Long-term Outcomes of Rotational Atherectomy for the Percutaneous Treatment of Chronic Total Occlusions

Lorenzo Azzalini, MD, PhD, MSc, Rustem Dautov, AD, PhD, Soledad Ojeda, MD, PhD, Antonio Serra, MD, PhD, Susanna Benincasa, MD, Barbara Bellini, MD, Francesco Giannini, MD, Jorge Chavarría, MD, Livia L. Gheorghe, MD, Manuel Pan, MD, PhD, Mauro Carlino, MD, Antonio Colombo, MD, and Stéphane Rinfret, MD, SM

Objectives, To study the long-term outcomes of rotational atherectomy (RA) for chronic total occlusion (CTO) percutaneous coronary intervention (PCI). Background. There is little evidence on the incidence, procedural results and long-term outcomes of RA for CTO PCI. Methods. This registry included data from consecutive patients undergoing CTO PCI at four specialized centers. Major adverse cardiac events (MACE: cardiac death, targetvessel myocardial infarction and ischemia-driven target-vessel revascularization) on follow-up were the primary endpoint. Results. A total of 1003 patients were included. Of these, 35 (3.5%) required RA. As compared with Conventional PCI, RA patients were older $(68.9 \pm 9.5 \text{ vs. } 64.6 \pm 10.7 \text{ years, } P = 0.02)$, had higher prevalence of diabetes (58% vs. 37%, P = 0.01) and of a J-CTO score \geq 2 (80% vs. 58%, P = 0.009), driven by severe calcification. Antegrade wire escalation was used more frequently in RA (74% vs. 53%, P = 0.08). RA was performed for balloon failure-to-cross in 51% and failure-to-expand in 49%. One burr was utilized in 86%. The 1.25-mm burr was the largest burr used in 43%. Slow flow/no-reflow was observed in 17%. No other serious RA-related complications were observed. Procedural success was 77% vs. 89% (P = 0.04) in RA vs. Conventional PCI. After a mean follow-up of 658 ± 412 days, MACE rates were similar between groups (15% vs. 13%, P = 0.70). Conclusions. The use of RA in CTO PCI was safe, despite a worse patient risk profile and higher procedural complexity, as compared with conventional techniques. Although procedural success was lower in the RA group, there were no differences in long-term clinical outcomes between groups. © 2016 Wiley Periodicals, Inc.

Key words: chronic total occlusion; rotational atherectomy; percutaneous coronary intervention

INTRODUCTION

Following the development and implementation of the "hybrid algorithm" [1], success rates for chronic total occlusion (CTO) percutaneous coronary intervention (PCI)

have reached \sim 90% in all-comers [2]. However, specific angiographic features still represent challenging scenarios. In particular, calcified occlusions have been associated with procedural failure [3]. This is frequently due to

Additional Supporting Information may be found in the online version of this article.

Conflict of interest: Dr. Rinfret received consulting fees from Boston Scientific and research funding from Medtronic and Abbott Vascular. The other authors report no conflict of interest.

*Correspondence to: Stéphane Rinfret, MD, SM, FSCAI, Associate Professor of Medicine, McGill University, Director, Interventional Cardiology, McGill University Health Centre, Royal Victoria Glen Site (B03.7200), 1001 Boulevard Décarie, Montreal (Québec), Canada. E-mail: stephane.rinfret@mcgill.ca

Received 10 August 2016; Revision accepted 8 October 2016

DOI: 10.1002/ccd.26829

Published online 28 December 2016 in Wiley Online Library (wileyonlinelibrary.com)

¹Interventional Cardiology, Cardio-Thoracic-Vascular Department, San Raffaele Scientific Institute, Milan, Italy

²Interventional Cardiology, Department of Medicine, McGill University Medical Center, Montreal, QC, Canada

³Interventional Cardiology, Department of Medicine, Quebec Heart and Lung Institute and Laval University, Quebec City, QC. Canada

⁴Interventional Cardiology, Department of Cardiology, Reina Sofía Hospital, University of Córdoba (IMIBIC), Córdoba, Spain

⁵Interventional Cardiology, Department of Cardiology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

balloon failure to cross after successful guidewire crossing, which is the second most common cause for CTO PCI failure, occurring in up to 7% of cases [4,5].

In such setting, rotational atherectomy (RA) represents an appealing strategy, since it allows adequate lesion preparation by calcium ablation. Data on RA in CTO PCI is mostly limited to case reports [6,7] and small registries including selected patient cohorts [4,8,9]. Moreover, data on long-term clinical outcomes of CTO patients undergoing RA are lacking.

