

The Efficacy of a Bilateral Approach for Treating Lesions With Chronic Total Occlusions

The CART (Controlled Antegrade and Retrograde subintimal Tracking) Registry

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Objectives The aim of this study was to evaluate the safety and feasibility of a new concept for chronic total occlusion (CTO) recanalization—using a bilateral approach that utilizes a Controlled Antegrade and Retrograde subintimal Tracking (CART) technique.

Background Successful percutaneous recanalization of coronary CTOs results in improved long-term outcomes. The recanalization of CTOs in native coronary arteries no doubt represents one of the most technically challenging of interventional procedures.

Methods A total of 224 consecutive patients (mean age 61 ± 9 years; 86.2% men) were enrolled in this prospective multicenter registry. This technique combines the simultaneous use of antegrade and retrograde approaches. A subintimal dissection is created in both antegrade and retrograde fashion, thereby limiting the extension of the subintimal dissection within the CTO portion.

Results Of 224 CTO lesions (>3 months in duration) undergoing attempted recanalization using the CART technique, 145 cases (64.7%) had undergone previous CTO recanalization attempts. The success rates of crossing in a retrograde fashion with a wire and a balloon were 87.9% and 79.9%, respectively. The overall technical and procedural success rates achieved in this registry were 92.4% and 90.6%, respectively.

Conclusions A bilateral approach for CTO lesions using the CART technique is feasible, safe, and has a higher success rate than previous approaches. These results indicate that a bilateral technique can solve a major dilemma that commonly affects CTO procedures. (J Am Coll Cardiol Intv 2009;2: 1135–41) © 2009 by the American College of Cardiology Foundation

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Successful percutaneous recanalization of coronary chronic total occlusions (CTOs) results in improved survival as well as enhanced left ventricular function, reduced angina, and improved exercise tolerance (1–6). Nevertheless, while percutaneous coronary intervention (PCI) with stenting in a persistently occluded, infarct-related artery in the subacute phase after myocardial infarction (MI) effectively maintains long-term patency, it has no effect on left ventricular ejection fraction. This suggests that routine PCI should not be recommended for stable patients with a persistently occluded infarct-related artery after MI (7). The practice of recanalization of CTO lesions is still controversial. The introduction of coronary stents, including drug-eluting stents, has resulted in a marked improvement in procedural success for CTO recanalization, but the procedural success rate has still remained around 70% and has not improved during the past decade (2,8). Further development of new techniques and devices to improve success rates for CTO recanalization is required.

Recently, we attempted to improve post-procedural outcomes using a bilateral approach for the treatment of complex CTO lesions. We have developed a new concept for CTO recanalization, the Controlled Antegrade and Retrograde Subintimal Tracking (CART) technique (9,10), which allows limited subintimal tracking only in the area of the CTO lesion. Used in combination with a retrograde approach, this technique avoids the difficulty of re-entering the distal true lumen.

Few previous studies have reported acute results with the introduction of this technique (11). The aim of this study was to evaluate the safety and feasibility of using a bilateral approach including the CART technique, a new concept for CTO recanalization.

Methods

Patient population and protocol. The CART registry is a prospective, nonrandomized, multicenter (43 centers) trial that enrolled 224 patients with CTO lesions from October 2005 to April 2008. Inclusion criteria were CTO lesions located in the left anterior descending artery, right coronary artery, left circumflex artery, or left main coronary artery with eligible collateral channels with greater than grade I fillings of the recipient artery assessed according to the Rentrop classification (12). In cases with eligible collateral channels (Rentrop class >1), after careful assessment by super-selective contrast injection with a microcatheter, the most suitable collateral with the best collateral connection grade (13) was assessed. Patients were excluded for any of

the following: use of heparin, aspirin, or clopidogrel; severe renal failure (patients with hemodialysis were included); or severe heart failure or acute MI (within 2 weeks). In addition, cases without any collateral channel (Rentrop class 0) and cases with a collateral channel (often epicardial channel) serving as the only remaining feeding donor artery were contraindications for the retrograde approach. The protocol was approved by ethics committees in each participating center, and all participants gave written informed consent.

