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Influence of Final Kissing Balloon Inflation on Long-term Outcomes After PCI of Distal Left Main Bifurcation Lesions: Analysis From the EXCEL Trial

Short title: FKBI and long-term outcomes after left main PCI

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ABSTRACT

AIMS: The impact of final kissing balloon inflation FKBI after percutaneous coronary intervention (PCI) of bifurcation lesions on long-term clinical outcomes remains controversial. We sought to determine the impact of FKBI on 4-year outcomes after PCI of distal left main (LM) bifurcation lesions.

METHODS AND RESULTS: The EXCEL trial compared PCI with everolimus-eluting stents and coronary artery bypass graft surgery in patients with LM disease. We examined 4-year clinical outcomes after PCI of distal LM bifurcation lesions according to use of FKBI. The primary endpoint was the composite rate of death, myocardial infarction (MI), or stroke. The major secondary endpoint was the composite rate of death, MI, stroke, or ischemia-driven revascularization (IDR). Among 948 patients randomized to PCI, 759 had distal LM lesions treated, 430 of which were treated with 1 stent and 329 of which were treated with 2 or more stents. The 4-year rates of the primary and major secondary endpoints were similar with versus without FKBI in both the 1-stent and ≥2-stent groups in both unadjusted and adjusted analyses.

CONCLUSIONS. In the EXCEL trial, the performance of FKBI after PCI of distal LM bifurcation lesions was not associated with improved 4-year clinical outcomes regardless of whether 1 stent or ≥2 stents were implanted.

Classifications: bifurcation, left main, drug-eluting stent

CONDENSED ABSTRACT

We investigated whether performance of FKBI influenced long-term clinical outcomes after PCI of a distal LM bifurcation in the EXCEL trial with implantation of either 1 stent or ≥2 stents. At 4 years, the rate of the composite primary endpoint of death, MI, or stroke and the composite major secondary endpoint of death, MI, stroke, or IDR were similar with or without FKBI suggesting that a routine strategy of FKBI after distal LM bifurcation treatment may not be necessary regardless of whether 1 or more stents were required for treatment.

ABBREVIATIONS

DS = diameter stenosis

FKBI = final kissing balloon inflation

IDR = ischemia-driven revascularization

IVUS = intravascular ultrasound

LM = left main coronary artery

MLD = minimum lumen diameter

MV = main vessel

POT = proximal optimization technique

SB = side branch

TLR = target lesion revascularization

INTRODUCTION

Coronary bifurcations remain one of the most challenging lesion subsets for percutaneous coronary intervention (PCI), with increased rates of acute complications and long-term adverse events compared with non-bifurcation lesions[1]. Optimal treatment of the distal left main (LM) bifurcation is particularly important given the large amount of myocardium subtended. Whether a provisional 1-stent or planned 2-stent strategy is preferred for bifurcation lesions continues to be debated. Several randomized trials demonstrated that a provisional side branch (SB) stenting approach is preferred to routine 2-stent implantation for many non-LM bifurcation lesions[1-4], although one study reported that the double kissing (DK)-crush 2-stent technique may be superior to the provisional approach in true bifurcation lesions[5]. The DK-crush 2-stent technique has also been reported to afford better 1-year outcomes than provisional stenting in true distal LM bifurcation lesions[6]. Regardless of whether 1 versus 2 or more stents are implanted in a coronary bifurcation, optimizing the post-treatment geometry is believed to be essential to prevent stent thrombosis and restenosis[1]. A final kissing balloon inflation (FKBI) was one of the first specific techniques developed for bifurcation PCI, and based on bench tests, computer simulation, and intravascular imaging studies, FKBI may optimize stent apposition, correct stent deformation, improve SB access, and mitigate flow disturbances[7-10]. Nonetheless, the impact of FKBI on long-term clinical outcomes remains uncertain. Some non-randomized studies[11,12] have suggested its utility in patients undergoing bifurcation PCI with a complex 2-stent strategy. The benefits of routine FKBI after provisional bifurcation stenting are even more controversial[13-15]. Moreover, to our knowledge, the impact of FKBI on clinical outcomes after PCI of distal LM bifurcation lesions has not been examined.

The EXCEL (Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial demonstrated that PCI with second-generation everolimus-eluting stents (EES) is an acceptable or preferred alternative to coronary artery bypass graft surgery in selected patients with LM coronary artery disease and low or intermediate SYNTAX scores[16]. More than 80% of patients enrolled in EXCEL had distal LM bifurcation or trifurcation lesions. The outcomes of distal LM bifurcation treatment with 1 versus 2 stents from the EXCEL trial have previously been reported[17]. In the present analysis we examined whether performance of FKBI influenced long-term outcomes after distal LM bifurcation PCI according to the number of stents implanted.

METHODS

Study population. The design, enrollment criteria, and principal findings from the EXCEL trial have been previously described[16,18]. Briefly, 1905 patients with LM disease and operator-assessed low or intermediate (≤32) SYNTAX scores were enrolled at 126 sites in 17 countries between September 2010 and March 2014 and randomly assigned to undergo either PCI with EES (948 patients) or coronary artery bypass graft surgery (957 patients). For distal LM bifurcation lesions, a 1-stent provisional technique was preferred unless a large side branch (usually the left circumflex) was present with a lesion length >5 mm or in the presence of specific anatomic considerations such as heavy calcification or marked LM bifurcation angulation. The decision to perform an FKBI was also left to the discretion of the operator, but in general was recommended after implantation of 1 stent if a >50% stenosis or other evidence of a sub-optimal side branch result was present and in most cases after 2-stent implantation.

Endpoints. Follow-up is currently complete through 4 years. The primary endpoint was the composite rate of death from any cause, myocardial infarction (MI), or stroke. The major secondary endpoint was the rate of death, MI, stroke, or ischemia-driven revascularization (IDR). Additional secondary endpoints included the components of the primary and secondary endpoints as well as stent thrombosis at 30 days and 4 years. Detailed definitions of the endpoints have been provided elsewhere[18]. All endpoints were adjudicated by an independent committee. An independent angiographic core laboratory assessed the baseline SYNTAX score, the severity of LM disease, and Medina classification as well as post-procedural outcomes.

