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EDITORIAL COMMENT: Expert Article Analysis for:
CHIP fellowships: Carving a path for complex PCI

A CHIP fellow's transition into practice: Building a complex coronary therapeutics program

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Abstract

Background: Both the prevalence and complexity of coronary artery disease are on the rise in the United States, leading to a resurgence in novel techniques and equipment utilized to treat complex coronary disease. However, declining percutaneous coronary intervention (PCI) volumes and lack of formal post-graduate education opportunities have created a gap in treatment delivery for this patient population. Several complex, high-risk, and indicated PCI (CHIP) fellowships have been developed in an attempt to bridge this disparity. We present data from the first year of practice from a former CHIP fellow during development of a formal complex coronary therapeutics program.

Methods: Data was prospectively collected for PCIs performed during the first 12 months of practice for the lead author and compared to procedures performed in the 12 months prior to the study period.

Results: Out of 371 PCIs performed during the study period, 53.4% (198/371) were considered complex, including 126 chronic total occlusion (CTO) procedures. Compared to the previous 12 months, there was a significant increase in the number and complexity (median J-CTO score 2.1 vs. 1.3, p .04) of CTOs performed during the study period. CTO procedural characteristics and complication rates were similar to those previously published in large U.S. registries, with technical success in 93.4% (118/126) and procedural success in 85.7% (108/126).

Conclusion: Following dedicated CHIP fellowship training and establishment of a formal CHIP program, procedural success and complication rates were achieved similar to those published in prior studies evaluating CTO PCI at high volume centers.

1 | INTRODUCTION

Both the prevalence and complexity of coronary artery disease (CAD) are on the rise in the United States.[1] While the terms "complex percutaneous coronary intervention (PCI)" and/or complex, high-risk and indicated PCI ("CHIP") have not yet been formally codified, various definitions exist, including anatomic/physiologic criteria (SYNTAX, SYNTAX II) and designations that include procedures with elevated periprocedural mortality risk compared to "routine PCI," such as: left main PCI (1.0%), chronic total occlusion PCI (CTO; 0.9%), lesions with significant calcification that require atherectomy (2.3%), device-assisted PCI (7.6%), PCI in patients turned down for CABG surgery

(7.0%), and PCI in the elderly (≥80 years old; 3.2%).[2–8] Regardless of how it is defined, interventional cardiologists are being increasingly asked to perform complex PCI in contemporary catheterization laboratories, as reflected in the direct relationship between CAD complexity and appropriateness for revascularization in societal guidelines and appropriate use criteria for PCI.[9,10] This has led to a resurgence in novel techniques, devices, and data surrounding "CHIP" procedures in order to meet this need.

However, rates of revascularization therapy for CAD, including PCI, have been on the decline for the past decade.[11] Given the direct association between procedural volume and outcomes for both routine and complex PCI, this represents a challenge for both those training to become interventional cardiologists as well as those already in practice, with limited availability for hands-on post-graduate education opportunities to meet the needs of an increasingly complex patient population.[12,13] This is particularly true for the treatment of coronary CTO lesions given recent advances in techniques and equipment for treating these lesions.[14] Novel fellowships termed "CHIP fellowships" have arisen to meet this need in several centers around the country. However, little is known about how this training translates into clinical practice. We present data from the first year in practice of a former CHIP fellow (RFR) to provide insights into this new training paradigm.

2 | METHODS

A 12-month Interventional Cardiology fellowship was completed by RFR at the University of Washington from July 1, 2015 to June 30, 2016, followed by a dedicated CHIP fellowship program under the directorship of WLL at the same institution. During that training period, 756 PCIs were performed, including 454 CTO PCIs. RFR was then hired by the Christ Hospital in Cincinnati, OH, a 555-bed tertiary referral hospital that performs ~1,500 PCI annually to develop a complex coronary therapeutics (aka "CHIP") program. Data was prospectively collected by a dedicated data abstracter on all PCI procedures performed by RFR for the first 12 months of clinical practice at the Christ Hospital from September 1, 2017 to September 1, 2018 and compared to data on similar procedures performed during the 12 months prior to the study period (September 1, 2016–August 30, 2017). Starting on April 1, 2018, patient-reported quality of life metrics were also collected for all patients considered for CTO PCI, both preprocedure and postprocedure, including the Rose Dyspnea Scale (RDS) and Seattle Angina Questionnaire (SAQ), by a trained CHIP coordinator. The SAQ is a validated, disease-specific 19-item questionnaire with three primary categories: physical limitation, angina frequency, and quality of life, as well as a summary score.[15] Scores range from 0 to 100, with higher scores indicating less symptoms and better health status. Angina frequency scores between 0 and 60 are consistent with daily/weekly limiting angina, scores of 70–99 representing monthly angina, and a score of 100 representing the absence of angina and optimal physical function and quality of life related to angina.[16] The RDS is a four-item questionnaire designed to assess breathlessness with a range of 0–4, with lower scores indicating less dyspnea.[17,18] These patient reported, disease-specific measures were supplemented with physician-reported assessments of patients' health status including Canadian Cardiovascular Society (CCS) for angina and New York Heart Association (NYHA) classification for dyspnea preoperatively and postoperatively. All quality of life metrics were collected by the same CTO coordinator at preprocedural and 2-week postoperative clinic visits.

