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# **Outcomes of Percutaneous Antegrade Intraluminal Coronary Intervention of Chronic Total Occlusion With Remote Surgical Backup**

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**Abstract:** Percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) is not favored in facilities without on-site surgical backup. We reviewed outcomes of patients who had CTO intervention with remote surgical backup in our institution. All patients who underwent attempted antegrade intraluminal CTO PCI from January 2013 to July 2017 were analyzed. Twenty cases (18 patients,  $58.1 \pm 7.0$  years, 70% males) were identified. Procedure was successful in 85% (17 of 20). There were 2 nonflow limiting dissections and 1 wire perforation. Two patients had post-PCI myocardial infarction. There was no cardiac death, myocardial infarction, target vessel revascularization, or stroke at 30 days and at mean follow-up of  $19.5 \pm 13.7$  months. There were 4 rehospitalizations for angina requiring repeat angiogram in 3 cases: 2 without intervention, and 1 referred for coronary artery bypass grafting. Careful attempt at antegrade intraluminal CTO intervention done at a center with remote surgical backup is feasible in selected patients.  
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## Introduction

**C**hronic total occlusion (CTO) of coronary artery is frequently encountered in patients with chronic stable angina. The overall prevalence is unknown because not all patients with CTO are symptomatic but a prevalence of approximately 20% has been reported in patients with coronary artery disease referred for nonemergent coronary angiogram.<sup>1</sup> Symptomatic patients have persistent angina symptoms and impaired daily quality of life despite optimal medical therapy but it is now well known that successful percutaneous coronary intervention (PCI) of CTOs improves quality of life, left ventricular systolic function, and mortality.<sup>2-4</sup>

The annual volume of coronary CTO intervention in stable coronary artery disease patients continues to increase (3.2% in 2009 to 4.8% in 2013)<sup>5</sup> due to improved technology, availability of new interventional wires and support microcatheters, improved operator skills and techniques, and observational evidence of improved clinical outcomes with successful intervention; however, only approximately 35% of CTO are treated with revascularization, either with PCI or coronary artery bypass grafting (CABG).<sup>1</sup> It is initially believed that the myocardial area supplied by the occluded coronary artery are infarcted and will not benefit from revascularization, but recent studies suggest that myocardium supplied by coronary arteries with CTO are ischemic and PCI of the CTO significantly reduced the associated ischemic burden.<sup>6,7</sup>

PCI of CTO is, however, not currently favored in facilities without on-site surgical backup and it is currently a Class III recommendation by the 2014 Society of Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology (ACC) and American Heart Association (AHA) expert consensus document.<sup>8</sup> However, there are subsets of patients with persistent angina despite optimal medical therapy, who receive their health care from local charity hospitals that are not equipped with cardiothoracic surgical capabilities, and a lack of health insurance precludes the referral to state-of-the-art facilities for CTO interventions, a scenario encountered in our facility. Although, our facility lacks on site surgical backup, we have a university medical center 4 minutes away from our facility. A careful attempt at antegrade intraluminal CTO intervention was done in patients with persistent angina symptoms despite optimal medical therapy and the present study evaluates the procedural success and safety of CTO PCI at our institution, including both the short- and long-term outcomes of these patients.

## Methods

This study was a single-center retrospective analysis of patients who underwent attempted revascularization of a native coronary artery CTO from January 2013 to July 2017 at our institution, the University of Tennessee Health Science Center, Regional One Hospital, Memphis, TN.

A CTO was defined as total occlusion (TIMI 0) of the coronary artery that was 3 months or more in duration. Baseline characteristics including age, sex, medical history, medications at time of intervention and at follow-up, echocardiographic parameters at the time of intervention were collected. Procedural characteristics and complications were also recorded. PCI was defined as successful if there was <20% residual stenosis and there was TIMI 2 or 3 flow. The clinical outcomes at 30 days and at the last recorded follow-up visit, which includes cardiac death, myocardial infarction (MI), target vessel revascularization, heart failure, stroke, and rehospitalization, were recorded.

All patients provided informed consent prior to the procedure. Due to the retrospective nature of our study, the informed consent requirement was waived. The Multicenter CTO Registry in Japan (J-CTO) score for each lesion as determined by 2 experienced interventional cardiologists was used in estimating the technical difficulty of recanalizing the coronary artery CTO. Angiographic in-stent restenosis was defined as stenosis  $\geq 50\%$  by visual estimation. Target vessel revascularization was defined as repeat CTO revascularization for symptoms from recurrent stenosis or occlusion. PostPCI-related MI was defined as an increase in cardiac troponin of  $>20\%$  from baseline level according to the ESC, ACC and AHA 2012 universal definition of MI, specifically types 4a and 5 (PCI-related and CABG-related MI, respectively).<sup>9</sup> All CTO interventions were by the antegrade intraluminal technique.