Statistical analysis. The study patients were grouped according to whether they were treated with 1 stent or 2 (or more) stents and according to the use of FKBI (as treated analysis). Continuous data were compared with *t* tests unless the normality assumption failed per the Shapiro-Wilk test, in which case a Wilcoxon rank-sum test for the difference in median outcomes was used. Categorical data are presented as percent (count) and were compared using the χ^2 test unless >20% of the expected cell frequencies were <5, in which case the Fisher exact test was used. Hazard ratios (HR) and 95% confidence intervals (CI) were generated using Cox regression. Multivariable analysis was performed using Cox proportional hazards regression to adjust for the effect of potential cofounders (selected for their historical relationship to the major clinical outcomes from prior studies) on the relationship between FKBI use and major composite adverse events at 4 years. The variables entered into these models included age, sex, diabetes, prior MI, and core laboratory-assessed SYNTAX score and Medina classification (1,1,1 versus other).

RESULTS

Baseline clinical and angiographic characteristics. PCI was the first procedure performed in 935 of the 948 patients randomized to PCI in the EXCEL trial, among whom 759 patients (81.1%) had distal LM bifurcation involvement. One stent was implanted in these lesions in 430 patients (56.7%), and ≥2 stents were implanted in 329 patients (43.3%). FKBI was performed in 175 (40.7%) of the 1-stent cases and in 235 (71.4%) of the ≥2 stent cases. There were no significant differences in the baseline clinical or demographic characteristics between the FKBI and no FKBI groups in either the 1-stent or ≥2-stent group (Supplemental Table 1). The SYNTAX score was higher in the FKBI group of patients treated with 1 stent and similar between the FKBI and no FKBI groups with ≥2 stents implanted. Patients in whom FKBI was performed had a higher prevalence of Medina classification 1,1,1 (involvement of the distal left main as well as both the ostial left anterior descending coronary artery and the left circumflex) in both the 1- and ≥2-stent groups. Patients treated with 1 stent followed by FKBI had longer lesions, smaller minimal lumen diameters (MLD), and higher percent diameter stenosis (%DS) in both the main vessel (MV) and SB compared with 1-stent cases in which FKBI was not performed (Supplemental Table 2). There were no significant differences in angiographic lesion characteristics between the FKBI and no FKBI groups in patients treated with ≥2 stents except that that SB lesion length was longer in FKBI cases. After 1-stent PCI, the in-stent MLD was comparable in the FKBI and no FKBI groups, but the MV %DS was higher in the FKBI group. Performance of FKBI resulted in greater acute gain and SB MLD compared to no FKBI. Patients treated with ≥2 stents followed by FKBI had a greater post-procedural MLD compared to those treated with ≥2 stents without FKBI.

Procedural outcomes. Performance of FKBI was associated with greater fluoroscopy time in both 1-stent and ≥2-stent groups, while the procedure duration was longer only in patients treated with 1 stent (Supplemental Table 3). In patients treated with 1 stent and FKBI, the implanted stents had smaller diameters and greater length compared with no FKBI. Longer stents were also implanted in patients treated with ≥2 stents and FKBI. LM post-stent dilatation was performed more frequently in the 1-stent FKBI group compared with no FKBI, although smaller balloons were inflated with lower pressure. Post-stent dilatation use was similar in FKBI and no FKBI patients treated with ≥2 stents. Site-reported procedural complications did not differ between the groups.

Clinical outcomes. The 4-year rate of the composite primary endpoint of death, MI, or stroke in patients with distal LM bifurcations treated with 1 stent was 17.5% after FKBI and 15.9% after no FKBI (adjusted HR 1.12, 95% CI 0.68-1.84, p=0.65) (Table 1, Figure 1 and Central Illustration). In distal LM bifurcations treated with ≥2 stents, the 4-year composite primary endpoint was 19.8% after FKBI and 25.8% after no FKBI (adjusted HR 0.65, 95% CI 0.38-1.10, p=0.11). Similarly, there were no significant differences in the composite major secondary endpoint of death, stroke, MI, or IDR at 4 years after FKBI versus no FKBI, whether treated with 1 stent (25.0% versus 25.9%, adjusted HR 1.02, 95% CI 0.68-1.53, p=0.92) or ≥2 stents (32.3% versus 33.2%, adjusted HR 0.77, 95% CI 0.49-1.22, p=0.27) (Table 1 and Figure 1). Additional 30-day and 4-year outcomes are shown in Supplemental Table 4. There were no significant outcome differences between the FKBI and no FKBI groups. A trend toward a higher 4-year rate of definite stent thrombosis was observed in the 1-stent FKBI group. A summary of each stent thrombosis case is provided in Supplemental Table 5 and Supplemental Table 6.

DISCUSSION

In the present study, we investigated the association between the performance of FKBI and long-term outcomes among patients undergoing distal LM bifurcation PCI in the EXCEL trial with implantation of either 1 stent or ≥2 stents. At 4 years, the rate of the composite primary endpoint of death, MI, or stroke and the composite major secondary endpoint of death, MI, stroke, or IDR were similar with or without FKBI regardless of the number of distal LM bifurcation stents implanted. No significant differences were noted with FKBI for other secondary endpoints at 30 days or 4 years. These findings suggest that a routine strategy of FKBI after distal LM bifurcation treatment may not be necessary regardless of whether 1 or more stents were required for treatment. Randomized trials are warranted to evaluate the utility of FKBI.

Notwithstanding the results of randomized trials with the DK-crush technique[5,6], a provisional 1-stent approach is considered the preferred strategy for the majority of LM[19-21] and non-LM coronary bifurcation lesions[1-4]; however, a second stent is required in ~10-25% of provisional attempts[1,2], and a planned routine 2-stent technique is recommended for complex or severely angulated bifurcations. Regardless of whether 1 stent or 2 stents are ultimately implanted in bifurcation lesions, the benefits of FKBI remain uncertain from both experimental and clinical studies.

In an *in vitro* model FKBI was demonstrated to restore distorted stent symmetry caused by SB balloon dilation through the MV struts and increased stent area[8] *in vivo* as assessed by intravascular ultrasound (IVUS)[22], which might translate into reduced restenosis and target lesion revascularization (TLR). Conversely, other bench tests with first-generation DES demonstrated that FKBI may damage the polymer coating leading to reduced drug delivery, proximal segment

elliptical deformation[23], residual stent deformation, and gap formation after stenting of LM bifurcation lesions[24]. Intravascular imaging studies have suggested that stent area and symmetry index might not be normalized in all cases after FKBI[25].