Definitions. Coronary CTO is defined as a true total occlusion with complete interruption of antegrade blood flow as assessed by coronary arteriography (Thrombolysis In Myocardial Infarction [TIMI] flow grade 0, known as a “true” total occlusion) and with an estimated duration of occlusion >3 months. Technical success was defined as the ability to cross the occluded segment with both a wire and a balloon and successfully open the artery; the restoration of antegrade, TIMI flow grade 3; and a <40% final residual stenosis on all views. Procedural success was defined as technical success with no in-hospital major adverse cardiac events (MACE). In-hospital MACE included death, Q-wave MI, or recurrent angina that resulted in urgent revascularization (coronary artery bypass graft surgery/urgent repeat percutaneous transluminal coronary angioplasty). MI was diagnosed by an increase in the creatine kinase level to >2× the upper limit of normal.

Interventional technique. Without attempting antegrade recanalization, the retrograde approach via collateral channels was attempted in all cases. During the retrograde approach, retrograde wire crossing, kissing wire technique (11), knuckle wire technique, CART technique, or reverse CART technique were attempted. First, a hydrophilic floppy wire was advanced in retrograde fashion through the intercoronary collateral using a microcatheter. After careful collateral channel assessment by super-selective contrast injection, the wire was advanced through the most suitable collateral. A small balloon (1.25 mm or 1.5 mm) or septal dilator (Asahi Intec, Aichi, Japan) was then advanced in the collateral channel.

With regard to the CART technique, as described previously (9,10), the retrograde wire is placed at the distal end of the CTO. The wire then penetrates in retrograde fashion from the distal true lumen into the CTO, and finally into the subintimal space at the CTO site. Simultaneously, another wire is advanced in antegrade fashion from the proximal true lumen into the CTO, then into the subintimal space at the CTO site. After advancing while inflating a small balloon (1.5 to 2.0 mm) over the retrograde wire into the subintima, the 2 dissections created by the antegrade wire and the retrograde balloon lie in the subintima at the CTO site, which allows them to be easily connected. Thereafter, the antegrade wire is advanced to the distal true lumen, after which balloon dilation and stent implantation

Abbreviations and Acronyms

CTO = chronic total occlusion

MACE = major adverse cardiac events

MI = myocardial infarction

PCI = percutaneous coronary intervention

are performed following successful recanalization. This technique allows limited subintimal tracking only in the portion of the CTO lesion. The reverse CART technique is a modified version of the CART technique in which a retrograde wire crosses the subintimal space after balloon dilation with an antegrade balloon. The knuckle wire technique is a procedure used to form the subintimal space, instead of using a balloon, with the rounded tip of the wire, which resembles a “knuckle” (Fig. 1). This technique is effective for CTO lesions characterized by heavy calcification or bending, in which only the wire crosses the lesion and the balloon is not able to enter. If we failed retrograde guidewire crossing, an antegrade approach was attempted. In this registry, patients were treated by a pair of highly skilled, experienced operators (O.K. and E.T.). Of 224 cases, 191 cases were treated by O.K. and 33 were treated by E.T. All patients were treated with a thienopyridine (ticlopidine or clopidogrel) and aspirin, and all patients received heparin at the time of the procedure to achieve an activated clotting time of 250 to 350 s.

End points and statistics. The primary end points for this analysis were technical and procedural success, and in-hospital MACE, defined as cardiac death and Q-wave MI. Each participating center was required to prospectively record all patient data on case report forms. Data were forwarded to the core laboratory for data entry and analysis. Data that were missing, inconsistent, or both were obtained or clarified by direct communication by the core laboratory with the respective clinical center. Continuous variables were expressed as the mean ± SD. Variable categories were expressed as frequencies.

