

Usefulness of Atherectomy in Chronic Total Occlusion Interventions (from the PROGRESS-CTO Registry)



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There is limited data on the use of atherectomy during chronic total occlusion (CTO) percutaneous coronary intervention (PCI). We compared the clinical and procedural characteristics and outcomes of CTO PCIs performed with or without atherectomy in a contemporary multicenter CTO PCI registry. Between 2012 and 2018, 3,607 CTO PCIs were performed at 21 participating centers. Atherectomy was used in 117 (3.2%) cases: rotational atherectomy in 105 cases, orbital atherectomy in 8, and both in 4 cases. Patients in whom atherectomy was used, were older (68 ± 8 vs 64 ± 10 years, $p < 0.0001$) and had higher Japan-chronic total occlusion score (3.0 ± 1.2 vs 2.4 ± 1.3 , $p < 0.0001$). CTO PCI cases in which atherectomy was used had similar technical (91% vs 87%, $p = 0.240$) and procedural (90% vs 85%, $p = 0.159$) success and in-hospital major adverse cardiac event (4% vs 3%, $p = 0.382$) rates. However, atherectomy cases were associated with higher rates of donor vessel injury (4% vs 1%, $p = 0.031$), tamponade requiring pericardiocentesis (2.6% vs 0.4%, $p = 0.012$) and more often required use of a left ventricular assist device (9% vs 5%, $p = 0.031$). Atherectomy cases were associated with longer procedural duration (196 [141, 247] vs 119 [76, 180] minutes, $p < 0.0001$), and higher patient air kerma radiation dose (3.6 [2.5, 5.6] vs 2.8 [1.6, 4.7] Gray, $p = 0.001$). In conclusion, atherectomy is currently performed in approximately 3% of CTO PCI cases and is associated with similar technical and procedural success and overall major adverse cardiac event rates, but higher risk for donor vessel injury and tamponade. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:1422–1428)

Balloon uncrossable CTOs (6% to 9% of all CTOs) are lesions that cannot be crossed with a balloon after successful guidewire crossing, while balloon undilatable CTOs (12% of all CTOs) are CTOs that cannot be expanded despite high-pressure balloon inflations.^{1–5} Rotational and

orbital atherectomy can be used during PCI for: (1) lesion preparation, (2) treatment of “balloon-uncrossable,” and (3) treatment of “balloon-undilatable” lesions.⁶ This study describes the patient population and outcomes of atherectomy performed during CTO PCI.

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Methods

Between January 2012 and May 2018, 3,607 CTO PCI cases were performed in 3,540 patients at 21 centers in the United States, Europe, and Russia and were included in the PROGRESS-CTO registry (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention, NCT02061436). Rotational atherectomy (RA), orbital atherectomy or both, were used in 117 cases in 116 patients (3.2% of cases). We compared the clinical, angiographic, and procedural characteristics and outcomes of CTO PCI cases performed with versus without atherectomy. The

Table 1
Clinical characteristics of the study patients, classified according to whether atherectomy was used

Atherectomy Variable	Yes (n = 116)	No (n = 3,424)	p value
Age (years)*	68 ± 8	64 ± 10	<0.0001
Men	87% (99)	85% (2511)	0.5615
BMI (kg/m ²)*	32 ± 7	31 ± 6	0.0982
Smoker (current)	13% (14)	27% (795)	0.0006
Diabetes mellitus	61% (69)	41% (1219)	<0.0001
Dyslipidemia [†]	96% (110)	90% (2659)	0.0221
Hypertension [‡]	94% (107)	90% (2648)	0.1541
CAD presentation			0.9673
STEMI	1% (1)	1% (32)	
NSTEMI	7% (7)	6% (155)	
Unstable angina pectoris	18% (19)	18% (483)	
Stable angina pectoris	66% (68)	65% (1744)	
Symptoms unlikely to be ischemic	2% (2)	3% (75)	
No symptoms	6% (6)	8% (205)	
Prior MI	49% (54)	47% (1353)	0.7682
Heart failure	36% (40)	31% (885)	0.2481
Prior valve procedure	7% (8)	3% (86)	0.0136
Prior PCI	70% (79)	65% (2137)	0.2452
Prior CABG	48% (55)	31% (1032)	0.0001
Prior CVD	15% (17)	11% (332)	0.2292
Prior PVD	14% (16)	15% (429)	0.9390
Chronic lung disease	17% (19)	14% (416)	0.4685
Baseline creatinine (mg/dL) [§]	1.1 (0.9, 1.4)	1.0 (0.9, 1.2)	0.0774
Left ventricular EF*	48 ± 14 (%)	50 ± 13 (%)	0.0844

BMI = body mass index; CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; CVD = cerebrovascular disease; EF = ejection fraction; MI = myocardial infarction; NSTEMI = non-ST segment elevation myocardial infarction; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease; STEMI = ST segment elevation myocardial infarction.