For the CTO procedures, a formal team was established that consisted of RFR and two senior interventional cardiologists (JAK and JPR). This team held weekly HEART team meetings where all referrals for complex PCI were reviewed for case appropriateness and to develop consensus on procedural strategy. A two-operator/case (one primary, one assistant) policy was implemented for all CTO procedures, and 2 days were reserved each week for scheduling CTO cases, based on the model published by Kandzari et al.[14]

For all CTO cases, technical success was defined as positioning of a guidewire in the distal true lumen of the CTO vessel attempted with residual TIMI flow of ≥2 and a residual stenosis of ≤50% after balloon or stent deployment.[4] Procedural success was defined as technical success in the absence of in-hospital major adverse cardiovascular events (MACE). MACE included: all-cause death, periprocedural clinical myocardial infarction (MI), coronary perforation, vascular injury requiring intervention, stroke/transient ischemic attack, major bleeding, and acute kidney injury (AKI). All-cause death was defined as death from any cause. Periprocedural MI was defined according to the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Health Federation task force for the redefinition of MI, specifically Type 4a, defined as an increase in serum troponin level of more than three times the 99th percentile upper reference limit post-PCI along with clinical evidence of ischemia, including angina, new ECG changes suggestive of ischemia, and/or new wall motion abnormalities on cardiac imaging.[6] As per standard of care at the Christ Hospital, serial cardiac biomarkers were only obtained in instances where procedural complications occurred and/or any clinical syndrome suggestive of ischemia developed postoperatively. Major bleeding was defined using the NCDR definition.[7] Coronary perforations were classified by the Ellis classification system.[19] AKI was defined according to the KDIGO working group as either a 25% increase in baseline serum creatinine or a 0.5 mg/dl increase in absolute serum creatinine value within 48 hr after intravenous contrast administration.[20] Major vascular injury was defined as any injury to the vascular access site requiring intervention (open or percutaneous repair, including injection). Stroke/TIA was defined as any new neurological deficit noted within 24 hr and confirmed by a board-certified neurologist.

Given the elevated cost of CTO PCI procedures compared to non-CTO PCI procedures due to prolonged procedural times and increased equipment use, we also collected cost and resource utilization data from our institutional database including patient charges and procedural costs per patient for both CTO and non-CTO procedures (for the entire hospital group, not just limited to those performed by RFR) performed during the study period.[14] Procedural billing analyses were performed using International Statistical Classification of Diseases (ICD-9) procedure codes for all patients and diagnostic-related groups

for inpatients. Resource utilization and associated costs for each procedure were derived from a hospital financial model that accounted for all labor (excluding physician fees), nonlabor, and supply expenses from patient billing. Catheterization laboratory-related medical supply costs were ascertained for all procedures through a departmental supply tracking system. Direct costs (staff, service, and operating costs) were based on average procedural time for each procedure, defined as time of arrival to time of departure from the catheterization laboratory. A net contribution margin for each case was then calculated by subtracting procedural costs (labor, nonlabor, and supply) from patient charges.[14]

Categorical variables were presented as frequencies and percentages whereas continuous variables were presented as means (SDs). All analyses were performed with JMP (version 13, Cary, NC). The institutional review board at the Christ Hospital approved collection of data for this prospective study.

3 | RESULTS

During the study period, 371 PCIs were performed by RFR, including 25 device-assisted PCIs, 21 unprotected left main PCIs, 87 PCIs that utilized atherectomy (laser and/or rotational), 12 using adjunctive brachytherapy, 87 in patients turned down for CABG surgery, and 126 CTO PCI procedures. Given that an individual case could span multiple categories (i.e., a CTO case that also utilized atherectomy), the total number of individual PCI cases considered "complex" as defined by these subgroups was 198, which was 53.4% (198/371) of the PCIs performed during the study period.