Data analysis was performed using descriptive statistics such as mean and standard deviations, frequencies, and percentage frequency distributions using SPSS software package, version 24 (IBM Corporation, Armonk, NY). Approval for the study was granted by the University of Tennessee Health Science Center Institutional Review Board (17-05596-XP).

## Results

A total of 20 cases (18 patients) were identified. The most common primary indication for CTO intervention was persistent angina symptoms ( $n = 12$ ) despite being on antianginal therapy. The second most common

indication was non–ST elevation acute coronary syndrome (n = 6). Antegrade intraluminal technique was utilized in all cases.

Baseline characteristics are summarized in [Table 1](#). Mean age (M ± standard deviation) was 58.1 ± 7.0 years and the patients were predominantly males (70%). Most patients had multiple comorbidities and risk factors ([Table 1](#)). In particular, the prevalence of hypertension was 85%, 80% had hyperlipidemia, 45% had diabetes mellitus, and 25% had experienced prior MI. Fifteen patients (75%) were active smokers at the time of intervention.

Left ventricular ejection fraction was mostly normal (45 ± 13.6%) and the most common indication for CTO PCI was angina. The indications for the CTO intervention are listed in [Table 2](#). Angiographic characteristics are shown in [Table 2](#): the CTO complexity was intermediate to difficult (mean J-CTO score 1.65 ± 1.2, range 0-4), with 58% of cases having J-CTO score of ≥2. The average J-CTO score was 2.33 ± 1.2 in unsuccessful cases compared to 1.53 ± 1.2 in cases that were successful. The most commonly intervened on coronary vessel was the right coronary artery (47%), followed by the left anterior

**Table 1.** Summary baseline characteristics, N = 20.

Baseline characteristics	
Age, yr	58.1 ± 7.0
Sex (male, %)	14 (70.0%)
Smoker (%)	15 (75.0%)
Hypertension (%)	17 (85.0%)
Diabetes mellitus (%)	9 (45.0%)
Hyperlipidemia (%)	16 (80.0%)
Chronic kidney disease (%)	0 (0%)
Peripheral vascular disease (%)	7 (35.0%)
Cerebrovascular accident (%)	2 (10.0%)
Congestive heart failure (%)	6 (30.0%)
Previous myocardial infarction (%)	5 (25.0%)
Left ventricular ejection fraction (%; n = 15)	45 ± 13.6
Aspirin	17 (85.0%)
Thienopyridine	11 (55.0%)
Statin	16 (80.0%)
ACEI and/or ARB	12 (60.0%)
Beta-blocker	15 (75.0%)
Calcium channel blocker	1 (5.0%)
Nitrate	7 (35.0%)
Ranolazine	2 (10.0%)

ACEI/ARB, angiotensin-converting enzyme inhibitor and/or aldosterone receptor blocker; CCS, Canadian Cardiology Society.

Values are mean ± standard deviation, n (%).

**Table 2.** Summary procedural characteristics, N = 20.

Procedural characteristics	
Indications for CTO intervention	
Angina, Class III and/or IV	13 (65%), 11 (55%)
Type II MI	3 (15%)
Abnormal stress test	4 (20%)
Cardiomyopathy	3 (15%)
Others*	3 (15%)
Contrast used, cc	306.7 ± 125.7
Fluoroscopy time, min	46.1 ± 21.1
Coronary artery successfully intervened on (n = 17)	
Right coronary artery	8 (47.0%)
Left anterior descending	5 (29.0%)
Left circumflex	3 (18.0%)
Obtuse marginal 2	1 (6.0%)
J-CTO score	1.74 ± 1.2
J-CTO score ≥ 2	11 (58%)
J-CTO score (successful cases, n = 17)	1.53 ± 1.2
J-CTO score (unsuccessful cases, n = 3)	2.33 ± 1.2
Procedural success <sup>†</sup>	17 (85.0%)
Successful wire crossing of CTO	18 (90.0%)
Balloon angioplasty only (n = 17)	1 (5.0%)
Stent type (n = 16)	
Drug eluting stent	13 (81.0%)
Bare metal stent	3 (19.0%)
Total stent length, mm (n = 16)	43.4 ± 20.9
Mean of largest stent diameter, mm (n = 16)	3.1 ± 0.4
Number of stent(s)/case (n = 16)	1.8 ± 0.8
1 stent used/case	6 (38.0%)
2 stents used/case	7 (44.0%)
≥3 stents used/case	3 (19.0%)
Thrombectomy device used	1 (5.0%)
Number of guidewire/case (n = 19)	2.5 ± 1.1
Number of balloon/case (n = 19)	2.7 ± 1.3
Number of microcatheters used	15 (75.0%)
TIMI flow postprocedure (all OTW balloon)	
Cases with TIMI flow 0	3 (15.0%)
Cases with TIMI flow 1	0 (0%)
Cases with TIMI flow 2	1 (5.0%)
Cases with TIMI flow 3	16 (80.0%)

