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Procedural and longer-term outcomes of wire- versus device-based antegrade dissection and re-entry techniques for the percutaneous revascularization of coronary chronic total occlusions☆

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ABSTRACT

Background: There are few data regarding the procedural and follow-up outcomes of different antegrade dissection/re-entry (ADR) techniques for chronic total occlusion (CTO) percutaneous coronary intervention (PCI).
Methods: We compiled a multicenter registry of consecutive patients undergoing ADR-based CTO PCI at four high-volume specialized institutions. Patients were divided according to the specific ADR technique used: subintimal tracking and re-entry (STAR), limited antegrade subintimal tracking (LAST), or device-based with the CrossBoss/Stingray system (Boston Scientific, Marlborough, MA). Major adverse cardiac events (MACE: cardiac death, target-vessel myocardial infarction and target-vessel revascularization) on follow-up were the main outcome of this study. Independent predictors of MACE were sought with Cox regression analysis.
Results: A total of 223 patients were included (STAR $n = 39$, LAST $n = 68$, CrossBoss/Stingray $n = 116$). Baseline characteristics were similar across groups. Technical and procedural success was lower with STAR (59% and 59%), as compared with LAST (96% and 96%) and CrossBoss/Stingray (89% and 87%; $p < 0.001$ for both). At 24-month follow-up, MACE rates were higher in STAR (15.4%) and LAST (17.5%), as compared with device-based ADR with CrossBoss/Stingray (4.3%, $p = 0.02$), driven by TVR (7.7% vs. 15.5% vs. 3.1%, respectively; $p = 0.02$). Multivariable Cox regression analysis identified wire-based ADR (STAR and LAST) and total stent length as independent predictors of MACE.
Conclusions: In this multicenter cohort of patients undergoing CTO PCI with ADR techniques, STAR had lower success rates, as compared with the CrossBoss/Stingray system and LAST. The CrossBoss/Stingray system was independently associated with lower risk of MACE on follow-up, as compared with wire-based ADR techniques.

1. Introduction

The development and widespread adoption of dissection/re-entry (DR) techniques have promoted a marked increase in success rates of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) [1]. Such techniques allow crossing of long and anatomically-complex occlusions. In particular, antegrade DR (ADR) is the preferred initial crossing strategy for long occlusions, with an unambiguous proximal cap and good-quality distal vessel [2].

Few studies specifically focused on ADR for CTO PCI, reporting similar outcomes as compared with antegrade wire escalation and the retrograde approach [3,4]. However, no comparison of the procedural and follow-up outcomes has been made according to the specific ADR technique used. The aim of the present study is to answer this important clinical question.

2. Methods

2.1. Patient population

This multicenter registry included all consecutive patients who underwent ADR-based CTO PCI at four participating hybrid CTO PCI programs (San Raffaele Hospital, Milan, Italy; Quebec Heart and Lung Institute, Quebec City, QC, Canada; VA North Texas

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Healthcare System, Dallas, TX, USA; Reina Sofia Hospital, Cordoba, Spain) between January 2010 and May 2016. Analyses were performed according to the specific ADR crossing strategy used (see next section). All procedures were indicated according to the presence of symptoms of angina, ischemia or both, and were performed electively after careful planning [1]. Baseline, procedural and hospitalization data were recorded. Follow-up was performed with phone calls, review of hospital records or outpatient visits. Informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in a priori approval by the institution's human research committee.

2.2. Definitions

CTO was defined as a 100% stenosis with antegrade Thrombolysis In Myocardial Infarction (TIMI) 0 flow for at least 3 months [5]. The J-CTO score [6] and the PROGRESS-CTO score [7] were calculated for all lesions.

ADR techniques included both wire- and device-based approaches. Wire-based techniques were: 1) subintimal tracking and re-entry (STAR) [8] (including mini-STAR [9] and contrast-guided STAR [10]); and 2) limited antegrade subintimal tracking (LAST) [11]. Device-facilitated techniques were represented by the use of the CrossBoss/Stingray system (Boston Scientific, Marlborough, MA).

DR success was defined as CTO crossing through a subadventitial plane followed by re-entry into the true lumen. Technical success was defined as an antegrade TIMI 3 flow in the CTO target vessel with a residual stenosis <30% [5]. Procedural success was defined as technical success in the absence of in-hospital adverse events (all-cause death, Q-wave myocardial infarction [MI], stroke, recurrent angina requiring target-vessel revascularization [TVR] with PCI or coronary artery bypass graft, tamponade requiring pericardiocentesis or surgery) [5].