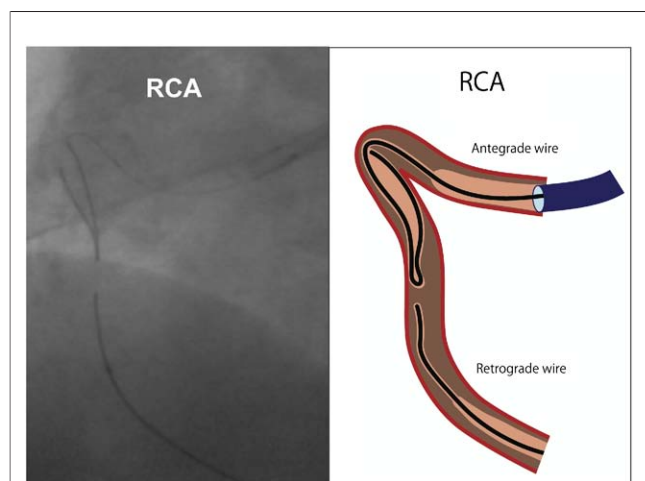


Figure 1. The Knuckle Wire Technique

The technique is used to make the subintimal space, instead of using the balloon, with the rounded tip of the wire, which resembles the “knuckle.” RCA = right coronary artery.

Table 1. Baseline Patient Characteristics (n = 224)

Age, yrs	61.3 ± 9.2
Men	193 (86.2)
Current smoker	85 (37.9)
Diabetes mellitus	67 (29.9)
Hypertension	172 (76.7)
Hyperlipidemia	141 (62.9)
Creatinine >1.5 mg/dl	31 (13.9)
Prior AMI	51.8
Prior CABG	17.6
History of CTO, months	46.2 ± 56.3
Ejection fraction	51.4
Target vessel	
LM	3 (1.3)
LAD	54 (24.1)
LCX	9 (4.0)
RCA	156 (69.6)
Bypass graft segment	2 (0.9)
Total cholesterol, mg/dl	194.1 ± 43
LDL cholesterol, mg/dl	120.0 ± 38.0
HDL cholesterol, mg/dl	46.4 ± 13.6
Triglyceride, mg/dl	175.1 ± 147.9
Fasting glucose, mg/dl	119.2 ± 40.8

Data presented as mean ± SD, n (%), or %.

AMI = acute myocardial infarction; CABG = coronary artery bypass graft; CTO = chronic total occlusion; HDL = high-density lipoprotein; LAD = left anterior descending artery; LCX = left circumflex artery; LDL = low-density lipoprotein; LM = left main coronary artery; RCA = right coronary artery.

Results

Baseline characteristics. All 224 consecutive patients (224 lesions) who underwent PCI for a chronically occluded native coronary vessel were included in this registry. Baseline patient demographic and clinical data are shown in Table 1. The CTO vessel was located in the right coronary artery in 156 (69.6%) patients, the left anterior descending coronary artery in 54 (24.1%) patients, the left circumflex coronary artery in 9 (4.0%) patients, the left main coronary artery in 3 (1.3%) patients, and bypass graft segments in 2 (0.9%) patients. Target CTO lesions showed “no-stump” ends in 170 (75.9%) lesions, were located at the branching point in 139 (62.1%) lesions, and had fluoroscopically visible calcification in 130 (58.0%) lesions. After failure upon first attempt with the antegrade approach, reattempts were made in 64.7% of the patients in this registry.

Acute results. The flow diagram of the procedure is shown in Figure 2. The septal branch, epicardial artery, and bypass graft served as retrograde access routes in 177 (79.0%), 40 (17.9%), and 7 (3.1%) patients, respectively. Successful retrograde wire crossing via collateral channels was achieved in 197 (87.9%) of 224 attempted cases. Of those cases, successful retrograde balloon crossing via collateral channels was achieved in 179 (79.9%) cases. In cases with successful wire and balloon crossing, technical success was achieved in