OTW balloon, over-the-wire balloon.

Values are mean ± standard deviation, n (%).

\* CTO at the time of non-ST elevation MI of another vessel.

<sup>†</sup> Procedure defined as successful if there was <20% residual stenosis and there was TIMI 2 or 3 flow.

descending artery (29%) and the left circumflex coronary artery (18%). Mean amount of contrast and fluoroscopy time was 306.7 ± 125.7 cc and 46.1 ± 21.1 minutes, respectively. [Table 2](#) includes the procedural characteristics for this study.

**Table 3.** Guidewires used, and frequency of use.

Guidewires	Number of cases in which guidewire was used (n = 20)	Frequency of use
Runthrough	15	75.0%
Long runthrough	3	15.0%
Hypercoat runthrough	2	10.0%
RT and/or long RT and/or hypercoat RT	16	80.0%
BMW	2	10.0%
Whisper	4	20.0%
Choice PT	3	15.0%
Pilot 150	2	10.0%
Pilot 200	3	15.0%
Fielder XT	9	45.0%

**Table 4.** Wires that crossed the coronary artery chronic total occlusion.

Wire most successful in crossing CTO	Number of cases (N = 18)
Runthrough	6
Whisper	3
Pilot 150	2
Pilot 200	2
Fielder XT	3
Choice PT	2

The antegrade intraluminal approach was chosen as first intention in all cases. Total stent length was  $43.4 \pm 20.9$  mm and the mean stent diameter was  $3.1 \pm 0.4$  mm, with 83% requiring only 2 stents or less. Drug eluting stent was most frequently used (81%) and bare metal stent was used in 19% of cases. There was no stent placement in 4 cases. Mean guidewire used per case was  $2.5 \pm 1.1$ . The runthrough, long RT, and hypercoat RT wires were most frequently used (80%) in the attempt to cross a CTO, followed by fielder XT wire (45%), whisper wire (20%), choice PT wire (15%), pilot 200 wire (15%), pilot 150 wire (10%), and BMW wire (10%; [Table 3](#)). The runthrough wire was most successful in crossing the CTO (6 cases), followed by the whisper wire (3 cases) and fielder XT wire (3 cases). The pilot 150, pilot 200, and choice PT wires each crossed the CTO in 2 cases ([Table 4](#)).

TIMI 3 flow was achieved in 16 of 20 (80%) cases, TIMI 2 in 1 case. Procedure was successful in 85% (17 of 20) of cases. There was successful wire crossing of CTO in 18 of 20 (90%) cases. Procedural complications, in-hospital and 30-day outcomes are listed in [Table 5](#). There were a total of 3 procedural complications (2 nonflow limiting coronary

**Table 5.** Outcomes and/or follow-up, N = 20.

<b>In-hospital adverse events</b>	
Procedural complication	3 (15.0%)
PCI-related myocardial infarction*	2 (10.0%)
No reflow	0 (0%)
Distal embolization	0 (0%)
Coronary dissection	2 (10.0%)
Perforation	1 (5.0%)
Hemodynamic instability	0 (0%)
Arrhythmia requiring therapy	1 (5.0%)
Cardiac tamponade	0 (0%)
Emergency CABG	0 (0%)
Death	0 (0%)
Outcome at 30 days	
Cardiac death	0 (0%)
Myocardial infarction	0 (0%)
Target vessel revascularization	0 (0%)
Heart failure	0 (0%)
Stroke	0 (0%)
Rehospitalization	0 (0%)
Outcome at last follow-up	
Cardiac death	0 (0%)
Myocardial infarction	0 (0%)
Target vessel revascularization	0 (0%)
Stroke	0 (0%)
Rehospitalization (for angina)	4 (20.0%)

Mean follow-up:  $19.5 \pm 13.7$  months (1-43 months).