One hundred twenty-six CTO PCI procedures were attempted during the study period, compared to 30 during the 12 months prior to the study period. The patient characteristics of the patients undergoing CTO PCI can be seen in Table 1. These patient characteristics are similar to those reported by contemporary large U.S. CTO

TABLE 1 Clinical characteristics of CTO PCI procedures performed during the 12 months prior to and during the study period

Clinical characteristics	12-months prior (*n* = 30)	Study period (*n* = 126)	*p* value
Age (years)	63.3 (±11.01)	65.2 (±8.6)	.78
Male gender	24 (75.0%)	94 (74.6%)	.92
Diabetes mellitus	13 (40.6%)	56 (44.4%)	.56
Hypertension	27 (84.4%)	97 (78.2%)	.88
Dyslipidemia	21 (70.0%)	105 (83.3%)	.20
Prior stroke	3 (10.0%)	21 (16.7%)	.45
Prior myocardial infarction	9 (30.0%)	61 (48.4%)	.08
Preprocedural CCS Class III/IV	24 (80.0%)	88 (69.8%)	.18
Pre-procedural NYHA Class III/IV	20 (66.7%)	76 (60.3%)	.88
LVEF	48.5 (± 12.2)	51.2 (± 11.4)	.78
Prior CABG surgery	5 (16.6%)	48 (38.1%)	.04
Surgical turndown for CABG surgery	n/a	28 (22.2%)	n/a
Prior CABG, surgical turndown, or single-vessel CAD	n/a	121 (96.0%)	n/a
Clinical indication			
CCS class ≥3 stable angina and/or NYHA stage ≥3 dyspnea on exertion	24 (80.0%)	98 (77.8%)	.56
Acute coronary syndrome	0 (0.0%)	5 (4.0%)	.78
Moderate-to-high risk stress test	12 (40.0%)	41 (32.5%)	.29
Ischemic cardiomyopathy	2 (6.7%)	16 (12.7%)	.14
AUC appropriate or may be appropriate	30 (100.0%)	126 (100.0%)	1.0
Target CTO vessel			
RCA	16 (60.0%)	69 (54.8%)	.54
LAD	5 (16.7%)	30 (23.8%)	.67
LCX	9 (30.0%)	15 (11.9%)	.14
Left Main	0 (0.0%)	10 (7.9%)	.19
Ramus	0 (0.0%)	2 (1.5%)	.45
Viability testing	8 (26.7%)	36 (28.6%)	.89
Number of preoperative anti-anginal medications	1.9 (±1.0)	2.3 (±0.9)	.22

Abbreviations: CCS, Canadian Cardiovascular Society; CTO PCI, chronic total occlusion percutaneous coronary intervention; NYHA, New York Heart Association.

TABLE 2 Procedural characteristics for CTO PCI procedures performed during the 12 months prior to and during the study period

Procedural characteristics	12-months prior (*n* = 30)	Study period (*n* = 126)	*p* value
J-CTO score	(1.3 ± 1.2)	2.1 (±1.0)	.04
Successful crossing strategy			
Anterograde wire escalation	22 (73.3%)	60 (47.6%)	.03
Anterograde dissection reentry	3 (10.0%)	16 (12.7%)	.82
Retrograde wire escalation	2 (6.7%)	7 (5.6%)	.91
Retrograde dissection reentry	3 (10.0%)	24 (19.0%)	.21
Subintimal tracking and reentry (STAR)	0 (0.0%)	19 (15.1%)	.02
Total procedural time (min)	131.4 (±49)	166.3 (±42)	.12
Total contrast (ml)	210 (±37)	173 (±27)	.11
Technical success	26 (86.6%)	118 (93.4%)	.34
Successful PCI after STAR during initial procedure	n/a	17/19 (89.5%)	n/a
Procedural success	23 (76.7%)	108 (85.7%)	.32

Abbreviation: CTO PCI, chronic total occlusion percutaneous coronary intervention.

TABLE 3 Complications reported during CTO PCI during the 12 months prior to and during the study period

Complication	12-months prior (*n* = 30)	Study period (*n* = 126)	*p* value
Death	0 (0.0%)	2 (1.6%)	.45
Post-PCI MI	1 (3.3%)	4 (3.2%)	.91
Cerebrovascular accident/transient ischemic attack	0 (0.0%)	0 (0.0%)	1.0
AKI	1 (3.3%)	3 (2.4%)	.89
Major vascular injury requiring intervention	2 (6.7%)	5 (4.0%)	.44
Major bleeding requiring transfusion	1 (3.3%)	2 (1.6%)	.21
Coronary perforations	3 (10.0%)	9 (7.1%)	.18
Required injection or covered stent	0 (0.0%)	3 (33.3%)	.09
Required surgical window	0 (0.0%)	1 (11.1%)	.08

Abbreviations: AKI, acute kidney injury; CTO PCI, chronic total occlusion percutaneous coronary intervention.

