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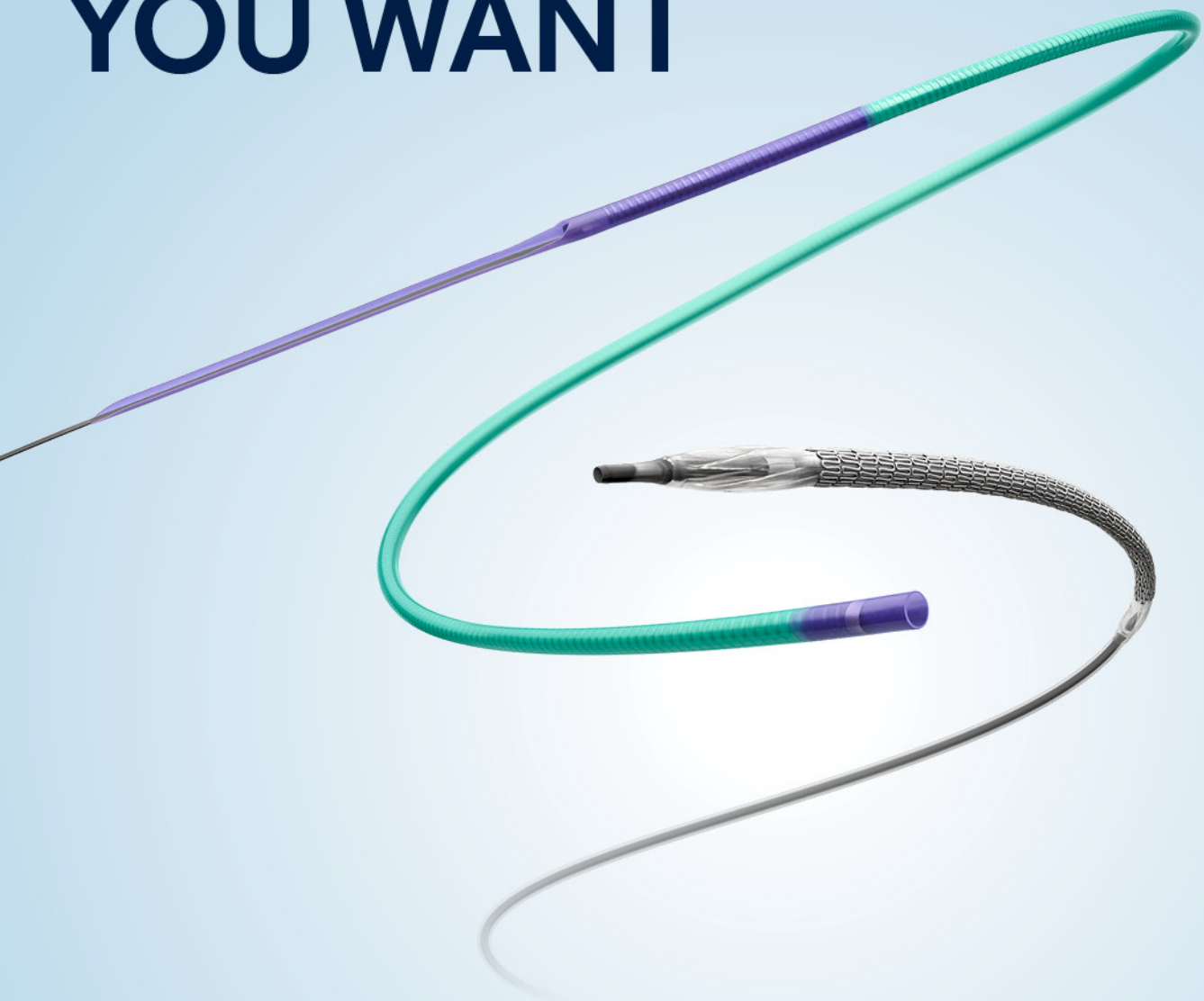

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ORIGINAL STUDIES

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EDITORIAL COMMENT: Expert Article Analysis for:
"PROGRESS is our most important product": Adventures in CTO intervention

Equipment utilization in chronic total occlusion percutaneous coronary interventions: Insights from the PROGRESS-CTO registry

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Abstract

Background: We examined guidewire and microcatheter utilization during chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

Methods: We examined device utilization in 2,968 CTO PCIs performed in 2,936 patients at 19 US and two international center between January 2016 and January 2019.