Among the 4 patients with rehospitalization for angina symptoms, 3 patients had repeat coronary angiography, 2 without intervention, and the third patient had CABG.

\* PCI-related myocardial infarction was defined as an increase in cardiac troponin of  $>20\%$  from baseline level.

dissection and 1 wire perforation with no adverse outcome). Only 2 patients had post-PCI MI, and there were no in-hospital deaths, need for emergent CABG, hemodynamic instability, or cardiac tamponade. At 30 days, no reported adverse event postprocedure. At a mean follow-up of  $19.5 \pm 13.7$  months (1–43 months), there was no cardiac death, MI, target vessel revascularization or stroke. Three patients were lost to follow-up and one of them had an unsuccessful procedure. There were 4 rehospitalizations (20%) for angina requiring repeat coronary angiography in 3 cases (2 without intervention and 1 was referred for CABG).

## Discussion

The present study demonstrates the feasibility of a CTO intervention in a carefully selected group of patients with antegrade intraluminal approach in hospitals without on-site surgical backup. The procedure was successful in

85% of cases and wire crossing was successful in 90% of cases. There were only 2 cases of nonflow limiting coronary dissection and 1 wire perforation with no adverse outcome, and no emergent need for CABG at the time of intervention or within 30 days of the CTO intervention being performed. The procedural success rate in present study is similar to those reported in earlier CTO studies. The European Registry of CTO study reported a procedural success rate of 83%.<sup>10</sup> In addition, the procedural success of present study is in keeping with the overall procedural success rate of 86.2% reported in the Toyohashi Heart Center study,<sup>11</sup> but higher than the average procedure success rate of 61.9% reported in the National Cardiovascular Data Registry.<sup>5</sup> The procedural complications reported in present study are also not significantly different from those reported in previous studies. A meta-analysis by Patel et al<sup>12</sup> analyzed 65 CTO PCI studies and reported low periprocedural complication of 0.2% death, 2.5% MI, 0.1% emergent CABG, 2.9% coronary perforation, and 0.3% cardiac tamponade. The outcomes, patient health status, and efficiency in CTO hybrid procedures study, a prospective study of 1000 patients undergoing CTO angioplasty reported 8.8% perforations, 2.6% periprocedural MI, 0.7% referral to emergent surgery.<sup>13</sup> In present study, there were 2 nonflow limiting coronary dissection, 2 post-PCI MI and 1 wire perforation with no adverse outcome. Although, coronary perforation is a major PCI complication, most cases are managed conservatively with prolonged balloon inflation and covered-stent placement, without need for bypass surgery.<sup>14,15</sup> The perforation in present cohort occurred during an unsuccessful attempt of a right coronary artery CTO PCI. This was managed conservatively without any adverse outcome.

Lower J-CTO score was associated with higher chance of successful CTO intervention in this cohort, suggesting that J-CTO score can be used to identify cases that are likely to be successful with antegrade intraluminal approach. Antegrade intraluminal approach was chosen as first intention in all our case. Antegrade intraluminal approach continues to be the most common strategy to target CTO lesions<sup>16</sup> with higher technical success rate,<sup>17</sup> lower incidence of target vessel revascularization,<sup>18</sup> and lower incidence of major adverse cardiovascular event when compared to the other strategies. Femoral access was used in all cases, but with recent national shift toward radial access,<sup>19,20</sup> studies have also shown higher procedural success rate with antegrade or retrograde CTO interventions through the radial access.<sup>21</sup> The present study showed that a careful attempt at antegrade intraluminal CTO intervention at a center without a cardiothoracic surgical backup is feasible in selected patients, and with a reasonable safety profile and success rate.