* Mean ± standard deviation.

[†] Dyslipidemia was defined as (National Cholesterol Education Program criteria): (1) Total cholesterol greater than 200 mg/dl (5.18 mmol/L); or (2) LDL greater than or equal to 130 mg/dl (3.37 mmol/L); or, (3) HDL less than 40 mg/dl (1.04 mmol/L); or (4) for patients with known coronary artery disease LDL greater than 100 mg/dl (2.59 mmol/L).

[‡] Hypertension was defined as: (1) History of hypertension diagnosed and treated with medication, diet and/or exercise; (2) Previous documentation of blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or previous documentation of blood pressure greater than 130 mm Hg systolic and/or 80 mm Hg diastolic on at least two occasions for patients with diabetes or chronic kidney disease.

[§] Median (interquartile range).

study was approved by the institutional review board of each center.

Coronary CTOs were defined as coronary lesions with Thrombolysis in Myocardial Infarction 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) 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. Proximal cap ambiguity was defined as inability to determine the exact location of the proximal cap of the occlusion, due to the presence of obscuring side branches or overlapping branches that could not be resolved despite multiple angiographic projections. 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 a collateral vessel or bypass graft supplying the target vessel distal to the lesion. Antegrade dissection/re-entry was defined as antegrade PCI during which a guidewire was intentionally introduced into the subintimal space proximal to the lesion, or attempt for re-entry into the distal true lumen following intentional or inadvertent subintimal guidewire or device crossing.

Technical success was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of Thrombolysis in Myocardial Infarction grade 3 antegrade flow. Procedural success was defined as achievement of

Table 2
Angiographic characteristics of the study lesions, classified according to whether atherectomy was used

Atherectomy Variable	Yes (n=117)	No (n = 3,490)	p value
Target coronary vessel			0.0068
Right	50% (57)	56% (1872)	
Left circumflex	15% (17)	19% (653)	
Left main	2% (2)	0% (8)	
Left anterior descending	33% (37)	23% (786)	
CTO length (mm)*	25 (15, 40)	30 (15, 40)	0.1867
Vessel diameter (mm)*	3.0 (2.5, 3.0)	3.0 (2.5, 3.0)	0.0694
Proximal cap ambiguity	32% (32)	35% (875)	0.5933
Moderate/severe calcification	95% (104)	51% (1632)	<0.0001
Moderate/severe tortuosity	51% (55)	34% (1089)	0.0003
Interventional collaterals	58% (57)	57% (1403)	0.8818
J-CTO score [†]	3.0 ± 1.2	2.4 ± 1.3	<0.0001
PROGRESS-CTO score [‡]	1.3 ± 1.0	1.3 ± 1.0	0.6331
PROGRESS-CTO complications score [‡]	3.5 ± 1.9	3.0 ± 1.9	0.0210

CTO = chronic total occlusion; J = Japan; PROGRESS-CTO = Prospective Global Registry of Chronic Total Occlusion Interventions.

* Median (interquartile range).

[†] Mean ± standard deviation.

technical success without any in-hospital major adverse cardiac events (MACE). In-hospital MACE included any of the following adverse events before hospital discharge: death, MI, recurrent symptoms requiring urgent repeat target vessel revascularization with PCI or coronary artery bypass graft surgery, tamponade requiring either pericardiocentesis or surgery, and stroke. MI was defined using the Third Universal Definition of Myocardial Infarction (type 4 MI).⁷ Donor vessel injury was defined as either iatrogenic dissection or thrombus formation in the donor vessel. The Japan-chronic total occlusion score was calculated as described by Morino et al,⁸ the PROGRESS-CTO score as described by Christopoulos et al,⁹ and the PROGRESS-CTO Complications score as described by Danek et al.¹⁰

“Non-atherectomy group” included procedures that did not include atherectomy, whereas the “atherectomy group”

included procedures in which either rotational or orbital atherectomy or both were used.

