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New-generation drug-eluting stents for left main coronary artery disease according to the EXCEL trial enrollment criteria: Insights from the all-comers, international, multicenter DELTA-2 registry

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) has been established as an alternative treatment option to coronary artery by-pass graft (CABG) surgery in patients with left main coronary artery disease (LMCAD). Whether the findings of randomized controlled trials are applicable to a real-world patient population is unclear.
Methods: We compared the outcomes of PCI with new-generation DES in the all-comer, international, multicenter DELTA-2 registry retrospectively evaluating mid-term clinical outcomes with the historical CABG cohort enrolled in the DELTA-1 registry according to the EXCEL key inclusion or exclusion criteria. The primary endpoint was the composite of death, myocardial infarction, or stroke at the median time of follow-up time of 501 days. The consistency of the effect of DELTA-2 PCI versus DELTA-1 CABG according to the EXCEL enrollment criteria was tested using propensity score-adjusted Cox regression models.
Results: Out of 3986 patients enrolled in the DELTA-2 PCI registry, 2418 were EXCEL candidates and 1568 were not EXCEL candidates. The occurrence of the primary endpoint was higher among non-EXCEL candidates compared with EXCEL candidates (15.4% vs. 6.9%; hazard ratio 2.52; 95% confidence interval 2.00–3.16; $p < 0.001$). Among 901 patients enrolled in the historical DELTA-1 CABG cohort, 471 were EXCEL candidates and 430 were not EXCEL candidates. When comparing the DELTA-2 PCI with the DELTA-1 CABG cohort, the occurrence of the primary endpoint was lower in the PCI group compared with the historical CABG cohort among EXCEL candidates (6.9% vs. 10.7%; adjusted hazard ratio: 0.65; 95% confidence interval: 0.45–0.92), while no significant difference was observed among non-EXCEL candidates (15.4% vs. 12.5%; adjusted hazard ratio: 0.94; 95% confidence interval: 0.67–1.33) with evidence of statistical interaction (adjusted interaction p-value = 0.002).
Conclusions: In a real-world population, PCI can be selected more favorably as an alternative to CABG in patients fulfilling the enrollment criteria of the EXCEL trial.

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1. Introduction

Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) for LMCAD has become an acceptable alternative to coronary artery bypass graft (CABG) in selected patients [1–6]. Newer generation DES demonstrated to have improved clinical outcomes compared to first generation DES [7,8], however, data regarding the efficacy and safety of new-generation DES in patients with LM disease is limited [9–11]. Recently, the Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization (EXCEL) trial demonstrated the non-inferiority of PCI with the new-generation everolimus-eluting stent compared with CABG in terms of death, myocardial infarction (MI) or stroke at 3 years in selected patients with LMCAD and with site-assessed low- or intermediate SYNTAX score [9].

The DELTA-2 registry, which is an all-comers, international, multicenter registry of unprotected LM PCI with new-generation DES, showed favorable outcomes of PCI over 1.5 years of follow-up. Of note, this real-world registry included patients who are commonly excluded from randomized controlled trials investigating revascularization strategies in LMCAD, such as those with high anatomical complexity or those presenting with acute MI (either ST-segment elevation MI or non-ST-segment elevation MI and/or cardiac shock) [12]. Therefore, the aim of this study was to evaluate the generalizability of the findings from the EXCEL trial among a real-world patient population of patients with LMCAD undergoing invasive revascularization with either PCI or CABG.

2. Methods

2.1. Study design

The methods of the DELTA-2 registry have been previously published [12]. In brief, the registry was an international, all-comers, multicenter registry that retrospectively evaluated clinical outcomes of unprotected LM coronary artery PCI with new-generation DES between March 2006 and December 2015 at 19 centers in 7 countries. All data related to clinical characteristics, procedures, and outcomes were collected at each center from hospital record, and clinical follow-up was collected by clinical visits and telephone interviews. All patients provided informed consent for the procedure and subsequent data collection and analysis. The inclusion of patients was approved in each center by a local ethics committee.

Among all patients of the DELTA-2 registry (n = 3986), those who met the key exclusion criteria of the EXCEL trial [9], including SYNTAX score of 33 or higher, presenting with acute MI, and prior CABG, were classified into non-EXCEL candidates (n = 1568). The remainder, who did not have any exclusion criteria of the EXCEL trial or data regarding the criteria, were classified into EXCEL candidates (n = 2418) in this study (Supplemental Fig. 1).

2.2. Study endpoints and definitions

The primary composite endpoint was the occurrence of all-cause death, MI, or cerebrovascular accident (CVA). Secondary endpoints included target vessel revascularization (TVR) and definite/probable stent thrombosis. As described previously [12], study definitions of the DELTA-2 registry were consistent with the DELTA-1 registry [13]. MI was defined as any of the following: 1) any Q-wave myocardial infarction occurring either before or after hospital discharge, or (2) any post-discharge spontaneous myocardial infarction (defined as any increase in troponin and/or CK-myocardial band greater than the upper limit of normal if associated with clinical and/or electrocardiogram change). The occurrence of stent thrombosis was defined according to the Academic Research Consortium criteria [14]. Diagnostic angiograms were scored according to the SYNTAX score algorithm at each site catheterization laboratory [15].