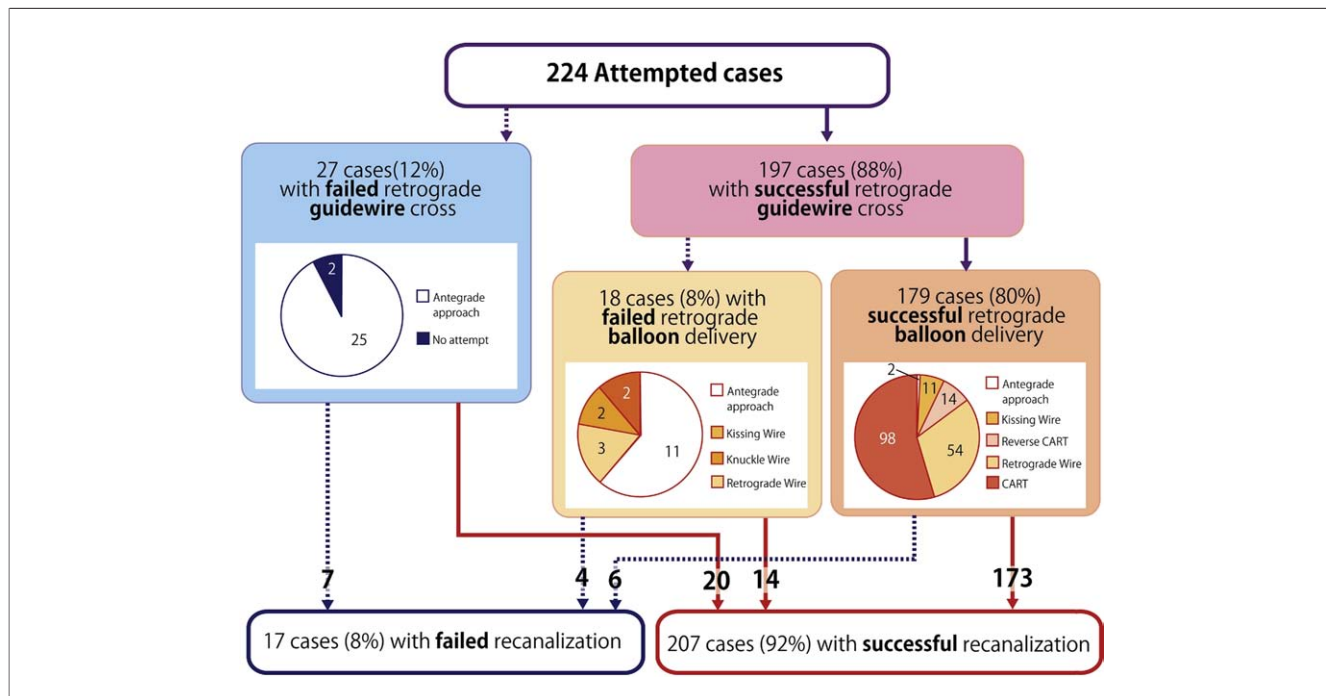


Figure 2. Flow Diagram of the Procedure

In 197 of 224 patients, a retrograde guidewire was successfully crossed into the target artery distal to the chronic total occlusion lesion. In 189 patients, a retrograde balloon was successfully crossed into the target artery distal to the chronic total occlusion lesion. Successful recanalization was achieved in 207 patients. **Solid arrows** shows "success," and **dashed arrows** "failure." CART = Controlled Antegrade and Retrograde subintimal Tracking.

173 (96.6%) of 179 patients. In 2 cases, we treated CTO lesions using an antegrade approach after successful wire and balloon crossing via collateral channels because the retrograde wire was unable to cross the CTO lesion due to excessive calcification. There were 6 failed cases after successful wire and balloon crossing. In 2 of these cases, both retrograde and antegrade wires were unable to cross the CTO lesion due to excessive bend caused by bypass grafting. In the other 2 cases, both retrograde and antegrade wires were unable to cross the CTO lesion due to excessive calcification. In 1 case, the retrograde wire was trapped by calcification, and the procedure was abandoned. In the final case, the CTO lesion could not be crossed with any device after wire crossing due to severe calcification. The CART technique was used in 112 (62.6%) cases with successful wire and balloon delivery through collateral channels. After failed retrograde guidewire crossing in 27 cases, 25 antegrade approaches were attempted, with technical success achieved in 20 cases.