Major adverse cardiac events (MACE) on follow-up were defined as the composite of cardiac death, target-vessel MI (Q-wave and non-Q-wave) and ischemia-driven TVR.

2.3. Statistical analysis

Continuous variables are presented as mean ± standard deviation and ANOVA was used for comparisons. Categorical variables are presented as frequency (percentages), and compared using chi-square test.

Procedural outcomes were assessed in all patients undergoing ADR-based CTO PCI during the study period. To avoid confounding in the assessment of outcomes on follow-up, these were assessed only in subjects who underwent successful CTO recanalization, since it is known that patients with unsuccessful revascularization suffer a higher incidence of adverse events [12,13]. Kaplan-Meier curves of survival free from MACE according to the specific ADR technique used were plotted and compared using the log-rank test.

Multivariable Cox regression analysis with backwards-stepwise selection method (p-entry = 0.05, p-exit = 0.05) was used to identify independent predictors of MACE during follow-up. Candidate variables were selected among those showing a $p < 0.10$ in univariate analyses, as well as based on clinical judgment. The results of such analysis are presented as hazard ratios (HR) and 95% confidence intervals (CI).

For all tests, a $p < 0.05$ was considered significant. Statistical analysis was performed using SPSS 24 (IBM Corp., Armonk, NY).

3. Results

3.1. Clinical and angiographic characteristics

A total of 1160 patients underwent CTO PCI at the four participating centers during the study period. Of those, 223 patients (19.2%) were treated with ADR techniques: $n = 116$ (52.0%) with the CrossBoss/Stingray system, $n = 39$ (17.5%) with STAR and $n = 68$ (30.5%) with LAST. Baseline characteristics were balanced across groups (Table 1). In particular, demographics, prevalence of diabetes, and left ventricular and renal function were similar across groups. CrossBoss/Stingray patients had a higher prevalence of dyslipidemia, as compared with the other two groups (95%; $p < 0.001$). The LAST group had a lower proportion of hypertensive patients (66%; $p = 0.03$). Although the most prevalent indication of CTO PCI was angina in all groups (50–77%), silent ischemia was observed more frequently in STAR patients (32%), and acute coronary syndrome in the LAST group (22%; $p = 0.005$).

3.2. Angiographic and procedural characteristics

Angiographic and procedural data are presented in Table 2. LAST patients had the highest burden of coronary artery disease, as compared with CrossBoss/Stingray and STAR (2.0 ± 0.8 vs. 1.8 ± 0.8 vs. 1.6 ± 0.8 diseased vessels, respectively; $p = 0.05$). The right coronary artery (RCA) was the most frequently treated vessel in CrossBoss/Stingray and STAR groups, while in LAST patients the proportions of RCA and circumflex CTO PCI were similar. CrossBoss/Stingray patients had the highest occlusion complexity, as assessed with the J-CTO score, compared with STAR and LAST (2.5 ± 1.2 vs. 2.0 ± 1.2 vs. 2.1 ± 1.2, respectively; $p = 0.03$). Drug-eluting stents were the most frequently implanted stents in all groups; bioresorbable scaffolds were implanted in 16% of LAST cases ($p < 0.001$). Total stent length was highest in the CrossBoss/Stingray group and lowest in STAR ($p = 0.04$). Fluoroscopy and total procedural time were shorter in STAR, as compared with the other groups. There were no differences in the incidence of procedural complications (five perforations with need for intervention and one stroke). However, DR ($p = 0.002$), technical ($p < 0.001$) and procedural ($p < 0.001$) success rates were lower in STAR (77%, 59% and 59%), as compared with CrossBoss/Stingray (94%, 89% and 87%) and LAST (96%, 96% and 96%).

3.3. Clinical outcomes on follow-up

Median follow-up was 388 (interquartile range 234–613) days. Fig. 1 shows clinical outcomes at 24-month follow-up. MACE rates were higher in STAR (15.4%) and LAST (17.5%), as compared with CrossBoss/Stingray (4.3%; $p = 0.02$), driven by TVR (7.7% vs. 15.5% vs. 3.1%, respectively; $p = 0.02$). Accordingly, MACE rates were higher in wire-based ADR techniques as a whole, when compared with CrossBoss/Stingray (16.9% vs. 4.3%, $p = 0.006$), driven by higher TVR (13.1% vs. 3.1%, $p = 0.01$).