2.3. Comparison with historical DELTA-1 CABG cohort

As described previously [12], the DELTA-2 registry did not include a parallel contemporary CABG group, and the CABG cohort of the DELTA-1 registry was used as a historical surgical group for comparison [13]. In this study, the DELTA-1 CABG patients were also divided into two groups; EXCEL candidate (n = 471) and non-EXCEL candidate (n = 430) (Supplemental Fig. 1), to be compared with each respective group of the DELTA 2 PCI population.

2.4. Statistical analysis

Data are reported as number (percentage), mean ± SD, or median (interquartile range). Differences in categorical data were tested with chi-square test or Fisher exact test, and differences in continuous variables were tested with unpaired *t*-test. Event rates with 95% confidence intervals (CI) and absolute rate differences at follow-up were estimated using the Kaplan-Meier method as time to first event. As described previously [12], considering the difference in follow-up duration (median 501 days in DELTA-2 and 1524 days in DELTA-1 CABG), endpoints were compared at 501 days of follow-up. To account for pre-treatment difference between the DELTA-2 cohort and the historical DELTA-1 CABG cohort, a propensity score was generated by means of a logistic regression model. Calibration of the logistic regression model was assessed using the Hosmer-Lemeshow test. The following covariates were included in the logistic regression model to generate the propensity score: age, male sex, diabetes, smoking history, family history of coronary artery disease, acute MI (ST-segment elevation MI or non-ST-segment elevation MI), previous CABG, previous PCI, and right coronary artery disease. The propensity score model was well calibrated (goodness-of fit test, p = 0.12; C-statistic 0.74). Subsequently, Cox regression models stratified by quintiles of propensity score were performed to estimate adjusted differences between treatments (PCI vs. CABG). The interaction between revascularization strategies (DELTA-2 PCI versus DELTA-1 CABG) and the EXCEL enrollment criteria was evaluated using Cox regression models that included the interaction term, stratified by quintiles of propensity score. In order to assess the robustness of our findings we repeated all analyses excluding all patients for whom the SYNTAX score was not available. A p-value <0.05 was considered to indicate statistical significance. Analyses were performed using SPSS version 21.0 (SPSS, Chicago, Illinois).

3. Results

The baseline clinical characteristics of the DELTA-2 population are shown in Supplemental Table 1. EXCEL candidates were younger than non-EXCEL candidates (68.9 ± 10.6 vs. 70.6 ± 11.2 years; p < 0.001). The rate of diabetes (28.5% vs. 34.2%; p < 0.001) was lower in EXCEL candidates than in non-EXCEL candidates, as well as chronic kidney disease (26.8% vs. 38.2%; p < 0.001), previous MI (26.1% vs. 31.5%; p < 0.001), and previous CABG (0% vs. 21.2%; p < 0.001). Mean left ventricular ejection fraction was higher (55.5 ± 10.1 vs. 49.7 ± 12.2%; p < 0.001) in EXCEL candidates. In EXCEL candidates, most of the cases were stable angina or silent ischemia, while >50% of cases were acute myocardial infarction in non-EXCEL candidates (p < 0.001).

Lesion and procedural characteristics are summarized in Supplemental Table 2. EXCEL candidates less frequently had multivessel disease (69.2% vs. 82.1%; p < 0.001), urgent/emergent procedures (13.2% vs. 51.5%; p < 0.001) and involved distal bifurcation of LM than non-EXCEL candidates (83.1% vs. 86.9%; p = 0.001). Mean stent diameter for left main was larger (3.62 ± 0.36 vs. 3.54 ± 0.39 mm; p < 0.001) and total stent length was shorter (25.3 ± 16.6 vs. 29.9 ± 23.1 mm; p < 0.001) in EXCEL candidates than in non-EXCEL candidates.

3.1. Clinical outcomes according to the EXCEL criteria in the DELTA-2 registry

The median follow-up term was 501 days (interquartile range: 318 to 1002 days; clinical follow-up rate 88.1%) in the DELTA-2 population. Kaplan-Meier estimates for the primary endpoint of all-cause death, MI, or CVA and the secondary endpoints are illustrated in Table 1 and Fig. 1. The risk for the primary endpoint of death, MI, and CVA was higher in the non-EXCEL candidates (15.4% vs. 6.9%; hazard ratio 2.52; 95% CI: 2.00–3.16; p < 0.001). In particular, non-EXCEL candidates had higher risk for death (11.8% vs. 5.2%; hazard ratio 2.55; 95% CI: 1.97–3.32; p < 0.001) and MI (4.5% vs. 1.8%; hazard ratio: 2.74; 95% CI: 1.73–4.32; p < 0.001). There was no significant difference in the occurrence of TVR between the 2 groups (15.0% vs. 13.6%; hazard ratio 1.17; 95% CI: 0.96–1.42; p = 0.13), while definite/probable ST occurred more frequent in non-EXCEL candidates (2.5% vs. 0.9%; hazard ratio 2.90; 95% CI 1.61–5.23; p < 0.001).

3.2. Comparison between DELTA-2 PCI and DELTA-1 CABG patients among EXCEL candidates and non-EXCEL candidates

Baseline differences between DELTA-2 and historical DELTA-1 CABG cohort among EXCEL candidates and non-EXCEL candidates respectively are summarized in Supplemental Table 3. Comparisons of clinical outcomes between the DELTA-2 PCI and historical DELTA-1 CABG cohorts according to the EXCEL criteria are illustrated in Table 2 and Fig.