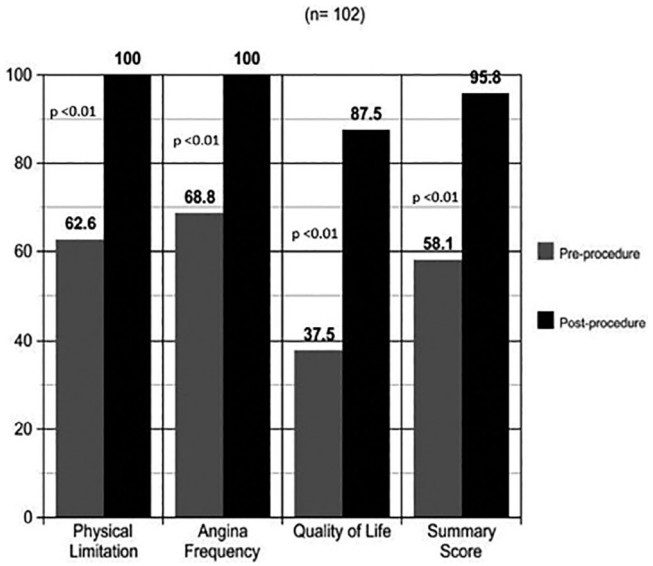

FIGURE 1 Mean patient reported Seattle Angina Questionnaire domains at baseline and at 2-weeks post-CTO PCI follow-up. CTO PCI, chronic total occlusion percutaneous coronary intervention

registries.[4] Patient characteristics between the two periods were similar except for an increased prevalence of post-CABG patients undergoing CTO PCI (38.1% vs. 16.6%, *p* .04) during the study period. Procedural characteristics for the CTO procedures can be seen in Table 2. Technical success was reported in 93.4% (118/126) of CTO procedures, with procedural success reported in 85.7% (108/126). The majority of cases were performed using anterograde strategies, though 31/126 (24.6%) utilized a retrograde approach. Median total procedural time was 166.3 (±42) min and median contrast use was 173 ml (±67 The only significant difference between patients treated in the 12 months prior to and during the study period was an increased J-CTO score (1.3 vs. 2.1, *p* .04) in patients treated during the study period and a decreased use of anterograde wire escalation (73.3 vs. 46.7%, *p* .03) during the study period. Complication rates during CTO PCI are shown in Table 3, which were also similar to those reported in other U.S. CTO registries.[21] There was no significant difference in the complication rates between the 12 months prior to and the study period.

Mean preprocedural RDS score was 1.6 (±0.4) while the postprocedural RDS was 1.1 (±0.3) ($p < .02$). Figure 1 shows preprocedural versus postprocedural mean SAQ scores, illustrating significant gains in quality of life metrics post-PCI (all $p < .01$). Mean preprocedural CCS classification was 3.0 (±0.8) and NYHA classification was 3.0

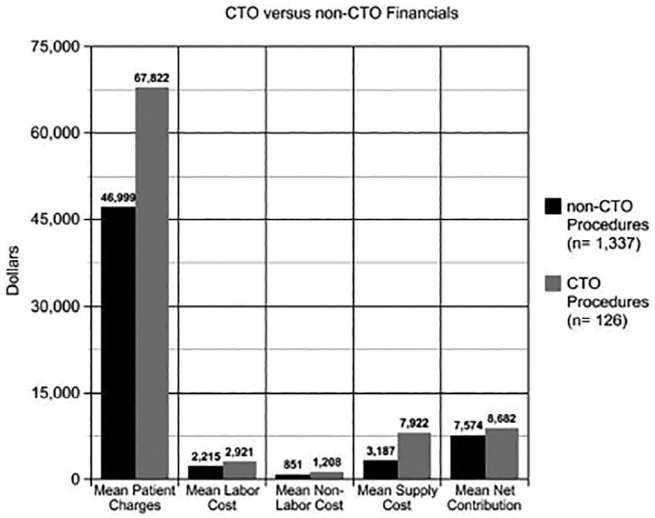

FIGURE 2 CTO versus non-CTO PCI procedural finances during the study period. CTO PCI, chronic total occlusion percutaneous coronary intervention

(±0.7), while the post CCS classification was 1.2 (±0.6) and the NYHA classification 1.3 (±0.4) (p .03 and .02, respectively).