Results: The median number of antegrade guidewires used per case declined (5 in 2016 vs 3 in 2019) and was higher in higher complexity lesions (2 in J-CTO 0 vs. 8 in

J-CTO 4 or 5 score). In antegrade-only procedures, the most frequently used guidewires were the Pilot 200 (Abbott Vascular, 37%), Fielder XT (Asahi Intecc, 25%) and Gaia third (Asahi Intecc, 18%), while the most commonly used microcatheters were the Turnpike Spiral (Vascular Solutions, 18%) and Turnpike (Vascular Solutions, 16%). Compared with 2012–2015, during 2016–2019 use of novel equipment such as the Gaia guidewires and the Turnpike microcatheters led to decreased use of Confianza Pro 12 (Asahi Intecc) wire and Corsair (Asahi Intecc) family of microcatheters. In retrograde cases, the guidewires most commonly used were the Sion (44%), Pilot 200 (27%) and Fielder FC (26%), while the Corsair/Corsair Pro, Turnpike LP (Vascular Solutions) and Caravel (Asahi Intecc) were the most frequently used microcatheters for collateral crossing (29%, 26% and 22%, respectively).

Conclusions: The most commonly used guidewires during CTO PCI are polymer-jacketed guidewires and the most commonly used microcatheters are torquable microcatheters.

KEYWORDS

chronic total occlusion, guidewire, microcatheter, percutaneous coronary intervention

1 | INTRODUCTION

Percutaneous coronary intervention (PCI) of coronary chronic total occlusions (CTOs) has evolved significantly during recent years, in large part due to developments in crossing techniques and advances in microcatheter and guidewire technology.[1-4] Antegrade wiring remains the most common crossing strategy,[5] although more complex cases are more likely to require antegrade dissection and re-entry and the retrograde approach.[6,7] We analyzed a contemporary multicenter CTO PCI registry to determine guidewire and microcatheter utilization patterns.

2 | METHODS

2.1 | Patient population

We examined the clinical, angiographic and procedural records of 2,936 patients enrolled in the PROGRESS-CTO (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention [NCT02061436]) registry who underwent 2,968 CTO PCIs between 2016 and 2019 at 19 US and two international experienced centers. The study was approved by the institutional review board of each center. Study data were collected and managed using Research Electronic Data Capture (REDCap)[8,9] hosted at the Minneapolis Heart Institute Foundation.

2.2 | Definitions

Coronary CTOs were defined as coronary lesions with thrombolysis in myocardial infarction (TIMI) grade 0 flow of at least 3 months' duration. Estimation of the duration of occlusion was clinical, based on the first onset of angina, history of myocardial infarction (MI) in the target vessel territory, or comparison with a previous angiogram. Calcification was assessed by angiography as mild (spots), moderate (involving 50% of the reference lesion diameter), or severe (involving >50% of the reference lesion diameter). Moderate proximal vessel tortuosity was defined as the presence of at least two bends >70° or one bend >90° and severe tortuosity as two bends >90° or one bend >120° in the CTO vessel. Blunt or no stump was defined as lack of tapering or lack of a funnel shape at the proximal cap. Interventional collaterals were defined as collaterals considered amenable to crossing by a guidewire and a microcatheter by the operator.

A procedure was defined as retrograde if an attempt was made to cross the lesion through interventional collateral or bypass graft supplying the target vessel distal to the lesion.

Technical success was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of TIMI grade 3 antegrade flow. Procedural success was defined as achievement of technical success without any in-hospital complications. In-hospital major adverse cardiac events (MACE) included any of the following adverse events prior to hospital discharge: death, myocardial infarction, recurrent symptoms requiring urgent repeat target vessel revascularization with PCI or coronary artery bypass graft surgery (CABG), tamponade requiring either pericardiocentesis or surgery, and stroke. MI was defined using the Third Universal Definition of Myocardial Infarction (type 4a MI).[10] The Japanese CTO (J-CTO) score was calculated as described by Morino et al.,[11] the PROGRESS CTO score as described by Christopoulos et al.,[12] and the PROGRESS CTO Complications score as described by Danek et al.[13]

2.3 | Statistical analysis

Categorical variables were expressed as percentages. Continuous variables were presented as mean ± standard deviation or median [interquartile range (IQR)]. The Cochran-Armitage test was used to identify trends in novel equipment utilization rates as well as procedural characteristics over time. All statistical analyses were performed with JMP 13.0 (SAS Institute, Cary, NC).

3 | RESULTS

Of the 2,968 CTO PCIs attempted in 2,936 patients and included in the current analysis, antegrade-only crossing was attempted in 2,023 (68%) and the retrograde approach in 935 (32%) CTO PCIs.

3.1 | Clinical characteristics

Mean patient age was 64 ± 10 years, and 82.6% were men, with high prevalence of hypertension, dyslipidemia, diabetes mellitus, current or past smoking, heart failure, peripheral artery disease, prior PCI and prior stroke (Table 1).

