. Rates of discontinuation or irregular use of dual antiplatelet therapy during the 3-year follow-up period after primary angioplasty with stent implantation during an ST-elevation myocardial infarction in the HORIZONS-AMI trial; results of the overall patient population. All "confirmed" categories exclude the patients with "irregular use" of antiplatelets.

	Patients with definite or probable stent thrombosis	No stent thrombosis	*p*-value*
Events beyond 1 year:	**n=45**	**n=2,850**	
Discontinuation/irregular use of thienopyridine	20/45 (44.4%)	1,913/2,850 (67.1%)	0.002
Discontinuation/irregular use of aspirin	13/45 (28.9%)	345/2,850 (12.1%)	0.002
Discontinuation/irregular use of thienopyridine or aspirin	22/45 (48.9%)	1,948/2,850 (68.4%)	0.009
Discontinuation/irregular use of both aspirin and thienopyridine	11/45 (24.4%)	310/2,850 (10.9%)	0.0131
Confirmed discontinuation of thienopyridine	11/36 (30.6%)	1,662/2,599 (63.9%)	0.0001
Confirmed discontinuation of aspirin	5/37 (13.5%)	89/2,594 (3.43%)	0.0092
Confirmed discontinuation of thienopyridine or aspirin	14/37 (37.8%)	1,697/2,599 (65.3%)	0.0008
Confirmed discontinuation of both aspirin and thienopyridine	2/25 (8.00%)	54/956 (5.65%)	0.6492
Factors associated with stent thrombosis events			
Surgical procedure	3/45 (6.67%)		
Trauma	1/45 (2.22%)		
Stent underexpansion	3/45 (6.67%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		
Events at any point during 3-year follow-up:	**n=147**	**n=2,850**	
Discontinuation/irregular use of thienopyridine	45/147 (30.6%)	2,034/2,850 (71.4%)	<0.0001
Discontinuation/irregular use of aspirin	34/147 (23.1%)	543/2,850 (19.1%)	0.2375
Discontinuation/irregular use of thienopyridine or aspirin	52/147 (35.4%)	2,081/2,850 (73.0%)	<0.0001
Discontinuation/irregular use of both aspirin and thienopyridine	27/147 (18.4%)	467/2,850 (16.4%)	0.4946
Confirmed discontinuation of thienopyridine	24/126 (19.0%)	1,779/2,783 (63.9%)	<0.0001
Confirmed discontinuation of aspirin	13/126 (10.3%)	178/2,780 (6.40%)	0.0953
Confirmed discontinuation of thienopyridine or aspirin	32/127 (25.2%)	1,839/2,783 (66.1%)	<0.0001
Confirmed discontinuation of both aspirin and thienopyridine	5/100 (5.00%)	88/2,749 (3.20%)	0.3795
Factors associated with stent thrombosis events			
Surgical procedure	4/147 (2.72%)		
Trauma	2/147 (1.36%)		
Stent underexpansion	10/147 (6.80%)		
Residual dissection adjacent to stent	3/147 (2.04%)		
Residual thrombus adjacent to stent	4/147 (2.72%)		
Stent malapposition	1/147 (0.68%)		

The **Online appendix** also includes baseline, procedure and angiographic data comparisons between the two groups that were compared at each time point.

Discussion

The rate of discontinuation or irregular use of one or both components of DAPT therapy after stent implantation occurs in variable rates during different post-procedure time frames but, as could be expected, increased beyond 12 months post-procedure. The recommended duration of DAPT after STEMI is 12 months and bears a Class I indication in both USA and European practice guidelines[9,10]. However, there are subtle differences in the recommended duration of DAPT after elective PCI in both guidelines. Therefore, DAPT non-usage should be even more variable after stent implantation for non-urgent indications or outside the selection process for inclusion in a prospective randomised trial.

We found the relationship between DAPT usage and stent thrombosis to be quite variable over time. Subacute thrombosis has a strong relationship with discontinuation or irregular use of either one or both DAPT components. At the same time, DAPT non-adherence is rather low during the first month post-procedure. The "fresh" not yet endothelialised stent surface and the reported underexpanded struts and local dissections may explain why even not clearly confirmed DAPT non-adherence may be implicated in such events.