Categorical variables were expressed as percentages and were compared using Pearson’s Chi-square test or 2-tail Fisher’s exact test. Continuous variables were presented as mean ± standard deviation or median (interquartile range) unless otherwise specified and were compared using *t* test or Wilcoxon rank-sum test, as appropriate. All statistical analyses were performed with JMP 14.0 (SAS Institute, Cary, North Carolina). A 2-sided *p* value of 0.05 was considered statistically significant.

Results

Among the 3,607 CTO PCI cases performed during the study period, RA was used in 105 (2.9%) cases, orbital

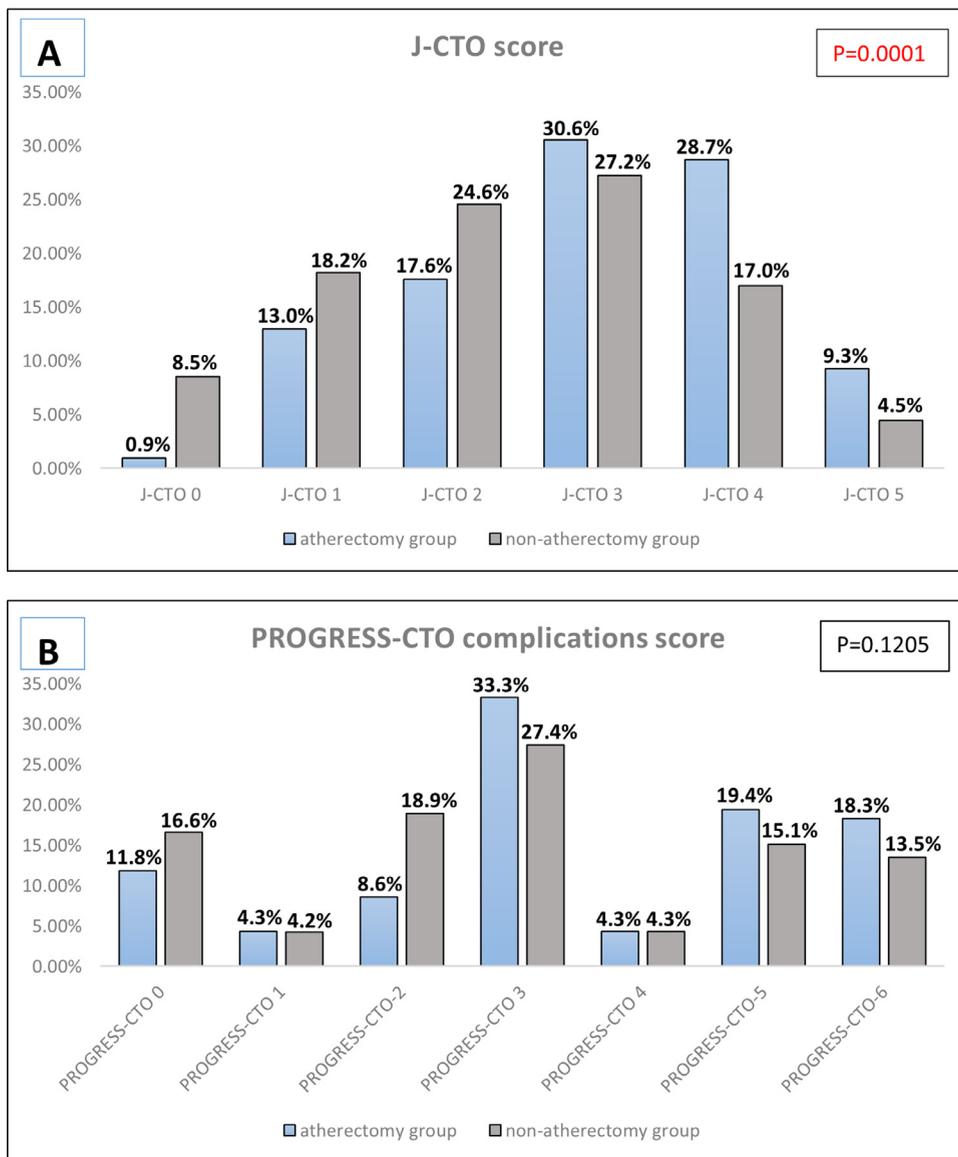


Figure 1. **Panel A:** J-CTO scores among the study patients, classified according to atherectomy use. **Panel B:** PROGRESS-CTO complications score among the study patients, classified according to atherectomy use. J-CTO = Japan-chronic total occlusion; PROGRESS-CTO = Prospective Global Registry of Chronic Total Occlusion Interventions.