The aim of the present study is to describe the incidence and characteristics of RA use in a large, contemporary and multicenter cohort of CTO patients, and the long-term outcomes of this challenging patient population, as compared with subjects undergoing CTO PCI with conventional techniques.

METHODS

Patient Population

We identified all consecutive patients that underwent CTO PCI at the four participating centers between January 2009 and December 2015. Patients were then classified according to whether RA was performed (RA group) or not (Conventional PCI group). RA was performed with the Rotablator system (Boston Scientific, Marlborough, MA). All procedures were indicated according to the presence of angina, ischemia or both [2]. Baseline, procedural, hospitalization and follow-up data were recorded. Follow-up was performed by means of phone interview, review of hospital records or outpatient visit. The study was approved by the institutional review boards of the four participating hospitals. Figures 1 and 2 show two cases of CTO PCI that required RA.

Definitions

CTO was defined as a 100% coronary stenosis with Thrombolysis In Myocardial Infarction (TIMI) 0 flow for ≥ 3 months [10]. The J-CTO score was calculated as previously described [11].

Procedural complications included: procedure-related death, periprocedural stroke, periprocedural type 4a myocardial infarction (MI) [12], major bleeding (bleeding requiring transfusion, vasopressors, surgery or percutaneous intervention), coronary perforation with cardiac tamponade, and contrast-induced nephropathy (CIN: increase in serum creatinine >25% or >0.5 mg dL $^{-1}$ at 48 h post-procedure).

Technical success was defined as a residual stenosis <30% with antegrade TIMI 3 flow in the CTO target vessel [10]. Procedural success was defined as technical success plus the absence of in-hospital adverse events (all-cause death, Q-wave MI, stroke, recurrent angina requiring target-vessel revascularization (TVR) with PCI

or coronary artery bypass graft [CABG], tamponade requiring pericardiocentesis or surgery) [10]. Bailout RA was defined as the decision to use RA made during CTO PCI, as opposed to a pre-procedurally planned utilization of this device. RA success was defined as adequate lesion modification of the coronary segment where RA was performed, according to the operator's criterion (i.e., adequate balloon expansion).

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, defined as any revascularization in the CTO vessel, including proximal segments or distal branches.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation and Student's t test was used for comparisons. Categorical variables are presented as frequency (percentages), and compared using chi-square test. Curves of survival free from MACE on follow-up were created with the Kaplan-Meier method and compared with the log-rank test. Independent predictors of procedural success were sought with backward stepwise logistic regression (P-entry/P-exit <0.05) and are presented as odds ratios (OR) and 95% confidence intervals (CI). Independent predictors of MACE on follow-up were identified with backward stepwise Cox regression (P-entry/P-exit <0.05) and are presented as hazard ratios (HR) and 95% CI. Candidate predictors for both multivariable models were selected among variables exhibiting a P < 0.10 in univariate analyses. For all tests, a P < 0.05 was considered significant. Statistical analysis was performed using SPSS 20 (IBM, Armonk, NY).

RESULTS

Baseline Clinical Characteristics

Table I shows clinical data of our patient population. A total of 1003 patients were included, of whom only 35 (3.5%) underwent RA. As compared with the Conventional PCI group, RA patients were older $(68.9 \pm 9.5 \text{ vs. } 64.6 \pm 10.7 \text{ years}, P = 0.02)$, had higher prevalence of diabetes (58% vs. 37%, P = 0.01) and worse left ventricular ejection fraction (47.7 \pm 13.6 vs. 53.7 \pm 11.3%, P = 0.02). RA patients also tended to have a higher prevalence of prior CABG (31% vs. 19%, P = 0.07). Indication of CTO PCI was driven mostly by silent ischemia in RA patients and by symptoms in the Conventional PCI group.

Baseline Angiographic Characteristics and Procedural Data

Angiographic and procedural data are shown in Table II. RA patients tended to have a higher number of

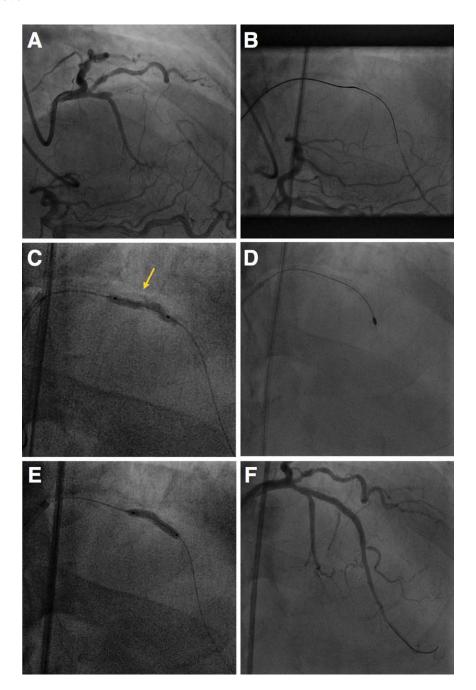


Fig. 1. Percutaneous coronary intervention on a left anterior descending chronic total occlusion. (A) J-CTO score was 3 (calcification, length >20 mm, retry). (B) The lesion was crossed antegradely, using a Gaia Third wire (Asahi Intecc, Nagoya, Japan) supported by a Corsair microcatheter (Asahi Intecc). (C) Aggressive lesion predilatation was performed with a 2.5-mm non-compliant balloon, which however could

