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CORONARY

Randomized Comparison of a CrossBoss First Versus Standard Wire Escalation Strategy for Crossing Coronary Chronic Total Occlusions

The CrossBoss First Trial

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ABSTRACT

OBJECTIVES The authors performed a multicenter, randomized-controlled, clinical trial comparing upfront use of the CrossBoss catheter versus antegrade wire escalation for antegrade crossing of coronary chronic total occlusions.

BACKGROUND There is equipoise about the optimal initial strategy for crossing coronary chronic total occlusions.

METHODS The primary endpoints were the time required to cross the chronic total occlusion or abort the procedure and the frequency of procedural major adverse cardiovascular events. The secondary endpoints were technical and procedural success, total procedure time, fluoroscopy time required to cross and total fluoroscopy time, total air kerma radiation dose, total contrast volume, and equipment use.

RESULTS Between 2015 and 2017, 246 patients were randomized to the CrossBoss catheter (n = 122) or wire escalation (n = 124) at 11 U.S. centers. The baseline clinical and angiographic characteristics of the study groups were similar. Technical and procedural success were 87.8% and 84.1%, respectively, and were similar in the 2 groups. Crossing time was similar: 56 min (interquartile range: 33 to 93 min) in the CrossBoss group and 66 min (interquartile range: 36 to 105 min) in the wire escalation group (p = 0.323), as was as the incidence of procedural major adverse cardiovascular events (3.28% vs. 4.03%; p = 1.000). There were no significant differences in the secondary study endpoints.

CONCLUSIONS As compared with wire escalation, upfront use of the CrossBoss catheter for antegrade crossing of coronary chronic total occlusions was associated with similar crossing time, similar success and complication rates, and similar equipment use and cost. (J Am Coll Cardiol Intv 2018;11:225–33) © 2018 the American College of Cardiology Foundation. Published by Elsevier. All rights reserved.

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ABBREVIATIONS AND ACRONYMS

CTO = chronic total occlusion

IQR = interquartile range

MACE = major adverse cardiovascular event(s)

PCI = percutaneous coronary intervention

Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) has been rapidly evolving with improvement in equipment and techniques, resulting in high success (approximately 85% to 90%) and acceptable complication (approximately 3%) rates at experienced centers (1–4). Crossing the occlusion with a guidewire is often the most challenging part of the procedure and can be accomplished using 3 main strategies: antegrade wire escalation, antegrade dissection or re-entry, and the retrograde approach. Antegrade dissection or re-entry can be achieved using guidewires or using a dedicated system, the CrossBoss catheter and the Stingray re-entry balloon and guidewire (Boston Scientific, Natick, Massachusetts) (5,6). The 1-mm blunt tip of the CrossBoss catheter, combined with its torquability using the "fast-spin" technique, allows for efficient crossing through occlusions, with true-to-true lumen crossing achieved in approximately one-third of cases (5). Use of the CrossBoss catheter limits the size of the dissection and the likelihood of false lumen hematoma formation, which can facilitate wire re-entry by limiting compression of the distal true lumen (7,8).

SEE PAGE 234

There is equipoise about the optimal initial crossing strategy during CTO PCI. The hybrid algorithm recommends antegrade dissection or re-entry as the initial crossing strategy for lesions ≥20 mm in length with a clearly defined proximal cap and large size distal vessel because subintimal guidewire entry is common when attempting to cross long lesions with guidewires (9). Conversely, the Asia Pacific CTO algorithm (http://apcto.club/apcto-algorithm/) favors use of parallel wiring and intravascular ultrasound-guided crossing. To provide further insight into crossing strategies during CTO PCI, we performed a randomized controlled trial (NCT02510547), to compare the speed, safety, and efficacy of initial use of the CrossBoss catheter versus antegrade wire escalation in antegrade crossing of coronary CTOs.