Table 3
Technical characteristics of the study procedures, classified according to whether atherectomy was used

Atherectomy Variable	Yes (n = 117)	No (n = 3,490)	p value
Vascular access			
Femoral artery	86% (101)	79% (2763)	0.0598
Radial artery	40% (47)	40% (1400)	0.9902
Crossing strategies used			
AWE	87% (102)	82% (2871)	0.1694
ADR	32% (37)	30% (1051)	0.7264
Retrograde	36% (42)	37% (1308)	0.7281
Successful crossing strategies			
AWE	59% (69)	45% (1555)	0.0085
ADR	12% (14)	18% (617)	
Retrograde	22% (26)	23% (795)	
Unknown	6% (7)	13% (458)	
Collaterals used			
Septal	21% (25)	23% (806)	0.6626
Epicardial-contralateral	9% (10)	12% (412)	0.2808
Epicardial-ipsilateral	1% (1)	1% (21)	1.0000
SVG	8% (9)	5% (170)	0.1669
LIMA	1% (1)	1% (21)	0.5169
IVUS used for crossing	6% (6)	9% (219)	0.2860
Number of stents used*	3 ± 1	2 ± 1	0.0158

ADR = antegrade dissection/re-entry; AWE = antegrade wire escalation; IVUS, intravascular ultrasound; LIMA, left internal mammary artery graft; SVG, saphenous vein graft.

* Mean ± standard deviation.

atherectomy in 8 (0.2%), and both in 4 (0.1%) cases. In 51 cases (1.4%) atherectomy was used for “balloon-uncrossable” or/and “balloon-undilatable” lesions (bailout strategy) while in the remaining 66 (1.8%) cases it was used for “lesion preparation” (planned strategy). The baseline clinical and angiographic characteristics of the study patients and lesions are summarized in Table 1 and Table 2. Patients in the atherectomy group were on average 3.7 years older and had more co-morbidities. Atherectomy-treated CTOs were more complex with higher risk for complications, as illustrated in Figure 1 and Table 2.

The CTO PCI techniques and outcomes are described in Table 3 and the procedural outcomes and complications are outlined in Table 4. There was no difference among the study groups in technical, procedural success, and MACE.

Table 4
Procedural outcomes among patients who underwent retrograde CTO PCI, classified according to whether atherectomy was used

Atherectomy Variable	Yes (n = 116)	No (n = 3,424)	p value
Technical success	91% (106)	87% (3032)	0.2391
Procedural success	90% (104)	85% (2695)	0.1588
Procedural complications	21% (24)	10% (292)	0.0001
Procedure time (min)*	196 (141, 247)	119 (76, 180)	<0.0001
Contrast volume (mL)*	233 (177, 320)	260 (195, 350)	0.1085
Fluoroscopy time (min)*	77.75 (45.70, 104.75)	45.50 (27.00, 74.59)	<0.0001
Patient AK dose (Gray)*	3.57 (2.48, 5.56)	2.78 (1.56, 4.65)	0.0012
In-hospital MACE	4% (5)	3% (95)	0.3818

AK = air kerma; MACE = in-hospital major adverse cardiovascular events.

* Median (interquartile range).

However, the incidence of perforation (10 % vs 4%, $p=0.002$), donor vessel injury (4% vs 1%, $p=0.031$) and tamponade requiring pericardiocentesis (2.6% vs 0.4%, $p=0.012$) were higher in the atherectomy group. On multi-variable analysis, the only factor that was associated independently with MACE was proximal cap ambiguity (Figure 2). If perforation and donor vessel injury were included in the composite end point of MACE, MACE rate was higher in the atherectomy group (14% vs 7%, $p=0.005$), but procedural success remained similar between the 2 groups (82% vs 80%, $p=0.576$). Left ventricular assist devices were utilized more frequently in the atherectomy group (9% vs 5%, $p=0.031$).

Cases in which atherectomy was used as a bail-out strategy had similar technical (92% vs 89%, $p=0.754$) and procedural (90% vs 89%, $p=0.850$) success, but numerically higher in-hospital MACE rates (7% vs 2%, $p=0.367$) compared with cases in which atherectomy was planned. “Balloon-uncrossable” and “balloon-undilatable” lesions treated with atherectomy had higher technical (92% vs 79%, $p=0.032$) and procedural (90% vs 79%, $p=0.046$) success and similar MACE rates (7% vs 4%, $p=0.422$) as compared with similar lesions not treated with atherectomy.