Kaplan-Meier curves also indicated that CrossBoss/Stingray was associated with significantly lower risk of MACE, when compared with STAR and LAST (analyzed both separately [$p = 0.03$] or together [$p = 0.02$; Fig. 2]).

3.4. Independent predictors of MACE

Supplementary Tables 1 and 2 show the multivariable analysis for the prediction of MACE. After adjustment with several models, only total stent length (HR ≥ 1.16 for each 10-mm increment, $p \leq 0.004$ for all) and crossing technique remained associated with MACE. In particular, both STAR (HR ≥ 5.31, $p \leq 0.05$ for all) and LAST (HR ≥ 7.76, $p \leq 0.003$ for all) were independent predictors of MACE, as compared with the CrossBoss/Stingray system. When wire-based DR techniques were analyzed together, similar results were obtained.

4. Discussion

The main findings of our study are: 1) in the setting of CTO PCI treated with ADR techniques, STAR has lower success rates, as compared with CrossBoss/Stingray and LAST; and 2) a device-based approach to ADR (CrossBoss/Stingray system) is independently associated with lower risk of MACE on follow-up, as compared with wire-based techniques (STAR and LAST).

Introduced in 2005 by Colombo et al., STAR was the first ADR technique [8]. In STAR, a subadventitial cleavage plane is created by advancing a knuckled polymer-jacketed guidewire to allow a blunt dissection between the anatomical planes of the vessel, with the aim to achieve re-entry into the distal true lumen. It represented a remarkable advance in the field of CTO PCI since it allowed the recanalization of long, tortuous and ambiguous occlusions, which had a low likelihood of success using a conventional wire escalation approach. In contrast-guided STAR [14], contrast injection delineates the vessel contour and also sometimes creates a fenestration towards the true lumen, thus facilitating re-entry. Mini-STAR [9] takes advantage of the higher maneuverability of the Fielder wire family (Asahi Intecc, Nagoya, Japan) to facilitate earlier and easier re-entry. However, both the original STAR technique and its successive iterations showed high rates of restenosis (25–54%) on follow-up [8,9,14]. This can be explained with the poor

Table 1
Baseline clinical characteristics.

Variable	Overall population ($n = 223$)	CrossBoss/Stingray ($n = 116$)	STAR ($n = 39$)	LAST ($n = 68$)	p-value
Age (years)	66.3 ± 10.1	66.2 ± 8.9	65.8 ± 12.7	66.6 ± 10.4	0.92
Male gender	197 (88%)	100 (86%)	34 (87%)	63 (93%)	0.41
Body mass index (kg/m^2)	29.2 ± 5.2	29.1 ± 5.0	29.6 ± 6.6	29.2 ± 4.5	0.87
Diabetes	81 (36%)	44 (38%)	11 (28%)	26 (39%)	0.49
Dyslipidemia	187 (85%)	109 (95%)	26 (67%)	52 (78%)	<0.001
Hypertension	170 (77%)	94 (82%)	32 (82%)	44 (66%)	0.03
Current smoker	54 (26%)	30 (29%)	12 (31%)	12 (18%)	0.25
Prior myocardial infarction	111 (51%)	56 (49%)	19 (50%)	35 (54%)	0.83
Prior PCI	150 (67%)	74 (64%)	27 (69%)	49 (72%)	0.49
Prior coronary artery bypass graft	60 (27%)	31 (27%)	10 (26%)	19 (28%)	0.97
eGFR (ml/min/1.73 m^2)	80.8 ± 26.8	79.5 ± 22.5	77.7 ± 27.1	84.6 ± 32.8	0.35
Left ventricular ejection fraction (%)	52.3 ± 12.3	52.8 ± 13.3	51.8 ± 11.1	51.7 ± 11.5	0.81
Indication of CTO PCI					
Symptoms	144 (67%)	84 (77%)	19 (50%)	41 (60%)	0.005
Silent ischemia	34 (16%)	12 (11%)	12 (32%)	10 (15%)	
Acute coronary syndrome	29 (14%)	8 (7%)	6 (16%)	15 (22%)	
Heart failure	8 (4%)	5 (5%)	1 (3%)	2 (3%)	