METHODS

TRIAL DESIGN AND OVERSIGHT. The CrossBoss First trial was a multicenter, randomized trial conducted at 11 centers. The trial was funded by Boston Scientific. All authors vouch for the accuracy and completeness of the data and the analyses, as well as for the fidelity of this report to the trial protocol. The trial was approved by the institutional review board of each participating site and all patients provided written informed consent. An independent Data Safety Monitoring Board provided additional trial oversight.

PATIENTS. Between September 2015 and July 2017, patients undergoing CTO PCI at 11 participating centers (Online Appendix) were evaluated for enrollment. Eligible patients were those who were at least 18 years of age, willing and able to give informed consent, and scheduled for clinically indicated CTO

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PCI with a planned antegrade crossing approach. Patients were excluded if they had ostial CTO lesions (within 5 mm of vessel ostium) or if the operator planned to use a primary retrograde approach for CTO crossing.

RANDOMIZATION AND PCI PROCEDURES. Enrolled patients were randomly assigned in a 1:1 ratio to initially attempt CTO crossing using the CrossBoss catheter or using antegrade wire escalation. Randomization was stratified by the J-CTO (Japan Chronic Total Occlusion) score (10) and by site. Choice of guidewires, microcatheters, and subsequent CTO crossing equipment and techniques was at the discretion of each operator, as was the decision to stop the procedure in case of crossing failure.

DEFINITIONS. Coronary CTOs were defined as coronary lesions with Thrombolysis In Myocardial Infarction flow grade 0 of at least 3-month duration. Estimation of the occlusion duration was based on first onset of anginal symptoms, prior history of myocardial infarction in the target vessel territory, or comparison with a prior angiogram. Calcification was assessed by angiography as mild (spots), moderate (involving ≤50% of the reference lesion diameter), and severe (involving >50% of the reference lesion diameter). Moderate proximal vessel tortuosity was defined as the presence of at least 2 bends >70° or 1 bend >90°, and severe tortuosity as 2 bends >90° or 1 bend >120° in the CTO vessel. The J-CTO score was calculated as described by Morino et al. (10). The PROGRESS-CTO (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention) score was calculated as described by Christopoulos et al. (11).

Technical success was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of TIMI (Thrombolysis In Myocardial Infarction) flow grade 3 antegrade flow. Procedural success was defined as achievement of technical success with no procedural major adverse cardiovascular events (MACE). Procedural MACE included any of the following adverse events before hospital discharge: death, myocardial infarction, urgent repeat target vessel revascularization with either PCI or coronary artery bypass graft surgery, tamponade requiring either pericardiocentesis or surgery, and stroke. Myocardial infarction was defined using the Third Universal Definition of Myocardial Infarction (12).

FOLLOW-UP AND OUTCOMES. Patients were followed until hospital discharge. The study had 2 primary endpoints. The primary efficacy endpoint was to compare the procedure time required to cross the CTO (time between administration of local anesthesia to the skin until successful wire entry into the distal true lumen for antegrade crossing or externalization for retrograde crossing or aborting the procedure) with an initial CrossBoss catheter versus antegrade wire escalation strategy. We hypothesized that upfront use of the CrossBoss catheter would be associated with shorter procedure time required for CTO crossing compared with an antegrade wire escalation strategy. The primary safety endpoint was to compare the frequency of procedural MACE with upfront use of the CrossBoss catheter versus a guidewire escalation strategy. We hypothesized that upfront use of the CrossBoss catheter would be associated with similar incidence of MACE compared with an antegrade wire escalation strategy.

The secondary endpoints were: 1) technical and procedural success; 2) total procedure time (defined as the interval between administration of local anesthesia for obtaining vascular access and removal of the last catheter); 3) fluoroscopy time to cross the CTO and total fluoroscopy time; 4) total air kerma radiation exposure; 5) total contrast volume; and 6) number of wires, microcatheters, balloons, and coronary stents used.