3.2 | Angiographic characteristics and outcomes

The median J-CTO score was 2 [1–3] overall, 2 [1–3] for antegrade-only cases and 3 [3, 4] for retrograde cases. The median PROGRESS-CTO score was 1 [1, 2] overall, 1 [0–2] for antegrade-only cases and 1 [1, 2] for retrograde cases. The median PROGRESS complications score was 3 [1–4] overall, 2 [0–3] in antegrade-only cases and 3 [3–6] in retrograde cases. The right coronary artery was the most common target vessel in all three categories (54%, 47%, 66%, respectively), followed by the left anterior descending artery (26%, 30%, 17%) and the circumflex (18%, 20%, 15%).

Median CTO length was 25 mm [15–40] and median vessel diameter was 3 mm [2.5–3]. Proximal cap ambiguity was present in 37% of the target CTOs, moderate/severe calcification in 50% and moderate/severe tortuosity in 33%. Interventional collaterals were present in 57% of the cases.

Technical success was 88% for antegrade-only and 76% for retrograde procedures. Procedural success were 88% and 72%, and in-hospital MACE was 1.1% vs 4.6% ($p < .0001$), respectively. Median procedure time was 110 min [69–166], median fluoroscopy time 44 [26–71] min, median fluoroscopy Air Kerma (AK) dose 2.2 [1.2–3.8] Gray and median contrast volume 230 [165–310] ml.

The demographic and angiographic characteristics of the study patients and lesions as well as the technical and procedural outcomes are presented in Table 1.

3.3 | Antegrade wiring: Guidewire and microcatheter utilization patterns

The median number of guidewires used for antegrade wiring numerically decreased from 5 [2–6] in 2016 to 3 [2–5] ($p = .2$) in 2017 and has remained stable since (Figure 1).

The median number of guidewires used during antegrade wiring increased with lesion complexity from 2 [2–4] for J-CTO score of 0 to 8 [6–12] for J-CTO score of 5. The relationships between the number of guidewires and angiographic characteristics indicating lesion complexity are shown in Table 2.

The most frequently used guidewires were the Pilot 200 (Abbott Vascular, used in 37% of AWE procedures), Fielder XT (Asahi Intecc, 25%) and Gaia third (Asahi Intecc, 18%) (Figure 2). These guidewires remained the most commonly used in various anatomic subgroups (Figure 3). Compared with 2012–2015, use of the Confianza Pro 12 guidewire decreased (28% vs 9%) (Table 3). The use of Gaia third was 17% in 2016 and 18% in 2019 (p for trend = .2). When comparing utilization rates between new centers (added between 2016–2019) and prior centers, use of the Pilot 200 (32% vs 34%, $p = .2$) and Confianza Pro 12 (10% vs 11%, $p = .6$) wires was similar, whereas use of the Fielder XT (25% vs 20%, $p = .006$) and Gaia third (22% vs 11%, $p < .0001$) wires was higher in the new centers. The most frequent final successful antegrade crossing guidewire was the Pilot 200 (16%), Fielder XT (12%) and Fielder XT-A (8%).

The most commonly used microcatheters were the Turnpike Spiral (Vascular Solutions, 18%), Turnpike (Vascular Solutions, 16%) and Corsair/Corsair Pro (Asahi Intecc, 9%) (Figure 2). Use of the Turnpike microcatheters increased whereas use of Corsair decreased over time (Table 3). The use of Turnpike was 18% in 2016 and 16% in 2019 (p for trend = .005). The use of Turnpike Spiral increased from 6% in 2016 in 16% in 2019 (p for trend<.0001). Use of the Turnpike (21% vs 8%, $p < .0001$) and Turnpike Spiral (18% vs 15%, $p = .01$) was higher among new centers, while use of the Corsair/Corsair Pro (5% vs 20%, p < .0001) was higher among existing centers and use of the Finecross (3% vs 4%, $p = .13$) was similar across all centers.

3.4 | Retrograde approach: Equipment utilization patterns

The guidewires most commonly used for retrograde techniques were the Sion (44%) (Asahi Intecc), the Pilot 200 (27%) and the Fielder FC (26%) (Asahi Intecc), as shown in Figure 4. The retrograde guidewire that most often successfully crossed the CTO lesion was the Pilot 200 (24%), Gaia third (16%) and Sion (10%). The most successful guidewires for collateral crossing were the Sion (40%), Fielder FC (9.6%) and Suoh 03 (9.3%) (Asahi Intecc). In retrograde cases with successful microcatheter collateral crossing, the microcatheters that more commonly crossed the collateral were the Corsair/Corsair Pro (29%), Turnpike LP (26%), Caravel (22%) and Turnpike (9%) (Figure 4).