Abbreviations: CTO, chronic total occlusion; eGFR, estimated glomerular filtration rate; LAST, limited antegrade subintimal tracking; PCI, percutaneous coronary intervention; STAR, subintimal tracking and re-entry.

distal runoff due to long dissections and loss of side branches [9,15], all resulting in reduced final flow [9,14]. LAST is another wire-based approach to ADR aimed at minimizing vessel disruption, which was introduced when dedicated devices for reentry (i.e., Stingray) were not yet available. In contrast with STAR, where the dissection is also performed with a knuckled guidewire, re-entry is performed with a straight-tip high-tipload wire in a more controlled fashion, with care to preserve most distal branches. However, minimal published data exist on this technique and its outcomes [16], besides its formal description [11].

A device-based approach to ADR, i.e. with the CrossBoss/Stingray system, has the advantage of minimizing vessel trauma during dissection (thanks to the blunt, low-profile tip of the CrossBoss catheter), as well as facilitating geographically precise and predictable successful re-entry (with the Stingray balloon and wire) [17]. In the early U.S. experience [17], successful true lumen distal wire passage with the CrossBoss/Stingray system was achieved in 87% after the initial learning curve, which was better than in historical controls. Similarly, fluoroscopy and procedure times also improved after the introduction of this device.

So far, only one study specifically focused on the long-term outcomes after CrossBoss/Stingray system use compared to other techniques. Mogabgab et al. reported on a single-center cohort including 170 consecutive patients, treated with either ADR using the CrossBoss/Stingray system ($n = 60$) or other strategies ($n = 110$). At a mean

Table 2
Angiographic and procedural data.

Variable	Overall population ($n = 223$)	CrossBoss/Stingray ($n = 116$)	STAR ($n = 39$)	LAST ($n = 68$)	p-Value
Number of diseased vessels	1.8 ± 0.8	1.8 ± 0.8	1.6 ± 0.8	2.0 ± 0.8	0.05
Target-vessel CTO					
Left anterior descending	45 (20%)	24 (21%)	4 (10%)	17 (25%)	0.009
Circumflex	56 (25%)	21 (18%)	10 (26%)	25 (37%)	
Right coronary artery	122 (55%)	71 (61%)	25 (64%)	26 (38%)	
In-stent CTO	24 (11%)	16 (14%)	1 (3%)	7 (10%)	0.15
Blunt stump	106 (48%)	61 (53%)	17 (44%)	28 (41%)	0.28
Moderate or severe calcifications	103 (46%)	55 (47%)	11 (28%)	37 (54%)	0.03
>45° bending	107 (48%)	63 (54%)	15 (38%)	29 (43%)	0.15
Lesion length > 20 mm	133 (60%)	78 (67%)	26 (67%)	29 (43%)	0.004
Retry	52 (23%)	27 (23%)	7 (18%)	18 (26%)	0.60
J-CTO score	2.3 ± 1.2	2.5 ± 1.2	2.0 ± 1.2	2.1 ± 1.2	0.03
Proximal cap ambiguity	83 (38%)	38 (34%)	19 (49%)	26 (39%)	0.24
Absence of interventional collaterals	101 (45%)	57 (49%)	12 (31%)	32 (48%)	0.12
Moderate or severe tortuosity	68 (31%)	39 (34%)	7 (18%)	22 (33%)	0.19
Circumflex CTO	56 (25%)	21 (18%)	10 (26%)	25 (37%)	0.02
PROGRESS-CTO score	1.4 ± 1.1	1.4 ± 1.0	1.2 ± 0.9	1.6 ± 1.2	0.21
Stents					
Drug-eluting stents	179 (94%)	100 (100%)	29 (97%)	50 (82%)	<0.001
Bioresorbable scaffolds	10 (5%)	0	0	10 (16%)	
Bare-metal stents	1 (0.5%)	0	0	1 (2%)	
Balloon angioplasty only	1 (0.5%)	0	1 (3%)	0	
Total stent length (mm)	82.1 ± 47.5	89.7 ± 46.4	68.5 ± 32.1	75.2 ± 53.3	0.04
Contrast volume (ml)	373 ± 143	383 ± 142	350 ± 108	365 ± 170	0.45
Fluoroscopy time (min)	49.6 ± 21.8	50.5 ± 21.6	42.0 ± 18.4	53.0 ± 24.1	0.07
Total procedure time (min)	137 ± 59	149 ± 59	98 ± 55	136 ± 52	<0.001
Procedural complications	6 (2.7%)	3 (2.6%)	2 (5.1%)	1 (1.5%)	0.53
Dissection/re-entry success	204 (91%)	109 (94%)	30 (77%)	65 (96%)	0.002
Technical success	191 (86%)	103 (89%)	23 (59%)	65 (96%)	<0.001
Procedural success	189 (85%)	101 (87%)	23 (59%)	65 (96%)	<0.001