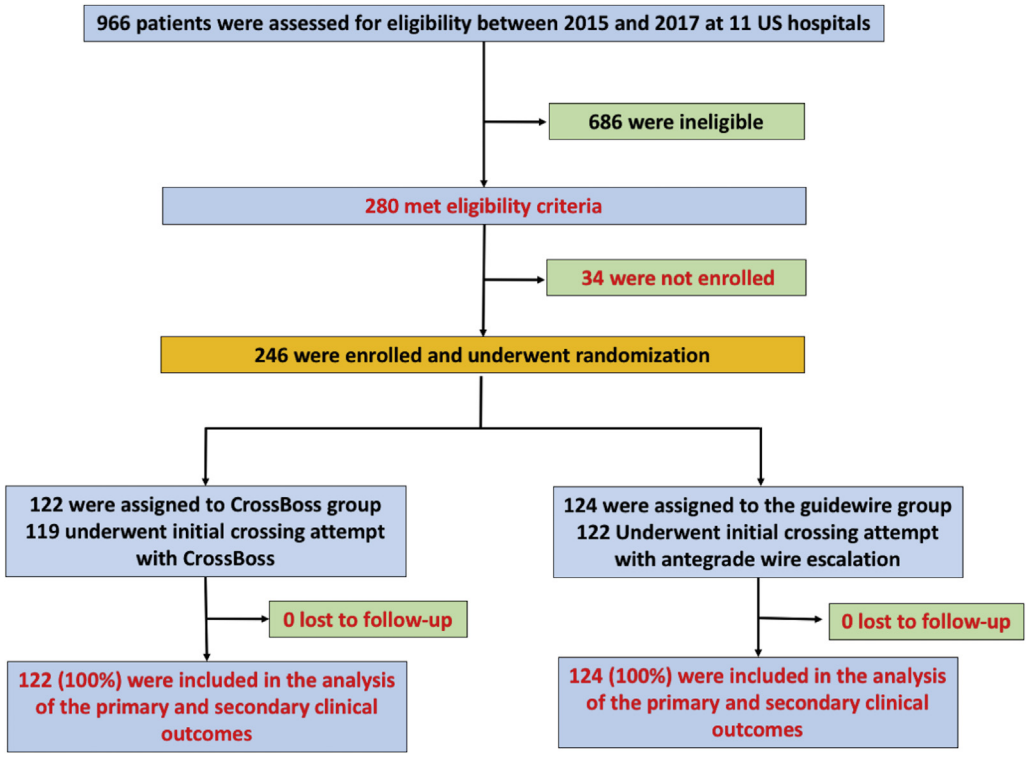
The interventionalists performing CTO PCI were not blinded to the study assignments, but the participants and the outcome assessors (angiographic core laboratory for assessment of the baseline lesion characteristics) were blinded.

STATISTICAL ANALYSIS. We estimated that a total sample size of 246 participants (123 per group) would provide 80% power for detecting the primary efficacy outcome (time required to cross the CTO or abort the procedure), assuming it would be 66.0 ± 55 min in the antegrade wire escalation group (13) and 46.2 ± 55 min in the CrossBoss group (30% relative reduction) with 2-sided alpha of 0.05. The study was not formally powered for any hypothesis concerning the primary safety outcome.

The analyses for all outcomes were done according to the intention-to-treat principle. The primary efficacy analysis was the comparison of time to cross the CTO with a wire between the CrossBoss group and the antegrade wire escalation group, and was performed using the Wilcoxon rank sum test. The primary safety analysis was the comparison of procedural MACE between the 2 study groups and was performed using the Fisher exact test.

Continuous variables were presented as mean ± SD or median (interquartile range [IQR]) and were compared using the *t* test or Wilcoxon rank sum test, as appropriate. The standardized mean difference (Cohen's *d*) was calculated for the primary efficacy endpoint (14). Categorical data were reported as

FIGURE 1 Enrollment, Randomization, and Follow-Up



Flowchart representing enrollment, randomization, and follow-up of the study patients.

frequencies or percentages and compared using the Fisher exact test. All statistical analyses were performed with JMP version 11.0 (SAS Institute, Cary, North Carolina). Two-sided p values <0.05 were considered statistically significant.