Non-randomized clinical studies have suggested that FKBI may be beneficial in bifurcation lesions treated with a 2-stent approach[11,12]. Conversely, previous studies have reported conflicting findings for the impact of FKBI after the 1-stent technique, either harmful (increased TLR), neutral, or favorable (reduced TLR)[13-15]. These discordant results may be explained by differences in study design, vessel size, lesion type and location, stenting approach, and immediate post-procedural outcomes. The only randomized trial performed to date (the Nordic-Baltic Bifurcation Study III) demonstrated reduced 8-month rates of SB angiographic restenosis with routine FKBI in 1-stent treated bifurcation lesions, but no significant differences in 6-month clinical outcomes, and contrast use and procedural and fluoroscopy times were greater with routine FKBI compared with no FKBI[14].

To our knowledge, no prior study has examined outcomes after LM distal bifurcation PCI according to the use of FKBI. The present report from EXCEL, the largest trial to date of LM PCI in which contemporary EES were used, are therefore novel and informative. Although drawn from non-randomized data, all events were monitored and adjudicated, an independent angiographic core laboratory evaluated all films, and multivariable analysis was used to adjust for clinical, angiographic, and procedural differences between groups stratified by performance of FKBI. The as-treated analysis of distal LM bifurcation lesions with 1 versus 2 or more stents implanted also provides insight to FKBI utility regardless whether a provisional 1-stent of planned 2-stent technique was initially adopted. The results of the present analysis did not demonstrate clinical benefits of FKBI in distal LM bifurcation lesions treated with either 1 stent

or ≥2 stents, and procedure duration and fluoroscopy times were greater with FKBI (although radiation dosage and contrast volume were not significantly increased). These data suggest that routine FKBI may not be necessary after distal LM bifurcation PCI if an acceptable procedural result is achieved. In this regard it should be noted that IVUS was used to guide LM-treatment in nearly 80% of patients in EXCEL, and it was used more in patients treated with 1-stent PCI without versus with FKBI. Whether the present results would be similar after treatment of distal LM bifurcation lesions without IVUS guidance is unknown. Finally, regardless of the technique utilized, the use of intravascular imaging guidance for stent optimization in all cases of distal LM bifurcation PCI is recommended to improve early and late outcomes.

Although the present study suggests that routine FKBI may not be necessary after distal LM bifurcation PCI, by 4 years death, MI, stroke, or IDR had occurred in >25% of 1-stent treated patients and in >32% of ≥2-stent treated patients (regardless of FKBI use), warranting further efforts to optimize bifurcation technique in these high-risk patients. The DK-crush technique may improve outcomes compared to a standard crush technique; alternatively, a sequential 2-step post-dilatation of the SB and MV without kissing has been proposed for provisional stenting of bifurcation lesions. This approach includes an initial proximal optimization technique (POT), SB dilation, and final POT sequence (re-POT); in bench models this resulted in greater stent circularity and better stent apposition at the proximal stent edge.

Limitations. The decision to use FKBI in the EXCEL trial was not randomized and the detailed reasons to perform or not perform a final kiss was not collected. Therefore, although multivariable analysis was used to adjust for measured differences, whether unmeasured confounders contributed to the lack of differences between the groups cannot be excluded. The results of the present study should this be considered hypothesis generating. Finally, although the

largest trial of its kind to date, EXCEL may still have been under-powered to detect modest differences between the groups in low frequency endpoints such as stent thrombosis. Adequately powered randomized trials are thus warranted to study the outcomes of FKBI, especially in 2-stent use applications.

Conclusion. In the EXCEL trial, the performance of FKBI after PCI of distal LM bifurcation lesions was not associated with improved rates of the composite primary endpoint of death, MI, or stroke or the composite major secondary endpoint of death, MI, stroke, or IDR regardless of the number of distal LM bifurcation stents implanted. No clinical benefits of FKBI were present in distal LM bifurcation lesions treated with either 1 stent or ≥2 stents, and procedure duration and fluoroscopy times were greater with FKBI, although radiation dosage and contrast volume were not significantly increased. These data suggest that routine FKBI may not be necessary after distal LM bifurcation PCI if an acceptable procedural result is achieved.

IMPACT ON DAILY PRACTICE

The performance of FKBI after PCI of distal LM bifurcation lesions was not associated with improved 4-year clinical outcomes in the EXCEL trial, regardless of whether 1 stent or ≥2 stents were implanted. No significant differences were observed with FKBI for other secondary endpoints at 30 days or 4 years. These findings suggest that a routine strategy of FKBI after distal LM bifurcation treatment may not be necessary regardless of whether 1 or more stents were required for treatment.

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CONFLICT OF INTERST STATEMENT

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FIGURE LEGENDS

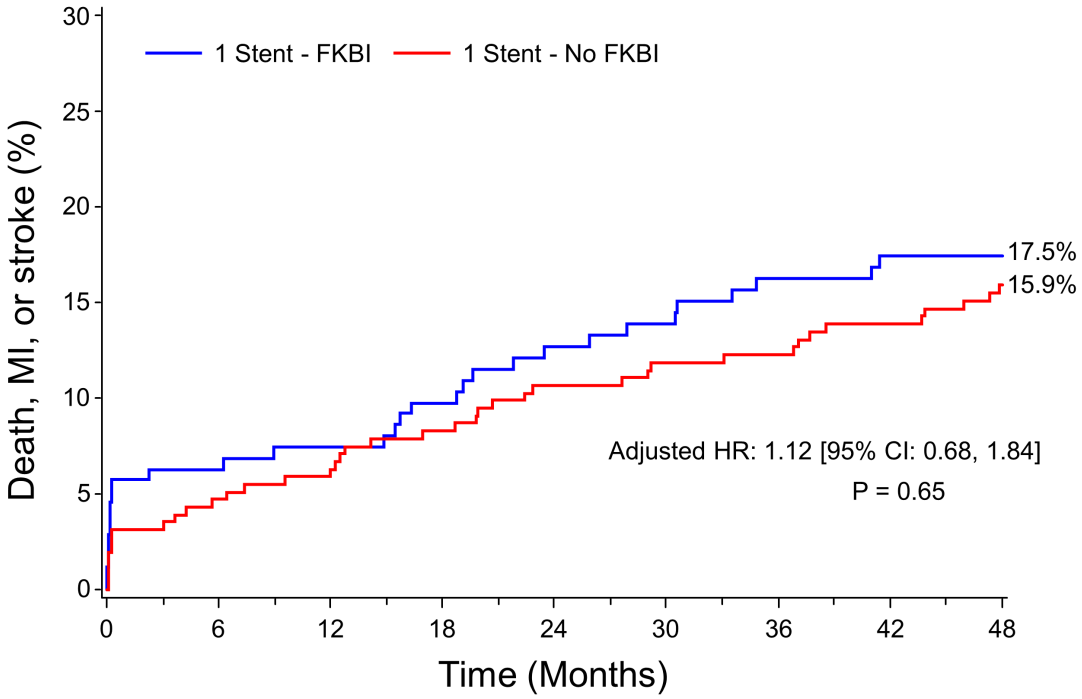
Figure 1. Time-to-Event Curves After Distal Left Main Treatment According to Final Kissing Balloon Inflation