In this registry, drug-eluting stents were implanted in 203 (98.1%) of 207 patients after successful recanalization. The mean number of implanted stent was 2.3 ± 1.1 , and the total stented length was 53.5 ± 23.9 mm. Mean procedure and fluoroscopy times were 173 ± 75 min and 73 ± 42 min, respectively. The average contrast amount used was 457 ± 199 ml.

Clinical outcomes. During the index hospitalization, in-hospital MACE occurred at a rate of 1.8%. The rates of

Q-wave MI and non-Q-wave MI were 0.9% and 3.6%, respectively (Table 2). After including those cases in which an antegrade approach was attempted after a retrograde approach failed, the overall technical and procedural success rates were 92.4% (207 of 224 patients) and 90.6% (203 of 224 patients), respectively. Major in-hospital complications are shown in Table 3. In addition, hematoma/perforation in the septal branch, minor perforation/dissection in a distal vessel, and minor distal embolism at post-procedure were observed in 3 cases, 2 cases, and 1 case, respectively. Dissection in the ostium of a donor artery due to the guiding catheter occurred in 1 case. No major collateral sources were lost.

Table 2. In-Hospital Clinical Outcome

Death	1 (0.4)
Q-wave MI	2 (0.9)
Non-Q-wave MI	8 (3.6)
Urgent re-PCI or CABG	1 (0.4)
Perforation	7 (3.1)
CVA	0 (0)
MACE	4 (1.8)

Values are n (%).

CABG = coronary artery bypass surgery; CVA = cerebrovascular accident; MACE = major cardiac events; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Table 3. In-Hospital Complications

Complications	No. of Cases	Caused By	Sequel
Distal embolization	1	Stenting (3.0 mm)	No flow
Coronary rupture	1	1.25 mm Rotablator Barr*	Emergency CABG
Renal artery rupture	1	A tip of guidewire	Death

*Rotablator Rotational Atherectomy System, Boston Scientific Corporation, Natick, Massachusetts.
 CABG = coronary artery bypass graft surgery.

Discussion

Recently, several studies investigating the retrograde approach have been published (11,14). However, small numbers of patients were enrolled in each study due to the recent development of the technique and the complexity of the procedure. This is the first prospective, multicenter registry to examine the safety and efficacy of the retrograde approach in the patient population with complex CTO lesions enrolled in the CART registry. The main findings of our analysis are as follows: 1) retrograde access for approach and treatment was available in 197 (88%) of 224 attempted patients, and the final procedural success rate was 90.6%; and 2) the CART technique was used in 62.6% of cases using the retrograde approach.

Success rate. Several large studies (2,5) have reported on the clinical impact of successful percutaneous CTO revascularization. In particular, studies have shown that successful PCI of a CTO lesion reduces the incidence of MI, cardiac death, and bypass surgery, resulting in enhanced 1-year survival. From this point of view, the influence of the immediate result of a CTO procedure on long-term outcomes is an important factor. In recent contemporary series, procedural success rates have ranged from 55% to 80%, with the variability reflecting differences in operator technique and experience, availability of advanced guidewires, CTO definitions, and case selection (2,15). Recent procedural outcomes after PCI for CTO lesions have increased significantly due to improved device technology, as well as technique and experience, such that successful recanalization of true CTOs may now be achieved in approximately 80% of attempted lesions (2,5,16). We reported that technical success was achieved in 207 (92.4%) of 224 attempted cases using a retrograde approach including the CART technique. In this registry, CTO lesions were most frequently located in the right coronary artery (69.6%), similar to previous reports of experience with a retrograde approach (11,17,18), although several studies (2,8) have demonstrated an equal distribution of CTO lesions in all 3 vessels. This discrepancy could be explained by the inclusion of cases with a retrograde approach and reattempted cases, which means that these cases included those with septal channels deemed suitable for approach as well as more complex cases. Additionally, in patients enrolled in this registry, there was a high