Table 1
EXCEL candidates vs. non-EXCEL candidates in DELTA-2 PCI cohort.

Outcome	EXCEL	Non-EXCEL	ARD (95% CI)	Univariate HR[a](95% CI)	p-Value
Death, myocardial infarction or cerebrovascular accident	120 (6.9% [5.7% to 8.1%])	192 (15.4% [13.4% to 17.4%])	−8.5% [−9.3% to −7.7%]	2.52 (2.00–3.16)	<0.001
Death	91 (5.2% [4.2% to 6.2%])	149 (11.8% [10.0% to 13.6%])	−6.6%[−7.4% to −5.8%]	2.55 (1.97–3.32)	<0.001
Myocardial infarction	29 (1.8% [1.2% to 2.4%])	50 (4.5% [3.3% to 5.7%])	−2.7% [−3.3% to −2.1%]	2.74 (1.73–4.32)	<0.001
Cerebrovascular accident	12 (0.7% [0.3% to 1.1%])	10 (0.9% [0.3% to 1.5%])	−0.2% [−0.4% to 0%]	1.30 (0.56–3.01)	0.54
Target vessel revascularization	232 (13.6% [12.0% to 15.2%])	170 (15.0% [12.8% to 17.2%])	−1.4% [−2.0% to −0.8%]	1.17 (0.96–1.42)	0.13
Definite/probable ST	17 (0.9% [0.5% to 1.3%])	32 (2.5% [1.7% to 3.3%])	−1.6% [−2.0% to −1.2%]	2.90 (1.61–5.23)	<0.001

Failure estimates reported as n (% [95% confidence interval]) by Kaplan-Meier analysis. All endpoints evaluated at 501 days of follow-up. ARD = Absolute Risk Difference; CABG = Coronary Artery Bypass Grafting; CI = Confidence Interval; HR: Hazard Ratio.
[a] HRs are shown with EXCEL candidates as reference group.

2. The occurrence of the primary endpoint was lower in PCI patients compared to the historical CABG cohort among EXCEL candidates (6.9% vs. 10.7%; adjusted hazard ratio: 0.65; 95% CI: 0.45–0.92), while no significant difference was observed among non-EXCEL candidates (15.4% vs. 12.5%; adjusted hazard ratio: 0.94; 95% CI: 0.67–1.42) with evidence of statistical interaction (adjusted interaction p-value = 0.002). PCI was associated with lower risk for MI among EXCEL candidates (1.8% vs. 3.9%; adjusted hazard ratio: 0.45; 95% CI: 0.23–0.85), but not among non-EXCEL candidates (4.5% vs. 1.9%; adjusted hazard ratio: 1.31; 95% CI: 0.59–2.91) with evidence of statistical interaction (adjusted interaction p-value = 0.001). Of note, PCI was associated with lower risk for CVA among EXCEL candidates, while no significant difference was observed among non-EXCEL candidates with tendency of statistical interaction (adjusted interaction p-value = 0.06). There were no significant differences in the occurrence of death between PCI and CABG among both EXCEL and non-EXCEL candidates without statistical interaction (adjusted interaction p-value = 0.29). PCI was associated with higher risk for TVR among both EXCEL and non-EXCEL candidates without statistical interaction (adjusted interaction p-value = 0.61). When excluding patients who were classified into EXCEL candidates without SYNTAX score data (1108 DELTA-2 PCI patients and 292 DELTA-1 CABG patients), the results of analysis were consistent with the main analyses (Supplemental Table 4).

4. Discussion

The main findings of this study are as follows; 1) In DELTA-2 PCI patients, non-EXCEL candidates had worse clinical and/or angiographic characteristics as compared to EXCEL candidates; 2) EXCEL candidates had lower incidence of death, MI, and stroke than non-EXCEL candidates; 3) When comparing the DELTA-2 PCI with the DELTA-1 CABG cohort according to the EXCEL criteria, PCI was associated with lower risk of death, MI or stroke at 501 days of follow-up only among EXCEL candidates.

4.1. EXCEL candidates and non-EXCEL candidates in PCI cohort

The DELTA-2 registry included patients usually excluded from randomized clinical trials investigating the comparative effectiveness of invasive revascularization strategies. This study showed that about two-fifth of DELTA-2 patients had at least one major exclusion criteria of the EXCEL trial [9], including patients with high SYNTAX score, and those presenting with acute MI, among others. Non-EXCEL candidates had worse clinical and angiographic characteristics as compared to EXCEL candidates. They were older, with higher prevalence of comorbidities including diabetes, chronic kidney disease, and previous MI, lower left ventricular ejection fraction, and more frequently presenting with acute MI (ST-segment elevation MI or non-ST-segment elevation). In addition non-EXCEL candidates more frequently had multivessel disease and higher SYNTAX score. Consistently, patients fulfilling the criteria for enrollment in the EXCEL trial had lower rates of adverse events over time compared with those who would not have been eligible for enrollment. These results suggest that in a real-world setting, a significant proportion of patients who would not be eligible for enrollment in randomized controlled trials receive treatment with either PCI or CABG.