Late stent thrombosis appears to have a relationship to DAPT non-adherence during the 1-6 month time frame, and this relation appeared

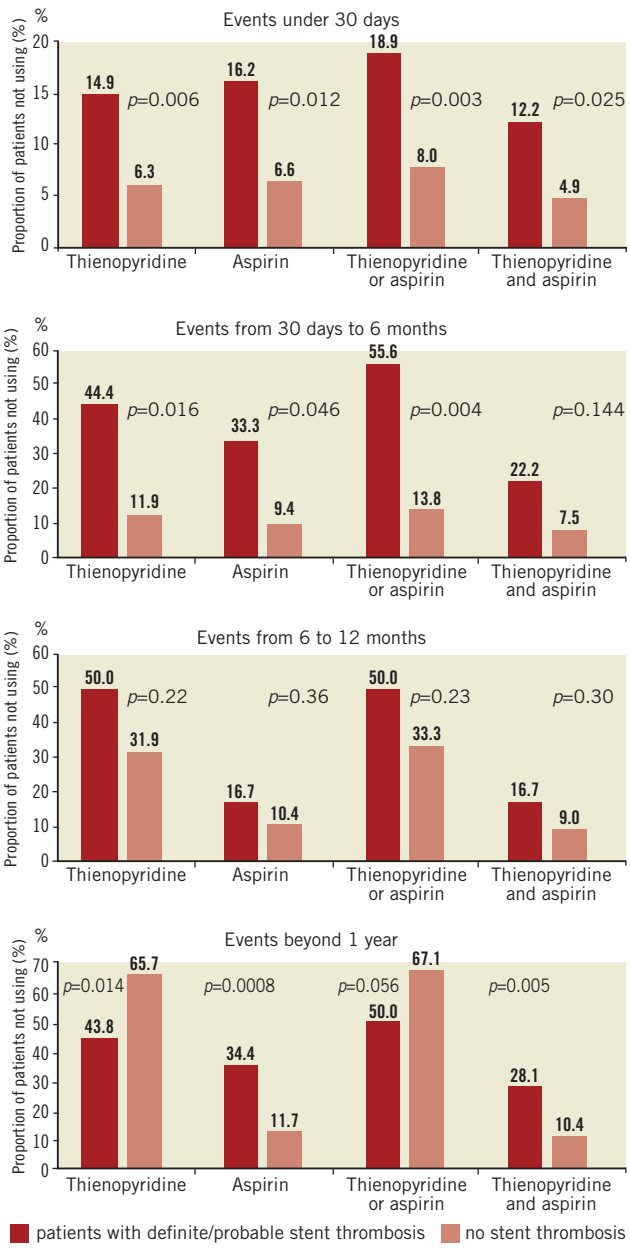

Figure 1. *Rates of discontinuation or irregular use of dual antiplatelet therapy during the 3-year follow-up period in patients suffering a definite/probable stent thrombosis and those without stent thrombosis.*

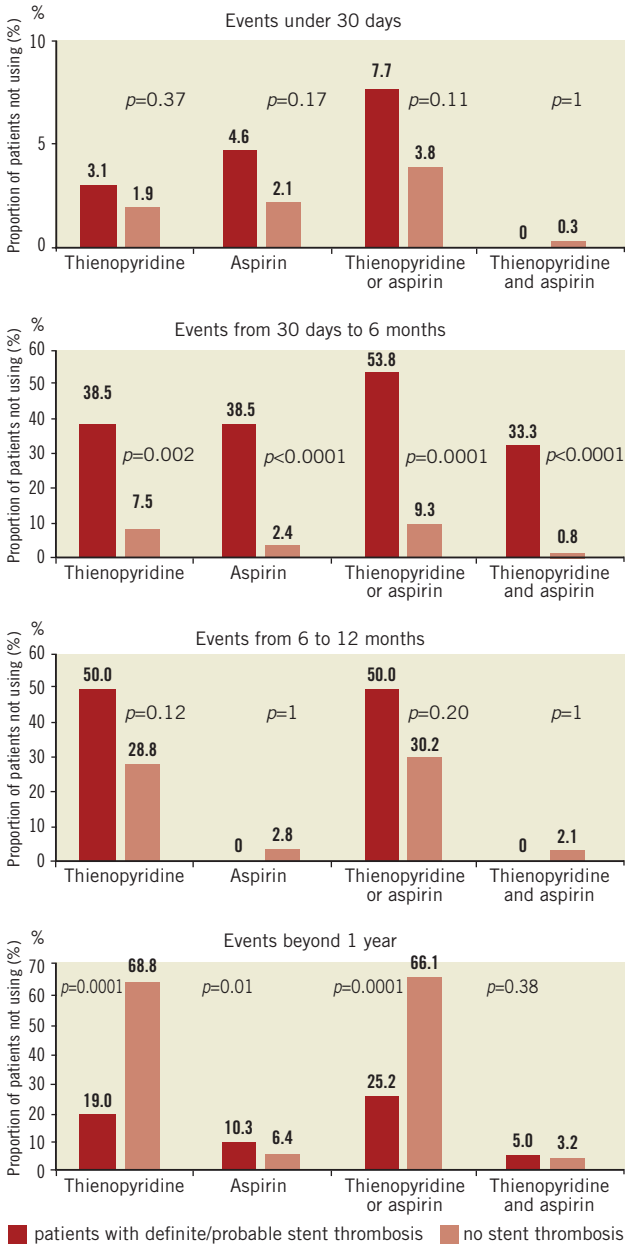

Figure 2. *Rates of confirmed discontinuation of dual antiplatelet therapy during the 3-year follow-up period in patients suffering a definite/probable stent thrombosis and those without stent thrombosis.*