TABLE 1 Clinical, angiographic characteristics and procedural outcomes

	Total	Antegrade approach	Retrograde approach	*p*-value
	N = 2,936	*N* = 2023	*N* = 935	
Clinical characteristics				
Age (years) (mean ± *SD*)	64 ± 10	63.8 ± 9.9	64.2 ± 10.3	.32
Men (%)	82.6 (2060)	82 (1468)	84 (602)	.19
Hypertension (%)	91 (2265)	91 (1622)	91 (651)	.71
Dyslipidemia (%)	85.6 (2129)	83.8 (1492)	90 (645)	<.0001
Current/past smoking (%)	63.2 (1554)	61.1 (1075)	68.7 (487)	.0001
Diabetes mellitus (%)	41 (1015)	40.8 (724)	41.5 (294)	.74
Prior MI (%)	51.3 (1222)	49.4 (836)	56.2 (390)	.004
Prior CABG (%)	30.1 (847)	24.5 (475)	42.7 (378)	<.0001
Prior PCI (%)	63.5 (1790)	59.3 (1155)	72.8 (639)	<.0001
Prior attempt to open CTO (%)	22.7 (656)	19.5 (387)	30 (276)	<.0001
Heart failure (%)	32.2 (780)	32.7 (565)	31.4 (219)	.55
Peripheral arterial disease (%)	11 (267)	11.5 (200)	14.8 (104)	.04
Prior stroke (%)	12.4 (302)	10.7 (187)	11.8 (83)	.45
Angiographic characteristics				
CTO target vessel (%)				
RCA	54 (1510)	47 (903)	66 (607)	<0.0001
LAD	26 (721)	30 (566)	17 (155)	
LCX	18 (521)	20 (385)	15 (136)	
LM	0.7 (19)	0.5 (10)	0.9 (9)	
SVG	0.2 (6)	0.2 (5)	0.1 (1)	
Other	1.6 (47)	2 (37)	1 (10)	
CTO length (mm) median [IQR]	25 [15–40]	24 [15–32]	35 [25–50]	<.0001
Vessel diameter (mm) median [IQR]	3 [2.5–3]	3 [2.5–3]	3 [2.5–3.1]	<.0001
Proximal cap ambiguity (%)	37 (894)	28 (471)	61 (423)	<.0001
Moderate/severe calcification (%)	50 (1346)	42 (748)	67 (598)	<.0001
Moderate/severe tortuosity (%)	33 (882)	25 (447)	49 (435)	<.0001
Interventional collaterals (%)	57 (1354)	46 (784)	81 (570)	<.0001
J-CTO score – median [IQR]	2 [1–3]	2 [1–3]	3 [3–4]	<.0001
PROGRESS CTO score – median [IQR]	1 [1–2]	1 [0–2]	1 [1–2]	<.0001
PROGRESS CTO complications score – median [IQR]	3 [1–4]	2 [0–3]	3 [3–6]	<.0001
Technical and procedural outcomes				
Technical success	85	88	77	<.0001
Procedural success	83	88	72	<.0001
In-hospital MACE	2.2	1.1	4.6	<.0001
Aorto-coronary dissection (%)	0.2 (7)	0.1 (3)	0.4 (4)	.16
Pericardiocentesis (%)	0.8 (24)	0.4 (10)	1.4 (14)	.006

Abbreviations: CABG, coronary artery bypass grafting; CTO, chronic total occlusion; IQR, interquartile range; J-CTO, Japanese multicenter chronic total occlusion registry; LAD, left anterior descending; LCX, left circumflex; LM, left main; MACE, major adverse cardiovascular events.; MI, myocardial infarction; PROGRESS CTO, Prospective Global Registry for the Study of Chronic Total Occlusion Intervention; RCA, right coronary artery; SD, standard deviation; SVG, saphenous vein graft.

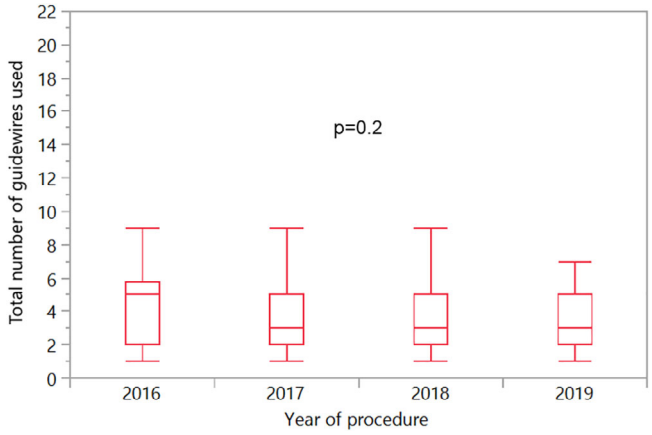

FIGURE 1 Median number of guidewires used for antegrade wiring during each year [Color figure can be viewed at wileyonlinelibrary.com]

4 | DISCUSSION

The main findings of our study are that: (a) higher lesion complexity is associated with the use of more guidewire types; (b) polymer-jacketed guidewires and large torquable microcatheters are most commonly used for antegrade wiring; and (c) torquable wires and smaller microcatheters are most commonly used for retrograde techniques.