Discussion

The main findings of our study are that atherectomy (RA in most cases): (1) is currently used infrequently during CTO PCI mainly for complex lesions, (2) is associated with similar technical success, but (3) higher risk for donor vessel injury and tamponade requiring pericardiocentesis.

There is wide variability in atherectomy use during CTO PCI, ranging from 3.5% to 9% (Table 5), likely due to variations in equipment availability and operator expertise. In our study, atherectomy use decreased during the last 3 years (Figure 3), possibly due to high rates of retrograde and antegrade dissection re-entry techniques.

In nearly all atherectomy cases, successful guidewire crossing preceded atherectomy. After excluding failed crossing cases and cases when the successful crossing technique was unknown, atherectomy was associated with lower technical success rates compared with the nonatherectomy group (95% vs 98%, $p=0.004$). However, procedural success (94% vs 96%, $p=0.358$) and MACE

Table 5
Previous studies evaluating the use of atherectomy in CTO interventions

Investigators/year	Number of cases where atherectomy was used	Atherectomy use %	Major findings
Pagnotta et al (2010) ⁴	45	7	• Peri-procedural MI more frequent with RA use (35 % vs 22%, p = 0.044)
Wen et al (2013) ¹⁶	27	3.5	• Cardiac death, peri-procedural MI, TVR were similar between 2 groups
Azzalini et al (2017) ¹¹	35	3.5	• Lower procedural success for RA group but similar long term MACE
Huang et al (2018) ¹⁵	26	9	• Short- and long-term outcomes were comparable between 2 groups

CTO = chronic total occlusion; MACE = major adverse cardiac events; MI = myocardial infarction; PCI = percutaneous coronary intervention; RA = rotational atherectomy; TVR = target vessel revascularization.

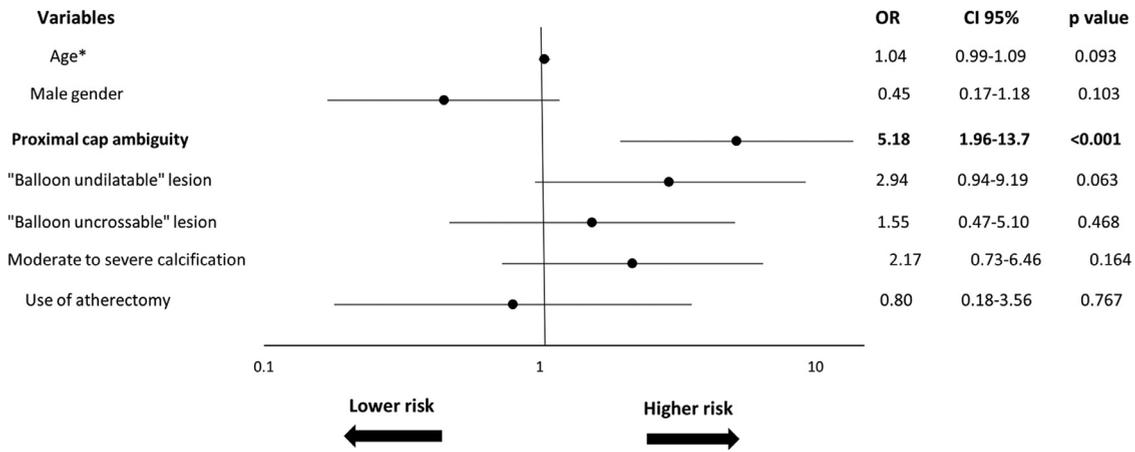


Figure 2. Multivariable logistic regression of baseline clinical and angiographic characteristics for in-hospital major adverse cardiac events in patients who underwent CTO PCI. *Per 1 unit (year) change.

