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Quality of Life Benefits of Percutaneous Coronary Intervention for Chronic Occlusions

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Abstract

Objectives—We aimed to compare quality of life benefits of percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) with non-CTO PCI.

Background—Data quantifying the benefits of PCI of CTO are inconsistent.

Methods—We leveraged a 10-center prospective PCI registry including Seattle Angina Questionnaire (SAQ) assessment at the time of PCI and in follow-up. We propensity matched attempted CTO PCIs with up to 10 non-CTO PCIs. The primary analysis compared changes between baseline and 6 months in SAQ Physical Limitation (PL), Quality of Life (QoL) and Angina Frequency (AF) scores as well as the Rose Dyspnea scores (RDS) and the EQ5D Visual Analogue Scale (VAS). Non-inferiority was assessed for quality of life changes between CTO and non-CTO PCI.

Results—In 3,303 patients enrolled, 167 single-vessel CTOs were attempted; 147 (88%) were matched with 1,616 non-CTO PCI. Baseline PL (73.0 vs. 77.4, $p=0.039$) and VAS (66.4 vs. 70.8, $p=0.005$) scores were lower for CTO. There was no difference in AF, QoL or RDS scores. At 6-month follow-up, all SAQ scores improved ($p<0.05$ vs. baseline for all) and were equivalent for CTO and Non-CTO ($p=NS$ for all). VAS scores remained lower for CTO, but improved in both groups ($p<0.05$ vs. baseline for both). Formal non-inferiority testing demonstrated that CTO PCI was not inferior to non-CTO PCI ($p=0.02$ for all).

Conclusions—Symptoms, function, QoL and dyspnea improve to the same degree following CTO PCI as compared with non-CTO PCI. Symptom relief supports CTO PCI to improve patients' quality of life.

Indexing Words

Coronary Occlusions; Angioplasty; Transluminal; Percutaneous Coronary

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Disclosures

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INTRODUCTION

Chronic total occlusions (CTOs) are frequently encountered, complex lesions that can be associated with angina, dyspnea, and fatigue. Percutaneous coronary intervention (PCI) of CTOs remains controversial as no randomized trial of CTO PCI versus medical therapy or CABG has ever been performed to assess whether long-term survival is improved after attempted CTO PCI. However, indirect data abound and the primary indication for the majority of PCIs is to improve patients' health status; their symptoms, function and quality of life. To date, there is only a single study, without a comparison group, demonstrating improved patient-reported health status after successful CTO PCI⁽¹⁾. In the absence of data documenting the health status benefits of CTO PCI, the Appropriate Use Criteria (AUC) committee of the American College of Cardiology Foundation systematically downgraded the appropriateness of CTO PCI as compared with non CTO PCI in five clinical scenarios^(1,2). Demonstrating comparable symptom relief and quality of life improvement with CTO PCI can support reappraisal of the AUC and underscore the potential of CTO revascularization to improve patients' health status. To address the gap in knowledge surrounding the health status benefits of CTO PCI, we sought to prospectively assess the patient-reported outcomes of CTO PCI, including dyspnea and disease-specific health status, and to determine if they are non-inferior to the health status outcomes of non CTO PCI.

MATERIALS AND METHODS

Patients were identified from a 10-center prospective PCI registry developed to test the benefits of a novel informed consent process that delivered individualized, evidence-based estimates of procedural risks (Clinicaltrials.gov registration: NCT01383382). Consecutive patients undergoing PCI were invited to participate in baseline and 6-month surveys of their health status, as quantified by the disease-specific Seattle Angina Questionnaire (SAQ), the Rose Dyspnea Score (RDS) and the EQ5D.⁽³⁻⁵⁾ These assessments were supplemented with detailed chart abstractions to capture patients' clinical comorbidities and coronary anatomy, as well as their peri-procedural outcomes.