The primary composite endpoint (death, myocardial infarction [MI], or stroke) with implantation of (A) 1 stent and (B) ≥2 stents, and for the major secondary composite endpoint (death, MI, stroke, or ischemia-driven revascularization [IDR]) with (C) 1 stent and (D) ≥2 stents. CI=confidence interval; FKBI=final kissing balloon inflation; HR=hazard ratio.

Table 1. Primary and Secondary Endpoints According to Performance of Final Kissing Balloon Inflation

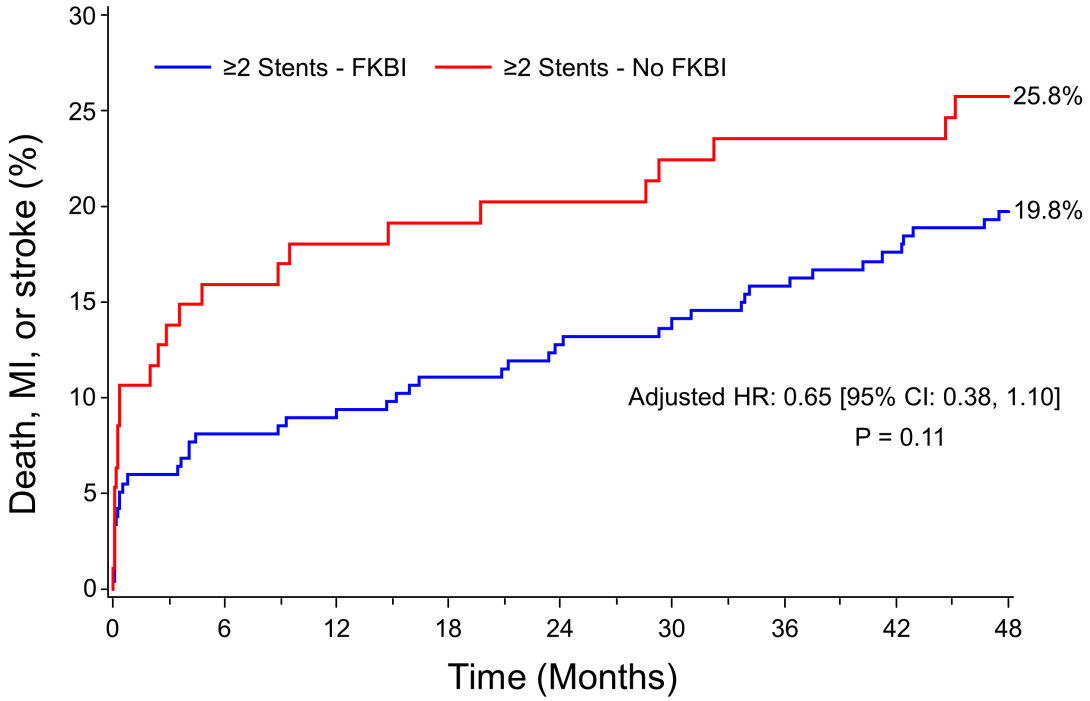
	FKBI	No FKBI	Unadjusted		Adjusted*	
			HR (95% CI)	p Value	HR (95% CI)	p Value
1 stent implanted	n = 175	n = 255				
Death, MI, or stroke	17.5% (30)	15.9% (40)	1.13 (0.70, 1.81)	0.62	1.12 (0.68, 1.84)	0.65
Death, MI, stroke, or IDR	25.0% (43)	25.9% (65)	1.00 (0.68, 1.47)	0.99	1.02 (0.68, 1.53)	0.92
≥2 stents implanted	n = 235	n = 94				
Death, MI, or stroke	19.8% (46)	25.8% (24)	0.71 (0.43, 1.17)	0.18	0.65 (0.38, 1.10)	0.11
Death, MI, stroke, or IDR	32.3% (75)	33.2% (31)	0.91 (0.60, 1.38)	0.66	0.77 (0.49, 1.22)	0.27

Event rates are Kaplan-Meier estimates, % (n). Cox proportional hazards regression model were used to estimate and compare hazard ratios. *Multivariable adjustments made for the following variables: Age, sex, diabetes, prior MI, core lab SYNTAX score, and core lab Medina class 1,1,1 (versus others). CI = confidence interval; FKBI =final kissing balloon inflation; HR=hazard ratio; IDR= ischemia-driven revascularization; MI = myocardial infarction.