not expand properly due to extensive calcification (arrow). (D) Rotational atherectomy was then performed with a 1.5-mm burr and (E) further predilatation followed (balloons could now expand properly). (F) Optimal final result, after implantation of two overlapping drug-eluting stents and high-pressure postdilatation with a 3.0-mm non-compliant balloon. [Color figure can be viewed at wileyonlinelibrary.com]

diseased vessels. There were no differences between the two groups with regards to target CTO vessel and most items of the J-CTO score. However, the overall J-CTO score was higher in the RA group $(2.5 \pm 1.1 \text{ vs.})$

 1.8 ± 1.2 , P = 0.003), driven, as expected, by moderate or severe calcification (86% vs. 43%, P < 0.001).

Modality of crossing the CTO differed between both groups. Procedures that required RA were more likely

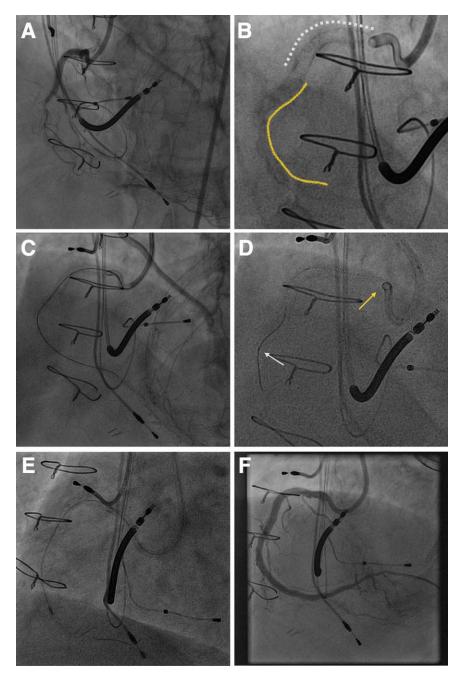


Fig. 2. Percutaneous coronary intervention on a right coronary artery chronic total occlusion. (A) J-CTO score was 4 (blunt stump, calcification, tortuosity >45°, length >20 mm). (B) Severe intraocclusional calcification is noted (yellow line), distal to a previously implanted stent (white dotted line). (C) The occlusion was crossed with a Confianza Pro 8-20 (Asahi Intecc) supported by a Finecross microcatheter (Terumo, Tokyo, Japan). (D) However, neither Tornus (Asahi Intecc) nor microcatheters (white arrow) could cross the lesion despite forceful steady advancement, causing guide catheter disen-

gagement (yellow arrow). (E) The Finecross was then advanced as distal as possible, and a Rotawire Floppy wire (Boston Scientific) was advanced distal to the occlusion tracking the channel created by the Confianza Pro 8-20. Rotational atherectomy was then performed with a 1.25-mm burr. Aggressive predilatation followed, and three drug-eluting stents were implanted from the posterolateral to the proximal right coronary artery. (F) Final result after high-pressure post-dilatation. [Color figure can be viewed at wileyonlinelibrary. com]

TABLE I. Baseline clinical characteristics

Variable	Overall $(n = 1003)$	Rotational atherectomy $(n = 35)$	Conventional PCI $(n = 968)$	P value
Age (years)	64.8 ± 10.7	68.9 ± 9.5	64.6 ± 10.7	0.02
Men	872 (87%)	31 (89%)	841 (87%)	0.77
Body mass index (kg m ⁻²)	29.0 ± 5.1	29.1 ± 5.7	29.0 ± 5.1	0.86
Diabetes mellitus	370 (37%)	19 (58%)	351 (37%)	0.01
Dyslipidemia	797 (80%)	32 (94%)	765 (80%)	0.04
Hypertension	738 (74%)	27 (79%)	711 (74%)	0.50
Current smoker	214 (23%)	9 (28%)	205 (23%)	0.46
Prior myocardial infarction	472 (48%)	16 (47%)	456 (48%)	0.91
Prior PCI	590 (59%)	18 (51%)	572 (59%)	0.36
Prior coronary artery bypass graft	196 (20%)	11 (31%)	185 (19%)	0.07
eGFR (ml/min/1.73 m ²)	83.6 ± 27.6	79.4 ± 26.3	83.8 ± 27.7	0.36
eGFR <60 ml/min/1.73 m ²	94 (10%)	5 (14%)	89 (10%)	0.35
LVEF (%)	53.5 ± 11.4	47.7 ± 13.6	53.7 ± 11.3	0.02
LVEF <50%	245 (26%)	16 (49%)	229 (25%)	0.002
Indication of CTO PCI				
Symptoms	589 (59%)	11 (31%)	578 (60%)	0.001
Silent ischemia	216 (22%)	17 (49%)	199 (21%)	
Acute coronary syndrome	163 (16%)	6 (17%)	157 (16%)	
Heart failure	27 (3%)	1 (3%)	26 (3%)	