An important factor in achieving a successful CTO intervention is adequate preplanning. In addition to procedural challenges, CTO interventions are longer procedures with tendency to use more contrast media and higher doses of x-ray radiation. Therefore, patient individualization is of paramount importance. The coronary anatomy, lesion length and characteristics including calcification burden, presence of collaterals and side branches, proximal and distal cap are to be considered when making a decision on a guide catheter, CTO guidewires and support equipments.<sup>22</sup> Patients at risk of contrast induced nephropathy should receive pre- and postprocedural intravenous hydration and a preplanned contrast media volume intended for the procedure should be known. In addition, the use of isosmolar contrast media agents should be favored in patients with mild renal impairment due to their limited impact on renal function.<sup>22</sup>

To the best of our knowledge, this is the first study reporting the outcomes of CTO PCI performed in the United States without a surgical backup. We hope that this study will generate the same predominant debate of 2 decades ago when elective PCI of non-CTO coronary lesion without on-site surgical backup was still a Class III indication. The 2005 PCI guideline update coauthored by SCAI, ACC and AHA designated elective PCI without on-site surgery as a Class III indication, and primary PCI for ST-segment elevation MI as a Class IIb indication in the absence of on-site surgery.<sup>23</sup> However, advances in pharmacotherapy, operator's experience and interventional techniques such as steerable guide wires, coronary stents, and procedural evolution have changed the landscape of PCI in the United States.<sup>24</sup> The MASS COMM (a randomized trial to compare PCI between Massachusetts Hospitals with cardiac surgery-on-site and Community Hospitals without cardiac surgery-on-site)<sup>25</sup> and Cardiovascular Patient Outcomes Research Team Non-Primary PCI (CPORT-E)<sup>26</sup> trials provided the strongest evidence that outcomes from nonprimary PCI were similar regardless of the presence of on-site surgery, and led to the 2014 SCAI, ACC and AHA consensus document that outlined the best practice methods and requirements for facilities engaged in performing PCI without on-site surgery.<sup>8</sup> The annual volume of CTO PCI has increased over the years, and more centers report success rates of >80%,<sup>10,16,27-29</sup> due to improved operator skills and technique, improved interventional technology, availability of new interventional wires, and support microcatheters. The procedure success in present study was 85%, which is consistent with the reported average in larger centers with in-hospital surgical backup as noted earlier. There is need for comparative observational and prospective studies to evaluate the

clinical outcomes of elective CTO PCI performed in facilities with on-site vs off-site surgery backup. A larger multicenter registry of CTO PCI without surgical backup may be required to establish safety of such high-risk interventions.

Thus, it is important to employ rigorous clinical and angiographic selection criteria when planning for a CTO PCI, more especially when it is done in a facility without on-site surgical backup. It is imperative to assess benefit of CTO intervention with the risk of PCI failure and patient's overall risk if complications were to occur. There should be a mutual and formalized agreement with an easily assessable cardiothoracic surgical center and surgeon, and ensure periodic structured drill protocols are held simulating emergency transfer of patient in case of an acute complication requiring surgical intervention. These facilities should engage in periodic procedural auditing, ensuring that their intervention program meets appropriate performance metrics that improves the quality of care delivered to patients. The interventional cardiologist should have extensive experience in an institution with a cardiothoracic surgical facility and should, in addition to the cardiac surgeons, regularly partake in CTO intervention conferences and risk management activities. Finally, we did not use advanced CTO techniques like dissection, re-entry or retrograde approach in this case series. We believe that these advanced strategies are more likely to have complications and should be avoided in the absence of CT surgery backup.

## **Study Limitation**

A major limitation of this study is its small sample size, which limits generalization of its findings. However, to the best of our knowledge, it is the first study reporting the outcomes of CTO PCI done in a facility without surgical backup. The results are also consistent with large CTO registry findings already published in the literature. Second, it is a retrospective study and it is, therefore, subject to the inherent limitations of such study design. Third, the decision to perform the PCI was based on the operator's clinical judgment, therefore a selection bias cannot be completely excluded. Finally, success of CTO intervention could be potentially higher if retrograde approach or dissection re-entry is used after the failure of antegrade wire escalation approach.

## **Conclusion**

Careful attempt at antegrade intraluminal CTO PCI of intermediate to difficult lesions done at a hospital without on-site cardiac surgery is

feasible in selected patients, and with a reasonable safety profile and success rate when performed by adequately trained interventionist. In present cohort, there was no procedural death or need for emergent CABG. A case of coronary perforation and 2 nonflow limiting dissections were conservatively managed with no adverse outcomes. A well-equipped PCI facility with well-trained interventional cardiologists and staffs, careful selection of elective cases and lesions, and a formalized agreement and structured transfer protocol with a facility with cardiothoracic surgery and open communication with the cardiac surgeons will result in a favorable outcome of a CTO PCI even when performed in a facility with no surgery backup. Participation in Multicenter National Data Registry will also allow for comparison of clinical outcomes with established standards and to facilitate consensus statements and updates by societal organizations on CTO PCI performed in nonsurgical sites.

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