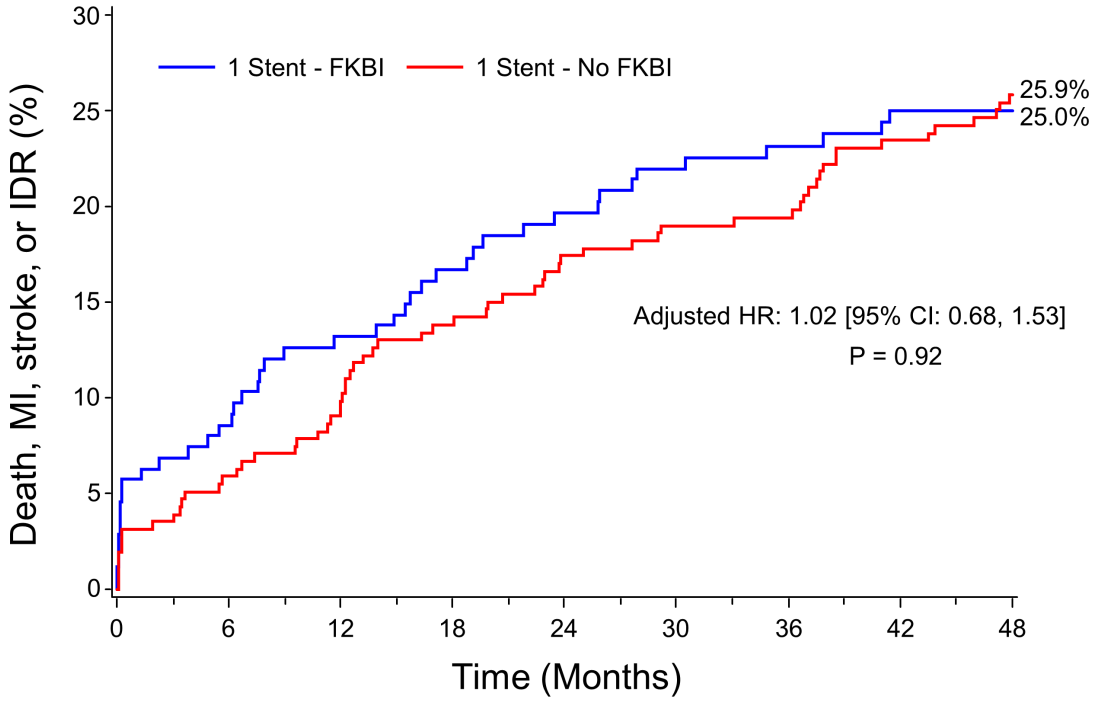
Number at risk:

FKBI	175	164	160	154	148	146	139	135	128
No FKBI	255	243	236	230	224	220	219	213	194



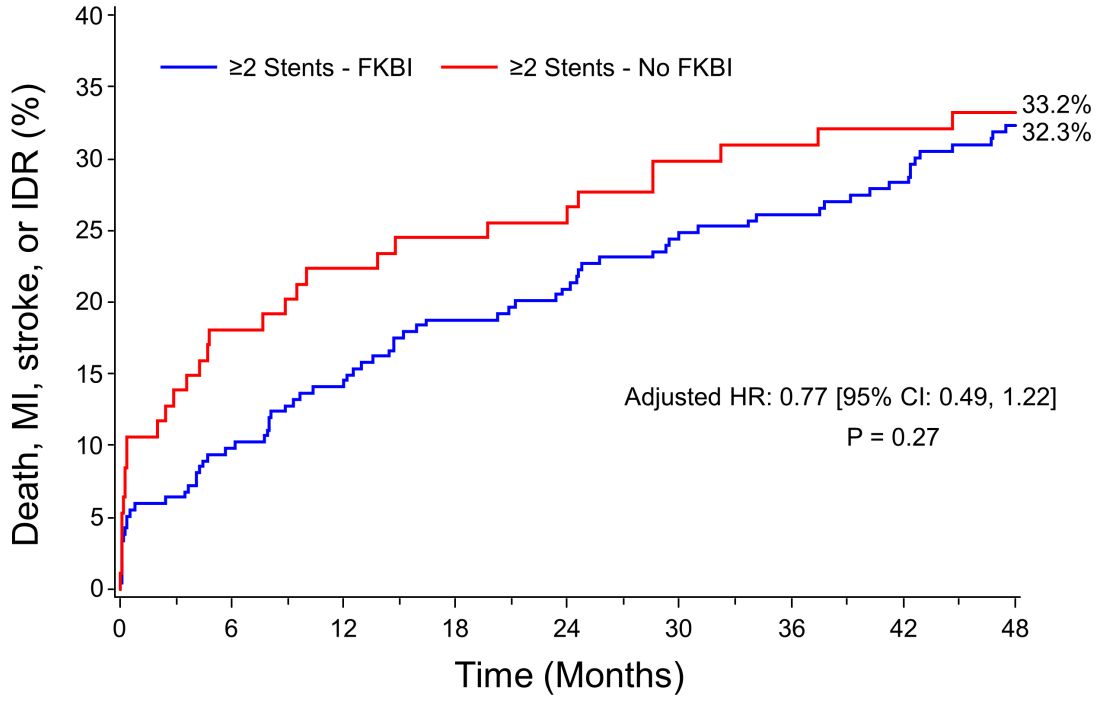
Number at risk:

FKBI	235	215	212	207	203	199	194	189	165
No FKBI	94	79	77	76	73	70	69	68	64



Number at risk:

FKBI	175	160	150	142	136	132	127	122	115
No FKBI	255	240	228	216	207	202	201	190	173



Number at risk:

FKBI	235	211	200	189	184	174	170	164	138
No FKBI	94	77	73	71	68	64	63	62	60

Supplemental Table 1. Baseline Clinical and Angiographic Characteristics According to Performance of Final Kissing Balloon Inflation

	1 Stent Implanted			≥2 Stents Implanted		
	FKBI (n=175)	**No FKBI (n=255)**	**p Value**	**FKBI (n=235)**	**No FKBI (n=94)**	**p Value**
Baseline characteristics						
Age, years	65.5 ± 10.0	65.8 ± 9.3	0.97	66.8 ± 8.6	66.0 ± 9.6	0.54
Male sex	141 (80.6)	195 (76.5)	0.31	182 (77.4)	72 (76.6)	0.87
Diabetes mellitus	56 (32.0)	72 (28.2)	0.40	72 (30.6)	36 (38.3)	0.18
Smoking history	43 (24.9)	61 (24.0)	0.84	49/234 (20.9)	22 (23.4)	0.62
Hypertension	135 (77.1)	177 (69.4)	0.08	175 (74.5)	67 (71.3)	0.55
Hyperlipidemia	129 (73.7)	176 (69.0)	0.29	167 (71.1)	65/93 (69.9)	0.83
Prior myocardial infarction	33/172 (19.2)	38/251(15.1)	0.27	46/234 (19.7)	17 (18.1)	0.74
Prior PCI	33 (18.9)	43 (16.9)	0.59	46/233 (19.7)	20 (21.3)	0.75
Prior TIA or CVA	9 (5.1)	12/254 (4.7)	0.84	12 (5.1)	6 (6.4)	0.65
Clinical presentation						
Stable angina	91 (52.0)	134/252 (53.2)	0.81	118/234 (50.4)	56 (59.6)	0.13
Unstable angina	38 (21.7)	70/252 (27.8)	0.16	61/234 (26.1)	17 (18.1)	0.12
Recent myocardial infarction (within 7 days)	28 (16.0)	30/252 (11.9)	0.22	38/234 (16.2)	16 (17.0)	0.86