to fade during the 6-12 month time frame. These events remained largely unexplained, as only isolated events were reported preceding these adverse events. These findings support the results of the recently published PRODIGY (Prolonging Dual Antiplatelet Treatment After Grading Stent-Induced Intimal Hyperplasia Study) trial[11]. In PRODIGY 2,013 patients receiving a mixture of bare metal stents (BMS) and DES were randomised to a regimen of six or 24 months of clopidogrel therapy in addition to aspirin and showed that a 24-month regimen was not more effective than a six-month regimen.

Our findings on very late stent thrombosis were intriguing. First, the rate of DAPT non-usage was generally higher beyond one-year follow-up; thienopyridine discontinuation was over 50%. Second, several events were reported in association with stent thrombosis, including surgery, trauma and stent underexpansion. On the one hand, practice guidelines recommend postponing a surgical procedure, whenever possible, beyond one year after STEMI treated with PCI and stent implantation. Therefore, the above findings are understandable. On the other hand, surgery as well as all other

reported events prior to stent thrombosis might indeed have created a prothrombotic milieu in certain cases. Discontinuation of aspirin or both DAPT components appeared to be strongly associated with stent thrombosis, whereas the opposite was evident for non-usage of thienopyridine alone.

Since our study utilised an imbalanced randomisation to drug-eluting versus bare metal stents (3:1), it is not surprising that the drug-eluting stent cohort yielded concordant results with the overall study population.

IMPLICATIONS

Previous studies have shown a considerable increase in the risk of developing ST in patients. Iakovou et al reported that premature antiplatelet therapy discontinuation was associated with an increased rate of ST. However, follow-up in this study was limited to nine months[7]. Airoldi et al also reported that discontinuation of thienopyridine was an important determinant of ST within the first six months of follow-up. With patients followed up to 18 months, the follow-up duration was again significantly shorter than in the current study[12]. The current study, which exclusively enrolled STEMI patients, therefore adds further insight into the relationship between DAPT non-usage and the occurrence of ST within a three-year follow-up period in this subgroup of patients at an increased risk of developing ST.

Based on our findings, DAPT therapy appears to be most important with respect to stent thrombosis avoidance during the first six months after stent implantation. Beyond one year, aspirin usage is very important and discontinuation of both agents should be avoided in relation to surgical procedures whenever feasible. These results may differ with non-paclitaxel-eluting DES, since lower stent thrombosis rates may be achieved with everolimus-eluting DES[13,14]. Randomised trials should further evaluate the utility of DAPT beyond six and 12 months after stenting.

Limitations

In this analysis, we did not have active surveillance for all non-cardiac surgical procedures or trauma that might have occurred in the group of patients who did not sustain a stent thrombosis event. In addition, clinical events that might have preceded a stent thrombosis event were collected by investigator initiative and were not adjudicated. The non-adherence to DAPT was assessed by a set questionnaire and did not include a pill count or other dedicated procedure. Both DAPT agents were not considered "investigational drugs" and were therefore administered through the regular prescription system of the treating cardiologists. However, we believe that the inclusion of STEMI patients who received a stent provided for a very strong clinical initiative to recommend and prescribe prolonged DAPT. Finally there was no periodic assessment of platelet inhibition in any of the study groups.

Funding

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Conflict of interest statement

G.D. Dangas has received speaker honoraria from Astra Zeneca, Bristol-Meiers Squibb, The Medicines Company, Sanofi Aventis, and Abbott Vascular. R. Mehran has received a research grant from Sanofi Aventis, and honoraria from The Medicines Company, Abbott Vascular, Sanofi Aventis, Bristol Meiers Squibb, Cordis, and Astra Zeneca. G.W. Stone is on the scientific advisory boards for and has received honoraria from Abbott Vascular and Boston Scientific, and has served as a consultant to The Medicines Company, Eli Lilly BMS/Sanofi and AstraZeneca. The other authors have no conflicts of interest to declare.

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Online data supplement

Table 1. Patient characteristics for time period 0-30 days after stent implantation

Table 2. Patient characteristics for time period 30 days to six months after stent implantation

Table 3. Patient characteristics for time period six months to one year after stent implantation

Table 4. Patient characteristics for time period 1-3 years after stent implantation

Table 5. Rates of discontinuation of antiplatelet therapy during 3 year follow-up in patients receiving drug-eluting stents

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Online appendix

Online Table 1. Baseline demographic, angiographic, and procedural characteristics of patients with stent thrombosis compared with those without stent thrombosis within the first 30 days after stent implantation.