RESULTS

PATIENTS AND CTO TARGET LESIONS. Between September 2015 and July 2017, 966 patients undergoing CTO PCI at the 11 participating centers were screened, of whom 280 were consented and 246 fulfilled the inclusion or exclusion criteria and were randomized to CrossBoss catheter (n = 122) or antegrade wire escalation (n = 124) (Figure 1). Mean patient age was 65.5 ± 10 years, 82% of them were men, 37% had diabetes mellitus, and 26% had prior coronary artery bypass graft surgery. The clinical and angiographic characteristics of the 2 study groups were well balanced (Tables 1 and 2).

Approximately two-thirds of target CTO lesions were located in the right coronary artery (Table 2). The target lesions were often complex: moderate or severe calcification was present in 44% and moderate or severe proximal vessel tortuosity in 24%. Mean J-CTO and PROGRESS-CTO scores were 2.07 ± 1.61 and 0.93 ± 0.95, respectively.

CTO CROSSING TECHNIQUES AND OUTCOMES. The procedural techniques and outcomes of the study patients and lesions are summarized in Table 3. Antegrade wire escalation was the initial crossing strategy in 98% of the wire escalation group (in 1 case a primary retrograde approach was used and in another case a primary antegrade dissection/re-entry strategy was used), but also in 22% of the CrossBoss group (wire escalation was done through the CrossBoss catheter in 25 cases; another case was performed via primary retrograde approach, another case with proximal cap ambiguity was crossed with the scratch and go technique, and in another case an antegrade wire escalation via microcatheter was performed). Technical and procedural success were 87.8% and 84.1%, respectively, and were similar in the 2 groups. The initial crossing strategy was successful in 114 (46%) patients, 6 (2%) patients had no further crossing attempt, and additional crossing strategies were attempted in 126 patients. The most common

final successful crossing strategy was antegrade dissection or re-entry in the CrossBoss group (50%) and antegrade wire escalation in the antegrade wire group (51%). Antegrade re-entry was attempted in 43 patients from the CrossBoss group and 38 patients from the guidewire group (using the Stingray system in 95% of the attempts) and was successful in 28 and 23 patients, respectively. The Stingray system was the most common successful re-entry strategy (n = 45 [88%]), followed by subintimal tracking and re-entry (STAR technique, n = 4 [8%]), limited antegrade subintimal tracking (n = 1, 2%), and contrast-guided STAR (n = 1 [2%]). Use of the retrograde approach was similar in the 2 groups. Use of the CrossBoss catheter was successful in true lumen crossing in 24.6% of the cases.

The primary efficacy endpoint (time to cross the CTO or abort the procedure) was similar in the 2 groups: median 56 min (interquartile range [IQR]: 33 to 93 min) in the CrossBoss group and 66 min (IQR: 36 to 105 min) in the wire escalation group (p = 0.323) (Figure 2). The standardized mean difference (Cohen's *d*) was 0.094. On post hoc subgroup analyses, upfront use of the CrossBoss was associated with shorter crossing time than wire escalation in CTOs due to in-stent restenosis (median 41 [IQR: 23 to 58] vs. 66 [IQR: 32 to 111] min; p = 0.047), but there was no difference in short (<20 mm) or longer (≥20 mm) lesions, lesions with and without proximal cap ambiguity, moderate or severe calcification, and moderate or severe tortuosity. When only cases in which the initial crossing strategy was successful were included in the analysis (n = 114), there was still no difference in crossing time between the CrossBoss group (n = 56; median crossing time 40 min [IQR]: 22 to 56 min) and the wire escalation group (n = 58; median crossing time 36 min [IQR]: 22 to 57 min; p = 0.753).