LVEF, %	58.4 ± 9.3	57.0 ± 9.5	0.23	56.8 ± 9.7	53.8 ± 10.6	0.07
Angiographic characteristics (site assessed)						
SYNTAX score	21.5 ± 6.2	19.5 ± 6.2	0.001	22.2 ± 5.9	22.9 ± 5.3	0.41
0-22 (low)	99/174 (56.9)	169 (66.3)	0.05	112 (47.7)	41 (43.6)	0.51
23-32 (intermediate)	75/174 (43.1)	86 (33.7)	0.05	123 (52.3)	53 (56.4)	0.51
>32 (high)	0/174 (0.0)	0 (0.0)	—	0 (0.0)	0 (0.0)	—
Angle between the LM and LCX, degrees	83.8 ± 24.7	86.0 ± 21.5	0.12	87.3 ± 20.3	86.3 ± 24.6	0.73
Angiographic characteristics (core lab assessed)						
SYNTAX score	27.9 ± 8.4	25.3 ± 8.1	0.002	30.7 ± 7.9	30.3 ± 8.9	0.85
0-22 (low)	49/172 (28.5)	99/251 (39.4)	0.02	33 (14.5)	15 (16.9)	0.60
23-32 (intermediate)	76/172 (44.2)	109/251 (43.4)	0.88	109 (47.8)	39 (43.8)	0.52
>32 (high)	47/172 (27.3)	43/251 (17.1)	0.01	86 (37.7)	35 (39.3)	0.79
Medina classification						
1,0,0	30/104 (28.8)	65/129 (50.4)	0.0009	20/154 (13.0)	21/53 (39.6)	<0.0001
1,1,0	29/104 (27.9)	38/129 (29.5)	0.79	20/154 (13.0)	14/53 (26.4)	0.02
1,0,1	13/104 (12.5)	11/129 (8.5)	0.32	23/154 (14.9)	6/53 (11.3)	0.51
0,0,1	0/104 (0.0)	3/129 (2.3)	0.26	0/154 (0.0)	1/53 (1.9)	0.26

0,1,0	5/104 (4.8)	3/129 (2.3)	0.47	2/154 (1.3)	2/53 (3.8)	0.27
0,1,1	1/104 (1.0)	1/129 (0.9)	1.0	4/154 (2.6)	2/53 (3.8)	0.65
1,1,1	26/104 (25.0)	8/129 (6.2)	<0.0001	85/154 (55.2)	7/53 (13.2)	<0.0001
PCI performed on distal LM bifurcation				193/235 (82.1)	60/94 (63.8)	0.0004
Provisional 1-stent strategy				51/193 (26.4)	36/60 (60.0)	<0.0001
- Treatment of side branch				48/51 (94.1)	18/36 (50.0)	<0.0001
- Side branch stent implanted				22/48 (45.8)	5/18 (27.8)	0.18
- T, modified T or TAP				16/22 (72.7)	3/5 (60.0)	0.62
- Culotte/reverse (mini) crush				5/22 (22.7)	1/5 (20.0)	1.00
- Other				1/22 (4.5)	1/5 (20.0)	0.34
Planned 2-stent approach				142/193 (73.6)	24/60 (40.0)	<0.0001
- T, modified T or TAP				62/141 (44.0)	18/23 (78.3)	0.002
- Cullotte				39/141 (27.7)	2/23 (8.7)	0.051
- Crush or mini Crush				24/141 (17.0)	0/23 (0.0)	0.03
- V-stent				10/141 (7.1)	0/23 (0.0)	0.36
- SKS				3/141 (2.1)	0/23 (0.0)	0.14
- Other				3/141 (2.1)	1/23 (4.3)	0.46

Values are n (%) or mean ± standard deviation. CVA = cerebrovascular accident; FKBI = final kissing balloon inflation; LM = left main coronary artery; LCX = left circumflex coronary artery; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; TIA = transient ischemic attack.

Supplemental Table 2. Core Laboratory-Assessed Quantitative Coronary Angiographic Results According to Performance of Final Kissing Balloon Inflation

	1 Stent Implanted			≥2 Stents Implanted		
	FKBI (n=175)	**No FKBI (n=255)**	**p Value**	**FKBI (n=235)**	**No FKBI (n=94)**	**p Value**
Baseline, main vessel						
Lesion length, mm	12.48 ± 7.99	10.78 ± 6.83	0.007	12.56 ± 10.27	13.10 ± 10.08	0.67
Reference vessel diameter, mm	3.32 ± 0.50	3.39 ± 0.50	0.17	3.35 ± 0.52	3.29 ± 0.59	0.43
Minimal lumen diameter, mm	1.00 ± 0.40	1.12 ± 0.42	0.003	1.04 ± 0.40	1.11 ± 0.50	0.38
Percent diameter stenosis, %	69.9 ± 11.2	67.0 ± 11.0	0.006	68.9 ± 10.8	66.7 ± 12.3	0.10
Baseline, side branch						
Lesion length, mm	5.06 ± 3.26	4.22 ± 2.45	0.02	7.80 ± 6.96	5.65 ± 4.97	0.0007
Reference vessel diameter, mm	2.83 ± 0.54	2.72 ± 0.55	0.05	2.87 ± 0.54	2.78 ± 0.59	0.21
Minimal lumen diameter, mm	1.76 ± 0.74	1.97 ± 0.71	0.003	1.04 ± 0.40	1.11 ± 0.50	0.38
Percent diameter stenosis, %	38.0 ± 22.8	27.5 ± 21.0	<0.0001	69.0 ± 10.8	66.7 ± 12.3	0.10
Final, main vessel						
In-stent						
Reference vessel diameter, mm	3.70 ± 0.47	3.68 ± 0.47	0.7	3.83 ± 0.51	3.69 ± 0.48	0.02
Minimal lumen diameter, mm	3.41 ± 0.47	3.45 ± 0.45	0.51	3.55 ± 0.50	3.41 ± 0.45	0.02
Percent diameter stenosis, %	7.7 ± 6.0	6.2 ± 5.4	0.004	7.3 ± 6.7	7.3 ± 5.6	0.73
In-segment						