Patient characteristics	Patients with stent thrombosis (n=74)	Patients without stent thrombosis (n=2,923)	*p*-value
Age	59.3 [50.6, 67.4] (n=74)	59.7 [52.3, 69.5] (n=2,923)	0.19
Male	70.3% (52/74)	77.7% (2,270/2,923)	0.13
Race			
White	94.6% (70/74)	94.0% (2,747/2,923)	1.00
Black	2.7% (2/74)	1.7% (50/2,923)	0.37
Asian	0.0% (0/74)	0.5% (16/2,923)	1.00
Hispanic	2.7% (2/74)	3.5% (101/2,923)	1.00
Other	0.0% (0/74)	0.3% (9/2,923)	1.00
Body mass index	28.4 [25.4, 31.0] (n=73)	27.1 [24.5, 30.2] (n=2,906)	0.13
History of hypertension	55.4% (41/74)	52.9% (1,546/2,923)	0.67
History of hyperlipidaemia	45.9% (34/74)	43.0% (1,257/2,923)	0.61
History of smoking	68.5% (50/73)	64.8% (1,887/2,914)	0.51
Current	52.1% (38/73)	47.7% (1,391/2,914)	0.47
Former	16.4% (12/73)	17.0% (495/2,914)	0.90
History of diabetes mellitus	21.6% (16/74)	16.0% (467/2,923)	0.19
Insulin-dependent	13.5% (10/74)	4.1% (120/2,923)	0.001
History of prior myocardial infarction	10.8% (8/74)	10.3% (300/2,923)	0.88
History of prior PCI	16.2% (12/74)	10.1% (295/2,922)	0.09
History of prior CABG	1.4% (1/74)	2.5% (73/2,923)	1.00
Family history of CAD	27.0% (20/74)	29.8% (870/2,923)	0.61
History of prior angina	21.6% (16/74)	22.2% (649/2,922)	0.90
History of CHF	5.4% (4/74)	2.6% (77/2,923)	0.14
Kilip class >1	16.2% (12/74)	7.8% (227/2,920)	0.008
History of peripheral vascular disease	6.8% (5/74)	4.1% (121/2,922)	0.24
History of renal insufficiency	6.8% (5/74)	2.7% (79/2,922)	0.055
Stent thrombosis risk score	8 [7, 9] (n=67)	7 [6, 8] (n=2,789)	<0.0001
Angiographic and procedural characteristics			
TIMI flow grade 0/1 pre-PCI	74.4% (61/82)	63.9% (2,028/3,172)	0.051
TIMI flow grade 3 post-PCI	85.4% (70/82)	94.0% (2,985/3,174)	0.001
Index PCI vessel = LAD	40.2% (33/82)	40.6% (1,290/3,178)	0.95
Any pre-dilation angioplasty	82.2% (60/73)	78.0% (2,263/2,903)	0.39
Post-stent dilation balloon used	40.3% (29/72)	38.5% (1,044/2,715)	0.75
Multiple vessels treated	6.8% (5/73)	4.3% (124/2,916)	0.24
Multiple lesions treated	16.4% (12/73)	10.9% (317/2,916)	0.13
Number of stents implanted	1.7±1.0	1.5±0.8	0.26
Total fluoroscopy time	11.5 [7.0, 20.0] (n=70)	11.0 [8.0, 17.0] (n=2,828)	0.56
Total amount of contrast	240.0 [180.0, 300.0] (n=72)	225.0 [180.0, 290.0] (n=2,888)	0.48
Left ventricular ejection fraction (%)	45 [40, 57] (n=55)	50 [43, 59] (n=2,528)	0.20
Use of glycoprotein IIb/IIIa inhibitors	68.9% (51/74)	55.5% (1,621/2,919)	0.02
Symptom onset to balloon time (h, median [IQR])	0.3 [0.1, 0.3] (n=73)	0.3 [0.2, 0.4] (n=2,849)	0.03

CABG: coronary artery bypass graft surgery; CAD: coronary artery disease; CHF: congestive heart failure; LAD: left anterior descending coronary artery; IQR: interquartile range; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

Online Table 2. Baseline demographic, angiographic, and procedural characteristics of patients with stent thrombosis compared with those without stent thrombosis between 30 days and six months after stent implantation.