As previously described, the antegrade approach remains the most commonly used CTO crossing technique.[3,14-17] Higher lesion complexity (higher J-CTO score, in-stent restenosis, distal cap at bifurcation, proximal cap ambiguity, moderate/severe calcification, moderate/severe tortuosity and blunt/no stamp) were associated with utilization of larger number of guidewires.

Most operators recommend initial antegrade wiring attempts with a soft, tapered-tip, polymer-jacketed guidewire, such as the Fielder XT (Asahi Intecc) or Fighter (Boston Scientific) guidewire.[18] If such wires fail to cross, it is recommended to attempt crossing with a composite core tapered tip guidewire, such as the Gaia family of wires if the course of the vessel is well understood, or with a stiff polymer-

TABLE 2 Number of guidewires used (antegrade-only approach) according to factors describing the angiographic complexity of the CTOs

Variable	Number of guidewires, median [IQR]	*p*-value	Number of microcatheters, median [IQR]	*p*-value
J-CTO score				
0	2 [2,4]	<.0001	0 [0–1]	<.0001
1	3 [2,5]		1 [0–1]	
2	4 [3–6]		1 [1–2]	
3	6 [3–8]		1 [1–2]	
4	8 [5–11]		2 [1–2]	
5	8 [6–12]		2 [1–3]	
In-stent restenosis				
Yes	4 [2–7]	.22	1 [1–2]	.22
No	5 [3–8]		1 [1–2]	
Distal cap at bifurcation				
Yes	5 [3–9]	.0003	1 [0–2]	<.0001
No	4 [2–7]		1 [1–2]	
Proximal cap ambiguity				
Yes	6 [4–9]	<.0001	1 [0–1]	<.0001
No	4 [2–6]		2 1–2]	
Moderate/severe calcification				
Yes	6 [4–9]	<.0001	1 [0–1]	<.0001
No	4 [2–6]		2 [1–2]	
Moderate/severe tortuosity				
Yes	6 [4–9]	<.0001	1 [0–1]	<.0001
No	4 [2–6]		2 [1–2]	
Blunt/no stump				
Yes	6 [4–9]	<.0001	1 [1–2]	<.0001
No	3 [2–5]		1 [0–1]	

Abbreviations: IQR, interquartile range; J-CTO, Japanese Multicenter Chronic Total Occlusion Registry.

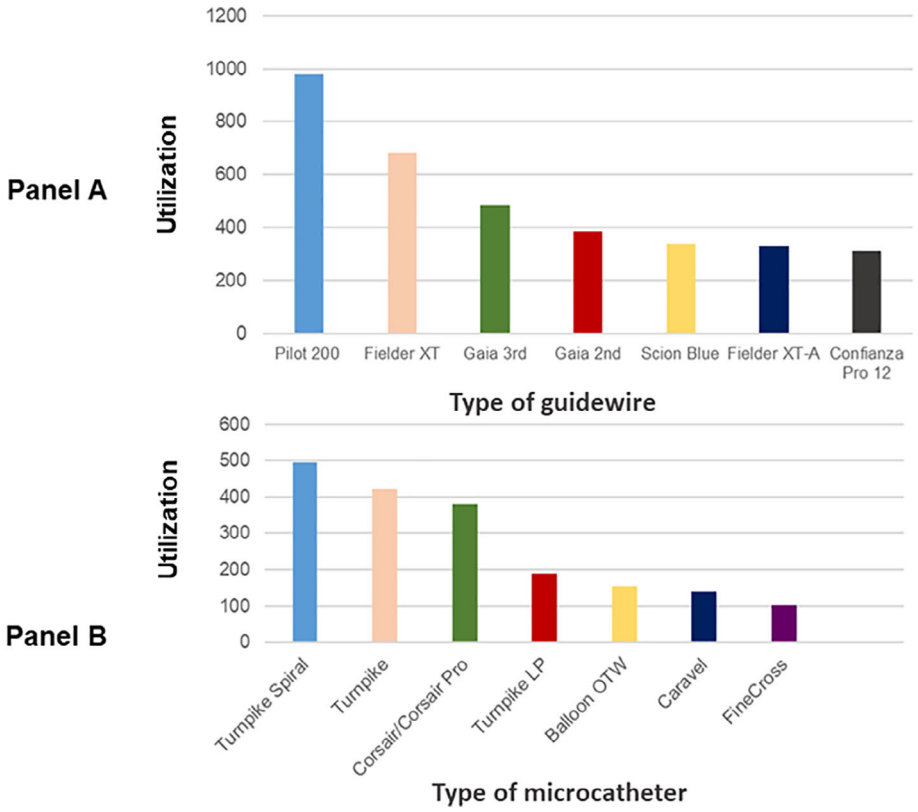

FIGURE 2 Most commonly used guidewires (a) and microcatheters (b) for antegrade wiring [Color figure can be viewed at wileyonlinelibrary.com]