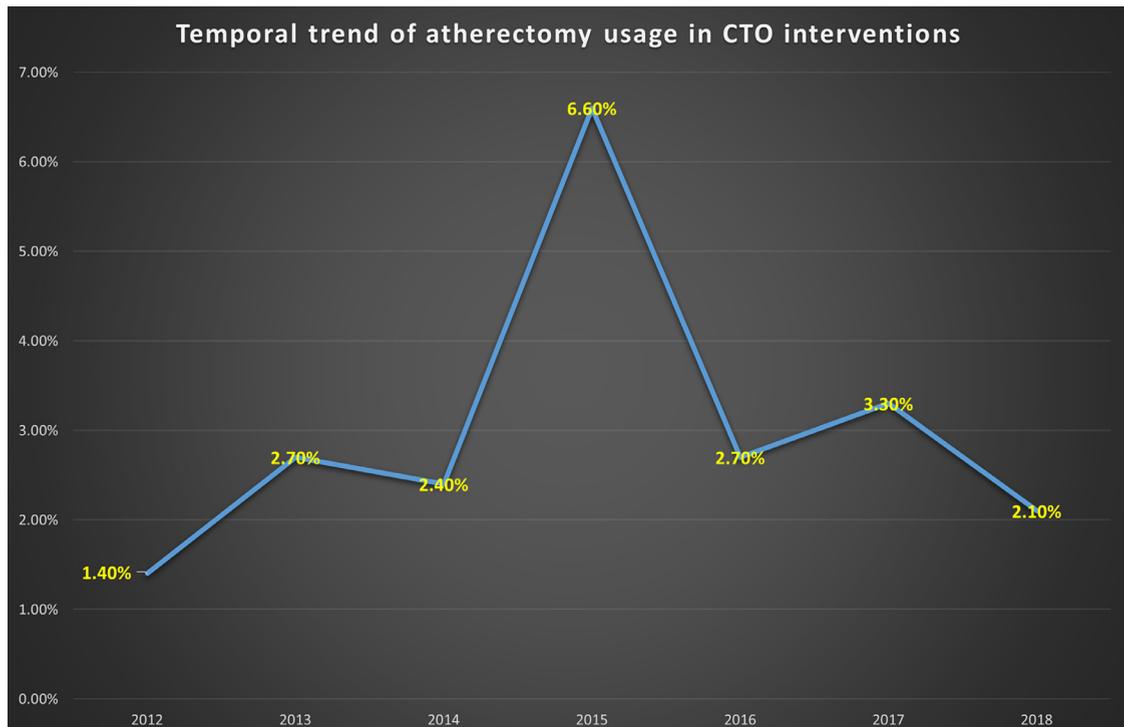


Figure 3. Temporal trend in atherectomy use for chronic total occlusion interventions.

(5% vs 3%, $p=0.195$) rates were similar. In previous studies, atherectomy cases had similar or better success rates than nonatherectomy cases with the exception of a study by Azzalini et al that reported lower procedural success with RA (77% vs 89%, $p=0.04$).¹¹ More than half of the atherectomy cases in our study had moderate or severe proximal vessel tortuosity, even though tortuosity is often considered a relative contraindication to performing atherectomy.¹²

Atherectomy is known to have higher risk for perforation in non-CTO cases.^{13–14} In a study of 35 patients who underwent RA during CTO PCI by Azzalini et al the following RA-associated complications were reported: 6 (17%) cases of slow/no reflow, 6 (17%) cases of bradyarrhythmia, and 10 (29%) cases of dissection. During a mean follow-up of 658 ± 412 days, MACE rates were similar in RA and non-RA cases (15% vs 13%, $p=0.7$).¹¹ In a study by Pagnotta et al, none of the patients in the atherectomy group experienced coronary perforation whereas in the conventional group 3 patients suffered a coronary perforation.⁴ Huang et al reported only 1 major complication associated with the use of RA utilization (a coronary perforation needing emergent surgical intervention of 26 RA cases).¹⁵

Coronary atherectomy has disadvantages: it can be time consuming, increases the cost of the procedure, and carries risk for complications, such as perforation, dissection, bradyarrhythmias, and burr/crown entrapment.¹¹ Atherectomy remains an indispensable tool for complex CTO and non-CTO PCI, but it should be used by experienced operators and with caution.

Our study has important limitations. First, it was an observational retrospective study without long-term follow-up. Second, there was no standard protocol regarding use of atherectomy, which was performed at the operator discretion. Third, the number of patients who were treated with atherectomy was relatively small (116 patients, approximately 3% of the total population) and the comparison group had lower angiographic and clinical complexity. Fourth, due to the large number of operators, there is possibility of reporting bias. Fifth, there was no core laboratory assessment of the study angiograms or clinical event adjudication. Sixth, in the vast majority of our cases RA was used, limiting conclusions regarding orbital atherectomy. Finally, the procedures were performed in dedicated, high volume CTO centers by experienced operators, limiting the extrapolation to less experienced operators and lower volume centers.

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