Patient characteristics	Patients with stent thrombosis (n=15)	Patients without stent thrombosis (n=2908)	*p*-value
Age	61.8 [51.4, 66.7] (n=15)	59.7 [52.3, 69.5] (n=2,908)	0.72
Male	100.0% (15/15)	77.5% (2,255/2,908)	0.03
Race			
White	86.7% (13/15)	94.0% (2,734/2,908)	0.23
Black	0.0% (0/15)	1.7% (50/2,908)	1.00
Asian	6.7% (1/15)	0.5% (15/2,908)	0.08
Hispanic	6.7% (1/15)	3.4% (100/2,908)	0.41
Other	0.0% (0/15)	0.3% (9/2,908)	1.00
Body mass index	26.7 [24.2, 29.8] (n=15)	27.1 [24.5, 30.3] (n=2,904)	0.59
History of hypertension	46.7% (7/15)	52.9% (1,539/2,908)	0.63
History of hyperlipidaemia	40.0% (6/15)	43.0% (1,251/2,908)	0.81
History of smoking	86.7% (13/15)	64.6% (1,874/2,899)	0.07
Current	66.7% (10/15)	47.6% (1,381/2,899)	0.14
Former	20.0% (3/15)	17.0% (492/2,899)	0.73
History of diabetes mellitus	20.0% (3/15)	16.0% (464/2,908)	0.72
Insulin-dependent	13.3% (2/15)	10.2% (296/2,908)	0.66
History of prior myocardial infarction	20.0% (3/15)	10.2% (297/2,908)	0.19
History of prior PCI	20.0% (3/15)	10.0% (292/2,907)	0.19
History of prior CABG	6.7% (1/15)	2.5% (72/2,908)	0.32
Family history of CAD	13.3% (2/15)	29.8% (868/2,908)	0.26
History of prior angina	26.7% (4/15)	22.2% (645/2,907)	0.75
History of CHF	0.0% (0/15)	2.6% (77/2,908)	1.00
Kilip class >1	6.7% (1/15)	7.8% (226/2,905)	1.00
History of peripheral vascular disease	13.3% (2/15)	4.1% (119/2,907)	0.13
History of renal insufficiency	0.0% (0/15)	2.7% (79/2,907)	1.00
Stent thrombosis risk score	8 [7, 9] (n=13)	7 [6, 8] (n=2,776)	0.04
Angiographic and procedural characteristics			
TIMI flow grade 0/1 pre-PCI	81.3% (13/16)	63.8% (2,015/3,156)	0.15
TIMI flow grade 3 post-PCI	87.5% (14/16)	94.1% (2,971/3,158)	0.25
Index PCI vessel = LAD	25.0% (4/16)	40.7% (1,286/3,162)	0.20
Any pre-dilation angioplasty	66.7% (10/15)	78.0% (2,253/2,888)	0.34
Post-stent dilation balloon used	64.3% (9/14)	38.3% (1,035/2,701)	0.046
Multiple vessels treated	6.7% (1/15)	4.2% (123/2,901)	0.48
Multiple lesions treated	13.3% (2/15)	10.9% (315/2,901)	0.67
Number of stents implanted	1.6±0.8 (n=14)	1.5±0.8 (n=2,908)	0.85
Total fluoroscopy time	14.0 [6.0, 24.0] (n=14)	11.0 [8.0, 17.0] (n=2,814)	0.31
Total amount of contrast	268.0 [200.0, 350.0] (n=15)	225.0 [180.0, 290.0] (n=2,873)	0.10
Left ventricular ejection fraction (%)	43 [35, 51] (n=12)	50 [43, 59] (n=2,516)	0.052
Use of glycoprotein IIb/IIIa inhibitors	53.3% (8/15)	28.7% (832/2,904)	0.045
Symptom onset to balloon time (h, median [IQR])	4.9 [3.1, 7.1] (n=15)	3.7 [2.7, 5.6] (n=2,818)	0.14

CABG: coronary artery bypass graft surgery; CAD: coronary artery disease; CHF: congestive heart failure; LAD: left anterior descending coronary artery; IQR: interquartile range; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

Online Table 3. Baseline demographic, angiographic, and procedural characteristics of patients with stent thrombosis compared with those without stent thrombosis between six months and one year after stent implantation.