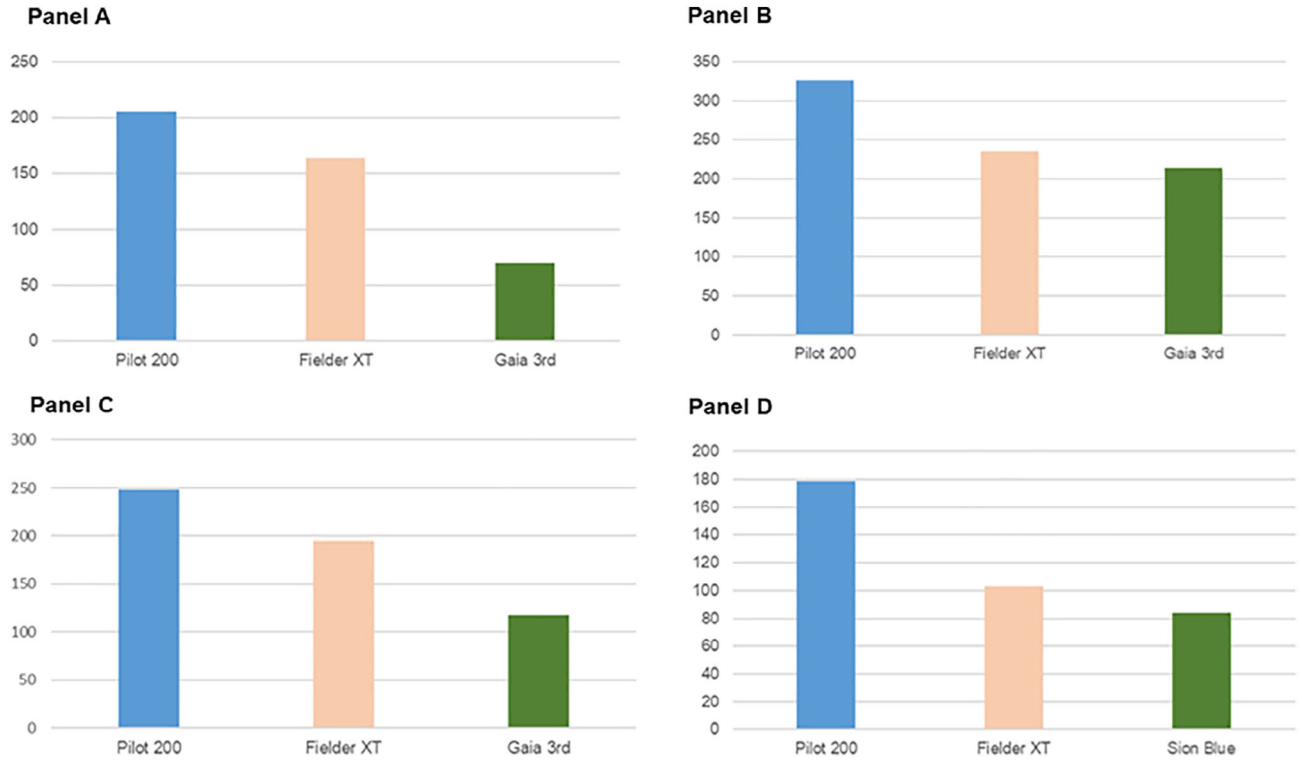

FIGURE 3 Most commonly used guidewires for antegrade wiring according to the presence of blunt/no stump (a), proximal cap ambiguity (b), moderate/severe calcification (c), and moderate/severe proximal tortuosity (d) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Recent changes in the most commonly used antegrade guidewires and microcatheters in chronic total occlusion percutaneous coronary intervention

ANTEGRADE ONLY	Utilization frequency: 2012–2015	Utilization frequency: 2016–2019	Net change in utilization frequency	Utilization ranking: 2012–2015	Utilization ranking: 2016–2019
Guidewires					
Pilot 200	56%	37%	−19%	First	First
Fielder XT	45%	25%	−20%	Second	Second
Gaia third	Not used	18%		Not used	Third
Confianza pro 12	28%	9%	−19%	Third	Seventh
Microcatheters					
Turnpike spiral	Not used	18%	+18%	Not used	First
Turnpike	Not used	16%		Not used	Second
Corsair/corsair pro	44%	9%	−35%	First	Third
FineCross	20%	4%	−16%	Second	Eighth