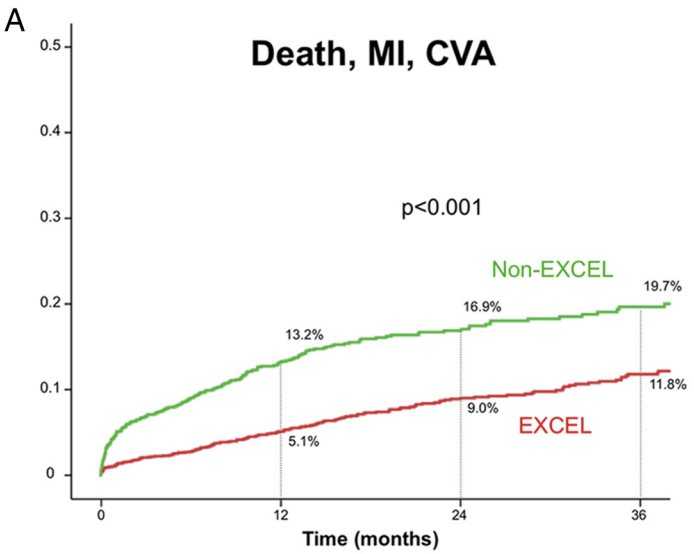
4.2. Comparison between PCI and CABG patients among EXCEL candidates and non-EXCEL candidates

In the EXCEL trial, PCI with new-generation DES had similar rates of death, MI, or stroke compared with CABG at 3 years [9]. In our study, when comparing the DELTA-2 PCI cohort versus the DELTA-1 CABG cohort according to the EXCEL major inclusion and exclusion criteria, we observed that PCI was associated with lower incidence of death, MI, or stroke up to 501 days as compared to CABG among EXCEL candidates. The difference between the two groups seems to gradually decrease over time, therefore longer follow-up might abrogate the early advantage observed with PCI and the event rates might have become comparable up to 3 years, consistently with the EXCEL trial. In terms of repeat revascularization, CABG was more advantageous than PCI, regardless of the fulfillment of the EXCEL trial inclusion or exclusion criteria. However, as previously proposed [16], important differences exist in terms of the prognostic impact of repeat revascularization versus other hard clinical endpoints such as death, MI or stroke.

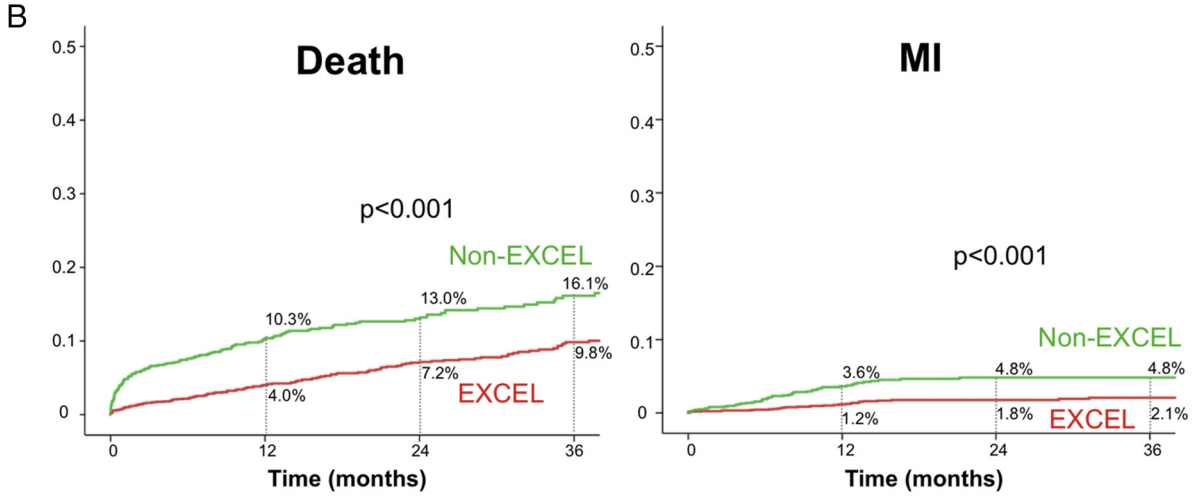
In this study, a benefit for PCI was observed among EXCEL candidates (primary endpoint; absolute risk difference between PCI and CABG: −4.8%), while a benefit of CABG was suggested among non-EXCEL candidates (primary endpoint; absolute risk difference between PCI and CABG: +2.9%). Therefore, PCI may not be always an appropriate alternative to CABG among non-EXCEL candidates. However, we also appraise the heterogeneity of non-EXCEL candidates. In particular, non-EXCEL candidates in this real-world population include acute MI (ST-segment elevation MI or non-ST-segment elevation) as well as cardiogenic shock patients. In emergency setting, PCI is inevitably selected in most situations and CABG is infrequently performed because time to reperfusion becomes longer, and emergent coronary revascularization is associated with very high risk for morbidity and mortality [17]. Furthermore, at the time of clinical decision-making between revascularization strategies one should consider not only clinical risk factors or anatomical characteristics but also other factors such as frailty or patient's preference [18], when selecting PCI or CABG. Thus, PCI is not necessarily inappropriate for LMCAD revascularization among all non-EXCEL candidates, and further characterization of the outcomes of LMCAD PCI in acute settings is required.