Abbreviations: eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction.

approached with an antegrade wire escalation technique (74%), while dissection/re-entry and the retrograde approach were used in approximately a half of cases in the Conventional PCI group. RA procedures required higher use of other plaque-modifying devices (cutting balloon and Tornus, Asahi Intecc, Nagoya, Japan). There were no differences with regards to the type of stent implanted, number of stents, total stent length, and contrast volume. However, RA procedures were longer, required more intensive use of fluoroscopy, and were associated with a trend towards a higher radiation dose, as compared with Conventional PCIs.

Procedural complications tended to be higher (6% vs. 2%, P = 0.17) and technical success lower (80% vs. 89%, P = 0.10) in RA patients (n = 2 patients with final TIMI flow <2, n = 5 with residual stenosis >30%). One case of CIN and one stroke were observed in the RA group. Patients in the Conventional PCI group experienced the following complications: 11 perforations with cardiac tamponade, 3 strokes, 3 cases of CIN, 3 periprocedural MIs, and 1 vascular complication with major bleeding. Overall, 3 patients (all in the Conventional PCI group) suffered in-hospital death (2 cases due to perforation and 1 due to stroke). Procedural success was achieved significantly less often in the RA group (77% vs. 89%, P = 0.04). Older age, the use of dissection/reentry techniques and RA were independently associated with procedural failure (Supporting Information Table).

Rotational Atherectomy Data

Table III shows data on RA procedures. An 8-Fr guiding catheter was used in 46% of cases. In three quarters

of cases, RA was performed as a bailout procedure. Indications were balloon failure-to-cross in 51% (Fig. 2), and failure-to-expand in 49% (Fig. 1). In most cases (86%) only one burr was used. The 1.25-mm burr was the largest burn that was used most commonly (43%). RA technique followed contemporary recommendations (multiple passes at relatively low speeds and with selective use of pacemaker backup) [13]. RA success was observed in all but one case (97%), where insufficient lesion preparation was observed. Complications included slow flow/no-reflow (17%), which was successfully treated with intracoronary nitroprusside or resolved spontaneously in all cases; bradyarrhythmias (17%), which all occurred in cases of RCA CTO PCI where pacemaker backup had been placed in advance; dissection (29%), none with hemodynamic compromise; no cases of perforation were observed.

Clinical Outcomes on Follow-up

Follow-up was available for 910/1003 patients (91%). Mean follow-up was 658 ± 412 days. Table IV shows clinical outcomes on follow-up. There were no differences in the incidence of overall MACE between the RA and the Conventional PCI group (15% vs. 13%, P = 0.70). However, RA patients suffered a higher incidence of target-vessel MI (9% vs. 3%, P = 0.04). Figure 3 shows the Kaplan–Meier curves of survival free from MACE in the two groups. No differences were observed at 3 years (P = 0.65). Prior CABG, a lower LVEF and a higher number of diseased vessels were independent predictors of MACE on follow-up (Supporting Information Table).