Abbreviations: CTO, chronic total occlusion; LAST, limited antegrade subintimal tracking; STAR, subintimal tracking and re-entry.

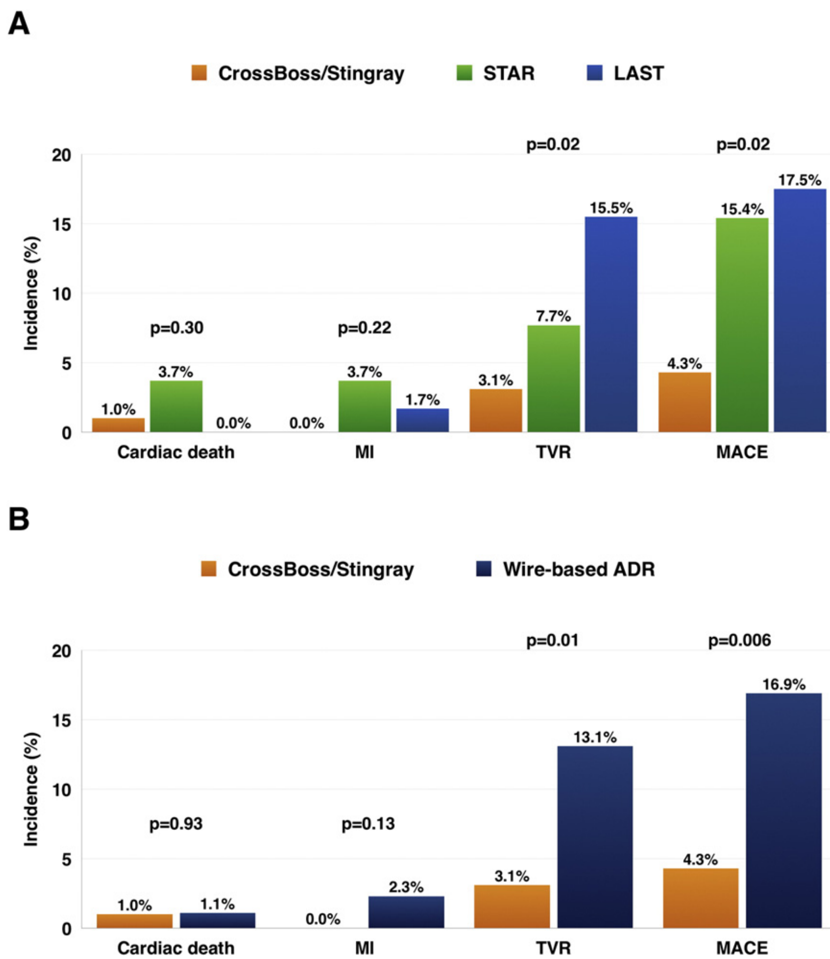


Fig. 1. Rates of cardiac death, myocardial infarction (MI), target-vessel revascularization (TVR) and major adverse cardiac events (MACE) at 24-month follow-up according to the specific antegrade dissection/re-entry (ADR) technique. (A) CrossBoss/Stingray vs. subintimal tracking and re-entry (STAR) vs. limited antegrade subintimal tracking (LAST). (B) CrossBoss/Stingray vs. wire-based ADR (STAR and LAST).