4.3. Study limitations

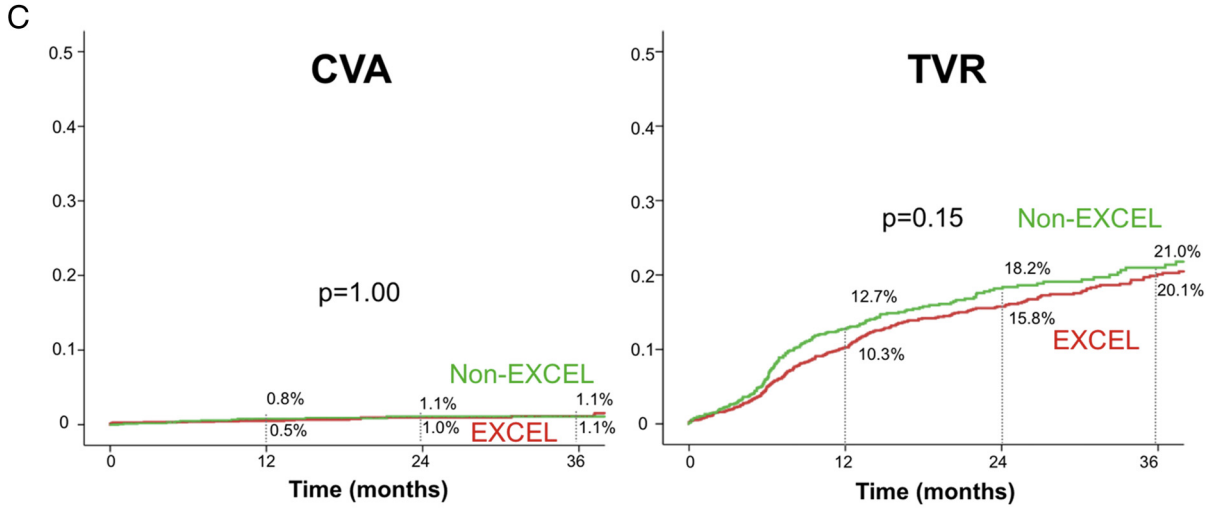
As previously described [12], there are several limitations in the DELTA-2 registry. Briefly, 1) given its observational, retrospective design these results have to be considered hypothesis-generating; 2) given the large number of participating centers and countries, and a large time period, substantial heterogeneity may exist in terms of patient population and local standard of care; 3) comparisons between PCI and CABG are



EXCEL	2102	1453	837	507
Non-EXCEL	1410	877	452	248



EXCEL	2102	1466	850	515	2102	1455	839	508
Non-EXCEL	1410	903	467	255	1410	881	456	249



EXCEL	2102	1461	846	512	2102	1344	730	421
Non-EXCEL	1410	895	460	252	1410	814	392	210

Table 2
DELTA-2 PCI vs DELTA-1 CABG within EXCEL candidate and non-EXCEL candidate.

Outcome	DELTA-2	CABG	ARD (95% CI)	Univariate HR (95% CI)	Adjusted HR[a] (95% CI)	Adjusted[a] p-value	Adjusted $p_{interaction}$[b]
Death, MI or CVA							
EXCEL	120 (6.9% [5.7% to 8.1%])	48 (10.7% [7.8% to 13.6%])	−3.8% (−5.5% to −2.1%)	0.57 (0.41–0.80)	0.65 (0.45–0.92)	0.02	0.002
Non-EXCEL	192 (15.4% [13.4% to 17.4%])	53 (12.5% [9.4% to 15.6%])	2.9% (1.8% to 4.0%)	1.19 (0.88–1.62)	0.94 (0.67–1.33)	0.73	
Death							
EXCEL	91 (5.2% [4.2% to 6.2%])	25 (5.7% [3.5% to 7.9%])	−0.5% (−1.7% to 0.7%)	0.86 (0.55–1.33)	1.04 (0.66–1.65)	0.87	0.29
Non-EXCEL	149 (11.8% [10.0% to13.6%])	43 (10.2% [7.3% to 13.1%])	1.6% (0.5% to 2.7%)	1.14 (0.81–1.60)	0.97 (0.66–1.42)	0.86	
MI							
EXCEL	29 (1.8% [1.2% to 2.4%])	17 (3.9% [2.1% to 5.7%])	−2.1% (−3.3% to −0.9%)	0.40 (0.22–0.73)	0.45 (0.23–0.85)	0.01	0.001
Non-EXCEL	50 (4.5% [3.3% to 5.7%])	8 (1.9% [0.5% to 3.3%])	2.6% (2.4% to 2.8%)	2.12 (1.01–4.49)	1.31 (0.59–2.91)	0.51	
CVA							
EXCEL	12 (0.7% [0.3% to 1.1%])	13 (2.9% [1.3% to 4.5%])	−2.2% (−3.4% to −1.0%)	0.20 (0.09–0.45)	0.19 (0.08–0.45)	<0.001	0.06
Non-EXCEL	10 (0.9% [0.3% to 1.5%])	4 (1.0% [0% to 2.0%])	−0.1% (−0.5% to 0.3%)	0.80 (0.25–2.55)	0.64 (0.17–2.41)	0.51	
TVR							
EXCEL	232 (13.6% [12.0% to15.2%])	12 (2.9% [1.3% to 4.5%])	10.7% (10.7% to 10.7%)	4.77 (2.67–8.52)	4.17 (2.31–7.54)	<0.001	0.61
Non-EXCEL	170 (15.0% [12.8% to 17.2%])	11 (2.8% [1.2% to 4.4%])	12.2% (11.6% to 12.8%)	5.57 (3.03–10.26)	7.84 (4.10–14.97)	<0.001	