TABLE II. Angiographic characteristics and procedural data

	Overall	Rotational	Conventional	
Variable	(n = 1003)	atherectomy $(n = 35)$	PCI $(n = 968)$	P value
Number of narrowed coronary arteries	1.8 ± 0.8	2.1 ± 0.8	1.8 ± 0.8	0.06
Target-vessel CTO				
Left anterior descending	290 (29%)	15 (43%)	275 (29%)	0.11
Circumflex	183 (18%)	3 (9%)	180 (19%)	
Right coronary artery	526 (53%)	17 (49%)	509 (53%)	
Blunt stump	451 (45%)	18 (51%)	433 (45%)	0.46
Moderate or severe calcifications	443 (44%)	30 (86%)	413 (43%)	< 0.001
>45° bending	294 (30%)	11 (31%)	283 (30%)	0.82
Lesion length >20 mm	453 (46%)	18 (51%)	435 (46%)	0.50
Retry	230 (23%)	10 (29%)	220 (23%)	0.42
J-CTO score	1.9 ± 1.2	2.5 ± 1.1	1.8 ± 1.2	0.003
J-CTO score ≥2	587 (59%)	28 (80%)	559 (58%)	0.009
Radial access ^a	406 (41%)	12 (34%)	394 (41%)	0.44
Successful crossing technique				
Antegrade wire escalation	482 (53%)	26 (74%)	456 (53%)	0.08
Antegrade dissection/re-entry	145 (16%)	2 (6%)	143 (17%)	
Retrograde wire escalation	87 (10%)	2 (6%)	85 (10%)	
Retrograde dissection/re-entry	189 (21%)	5 (14%)	184 (21%)	
Tornus	105 (11%)	9 (26%)	96 (10%)	0.003
Cutting balloon	28 (3%)	4 (11%)	24 (3%)	0.002
Mother-and-child catheter	127 (13%)	7 (21%)	120 (13%)	0.17
Type of stents				
Balloon angioplasty only	1 (0.1%)	0	1 (0.1%)	0.86
Bare-metal stents	14 (2%)	1 (3%)	13 (2%)	
Drug-eluting stents	779 (87%)	27 (87%)	752 (86%)	
Bioresorbable scaffolds	107 (12%)	3 (10%)	104 (12%)	
Number of stents implanted	2.2 ± 1.2	2.0 ± 1.2	2.2 ± 1.2	0.42
Total stent length (mm)	68.5 ± 40.7	72.8 ± 33.5	68.4 ± 40.9	0.50
Contrast volume (ml)	331 ± 140	352 ± 132	331 ± 140	0.42
Fluoroscopy time (min)	56.2 ± 34.4	79.6 ± 36.9	55.2 ± 34.0	< 0.001
Dose area product radiation dose (Gy cm ⁻²)	221 ± 150	267 ± 181	219 ± 149	0.11
Total procedure time (min)	135 ± 74	197 ± 72	133 ± 73	< 0.001
Procedural complications	23 (2%)	2 (6%)	21 (2%)	0.17
Technical success	889 (89%)	28 (80%)	861 (89%)	0.10
Procedural success	884 (88%)	27 (77%)	857 (89%)	0.04

^aIndicates cases with dual radial access or cases with a single access, being radial.

DISCUSSION

The main findings of our study are as follows: (1) RA is currently needed in a small proportion of CTO PCIs that present more challenging patient- and procedure-related characteristics; (2) even though RA is safe and effective in achieving adequate lesion preparation in the majority of patients, final procedural success is lower, as compared with Conventional PCI; (3) however, MACE at long-term follow-up are similar between the RA and Conventional PCI group.

Most of available data on RA concern its use in non-occlusive coronary artery disease [14]. Few studies have specifically analyzed the outcomes of this technique in CTO patients [4,8,9]. In particular, the only report evaluating RA in a large cohort of CTO patients is the registry by Pagnotta et al. [4]. They studied 648 patients who underwent successful wiring of the occlusion at their centers (out of 885 CTO PCIs attempted) between 2006 and 2009 (n = 45 were treated with RA;

5% of total CTO PCIs). In our study, the prevalence of RA (3.5%) is slightly lower than in Pagnotta et al. This can be explained with the technical developments that occurred in the time frame between the two studies, which include more supportive guiding catheters, very low-profile balloons with higher inflation pressure capability, microcatheters, alternative plaque modifying devices and dissection-reentry techniques. Similar to our study, RA procedures were longer and final TIMI flow (a surrogate of procedural success) was similar between the two groups. No coronary perforation or inhospital mortality was observed in the RA group, but no longer-term follow-up data were provided.

Our study adds important data to the literature on RA for CTO PCI. As compared with the aforementioned report [4], our registry includes a larger sample from four centers with several experienced operators involved. We performed a detailed angiographic analysis, with currently used angiographic variables (e.g., J-

CTO score). Procedures were carried out using contemporary techniques ("hybrid algorithm" [1]) and devices (lower profile balloons, microcatheters, etc.). Finally, we provide relevant data on the long-term clinical outcomes of this challenging patient population.

In our experience, RA is seldom necessary in contemporary CTO PCI. However, when needed, it was safe and effective in achieving adequate lesion preparation in the vast majority of patients (97%). Nevertheless, final success rates were lower, as compared with Conventional PCI. The need for RA was an independent predictor of procedural failure, together with the use of dissection/re-entry techniques and age. This likely reflects the higher complexity of the occlusions where aggressive techniques such as RA and dissection/re-entry were required. However, it also underscores the need to be very selective in the use of this device in CTO PCI, as in our series.