Reference vessel diameter, mm	2.98 ± 0.50	3.07 ± 0.57	0.13	2.92 ± 0.53	2.87 ± 0.55	0.32
Minimal lumen diameter, mm	2.54 ± 0.47	2.58 ± 0.54	0.67	2.45 ± 0.47	2.45 ± 0.52	0.89
Percent diameter stenosis, %	14.6 ± 8.1	15.8 ± 9.5	0.34	15.9 ± 8.0	14.8 ± 7.8	0.29
Final, side branch						
In-segment						
Reference vessel diameter, mm	2.84 ± 0.49	2.74 ± 0.53	0.02	2.80 ± 0.49	2.80 ± 0.61	0.86
Minimal lumen diameter, mm	2.05 ± 0.58	1.90 ± 0.74	0.02	2.30 ± 0.55	2.13 ± 0.74	0.07
Percent diameter stenosis, %	27.5 ± 18.4	30.6 ± 22.4	0.43	17.7 ± 14.4	24.0 ± 20.4	0.02
Acute gain, mm	0.27 ± 0.69	-0.07 ± 0.53	<0.0001	1.06 ± 1.05	0.29 ± 0.86	<0.0001

Values are mean ± standard deviation. FKBI = final kissing balloon inflation.

Supplemental Table 3. Procedural Characteristics According to Performance of Final Kissing Balloon Inflation

	1 Stent Implanted			≥2 Stents Implanted		
	FKBI (n=175)	**No FKBI (n=255)**	**p Value**	**FKBI (n=235)**	**No FKBI (n=94)**	**p Value**
Guiding catheter size						
6F	79 (45.1)	136 (53.3)	0.10	70 (29.8)	44 (46.8)	0.003
7F	79 (45.1)	91 (35.7)	0.05	96 (40.9)	33 (35.1)	0.33
8F	17 (9.7)	28 (11.0)	0.67	69 (29.4)	17 (18.1)	0.04
Radial artery access	65 (33.3)	91 (33.3)	1.00	51 (19.4)	27 (26.2)	0.15
Intravascular ultrasound used	125 (71.4)	213 (85.3)	0.003	169 (71.9)	72 (76.6)	0.39
Rotational atherectomy used	6 (3.4)	18 (7.1)	0.11	19(8.1)	5(5.3)	0.38
Hemodynamic support used	5 (2.6)	16 (5.9)	0.09	21 (8.0)	5 (4.9)	0.29
Contrast volume, mL	252.5 ± 133.4	235.6 ± 119.5	0.24	285.9 ± 128.5	272.5 ± 137.7	0.22
Procedure duration, min	80.0 ± 42.0	71.6 ± 40.1	0.02	93.7 ± 42.9	86.0 ± 43.4	0.07
Fluoroscopy time, min	23.5 ± 14.7	20.7 ± 15.2	0.002	29.6 ± 16.9	25.6 ± 17.6	0.01
Radiation dosage, Gy	3.1 ± 2.4	3.1 ± 2.4	0.98	3.3 ± 2.6	3.3 ± 2.2	0.64
Procedural complications*	15 (7.7)	26 (9.5)	0.49	39 (14.8)	12 (11.7)	0.43

Left main lesion or stent data						
Stent diameter, per stent	3.53 ± 0.41	3.66 ± 0.34	<0.0001	3.34 ± 0.45	3.36 ± 0.49	0.55
Stent length, per stent	21.2 ± 6.8	18.4 ± 7.1	<0.0001	19.5 ± 7.6	18.3 ± 7.7	0.02
Total stent length, per subject	22.0 ± 9.3	18.5 ± 7.3	<0.0001	44.4 ± 15.8	40.5 ± 16.2	0.02
Post-stent dilatation performed	162 (92.6)	220 (86.3)	0.04	222 (94.5)	83 (88.3)	0.052
Maximum balloon diameter, mm	3.9 ± 0.6	4.1 ± 0.5	0.01	3.9 ± 0.6	4.0 ± 0.6	0.21
Maximum balloon pressure, atm	16.8 ± 3.8	17.8 ± 3.8	0.03	17.6 ± 3.7	18.3 ± 3.9	0.30
Max device diameter, mm	4.0 ± 0.5	4.1 ± 0.5	0.16	4.0 ± 0.5	4.1 ± 0.5	0.30

Values are n (%) or mean ± standard deviation. *Chest pain or ECG changes for more than 10 min, slow flow or no reflow, distal embolization, acute vessel closure, perforation, stent thrombosis, tamponade requiring pericardial synthesis, cardiac arrest, stroke, bleeding, or severe arrhythmias. FKBI = final kissing balloon inflation.

Supplemental Table 4. Thirty-Day and 4-Year Clinical Outcomes According to Performance of Final Kissing Balloon Inflation