Failure estimates reported as n (% [95% confidence interval]) by Kaplan-Meier analysis. All endpoints evaluated at 501 days of follow-up.
ARD = Absolute Risk Difference; CABG = Coronary Artery Bypass Grafting; CI = Confidence Interval; HR: Hazard Ratio.
[a] Adjusted hazards ratios generated with Cox models stratified by quintiles of propensity score.
[b] The interaction between revascularization strategies (DELTA-2 PCI versus DELTA-1 CABG) and the EXCEL enrollment criteria was evaluated using Cox regression models that included the interaction term, stratified by quintiles of propensity score.

based on contemporary and historical cohorts, respectively, so the comparative effectiveness of contemporary CABG versus PCI in a contemporary real-world setting remains unclear. Furthermore, a propensity score was generated by means of a logistic regression model to account for pre-treatment difference, but potential selection biases and unmeasured cofounders might exist. Our results can only be considered as hypothesis generating; 4) data were collected at each center and adjudication of the outcomes was largely dependent on individual institutions, therefore we cannot exclude that in the absence of site monitoring and a formal clinical event committee adjudication misreporting or underreporting of major adverse events may have occurred; 5) the length of follow-up for comparisons between the DELTA-2 PCI and the DELTA-1 CABG cohorts was relatively short, therefore long-term follow-up is needed to better evaluate the comparative effectiveness of these revascularization strategies over time. 6) In this registry, site-determined SYNTAX scores were used and central core-laboratory analyses for angiograms and SYNTAX score calculations were not performed. 7) Due to retrospective study design and using historical CABG cohort, some data regarding inclusion/exclusion criteria of the EXCEL trial were not available. In particular, 1108 patients were classified into EXCEL candidates without SYNTAX score. However, in a sensitivity analysis excluding all patients for whom the SYNTAX score was not available the results were consistent with our primary analysis. 8) we also could not use same definitions as EXCEL trial with regard to MI.

5. Conclusions

In the all-comers, international, multicenter DELTA-2 registry patients with LMCAD fulfilling the inclusion criteria of the EXCEL trial had lower risk of major adverse cardiac events compared with patients that would have been excluded in the EXCEL trial. For this selected patient population, PCI can be selected more favorably as an alternative to CABG. Uptake of evidence-based findings into real-world clinical practice requires a careful evaluation of the applicability and generalizability of the individual randomized trial design to optimally inform clinical decision-making.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.12.003.

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None.