Despite this finding, long-term follow-up showed similar MACE rates between the two groups. Interestingly, the incidence of target-vessel MI was higher in RA

TABLE III. Rotational atherectomy data

Variable	N = 35	
Guiding catheter (French)		
6	11 (31%)	
7	8 (23%)	
8	16 (46%)	
Bailout rotational atherectomy	27 (77%)	
Indication		
Balloon failure-to-cross	18 (51%)	
Balloon failure-to-expand	17 (49%)	
Number of burrs used		
One	30 (86%)	
Two	5 (14%)	
Largest burr used (mm)		
1.25	15 (43%)	
1.50	12 (34%)	
1.75	5 (14%)	
2.00	3 (9%)	
Number of passes	4.1 ± 1.3	
Revolutions per minute	$170,217 \pm 13,010$	
Temporary pacemaker	9 (26%)	
Rotational atherectomy success	34 (97%)	
Complications		
Slow flow/no reflow	6 (17%)	
Bradyarrhythmia	6 (17%)	
Dissection	10 (29%)	
Perforation	0	

patients. This observation must be taken with caution, since it was driven by just three events in the RA group, and might hence be due to the play of chance. Well-known clinical characteristics (prior CABG, left ventricular dysfunction and number of diseased vessels) were confirmed as independent predictors of MACE, while—importantly—RA showed no such association.

According to experts' recommendations, RA should not be performed in dissection planes, or it should be stopped when an angiographic image of dissection is observed, as further passages of the burr could cause vessel wall rupture [13]. However, this concern is not up-to-date with evidence from current practice. Indeed, with the recent development of advanced CTO devices and the evolution of procedural strategy, expert CTO PCI operators have pushed the boundaries of their comfort zone from the true lumen to the subadventitial space. The latter has been shown to be an environment where devices such as knuckled wires, microcatheters and blunt dissection tools (e.g., CrossBoss, Boston Scientific), can be safely manipulated within the limit of the resistant adventitia ("vessel architecture"). When the occlusion is extensively calcified and resistant to balloon dilatation, RA can be performed, even in dissection planes, as long as wire positioning in the vessel architecture is confirmed. Fairley et al. [15] reported a successful and uncomplicated case of RA through a heavily calcified subintimal channel following retrograde recanalization of a CTO using reverse controlled antegrade and retrograde subintimal tracking. In our cohort, RA was safely performed after dissection/re-entry in seven cases (20%). No complications occurred.

As observed in our study, the need for RA is increased when true-to-true lumen crossing is performed, as the CTO wire traverses very complex and resistant tissue, as compared with a dissection-reentry technique that tracks around calcified plaques. Although very effective, RA has few important drawbacks, including high cost, need for specific training, as well as specific and potentially serious complications (burr entrapment, bradyarrhythmias, perforation, dissection, and slow flow/no-reflow) [13]. As a consequence, several alternatives to RA in CTO PCI have been sought. Recently, low-profile high-pressure non-compliant balloons have become available, and represent the first step in the treatment of resistant, highly-calcified lesions. If

TABLE IV. Clinical outcomes on follow-up

	Overall $(n = 910)$	Rotational atherectomy $(n = 33)$	Conventional PCI (n = 877)	P value
Major adverse cardiac events	118 (13%)	5 (15%)	113 (13%)	0.70
Cardiac death	29 (3%)	2 (6%)	27 (3%)	0.34
Target-vessel myocardial infarction	27 (3%)	3 (9%)	24 (3%)	0.04
Ischemia-driven target-vessel revascularization	82 (9%)	2 (6%)	80 (9%)	0.55

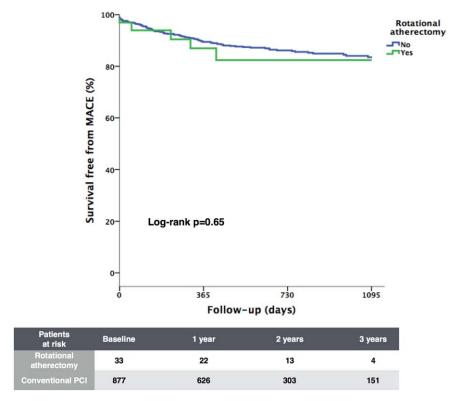


Fig. 3. Kaplan-Meier curves of survival free from major adverse cardiac events (MACE) on follow-up in CTO patients treated with rotational atherectomy versus conventional techniques. [Color figure can be viewed at wileyonlinelibrary.com]