incidence of diabetes, calcified lesions, previous attempts to open the occlusion, and longer CTO length. With such a complex patient population, it could be argued that CTO lesions attempted in this registry were more difficult to successfully treat than those of previous CTO studies. The high success rate in this registry was achieved despite the complex nature of the treated lesions (more repeat cases, diabetes, older CTO ages, and so on), which negatively affect the ability to successfully cross a CTO (3,5,19-23). Even with improvements in guidewire technology, guidewire crossing of a CTO is the most technically demanding phase of the procedure and the point at which success or failure is typically determined. The most common PCI failure mode for CTOs is the inability to successfully pass a guidewire across the lesion into the true lumen of the distal vessel when attempting to cross in an antegrade fashion (24). Jaffe et al. (25) analyzed the natural history of CTOs in an experimental model. In their histological analysis, anatomic evidence was shown of a "proximal fibrous cap," which was a thickened structure at the entrance of the CTO containing particularly densely packed collagen. Microcomputed tomographic imaging also demonstrated spatial differences in vascular geometry. Regression of the proximal recanalization channel and the blunt entrance appeared at 24 weeks (25). The histological composition of the proximal fibrous cap is thicker and harder than that of the distal fibrous cap (9,25). In addition, on angiography, the distal end of the CTO is typically tapered, although whether the proximal end of the CTO shows a tapered or abrupt occlusion depends on the individual case. Ozawa et al. (26) found that the CTO lesion could be crossed without difficulty even with a soft wire by following the retrograde approach. This was probably because the distal lesion was tapered and the fibrous cap at that end was either very thin or nonexistent (26). These 2 characteristics (thin, tapered) of the distal fibrous cap have been of paramount importance in spurring the development and successful application of the retrograde approach for percutaneous CTO recanalization (9). This anatomy and technique may account in large part for the ease of retrograde wiring and could be associated with the higher success rate achieved in this registry. We believe that the degree of difficulty in crossing a CTO lesion with a wire is, in part, different between the antegrade and retrograde approaches.

Complications of CTO angioplasty. Typical complications with an antegrade approach are often induced by excessive challenges to cross with stiffer guidewires. During CTO angioplasty, death and MI may occur from shearing off the collateral circulation, damaging the proximal epicardial coronary artery or proximal side branches, thrombus formation, arrhythmia, air embolism, or perforation (27,28). A bilateral approach allows us to avoid such excessive challenges because it is possible to change the approach side if either side proves too difficult to cross with a wire. The

complications that accompany the retrograde approach are similar to those encountered with the antegrade approach, except for device-induced thrombosis in the donor artery, collateral perforations, subendocardial hematoma, and collateral channel rupture. The rate of in-hospital MACE in this registry was 1.8%. This was lower than previously reported (2,5), although the strategy was more complicated and required a steeper learning curve than the conventional approach. A total of 3 in-hospital major complications occurred in the early phase (within 8 months of the beginning of this registry). These results may suggest that the retrograde approach with the CART technique is safe and secure, but requires a learning period. A possible reason for the low rate of in-hospital MACE could be the participation of experienced, highly skilled operators in this registry. Minor complications such as hematoma/perforation/dissection/embolism in septal branches and distal vessels were also observed. These minor complications did not induce residual ischemia or loss of the major collateral source.

Study limitations. Although this was a multicenter registry, the study was performed in a nonrandomized manner. We included CTO lesions for a retrograde approach with eligible collateral channels with greater than grade I fillings of the recipient artery assessed according to Rentrop classification. The success of CTO angioplasty is highly dependent on the operator's experience. In this registry, patients were treated by a pair of highly skilled, experienced operators (O.K. and E.T.). There were other CTO cases in each institute that were unsuitable for a retrograde approach during this registry that were difficult to investigate. In this registry, as we examined the feasibility of the retrograde approach, all procedures were initiated in a retrograde manner, unlike the general strategy for CTO lesions. Appropriately powered randomized trials using the latest technology are required to definitively prove their safety and efficacy for this application.

Conclusions

The use of a combination of antegrade and retrograde approaches including the CART technique for CTO lesions is feasible and safe. This approach can provide a higher rate of successful CTO recanalization than the previous approach. These results indicate that this technique can solve a major dilemma with current CTO procedures.

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