Patient characteristics	Patients with stent thrombosis (n=13)	Patients without stent thrombosis (n=2,895)	*p*-value
Age	59.0 [49.5, 65.0] (n=13)	59.7 [52.3, 69.5] (n=2,895)	0.33
Male	69.2% (9/13)	77.6% (2,246/2,895)	0.50
Race			
White	84.6% (11/13)	94.1% (2,723/2,895)	0.18
Black	15.4% (2/13)	1.7% (48/2,895)	0.02
Asian	0.0% (0/13)	0.5% (15/2,895)	1.00
Hispanic	0.0% (0/13)	3.5% (100/2,895)	1.00
Other	0.0% (0/13)	0.3% (9/2,895)	1.00
Body mass index	24.7 [22.7, 29.1] (n=13)	27.1 [24.5, 30.3] (n=2,878)	0.18
History of hypertension	38.5% (5/13)	53.0% (1,534/2,895)	0.30
History of hyperlipidaemia	61.5% (8/13)	42.9% (1,243/2,895)	0.18
History of smoking	92.3% (12/13)	64.5% (1,862/2,886)	0.04
Current	84.6% (11/13)	47.5% (1,370/2,886)	0.01
Former	7.7% (1/13)	17.0% (491/2,886)	0.71
History of diabetes mellitus	7.7% (1/13)	16.0% (463/2,895)	0.71
Insulin-dependent	0.0% (0/13)	4.0% (117/2,895)	1.00
History of prior myocardial infarction	15.4% (2/13)	10.2% (295/2,895)	0.64
History of prior PCI	15.4% (2/13)	10.0% (290/2,894)	0.38
History of prior CABG	0.0% (0/13)	2.5% (72/2,895)	1.00
Family history of CAD	46.2% (6/13)	29.8% (862/2,895)	0.23
History of prior angina	15.4% (2/13)	22.2% (643/2,894)	0.75
History of CHF	0.0% (0/13)	2.7% (77/2,895)	1.00
Kilip class >1	7.7% (1/13)	7.8% (225/2,892)	1.00
History of peripheral vascular disease	7.7% (1/13)	4.1% (118/2,894)	0.42
History of renal insufficiency	0.0% (0/13)	2.7% (79/2,894)	1.00
Stent thrombosis risk score	7 [6, 8] (n=13)	7 [6, 8] (n=2,763)	0.26
Angiographic and procedural characteristics			
TIMI flow grade 0/1 pre-PCI	76.9% (10/13)	63.8% (2,005/3,143)	0.40
TIMI flow grade 3 post-PCI	92.3% (12/13)	94.1% (2,959/3,145)	0.55
Index PCI vessel = LAD	61.5% (8/13)	40.6% (1,278/3,149)	0.12
Any pre-dilation angioplasty	84.6% (11/13)	78.0% (2,242/2,875)	0.75
Post-stent dilation balloon used	76.9% (10/13)	38.1% (1,025/2,688)	0.007
Multiple vessels treated	0.0% (0/13)	4.3% (123/2,888)	1.00
Multiple lesions treated	23.1% (3/13)	10.8% (312/2,888)	0.16
Number of stents implanted	1.5±1.1 (n=13)	1.5±0.8 (n=2,895)	0.97
Total fluoroscopy time	10.0 [7.0, 16.0] (n=13)	11.0 [8.0, 17.0] (n=2,801)	0.60
Total amount of contrast	250.0 [215.0, 285.0] (n=13)	225.0 [180.0, 290.0] (n=2,860)	0.16
Left ventricular ejection fraction (%)	51 [40, 55] (n=13)	50 [43, 59] (n=2,503)	0.95
Use of glycoprotein IIb/IIIa inhibitors	46.2% (6/13)	55.4% (1,602/2,891)	0.50
Symptom onset to balloon time (h, median [IQR])	2.7 [2.2, 5.8] (n=13)	3.7 [2.7, 5.6] (n=2,805)	0.29

CABG: coronary artery bypass graft surgery; CAD: coronary artery disease; CHF: congestive heart failure; LAD: left anterior descending coronary artery; IQR: interquartile range; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

Online Table 4. Baseline demographic, angiographic, and procedural characteristics of patients with stent thrombosis compared with those without stent thrombosis between one and three years after stent implantation.