The primary safety endpoint, the incidence of procedural MACE, was also similar in the CrossBoss and wire escalation groups (3.28% vs. 4.03%; p = 1.000) (Figure 2). There was no significant difference in any of the secondary endpoints, including equipment use and equipment cost (Table 3).

Three patients died. One patient who was randomized to antegrade wire escalation underwent an attempt to treat a right coronary artery CTO that was unsuccessful, followed by an attempt to treat a circumflex lesion, that was heavily calcified. Rotational atherectomy was performed, causing perforation that led to the patient's death the following day. Another patient who was randomized to CrossBoss had a successful PCI of a right coronary artery CTO, but then developed hypotension and despite insertion of an intra-aortic balloon pump, an Impella (Abiomed, Danvers, Massachusetts) and a right-sided Tandem Heart (CardiacAssist Inc., Pittsburgh, Pennsylvania) he could not be resuscitated. A third patient, who was also randomized to CrossBoss, underwent successful PCI of a right coronary artery CTO that was complicated by an Ellis class 2 perforation that was treated with prolonged balloon inflation without causing tamponade or requiring

TABLE 1 Baseline Clinical Characteristics of the Study Patients

	CrossBoss (n = 122)	Guidewire (n = 124)	p Value
Age, yrs	64.7 ± 11.0	66.2 ± 10.0	0.269
Men	104 (85)	96 (79)	0.244
Body mass index, kg/m^2	31.4 ± 7.0	31.2 ± 7.0	0.792
Diabetes mellitus	45 (37)	45 (36)	1.000
Hypertension	106 (87)	109 (89)	0.701
Dyslipidemia	111 (91)	107 (88)	0.534
Smoking (current)	29 (24)	24 (19)	0.440
Left ventricular ejection fraction, %	52.3 ± 10.0	52.1 ± 14.0	0.885
Family history of coronary artery disease	50 (42)	45 (37)	0.510
Congestive heart failure	36 (30)	24 (20)	0.101
Prior myocardial infarction	53 (44)	51 (42)	0.796
Prior coronary artery bypass graft surgery	34 (28)	29 (23)	0.466
Prior cerebrovascular disease	9 (7)	12 (10)	0.649
Prior peripheral arterial disease	15 (12)	17 (14)	0.850
Baseline creatinine, mg/dl	1.0 (0.9–1.2)	1.0 (0.9–1.2)	0.511

Values are mean ± SD, n (%), or median (interquartile range).

TABLE 2 Angiographic Characteristics of the Study Lesions

	CrossBoss (n = 122)	Guidewire (n = 124)	p Value
CTO target vessel			0.735
Right coronary artery	79 (65.0)	79 (64.0)	
Left anterior descending artery	22 (18.0)	25 (20.0)	
Circumflex	21 (17.0)	19 (15.0)	
Other (ramus)	0 (0.0)	1 (0.8)	
Calcification (moderate/severe)	51 (42)	57 (46)	0.523
Proximal vessel tortuosity (moderate/severe)	32 (26)	28 (23)	0.553
Proximal cap ambiguity	19 (16)	19 (15)	1.000
In-stent restenosis	28 (23)	28 (23)	1.000
Bifurcation involvement	48 (39)	36 (29)	0.107
Blunt/no stump	48 (39)	60 (48)	0.125
Good distal landing zone	97 (80)	99 (81)	0.872
Proximal reference vessel diameter, mm	2.6 (2.3–3.1)	2.6 (2.2–2.9)	0.384
Distal reference vessel diameter, mm	1.7 (1.4–2.1)	1.8 (1.4–2.1)	0.998
Occlusion length, mm	23 (12–35)	20 (11–37)	0.799
Prior failure to open CTO	25 (20)	22 (18)	0.629
J-CTO score	2.02 ± 1.10	2.12 ± 1.22	0.511
PROGRESS-CTO score	0.91 ± 0.94	0.95 ± 0.96	0.731

Values are n (%), median (interquartile range), or mean ± SD.