Financial analyses of the CTO procedures versus non-CTO PCI (n = 1,337) procedures performed during the study period at the parent institution are summarized in Figure 2. Mean patient charges of $67,882.17 (±$12,336) were reported for each CTO procedure, compared to $46,999.50 (±$7,556) for non-CTO PCI procedures. Mean costs (excluding physician billing) for each CTO procedure were: $2,921.65 (±$456.76) for labor compared to $2,215.75 (±$456) for non-CTO PCI labor; $1,207.95 (±$334.56) per CTO procedure for nonlabor costs compared to $851.33 (±$167) for non-CTO PCI cases; and $7,922.85 (±$1,985.66) per CTO procedure for supply costs, compared to $3,187.68 (±$876) for non-CTO PCI supply costs. The mean calculated net contribution margin for each CTO case was $8,682.29 (±$ 2,001.11), compared to $7,573.94 (±$2,022) for each non-CTO PCI.

4 | DISCUSSION

Following a dedicated CHIP fellowship training program, a formal complex coronary therapeutics program was developed at a moderate-to-high volume PCI center. In subgroup analyses of the CTO procedures, procedural success and complication rates were similar to those published in prior studies evaluating CTO PCI performed at high-volume centers by experienced operators.[4,14,22] Additionally, despite longer procedural times and elevated cost compared to non-CTO PCI procedures, CTO cases were financially profitable for the institution, as noted by positive contribution margins similar to those previously published at high-volume CTO centers in the United States.[14,23] Compared to the year prior to the study period, there was a large increase in CTO PCI volume, including more complex CTOs (increase in post-CABG patients and median J-CTO score), with similar success and complication rates.

Over the past decade, there have been numerous subspecialties that have developed within Interventional Cardiology, including disciplines dedicated to structural heart and peripheral arterial disease. The recent prolific advances in percutaneous treatment modalities for aortic and mitral valvular disease have led to a proliferation of structural heart disease training programs across the United States.[24] Conversely, despite the increasing prevalence of complex CAD, there has not been commensurate evolution of formal training efforts aimed at treating this expanding patient population. In order to address this gap, Kirtane et al published a white paper on the treatment of higher-risk CAD patients with indications for revascularization in 2016, which has served as a cornerstone of the CHIP training movement.[25] However, there are only a few formal programs in the United States dedicated to advanced CHIP training, with no formal application process or standards for training. Additionally, post-fellowship training opportunities geared toward improving techniques and proficiency with the tools required to perform CHIP procedures are few and far between, mostly limited to industry-sponsored courses, though some larger conferences are moving toward more hands-on, interactive teaching sessions (most notably the Transcatheter Cardiovascular Therapeutics meeting). Given the small number of formally trained CHIP operators in the United States despite the burgeoning prevalence of complex CAD, this appears to be an opportunity to impact patient care by increasing educational opportunities in this space.

While a single-center prospective registry cannot provide enough data for definitive evidence on how to gain experience in performing CHIP procedures nor how to develop a complex coronary therapeutics program, our results allow for several important insights. First, with proper training, complex and indicated percutaneous revascularization procedures, including CTOs, can be performed safely and with reasonable outcomes. Second, following the structural heart disease mantra, a team-based approach to diagnosing and treating complex CAD likely provides better patient-centered outcomes compared to a "lone operator" approach. While there is no randomized data to support double-scrubbing complex PCI procedures, this model currently exists in the structural heart disease space, with compensatory changes in reimbursement. Third, this team-based approach combined with a well-designed, comprehensive database to track outcomes and safety metrics can allow for a program to grow in a responsible manner. Fourth, these procedures, while long and resource intense, are financially viable for the institution, similar to reports from other institutions and registries evaluating CTO PCI.[14,23]

Our results have a number of limitations. First and foremost, this is a single-center report from a single operator, which entails significant selection and observer bias. The individual training and patient population of a single operator may not be generalizable. Additionally, a comprehensive data collection process on procedures performed at the parent institution was not in-place prior to the development of the CHIP program, so direct comparisons are limited. Still, this is the first report regarding the impact of CHIP training and should serve as

a starting point for future rigorous, structured evaluations of CHIP training and program development as patients require increasingly complex revascularization.

5 | CONCLUSION

Formal CHIP fellowships are slowly being developed to meet the demands of modern day interventionalists in treating the growing patient population with complex CAD in the United States. This single-center prospective experience illustrates that formal CHIP training can facilitate the development of a formal complex coronary therapeutics program with procedural success rates, financial metrics, and safety outcomes similar to those published in prior studies at high-volume centers.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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