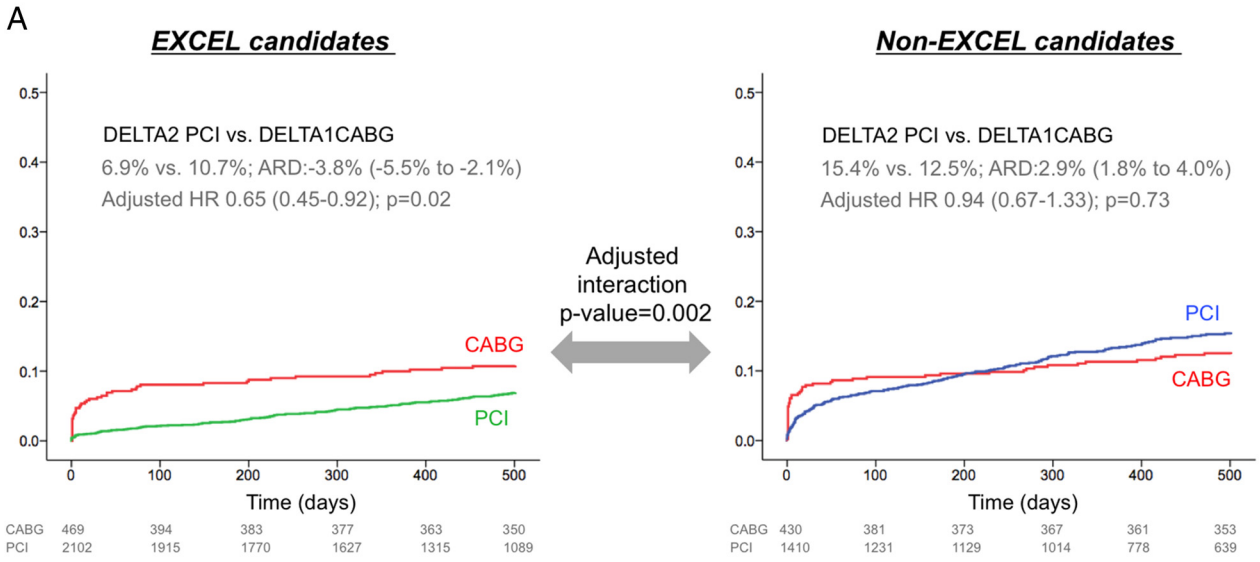
Conflict of interest

Dr. Daemen reports to have received institutional research grants from Acist, Abbott Vascular, Pie Medical, Medtronic, and Boston Scientific and speaker/consultancy fees from Medtronic, Acist, Pythagoras medical, ReCor medical. Dr. D'Ascenzo is a consultant for Abbott Srl, Aztrazeneca, Chiesi, Mediserve, Medtronic, and CID. Dr. Cerrato has received speaker fees from Volcano, Astrazeneca, Menarini, and Abott Vascular. Dr. Stefanini has received institutional research grant support from Boston Scientific and speaker/consultant fees from Boston Scientific, B. Braun, and Edwards Lifesciences. Dr. Erglis has received grant/research support from Abbott Vascular, Boston Scientific, and consulting fees/honoraria from Abbott Vascular, Biosensors, Biotronik, Boston Scientific, Cordis. Dr. Mehran has received institutional research grant support from the Medicines Company, Bristol-Myers Squibb and Sanofi-Aventis, Eli Lilly and AstraZeneca, and consulting fees from AstraZeneca, Bayer, CSL Behring, Janssen Pharmaceuticals inc, Merck & Co., Osprey Medical Inc., Watermark Research Partners; serves on the advisory board of Abbott Laboratories, Boston Scientific Corporation, Merck & Co., Covidien, Janssen Pharmaceuticals, The Medicines Company, Sanofi-Aventis; is equity owner of Claret Medical Inc. and Elixir Medical Corporation. Dr. Van Mieghem is a consultant for Abbott Vascular. Dr. Varbella is on the advisory board and has received lecture fees from Astrazeneca, Bayer, Daiichi-Sankyo, Pfizer and Boeringher, and institutional research grants from Mayor Companies operating in the field of Interventional Cardiology. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Fig. 1. Kaplan-Meier failure curves for the primary endpoint of death, myocardial infarction (MI), or cerebrovascular accident (CVA), and death, MI, CVA and target vessel revascularization in EXCEL candidates and non-EXCEL candidates in the DELTA-2 PCI cohort MI = myocardial infarction; CVA = cerebrovascular accident; TVR = target vessel revascularization; ST = stent thrombosis.