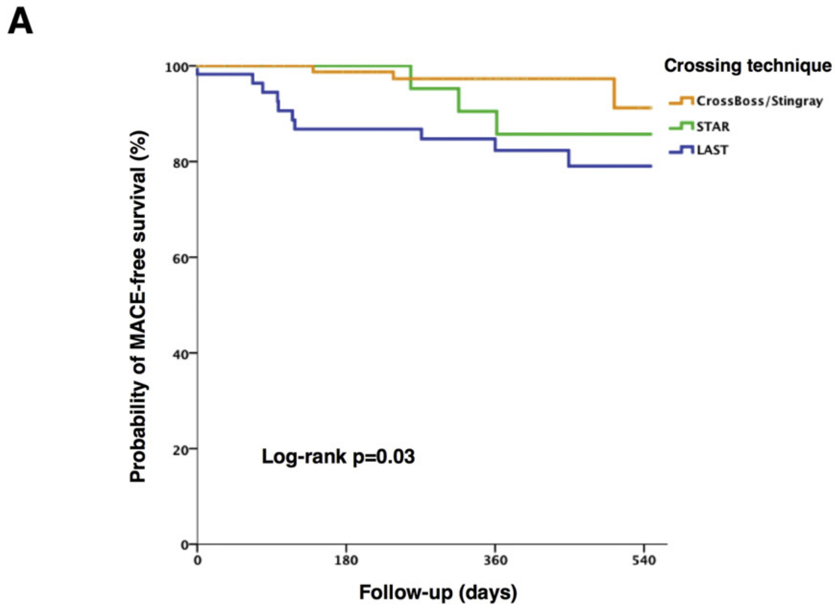
follow-up of 1.81 years, there were no differences in procedural success (75.8% vs 76.2%), complications (4.8% vs 3.2%) and MACE rates on follow-up (40.3% vs 35.2%) between the two groups [4].

Two other studies compared the mid-term outcomes of DR-based (both antegrade and retrograde) recanalization versus a true-to-true approach. In a single-center study by Rinfret et al. [16], 187 consecutive patients underwent successful CTO PCI and were followed-up for a median of 398 days. There were no differences in MACE rates between DR techniques and a wire escalation strategy (15.1% vs. 7.3%, $p = 0.17$). Multivariable analysis confirmed that DR techniques had no significant impact on outcomes. In a similar single-center experience including 173 patients, Amsavelu et al. [18] reported that the 12-month incidence of death, MI, and the composite of acute coronary syndrome/target-lesion revascularization/TVR was 2.5%, 4.9%, and 24.4%, respectively, and was similar regardless of the crossing strategy used. Multivariable analysis indicated that DR techniques were not associated with clinical outcomes on follow-up. However, none of these studies specifically addressed the comparison between the different types of ADR techniques.

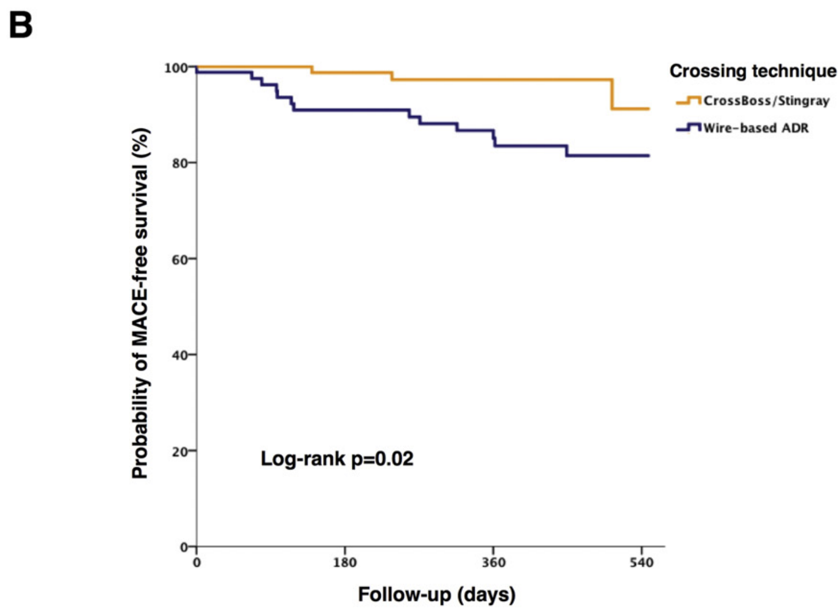
The present report is the first published experience comparing STAR, LAST and CrossBoss/Stingray for ADR. We found that STAR is associated with lower success rates, despite lower angiographic complexity in the treated lesions, as compared with the other two techniques. This can be explained by two factors. The first challenge encountered with this technique is the difficulty in achieving successful lesion crossing and re-entry into the distal true lumen. Indeed, DR success rate with STAR (77%) was lower than with LAST (96%) and CrossBoss/Stingray (94%, $p = 0.002$; Table 2). Secondly, even in cases where lesion crossing and re-entry is successful, STAR-based recanalization has been associated with suboptimal runoff in the distal bed (i.e., TIMI flow < 3), secondary to extensive dissection and loss of side branches. In accordance with this explanation, in our series technical success rates further decreased with STAR (59%), as compared with LAST (96%) and CrossBoss/Stingray (89%, $p < 0.001$). Furthermore, we found that both wire-based ADR techniques were associated with higher adjusted risk of MACE on follow-up, which can be explained with the more aggressive manipulation of the subadventitial space and more distal re-entry, as compared with the CrossBoss/Stingray system. Total stent length was also identified as an independent predictor of MACE, as previously reported [14].