complete expansion of such balloons is not achieved, the use of alternative devices must be considered. The Tornus is a dedicated penetration microcatheter that is manually "screwed" into the occlusion over a conventional 0.014-in. guidewire by up to 20 consecutive counterclockwise rotations. Small registries suggested the efficacy and safety of this device in moderately calcified occlusions [8,9,16]. However, when Tornus was compared with RA, the former was less successful in case of severe calcification [9,16], where RA showed superior success rates and lower procedural times [8]. In our experience, while Tornus is useful to traverse the occlusion in balloon-uncrossable CTOs, RA is rather used in balloon-resistant lesions that have been successfully crossed with a microcatheter, thus allowing exchange with a guidewire. Excimer laser atherectomy represent another tool to deal with severely calcified occlusions. Experience in CTO is mostly limited to case reports and small series [17,18]. In a small British single-center study, laser—either alone or in combination with RA-was successful in 89% of cases, with no cases of perforation or other laserrelated complications [18]. Finally, another technique that can be useful in cases of balloon failure-to-cross/ expand is "external crush": after successful wiring of the occlusion, a second wire is advanced into the subadventitial space, and a balloon is subsequently inflated to crush the plaque from the subadventitial space, thus enabling to move gear on the wire initially placed in the true lumen [19].

Our study has some limitations. First, it is an observational study, with all the inherent bias ascribed to this kind of design. However, randomized data on RA in CTO PCI are lacking (and unlikely to be ever available), and evidence presently derives from cohort studies like the present report. Second, follow-up was not available for the whole study population, which however is unlikely to have biased conclusions, since only 9% of patients were lost to follow-up. Third, we could not identify cases where RA was possibly desired in the setting of a balloon-uncrossable lesion, but it could not be performed due to impossibility to rewire the occlusion with the RotaWire (Boston Scientific). Such cases probably represented only a very small fraction among Conventional PCI procedures, and, if reclassified into the RA group, would have only amplified the already observed differences in technical and procedural success rates favoring the Conventional PCI group. Finally, the small sample size of the RA group might have led to inaccurate estimation of the true incidence of procedural complications and adverse events both in-hospital and during follow-up. Still, our study provides relevant data on the real-world utilization and outcomes of RA in a large cohort of CTO patients treated at four high-volume specialized institutions.

CONCLUSIONS

In a large, contemporary and multicenter registry of all-comer patients undergoing CTO PCI, RA was required in a small proportion of cases. The use of RA to achieve CTO recanalization was safe, both following a true-to-true lumen approach and when dissection/reentry techniques were used. As compared with conventional PCI techniques, RA was used in more challenging clinical and angiographic scenarios. As such, the procedural success rate was lower in the RA group. However, there were no differences in clinical outcomes on long-term follow-up between the RA and Conventional PCI groups.

LITERATURE CITED

- Brilakis ES, Grantham JA, Rinfret S, Wyman RM, Burke MN, Karmpaliotis D, Lembo N, Pershad A, Kandzari DE, Buller CE, DeMartini T, Lombardi WL, Thompson CA. A percutaneous treatment algorithm for crossing coronary chronic total occlusions. JACC Cardiovasc Interv 2012;5:367–379.
- Azzalini L, Vo M, Dens J, Agostoni P. Myths to debunk to improve management, referral, and outcomes in patients with chronic total occlusion of an epicardial coronary artery. Am J Cardiol 2015;116:1774–1780.
- Wilson WM, Walsh SJ, Yan AT, Hanratty CG, Bagnall AJ, Egred M, Smith E, Oldroyd KG, McEntegart M, Irving J, Strange J, Douglas H, Spratt JC. Hybrid approach improves success of chronic total occlusion angioplasty. Heart 2016;102: 1486–1493.
- Pagnotta P, Briguori C, Mango R, Visconti G, Focaccio A, Belli G, Presbitero P. Rotational atherectomy in resistant chronic total occlusions. Catheter Cardiovasc Interv 2010;76:366–371.
- Patel SM, Pokala NR, Menon RV, Kotsia AP, Raja V, Christopoulos G, Michael TT, Rangan BV, Sherbet D, Patel VG, Abdullah SA, Hastings J, Grodin JM, Banerjee S, Brilakis ES. Prevalence and treatment of "balloon-uncrossable" coronary chronic total occlusions. J Invasive Cardiol 2015;27:78–84.
- Tanabe M, Wada A, Doi O. Successful interventional revascularization utilizing hybrid procedural steps of rotational atherectomy and retrograde approach via an ipsilateral collateral. Cardiovasc Interv Ther 2016;31:309–315.
- Fang HY, Wu CJ. Recanalization of calcified left anterior descending artery chronic total occlusion with rotational atherectomy via bilateral radial approach. Catheter Cardiovasc Interv 2011;78:873–879.
- Fang HY, Fang CY, Hussein H, Hsueh SK, Yang CH, Chen CJ, Hsieh YK, Hang CL, Yip HK, Wu CJ. Can a penetration catheter (Tornus) substitute traditional rotational atherectomy for recanalizing chronic total occlusions? Int Heart J 2010;51:147– 152
- Pagnotta P, Briguori C, Ferrante G, Visconti G, Focaccio A, Belli G, Presbitero P. Tornus catheter and rotational atherec-