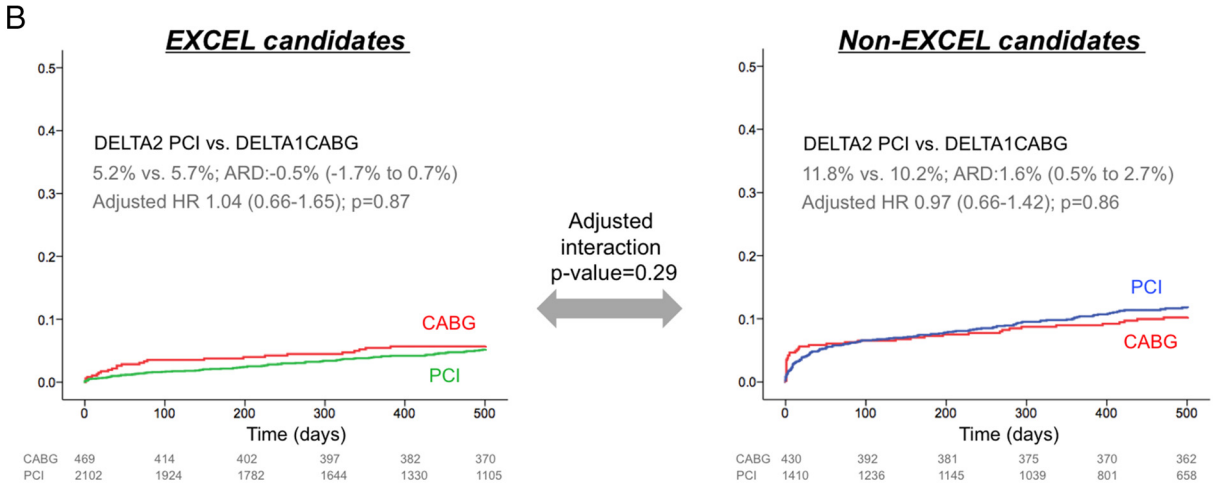
Death, MI, CVA

A



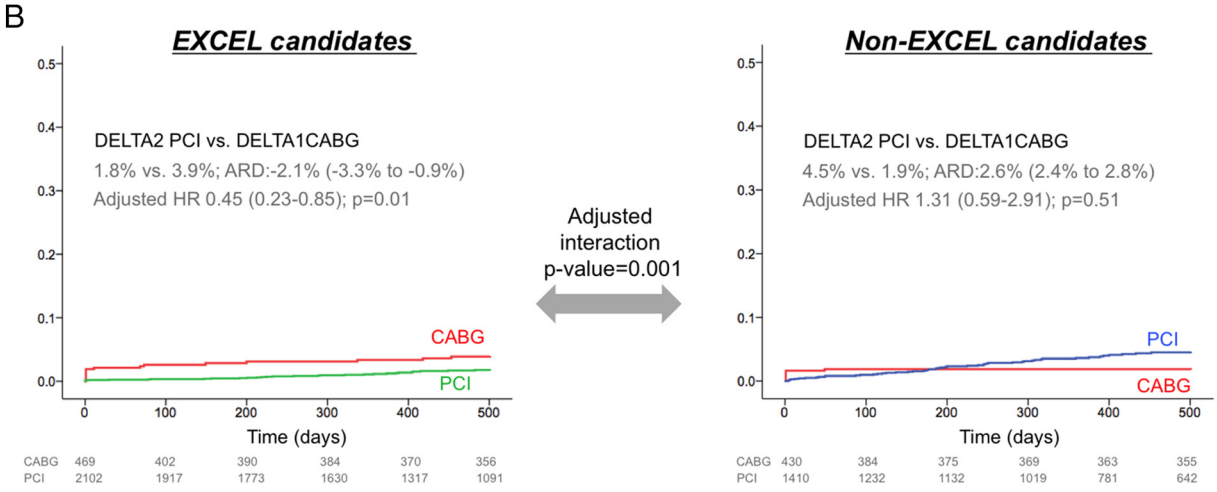
Death

B



MI

B



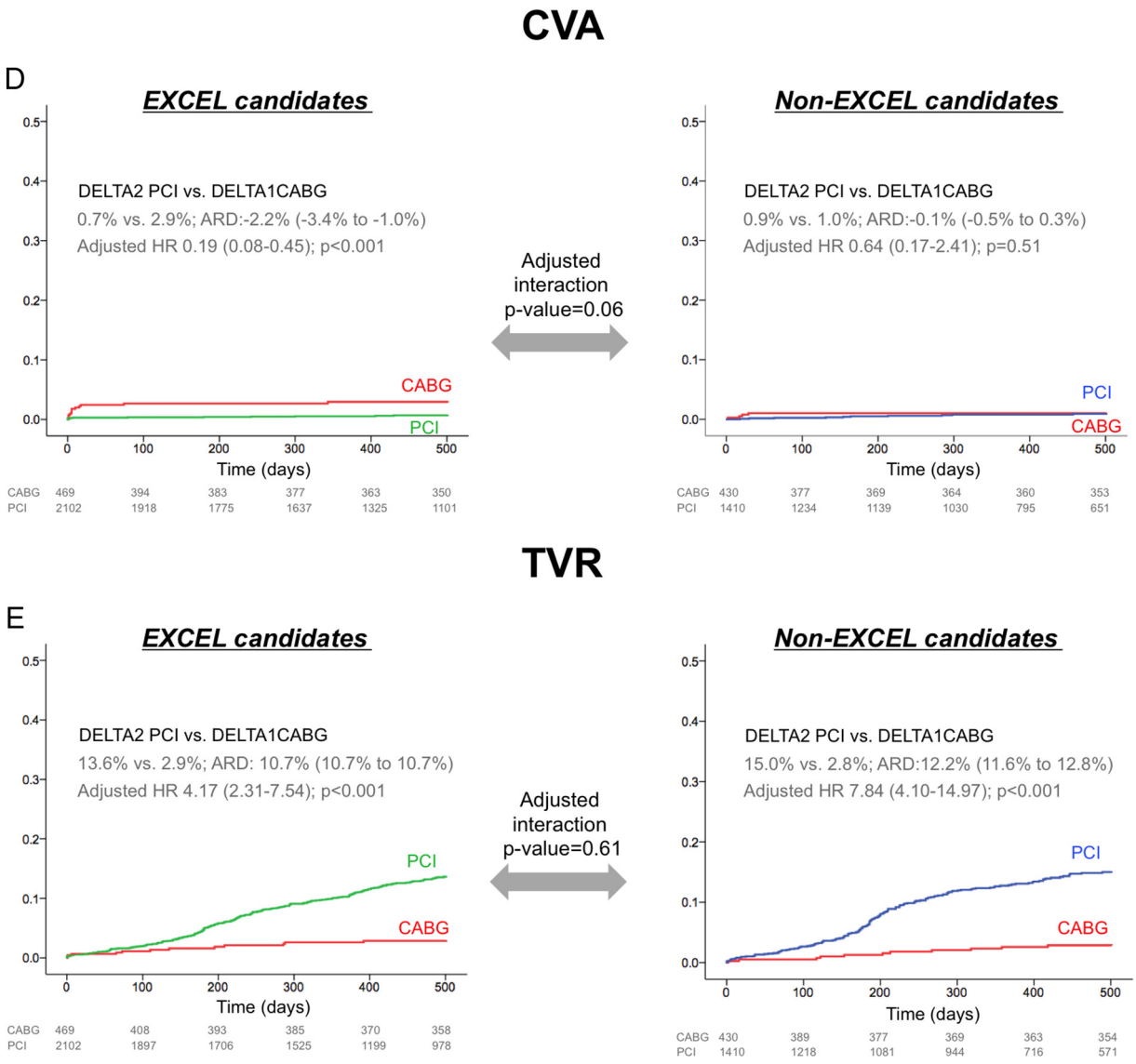


Fig. 2. Kaplan-Meier failure curves for the primary endpoint of death, myocardial infarction (MI), or cerebrovascular accident (CVA), and death, MI, CVA or target vessel revascularization in DELTA-2 PCI and DELTA-1 CABG cohorts among EXCEL candidates and non-EXCEL candidates.

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