CTO = chronic total occlusion; J-CTO score = Japan Chronic Total Occlusion; PROGRESS-CTO = Prospective Global Registry for the Study of Chronic Total Occlusion Intervention.

TABLE 3 Procedural Outcomes

	CrossBoss (n = 122)	Guidewire (n = 124)	p Value
First crossing strategy			<0.001
Antegrade wire escalation	27 (22)	122 (98)	
Retrograde	1 (1)	1 (1)	
Antegrade dissection/re-entry	94 (77)	1 (1)	
Successful crossing strategy			<0.001
Antegrade wire escalation	29 (24)	63 (51)	
Retrograde	22 (18)	21 (17)	
Antegrade dissection/re-entry	61 (50)	27 (22)	
None	10 (8)	13 (10)	
Technical success	108 (88.5)	108 (87.1)	0.846
Procedural success	104 (85.3)	103 (83.1)	0.728
Mean crossing time, min	74 ± 59	79 ± 59	0.323
Median crossing time, min	56 (33–93)	66 (36–105)	0.323
Total procedural time, min	109 (78–185)	109 (75–161)	0.670
Total fluoroscopy time, min	40 (28–66)	37 (24–65)	0.339
Total AK radiation dose	2.18 (1.23–3.56)	2.34 (1.23–3.91)	0.752
Contrast volume	260 (168–350)	250 (155–329)	0.492
Fluoroscopy time at crossing, min	20 (11–44)	25 (12–48)	0.638
AK radiation dose at crossing, min	0.88 (0.48–1.97)	1.08 (0.33–2.44)	0.644
Procedural MACE	4 (3.28)	5 (4.03)	1.000
Death	2 (1.64)	1 (0.81)	0.620
Acute Q-wave myocardial infarction	1 (0.82)	0 (0.00)	0.496
Acute myocardial infarction	3 (2.46)	1 (0.81)	0.368
Repeat PCI	0 (0.00)	1 (0.81)	1.000
Stroke	0 (0.00)	1 (0.81)	1.000
Emergency coronary artery bypass graft surgery	0 (0.00)	0 (0.00)	
Perforation	1.64 (2)	7.26 (9)	0.060
Pericardiocentesis	0.00 (0)	3.23 (4)	0.122
Side branch loss	9 (19)	6 (17)	1.000
Guidewires used	7.4 ± 6.4	8.1 ± 7.2	0.465
Balloons used	4.5 ± 4.6	3.9 ± 2.8	0.274
Microcatheters used	2.5 ± 1.6	2.2 ± 1.6	0.122
Stents used	2.5 ± 1.1	2.5 ± 1.2	0.761
Overall equipment cost, $	5,500 (3,788–7,275)	5,038 (3,650–6,681)	0.176
Guidewire cost	625 (375–1,281)	750 (500–1,218)	0.405
Balloon cost	450 (150–750)	450 (300–750)	0.523
Microcatheter cost	500 (0–500)	500 (500–1,000)	0.0048
Plaque modification devices cost	293 ± 937	392 ± 1,009	0.425
CrossBoss and Stingray cost	800 (800–1,900)	0 (0–1,100)	<0.0001
Stent cost	1,800 (1,800–2,700)	1,800 (1,800–2,700)	0.845

Values are n (%), mean ± SD, or median (interquartile range).
AK = air kerma; MACE = major adverse cardiovascular event(s); PCI = percutaneous coronary intervention.

pericardiocentesis. The following day the patient developed ST-segment elevation and repeat angiography was planned; however, the patient refused. The patient died 2 days later due to Q-wave myocardial infarction and septic shock.