- tomy in resistant chronic total occlusions. Int J Cardiol 2013; 167:2653.
- Christopoulos G, Karmpaliotis D, Alaswad K, Lombardi WL, Grantham JA, Rangan BV, Kotsia AP, Lembo N, Kandzari DE, Lee J, Kalynych A, Carlson H, Garcia S, Banerjee S, Thompson CA, Brilakis ES. The efficacy of "hybrid" percutaneous coronary intervention in chronic total occlusions caused by in-stent restenosis: Insights from a US multicenter registry. Catheter Cardiovasc Interv 2014;84:646–651.
- 11. Morino Y, Abe M, Morimoto T, Kimura T, Hayashi Y, Muramatsu T, Ochiai M, Noguchi Y, Kato K, Shibata Y, Hiasa Y, Doi O, Yamashita T, Hinohara T, Tanaka H, Mitsudo K. Predicting successful guidewire crossing through chronic total occlusion of native coronary lesions within 30 minutes: The J-CTO (Multicenter CTO Registry in Japan) score as a difficulty grading and time assessment tool. JACC Cardiovasc Interv 2011;4:213–221.
- 12. Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD, Infarction WG, on the JETF for the UD, of M, Katus HA, Apple FS, Lindahl B, Morrow DA, Chaitman BA, Clemmensen PM, Johanson P, Hod H, Underwood R, Bax JJ, Bonow RO, Pinto F, Gibbons RJ, Fox KA, Atar D, Newby LK, Galvani M, Hamm CW, Uretsky BF, Steg PG, Wijns W, Bassand J-P, Menasche P, Ravkilde J, Ohman EM, Antman EM, Wallentin LC, Armstrong PW, Januzzi JL, Nieminen MS, Gheorghiade M, Filippatos G, Luepker RV, Fortmann SP, Rosamond WD, Levy D, Wood D, Smith SC, Hu D, Lopez-Sendon J-L, Robertson RM, Weaver D, Tendera M, Bove AA, Parkhomenko AN, Vasilieva EJ, Mendis S. Third universal definition of myocardial infarction. Eur Heart J 2012;33:2551–2567.
- 13. Barbato E, Carrié D, Dardas P, Fajadet J, Gaul G, Haude M, Khashaba A, Koch K, Meyer-Gessner M, Palazuelos J, Reczuch K, Ribichini FL, Sharma S, Sipötz J, Sjögren I, Suetsch G, Szabó G, Valdés-Chávarri M, Vaquerizo B, Wijns W, Windecker S, De Belder A, Valgimigli M, Byrne RA, Colombo A, Di Mario C, Latib A, Hamm C. European expert consensus on rotational atherectomy. EuroIntervention 2015;11:30–36.
- Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. JACC Cardiovasc Interv 2014;7:345–353.
- 15. Fairley SL, Spratt JC, Rana O, Talwar S, Hanratty C, Walsh S. Adjunctive strategies in the management of resistant, "undilatable" coronary lesions after successfully crossing a CTO with a guidewire. Curr Cardiol Rev 2014;10:145–157.
- 16. Fang H-Y, Lee C-H, Fang C-Y, Lin C-J, Wu C-C, Yang C-H, Chen C-J, Hsieh Y-K, Yip H-K, Wu C-J. Application of penetration device (Tornus) for percutaneous coronary intervention in balloon uncrossable chronic total occlusion-procedure outcomes, complications, and predictors of device success. Catheter Cardiovasc Interv 2011;78:356–362.
- Azzalini L, Ly HQ. Laser atherectomy for balloon failure in chronic total occlusion. When the going gets tough. Int Heart J 2014;55:546–549.
- 18. Fernandez JP, Hobson AR, McKenzie D, Shah N, Sinha MK, Wells TA, Levy TM, Swallow RA, Talwar S, O'Kane PD. Beyond the balloon: excimer coronary laser atherectomy used alone or in combination with rotational atherectomy in the treatment of chronic total occlusions, non-crossable and non-expansible coronary lesions. EuroIntervention 2013;9: 243–250.
- Vo MN, Ravandi A, Grantham JA. Subintimal space plaque modification for "balloon-uncrossable" chronic total occlusions. J Invasive Cardiol 2014;26:E133–E136.