	1 Stent Implanted				≥2 Stents Implanted			
	FKBI (n=175)	No FKBI (n=225)	HR (95% CI)	p Value	FKBI (n=235)	No FKBI (n=94)	HR (95% CI)	p Value
30-day adverse events								
Death	1.1 (2)	0.0 (0)	—	1.00	1.7 (4)	2.1 (2)	0.80 (0.15, 4.38)	0.80
Cardiovascular	1.1 (2)	0.0 (0)	—	1.00	1.7 (4)	2.1 (2)	0.80 (0.15, 4.38)	0.80
MI	4.0 (7)	2.7 (7)	1.48 (0.52, 4.22)	0.46	5.6 (13)	7.4 (7)	0.73 (0.29, 1.82)	0.50
Periprocedural	3.4 (6)	2.7 (7)	1.27 (0.43, 3.77)	0.67	4.7 (11)	7.4 (7)	0.62 (0.24, 1.59)	0.31
Non-periprocedural	0.6 (1)	0.0 (0)	—	0.22	0.9 (2)	0.0 (0)	—	0.37
Stroke	1.1 (2)	0.4(1)	0.34 (0.03, 3.78)	0.38	1.4(3)	1.2(1)	1.12 (0.12,10.77)	0.19
All revascularization	1.7 (3)	0.0 (0)	—	1.00	1.3 (3)	1.1 (1)	1.19 (0.12, 11.47)	0.88
IDR	1.7 (3)	0.0 (0)	—	1.00	1.3 (3)	0.0 (0)	—	1.00
Definite or probable stent thrombosis	1.1 (2)	0.0 (0)	—	1.00	0.4 (1)	2.1 (2)	0.20 (0.02, 2.21)	0.19
Definite stent thrombosis	1.1 (2)	0.0 (0)	—	1.00	0.4 (1)	0.0 (0)	—	1.00
Death, MI, or stroke	5.7 (10)	3.1 (8)	1.85 (0.73, 4.68)	0.20	6.0 (14)	10.6 (10)	0.55 (0.24, 1.23)	0.14
Death, MI, stroke, or IDR	5.7 (10)	3.1 (8)	1.85 (0.73, 4.68)	0.20	6.0 (14)	10.6 (10)	0.55 (0.24, 1.23)	0.14
4-year adverse events								
Death	10.0 (17)	9.3 (23)	1.11 (0.59, 2.07)	0.75	8.6 (20)	17.4 (16)	0.47 (0.24, 0.91)	0.02
Cardiovascular	4.8 (8)	3.6 (9)	1.32 (0.51, 3.43)	0.56	7.4 (17)	10.0 (9)	0.71 (0.32, 1.60)	0.61
MI	8.4 (14)	5.6 (14)	1.50 (0.72, 3.15)	0.28	13.5 (31)	14.4 (13)	0.90 (0.47, 1.71)	0.74

Stroke	3.0 (5)	2.4 (6)	1.23(0.38, 4.03)	0.73	1.4 (3)	1.2 (1)	1.12 (0.12, 0.77)	0.53
All revascularization	13.7 (23)	14.4 (35)	1.00 (0.59,1.69)	0.99	21.8 (49)	19.9 (17)	1.09 (0.63, 1.90)	0.75
IDR	13.1 (22)	14.4 (35)	0.95 (0.56, 1.62)	0.86	21.8 (49)	17.5 (15)	1.26 (0.70, 2.24)	0.44
TLR	9.5 (16)	9.5 (23)	1.05(0.56, 2.00)	0.87	17.3 (39)	14.1 (12)	1.26 (0.66, 2.40)	0.49
Definite or probable stent thrombosis	3.1 (5)	0.9 (2)	3.76 (0.73, 19.36)	0.11	2.7 (6)	2.1 (2)	1.16 (0.23, 5.73)	0.86
Definite stent thrombosis	3.1 (5)	0.4 (1)	7.53 (0.88, 64.41)	0.07	1.8 (4)	0.0 (0)	—	1.00
Acute (≤24 hours)	0.6 (1)	0.0 (0)	—	1.00	0.0 (0)	0.0 (0)	—	—
Subacute (1-30 days)	0.6 (1)	0.0 (0)	—	1.00	0.9 (2)	2.1 (2)	0.40 (0.06, 2.85)	0.53
Early (0-30 days)	1.1 (2)	0.0 (0)	—	1.00	0.9 (2)	2.1 (2)	0.40 (0.06, 2.85)	0.53
Late (>30 days to 1 year)	0.0 (0)	0.0 (0)	—	—	0.4 (1)	0.0 (0)	—	—
Very late (>1 year)	1.9 (3)	0.9 (2)	4.57 (0.48, 43.96)	0.19	1.4 (3)	0.0 (0)	—	—

Rates are Kaplan-Meier estimates, % (n). Cox proportional hazard regression was used to estimate and compare HRs. CI = confidence interval; FKBI = final kissing balloon inflation; HR = hazard ratio; IDR = ischemia-driven revascularization; TLR = target lesion revascularization.

Supplemental Table 5. Details of the Stent Thrombosis Cases: 1-Stent Group

	N	Age/Sex	Definite/ Probable	Days After Index PCI	Thrombosed Vessel	MACE	Procedural Details
FKBI	1	76/M	D	0 day	LM	MI, death	Thrombus aspiration
	2	44/F	D	5 days	LAD	MI	DES implantation in the mid LAD
	3	52/M	D	662 days	LCX	MI	DES implantation in the proximal LCX
	4	52/M	D	787 days	LAD	MI	n/a
	5	45/M	D	1244 days	LAD	MI	DES implantation in the LAD
No FKBI	1	57/M	D	1440 days	Proximal RCA	MI	Thrombus aspiration
	2	n/a	P	892 days	n/a	MI, CABG	n/a

CABG = coronary artery bypass graft surgery; D = definite; DES = drug-eluting stent; F = female; FKBI = final kissing balloon inflation; LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; M = male; MACE = major adverse coronary event; MI = myocardial infarction; n/a = data not available; P = probable; PCI = percutaneous coronary intervention; RCA = right coronary artery.

Supplemental Table 6. Details of the Stent Thrombosis Cases: ≥2 Stent Group

	N	Age/Sex	Definite/Probable	Days After Index PCI	Thrombosed Vessel	MACE	Procedural Details
FKBI	1	64/M	D	13 days	LM	MI, death	Thrombus aspiration and bare metal stent
	2	78/M	P	26 days	n/a	MI, death	n/a
	3	80/M	P	269 days	n/a	MI	n/a
	4	61/M	D	499 days	LAD	MI	Two DES deployed in the mid-LAD
	5	60/M	D	1103 days	LCX	CABG, death (respiratory failure)	Stent in the proximal LCX and balloon angioplasty in OM1
	6	58/M	D	1141 days	Proximal LAD	MI	Thrombus aspiration in the proximal LAD
No FKBI	1	50/M	P	6 days	n/a	MI, death	n/a
	2	54/M	P	8 days	n/a	MI, death	Immediate cause of death due to ACS (death certificate)

CABG = coronary artery bypass graft surgery; D = definite; DES = drug-eluting stent; F = female; FKBI = final kissing balloon inflation; LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; M = male; MACE = major adverse coronary event; MI = myocardial infarction; n/a = data not available; OM = obtuse marginal; P = probable; PCI = percutaneous coronary intervention; RCA = right coronary artery.