Patient characteristics	Patients with stent thrombosis (n=41)	Patients without stent thrombosis (n=2,722)	*p*-value
Age			
Male	77.8% (35/45)	77.6% (2,211/2,850)	0.97
Race			
White	95.6% (43/45)	94.0% (2,680/2,850)	1.00
Black	2.2% (1/45)	1.6% (47/2,850)	0.53
Asian	0.0% (0/45)	0.5% (15/2,850)	1.00
Hispanic	2.2% (1/45)	3.5% (99/2,850)	1.00
Other	0.0% (0/45)	0.3% (9/2,850)	1.00
Body mass index	27.3 [25.3, 29.7] (n=45)	27.1 [24.5, 30.3] (n=2,833)	0.79
History of hypertension	62.2% (28/45)	52.8% (1,506/2,850)	0.21
History of hyperlipidaemia	51.1% (23/45)	42.8% (1,220/2,850)	0.26
History of smoking	82.2% (37/45)	64.2% (1,825/2,841)	0.01
Current	64.4% (29/45)	47.2% (1,341/2,841)	0.02
Former	17.8% (8/45)	17.0% (483/2,841)	0.89
History of diabetes mellitus	22.2% (10/45)	15.9% (453/2,850)	0.25
Insulin-dependent	8.9% (4/45)	4.0% (113/2,850)	0.11
History of prior myocardial infarction	22.2% (10/45)	10.0% (285/2,850)	0.02
History of prior PCI	24.4% (11/45)	9.8% (279/2,849)	0.004
History of prior CABG	0.0% (0/45)	2.5% (72/2,850)	0.63
Family history of CAD	37.8% (17/45)	29.6% (845/2,850)	0.24
History of prior angina	24.4% (11/45)	22.2% (632/2,849)	0.72
History of CHF	8.9% (4/45)	2.6% (73/2,850)	0.03
Kilip class >1	13.3% (6/45)	7.7% (219/2,847)	0.16
History of peripheral vascular disease	2.2% (1/45)	4.1% (117/2,849)	1.00
History of renal insufficiency	6.7% (3/45)	2.7% (76/2,849)	0.12
Stent thrombosis risk score	8 [7, 8] (n=41)	7 [6, 8] (n=2,722)	0.001
Angiographic and procedural characteristics			
TIMI flow grade 0/1 pre-PCI	60.9% (28/46)	63.8% (1,977/3,097)	0.68
TIMI flow grade 3 post-PCI	95.7% (44/46)	94.1% (2,915/3,099)	1.00
Index PCI vessel = LAD	37.0% (17/46)	40.6% (1,261/3,103)	0.61
Any pre-dilation angioplasty	75.6% (34/45)	78.0% (2,208/2,830)	0.69
Post-stent dilation balloon used	44.4% (20/45)	38.0% (1,005/2,643)	0.38
Multiple vessels treated	0.0% (0/44)	4.3% (123/2,844)	0.26
Multiple lesions treated	13.6% (6/44)	10.8% (306/2,844)	0.47
Number of stents implanted	1.8±1.2 (n=45)	1.5±0.8 (n=2,850)	0.22
Total fluoroscopy time	11.0 [7.0, 17.0] (n=43)	11.0 [8.0, 17.0] (n=2,758)	0.91
Total amount of contrast	220.0 [180.0, 250.0] (n=43)	225.0 [180.0, 290.0] (n=2,817)	0.72
Left ventricular ejection fraction (%)	50 [42, 60] (n=37)	50 [43, 59] (n=2,466)	0.75
Use of glycoprotein IIb/IIIa inhibitors	70.5% (31/44)	55.2% (1,571/2,847)	0.04
Symptom onset to balloon time (h, median [IQR])	3.6 [2.5, 5.3] (n=43)	3.7 [2.7, 5.6] (n=2,762)	0.75

CABG: coronary artery bypass graft surgery; CAD: coronary artery disease; CHF: congestive heart failure; LAD: left anterior descending coronary artery; IQR: interquartile range; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

Online Table 5. Rates of discontinuation or irregular use of dual antiplatelet therapy during the 3-year follow-up period after primary angioplasty with stent implantation during an ST-elevation myocardial infarction in the HORIZONS-AMI trial; results of the patients initially treated with a drug-eluting stent. All "confirmed" categories exclude the patients with "irregular use" of antiplatelets.

	Patients with definite or probable stent thrombosis	No stent thrombosis	*p*-value*
Events under 30 days:	**n=48**	**n=2,117**	
Discontinuation/irregular use of thienopyridine	8/48 (16.7%)	121/2,117 (5.72%)	0.0064
Discontinuation/irregular use of aspirin	8/48 (16.7%)	136/2,117 (6.42%)	0.0122
Discontinuation/irregular use of thienopyridine or aspirin	10/48 (20.8%)	159/2,117 (7.51%)	0.0031
Discontinuation/irregular on both aspirin and thienopyridine	6/48 (12.5%)	98/2,117 (4.63%)	0.0252
Confirmed discontinuation of thienopyridine	2/42 (4.76%)	31/2,027 (1.53%)	0.1432
Confirmed discontinuation of aspirin	2/42 (4.76%)	43/2,024 (2.12%)	0.2322
Confirmed discontinuation of thienopyridine or aspirin	4/42 (9.52%)	70/2,028 (3.45%)	0.0604
Confirmed discontinuation of both aspirin and thienopyridine	0/38 (0%)	4/1,962 (0.20%)	1
Factors associated with stent thrombosis events			
Surgical procedure	0 (0%)		
Trauma	1/48 (2.08%)		
Stent under-expansion	4/48 (8.33%)		
Residual dissection adjacent to stent	2/48 (4.17%)		
Residual thrombus adjacent to stent	4/48 (8.33%)		
Stent malapposition	0 (0%)		
Events from 30 days to 6 months:	**n=9**	**n=2,108**	
Discontinuation/irregular use of thienopyridine	4/9 (44.4%)	251/2,108 (11.9%)	0.0158
Discontinuation/irregular use of aspirin	3/9 (33.3%)	198/2,108 (9.39%)	0.046
Discontinuation/irregular use of thienopyridine or aspirin	5/9 (55.6%)	291/2,108 (13.8%)	0.004
Discontinuation/irregular on both aspirin and thienopyridine	2/9 (22.2%)	158/2,108 (7.50%)	0.144
Confirmed discontinuation of thienopyridine	3/8 (37.5%)	108/1,965 (5.50%)	0.0079
Confirmed discontinuation of aspirin	2/8 (25.0%)	54/1,964 (2.75%)	0.0002
Confirmed discontinuation of thienopyridine or aspirin	4/8 (50.0%)	149/1,966 (7.58%)	0.0019
Confirmed discontinuation of both aspirin and thienopyridine	1/5 (20.0%)	13/1,830 (0.71%)	0.0376
Factors associated with stent thrombosis events			
Surgical procedure	0 (0%)		
Trauma	0 (0%)		
Stent under-expansion	0 (0%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		
Events from 6 to 12 months:	**n=12**	**n=2,096**	
Discontinuation/irregular use of thienopyridine	6/12 (50.0%)	668/2,096 (31.9%)	0.2156
Discontinuation/irregular use of aspirin	2/12 (16.7%)	218/2,096 (10.4%)	0.3612
Discontinuation/irregular use of thienopyridine or aspirin	6/12 (50.0%)	698/2,096 (33.3%)	0.2313
Discontinuation/irregular on both aspirin and thienopyridine	2/12 (16.7%)	188/2,096 (8.97%)	0.2954
Confirmed discontinuation of thienopyridine	5/11 (45.5%)	510/1,938 (26.3%)	0.172
Confirmed discontinuation of aspirin	0/10 (0%)	59/1,937 (3.05%)	1
Confirmed discontinuation of thienopyridine or aspirin	5/11 (45.5%)	541/1,939 (27.9%)	0.1945
Confirmed discontinuation of both aspirin and thienopyridine	0/6 (0%)	28/1,426 (1.96%)	1
Factors associated with stent thrombosis events			
Surgical procedure	0 (0%)		
Trauma	0 (0%)		
Stent under-expansion	1/12 (8.33%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		