Consequently, our data indicate that STAR should not be used as first-line strategy in CTO recanalization, since it is associated with lower success rates, compared with other ADR techniques, and worse MACE rate on follow-up, in comparison with CrossBoss/Stingray. Albeit LAST compared favorably with the CrossBoss/Stingray system, as far as success rates are concerned, mid-term follow-up indicated an increase in the risk of adverse events, likely due to the fact that precise re-entry is sometimes much more difficult to achieve with this technique rather than with the Stingray system. The worse outcomes seen with wire-based ADR are likely explained with the more pronounced disruption of the subadventitial space, and proved to be independent of total stent length in our cohort. Our data thus provides evidence supporting the use of the CrossBoss/Stingray system as first-line strategy for ADR in CTO PCI.

However, wire-based ADR techniques still represent a valuable asset in the interventionalist's toolbox, which should be considered as a last



Patients at risk	Baseline	6 months	12 months	18 months
CrossBoss/ Stingray	102	73	47	12
STAR	28	21	19	15
LAST	61	45	34	21



Patients at risk	Baseline	6 months	12 months	18 months
CrossBoss/ Stingray	102	73	47	12
Wire-based ADR	89	66	53	36

Fig. 2. Kaplan-Meier curves of survival free from major adverse cardiac events (MACE) according to (A) CrossBoss/Stingray vs. subintimal tracking and re-entry (STAR) vs. limited antegrade subintimal tracking (LAST), and (B) CrossBoss/Stingray vs. wire-based antegrade dissection/re-entry (ADR) techniques.

resort when other techniques (wire escalation and the retrograde approach) have failed or when the CrossBoss/Stingray system is not available. In such setting, the benefit of being able to recanalize the occlusion may still outweigh the increased risk of MACE (largely driven by TVR) on follow-up. Additionally, STAR has also been shown to be a useful bailout approach in case of iatrogenic occlusive coronary dissections in non-CTO PCI [19], highlighting the importance of mastering this historical technique.

Our study has several limitations. First, it is an observational study, with all the inherent bias ascribed to this kind of design. However, no randomized data are available on this topic. Second, central adjudication of clinical outcomes and core laboratory analyses were not performed.

Third, the relatively small sample size might have represented a source for type II error for the detection of differences for certain variables. However, our sample size still allowed us to detect statistically-significant differences in clinical outcomes. Finally, even though this is a multicenter registry with several operators involved, our findings might not be generalizable to other institutions that do not have interventionalists experienced with ADR techniques.

5. Conclusions

In this multicenter cohort of patients undergoing CTO PCI with ADR techniques, STAR had lower success rates, as compared with the CrossBoss/Stingray system and LAST. The CrossBoss/Stingray system was independently associated with lower risk of MACE on follow-up, compared with wire-based ADR techniques (LAST and STAR). Future techniques and devices for ADR-based CTO recanalization shall be compared against the benchmark represented by the CrossBoss/Stingray system.

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None.

Conflict of interest

Dr. Brilakis received consulting/speaker honoraria from Abbott Vascular, Asahi, Cardinal Health, Elsevier, GE Healthcare, and St Jude Medical as well as research support from InfraRedx and Boston Scientific; spouse is an employee of Medtronic. Dr. Rinfret received consulting fees from Boston Scientific. The other authors have no disclosures.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ijcard.2016.11.273.

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