Four patients, all from the antegrade wire escalation group required pericardiocentesis. One patient died as discussed previously. A second patient underwent right coronary artery CTO PCI and had a septal collateral perforation requiring pericardiocentesis after the procedure. A third patient also underwent right coronary artery CTO and developed a perforation in the distal right coronary artery after stenting, requiring pericardiocentesis. A fourth patient had an Ellis class 3 perforation of the CTO target vessel and required pericardiocentesis after the procedure.

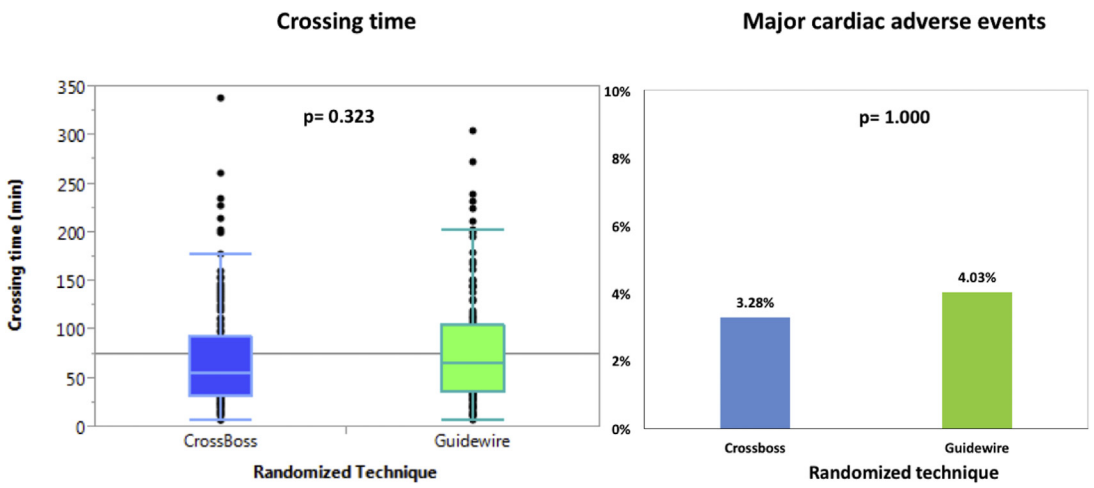
DISCUSSION

Due to a lack of randomized trials, selection of coronary CTO crossing strategies currently relies heavily on personal preferences and expert opinion (9,15). The CrossBoss First trial is the first randomized controlled trial designed to compare 2 commonly used crossing techniques (antegrade dissection or re-entry using the CrossBoss catheter and antegrade wire escalation) as the initial CTO crossing strategy. Upfront use of the CrossBoss catheter demonstrated similar success rates, similar crossing time and equipment use, and similar risk for procedural complications with antegrade wire escalation.

Antegrade wire escalation is the most commonly used CTO strategy and has many advantages, including simplicity and widespread availability (15). Wires with varying tip stiffness and construction are advanced through a microcatheter or over-the-wire balloon aiming to cross the occlusion (16). Wires with differing characteristics are often used, such as increasing tip stiffness to improve the guidewire penetration capacity (at the cost of increased risk for perforation) or decreasing tip stiffness to improve wire maneuverability through areas of tortuosity after crossing the proximal cap (16). Antegrade wire escalation is the final crossing strategy in approximately 50% of cases in various contemporary CTO PCI registries (1–3), although advanced crossing strategies, such as antegrade dissection or re-entry and the retrograde approach are often needed, especially for treating more complex CTOs (17).

Antegrade dissection or re-entry can be performed using guidewires or dedicated equipment, such as the CrossBoss catheter and Stingray balloon and guidewire (18). The CrossBoss catheter facilitates controlled dissection through the subintimal space and the Stingray system facilitates re-entry into the distal true lumen. There is a learning curve for using these devices and techniques but high success rates can be achieved (19). Although the CrossBoss catheter can cause perforation when inadvertently advanced through a small coronary vessel, antegrade dissection or re-entry may be safer than wire escalation, as the guidewire or CrossBoss catheter are more likely to track through the soft subintimal space instead of

FIGURE 2 Primary Endpoints



Time to cross the chronic total occlusion or abort the procedure (primary efficacy endpoint) and incidence of procedural major adverse cardiovascular events (primary safety endpoint).

exiting and causing a perforation. Moreover, antegrade dissection or re-entry has been proposed as an efficient technique that may allow faster CTO recanalization (9).