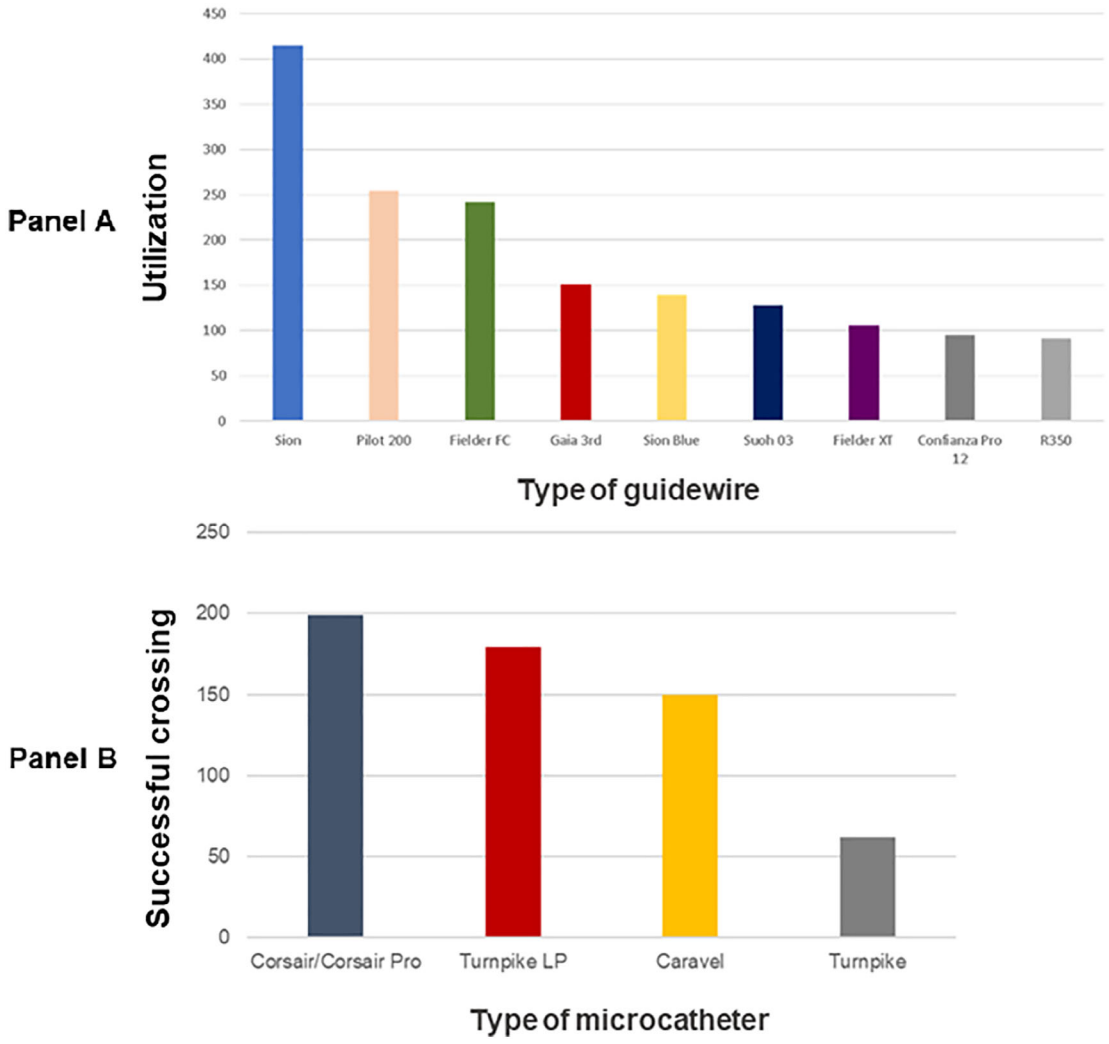

FIGURE 4 Most commonly used guidewires (a) and microcatheters (b) for retrograde CTO crossing [Color figure can be viewed at wileyonlinelibrary.com]

jacketed guidewire if the course of the vessel is unclear. In our series, the Pilot 200 was more commonly used both as the initial and subsequent steps for antegrade wiring with high crossing success rates.

In a past, use of stiff and tapered tip guidewires, such as the Confianza Pro 12 (Asahi Intecc) was recommended if tapered tip, polymer jacketed guidewires failed.[14,18] In our study use of these guidewires declined in favor of the Gaia guidewires, which have a microcone tip and composite core technology designed to enhance torquability.[7,19,20]

Use of a microcatheter is strongly recommended in CTO PCI, as it significantly improves handling of the guidewire and facilitates guidewire exchanges.[21] At least one microcatheter was used in 75% of antegrade-only procedures. Compared with earlier data from the PROGRESS-CTO Registry between 2012 and 2015, successful crossing rates when a microcatheter was used for antegrade procedures increased from 60% to 88%, showing that increased success rates can be achieved as experience with microcatheter use accumulates.[14,22]