	Patients with definite or probable stent thrombosis	No stent thrombosis	*p*-value*
Events beyond 1 year:	**n=32**	**n=2,064**	
Discontinuation/irregular use of thienopyridine	14/32 (43.8%)	1,357/2,064 (65.7%)	0.0138
Discontinuation/irregular use of aspirin	11/32 (34.4%)	242/2,064 (11.7%)	0.0008
Discontinuation/irregular use of thienopyridine or aspirin	16/32 (50.0%)	1,385/2,064 (67.1%)	0.0566
Discontinuation/irregular on both aspirin and thienopyridine	9/32 (28.1%)	214/2,064 (10.4%)	0.0047
Confirmed discontinuation of thienopyridine	7/25 (28.0%)	1,183/1,890 (62.6%)	0.0006
Confirmed discontinuation of aspirin	5/26 (19.2%)	66/1,888 (3.50%)	0.0022
Confirmed discontinuation of thienopyridine or aspirin	10/26 (38.5%)	1,211/1,890 (64.1%)	0.012
Confirmed discontinuation of both aspirin and thienopyridine	2/18 (11.1%)	38/717 (5.30%)	0.6089
Factors associated with stent thrombosis events			
Surgical procedure	3/32 (9.38%)		
Trauma	1/32 (3.13%)		
Stent under-expansion	2/32 (6.25%)		
Residual dissection adjacent to stent	0 (0%)		
Residual thrombus adjacent to stent	0 (0%)		
Stent malapposition	0 (0%)		
Events at any point during 3-year follow-up:	**n=101**	**n=2,064**	
Discontinuation/irregular use of thienopyridine	32/101 (31.7%)	1,441/2,064 (69.8%)	<0.0001
Discontinuation/irregular use of aspirin	24/101 (23.8%)	388/2,064 (18.8%)	0.2416
Discontinuation/irregular use of thienopyridine or aspirin	37/101 (36.6%)	1,477/2,064 (71.6%)	<0.0001
Discontinuation/irregular use of both aspirin and thienopyridine	19/101 (18.8%)	328/2,064 (15.9%)	0.4071
Confirmed discontinuation of thienopyridine	17/86 (19.8%)	1,267/2,021 (62.7%)	<0.0001
Confirmed discontinuation of aspirin	9/86 (10.5%)	135/2,019 (6.69%)	0.1862
Confirmed discontinuation of thienopyridine or aspirin	23/87 (26.4%)	1,313/2,021 (65.0%)	<0.0001
Confirmed discontinuation on both aspirin and thienopyridine	3/67 (4.48%)	63/2,004 (3.14%)	0.278
Factors associated with stent thrombosis events			
Surgical procedure	3/101 (2.97%)		
Trauma	2/101 (1.98%)		
Stent under-expansion	7/101 (6.93%)		
Residual dissection adjacent to stent	2/101 (1.98%)		
Residual thrombus adjacent to stent	4/101 (3.96%)		
Stent malapposition	0 (0%)		