CrossBoss First found equally high success rates in both study groups, which was anticipated given that experienced centers and CTO operators participated in the study. Higher CTO PCI volume has been associated with higher success with similar (or lower) complication rates in multiple patient cohorts (20,21). In CrossBoss First trial the incidence of procedural MACE was similar in the 2 study groups, suggesting that both strategies are equally safe. The incidence of perforation and pericardiocentesis was numerically lower in the CrossBoss group, which is reassuring for a catheter that is advanced after the guidewire is withdrawn inside the catheter lumen. Increasing stent length is a frequent concern when antegrade dissection or re-entry is used; however, stent use was similar in both groups in our study, suggesting no adverse impact of dissection or re-entry on stent length.

CTO crossing time was similar in the 2 study groups, suggesting that use of the CrossBoss does not improve the efficiency of the procedure. The standardized difference (Cohen's *d*) was 0.094, which according to Cohen's guidelines is suggestive of a small difference (14). It is, however, possible that use of the CrossBoss catheter could improve procedural efficiency when used by operators with less experience at CTO PCI. Use of the CrossBoss catheter was associated with shorter crossing time in CTOs due to in-stent restenosis. Prior studies have suggested high success rates with use of the CrossBoss in restenotic CTOs (22,23), as the stent struts act as a barrier preventing entry of the catheter into the subintimal space, although this has been reported in some cases (24).

STUDY LIMITATIONS. First, procedures were performed by operators who were experienced in CTO PCI, limiting extrapolation of the study results to less experienced centers and operators. Second, in 22% of patients randomized to the CrossBoss group crossing was achieved by advancing a guidewire through the CrossBoss catheter, instead of using the fast spin CrossBoss advancement technique, which was done at the discretion of the operator. Third, in 3 cases of the CrossBoss group and 2 cases of the guidewire group, the initially selected strategy was not used, likely due to repeat angiographic assessment after performance of dual injection that allows better characterization of the CTO's angiographic characteristics. For example, approximately 15% of the target occlusions had proximal cap ambiguity, which is a relative contraindication to antegrade crossing strategies. Fourth, the observed difference in crossing time between the 2 groups was smaller than anticipated (10 min instead of 20 min), which could possibly represent type II error, yet the standardized mean difference suggests that the difference was small. Fifth, the study was not powered to detect differences in the safety endpoint. Sixth, long-term follow-up was not performed as part of the study, however several studies

have shown favorable long-term outcomes with use of limited antegrade dissection or re-entry techniques (25,26).

CONCLUSIONS

As compared with a primary wire escalation strategy, upfront use of the CrossBoss catheter for crossing CTOs was associated with similar crossing time, similar success and procedural MACE rates, and similar equipment use and cost.

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools managed by Veterans Affairs Information Resource Center (27). REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

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PERSPECTIVES

WHAT IS KNOWN? Antegrade wire escalation and the CrossBoss catheter can be used as initial crossing strategy for coronary chronic total occlusions.

WHAT IS NEW? Antegrade wire escalation and upfront use of the CrossBoss catheter for crossing coronary chronic total occlusions had similar success and complication rates, crossing time, equipment use, and cost.

WHAT IS NEXT? New devices and crossing techniques are needed to further improve the success rates and procedural efficiency and reduce the complication rates of coronary chronic total occlusion interventions.

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KEY WORDS antegrade dissection/re-entry, antegrade wire escalation, chronic total occlusion, CrossBoss, percutaneous coronary intervention

APPENDIX For a list of the participating sites, please see the online version of this paper.