The most commonly used microcatheters for antegrade crossing in our study were larger, torquable microcatheters, such as the Turnpike Spiral (Vascular Solutions, 18% of AWE procedures), Turnpike (Vascular Solutions, 16%) and Corsair/Corsair Pro (Asahi Intecc, 9%).[18] In a prior analysis of the PROGRESS-CTO registry, between 2012 and 2015, the most commonly used microcatheters were the Corsair (44% of AWE procedures) and the FineCross (Terumo, 20%).[14] Availability of more microcatheter types has provided additional options for CTO operators.[22]

Centers that joined the registry after 2015 were more likely to adopt newer guidewires (such as the Gaia third) and microcatheters (such as the Turnpike and Turnpike Spiral), while prior centers were more likely to use the Corsair/Corsair Pro family of microcatheters. The higher rates of moderate/severe tortuosity (78% vs 58%, $p < .0001$) and balloon undilatable lesions (90% vs 86%, $p = .003$) reported at new centers indicate that lesion characteristics might have also contributed to this difference.

Contrast volume (265 [200,360 vs 200 [165,310], $p < .0001$) and procedure time (110 [70,167] vs 125 [85,185], $p < .0001$) were lower during 2016–2019 as compared with 2012–2015. Fluoroscopy air kerma dose was also lower between 2016–2019 (2.3 [1.3, 3.7], vs 3.3 [2, 5.3] Gray, $p < .0001$). Availability of multiple wire/catheter options may have contributed to this reduction, although this could also be related to lower use of the retrograde approach.[23] Also, the X-ray systems utilized during each time period are not known.

The Sion was the most commonly used guidewire for collateral crossing, whereas final retrograde crossing was more frequently achieved with the Pilot 200 and the Gaia third. The torquability of Sion makes it an excellent choice for advancing through collaterals, whereas a stiffer wire is usually needed for crossing the lesion.[18] The use of the Pilot 200 guidewire for retrograde crossing is limited outside the United States.[24]

The Corsair/Corsair Pro was the most common microcatheter that successfully crossed collaterals with the retrograde approach. The Corsair shaft features eight thin wires interwoven with two larger wires, enhancing trackability, while the Corsair Pro allows for increased tip flexibility.[18,22] The use of smaller torquable microcatheters, such as the Turnpike LP and the Caravel also increased for retrograde collateral crossing.

Our study has limitations. First, PROGRESS CTO is an observational registry without adjudication of clinical events by an independent events committee. Second, we only recorded the total number of guidewires and the different guidewire types used but not the actual number of guidewires per type of guidewire or the sequence of guidewire use. Third, equipment choice was at the discretion of the operator; thus, selection bias may be present. Fourth, procedures were performed by experienced operators and may not apply to centers with limited experience.

5 | CONCLUSION

The most commonly used guidewires during CTO PCI are polymer-jacketed guidewires and the most commonly used microcatheters are torquable microcatheters.

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Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at the Minneapolis Heart Institute Foundation (MHIF), Minneapolis, Minnesota. REDCap is a secure, web-based application designed to support data capture for research studies, providing: (a) an intuitive interface for validated data entry; (b) audit trails for tracking data manipulation and export procedures; (c) automated export procedures for seamless data downloads to common statistical packages; and (d) procedures for importing data from external sources.

CONFLICT OF INTEREST

L. N.: nothing to disclose; J. W. C: nothing to disclose; K. A.: consulting fees from Terumo and Boston Scientific; consultant, no financial, Abbott Laboratories; J. J. K.: Asahi Intecc, Speaker/Proctor: Abbott Vascular; O. K.: nothing to disclose; D. K.: nothing to disclose; Dr R. W. Y.: career development award (1K23HL118138) from the National Heart, Lung, and Blood Institute; F. A. J.: Consultant: Abbott Vascular, Boston Scientific, and Siemens. Research grant: Canon, Siemens and National Institutes of Health; C. T.: nothing to disclose; M. P.: speakers' bureau for Astra Zeneca; E. M.: consulting fees from Medtronic and Corindus; speaker's fees from Medtronic, Corindus, and Abbott Vascular; educational program fees from Abbott Vascular; and clinical events committee fees from St. Jude; N. J. L.: speaker bureau: Medtronic. Consultant/Advisory Board: Abbott Vascular and Medtronic; M. P.: speaker bureau: Abbot Vascular, Medtronic, CSI, BSC, Trireme; advisory boards: Medtronic, Abbott Vascular, Philips; A. J. K.: Institutional research grants to Columbia University from Boston Scientific, Medtronic, Abbott Vascular, Abiomed, St. Jude Medical, Vascular Dynamics, Glaxo SmithKline, and Eli Lilly; Z. A. A.: consultant fees/honoraria from St. Jude Medical, and AstraZeneca Pharmaceuticals; ownership interest/partnership/principal in Shockwave Medical and VitaBx Inc; and research grants from Medtronic and St. Jude

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