There were 3,303 patients enrolled at 10 hospitals during the study. Patients with incomplete baseline data (26), STEMI (75), no significant CAD on angiography (150), more than one CTO (170) and those with a CTO that was not attempted (194) were not eligible for inclusion. The latter were excluded because the goal of the analysis was to explicitly compare the outcomes of treating a patient with CTO to a similar patient whose coronary artery was not completely occluded. PCI was attempted in 167 of 361 identified single vessel CTO cases (46%) and 2,521 non-CTO cases. Of these, 141 CTO PCI patients (84%, CTO Group) with complete 6-month health status data were propensity-matched with 1,616 non-CTO PCI patients (non-CTO Group) for adjusted analyses.

Definitions

A CTO was defined as a 100% pre-procedure stenosis that was presumed to be occluded for at least 3 months and not related to an acute clinical event (<http://www.acc.org/NCDR@cathlab.htm>). PCI success was assessed by the interventional cardiologist performing the procedure. Significant bleeding was defined as access site hematoma >10cm,

gastrointestinal, genitourinary or retroperitoneal bleeding with or without the need for transfusion.

Outcome Measures

The SAQ is a 19-item questionnaire which assesses symptoms, functioning and quality of life in patients with coronary artery disease.⁽³⁾ There are 5 subscales – Physical Limitation, Quality of Life, Angina Stability, Angina Frequency and Treatment Satisfaction. A summary scale is calculated from the average of the Angina Frequency, Physical Limitation and Quality of Life subscales (details available from the senior author). Scores range from 0–100, with higher scores indicating lower symptom burden, better physical function and better quality of life. The RDS is a 4-item survey assessing dyspnea with common activities.⁽⁴⁾ Each answer of “yes” adds 1 to the score. Scores range from 0–4 and higher scores indicate more limitation due to dyspnea. The EQ5D includes both 5 single items and a Visual Analogue Scale (VAS). In this study we used the VAS, which produces scores of 0–100 with higher scores indicating better overall quality of life.⁽⁵⁾

Statistical Methods

Baseline characteristics between CTO and non-CTO patients were compared using t-tests for continuous variables and chi-square tests for categorical variables. Propensity score matching was used to adjust for patient factors in the comparison of health status outcomes. The propensity score model included hospital, patient demographics (age, sex, race), clinical history (BMI, diabetes mellitus, prior MI, prior PCI, prior CABG, chronic heart failure, prior stroke, chronic kidney disease, chronic lung disease), baseline health status, indication for PCI, number of diseased vessels, the specific coronary artery segments approached and discharge medications. The propensity score for a treated CTO had a c-statistic of 0.83. Variable matching on the logit of the propensity score, using a caliper width of 0.2 times the average standard deviation of the logits, was used to match each CTO patient to variable numbers (1 to 10) of non-CTO patients. Standardized differences of covariates between groups were calculated pre- and post-matching to evaluate the effectiveness of the propensity match and demonstrated excellent balance with the highest standardized difference being 8.3 (matching is considered successful when measured covariates have a standardized difference between groups of <10).

The effect of CTO PCI on 6-month health status outcomes (SAQ Physical Limitation, Angina Frequency and Quality of Life scores; Rose Dyspnea score; EQ5D) was then estimated using mixed effect models, including a random effect for propensity-matched groups, a within-group effect for CTO, and also adjusting for the corresponding baseline health status score. Non-inferiority was formally assessed for changes in health status scores between CTO and non-CTO PCI. To define a threshold for clinical significance below which we believe there was no meaningful difference, we selected non-inferiority margins of 5 points for the SAQ⁽⁶⁾ and EQ-5D scales and 0.5 points for the Rose dyspnea scale.⁽⁷⁾ Prior work has shown these margins to consistently correlate with a clinically relevant change in functional status and patient symptom improvement^(3,6).

Missing data was negligible for all variables except for the SAQ Physical Limitation score (baseline scores missing on 10% of patients). Missing covariate data were imputed using multiple imputation methods incorporating all baseline and 6-month variables. For the propensity matched analysis five imputed data sets were generated; analyses were replicated on each data set and the results were pooled to obtain final estimates of the effect of CTO on outcomes.

The Saint Luke's Hospital Mid America Heart Institute Institutional Review Board approved this study and all patients signed informed consent prior to participation.

RESULTS

Baseline Patient Characteristics

There were 2,688 patients included in this study, 167 with attempted CTO PCI and 2,521 with attempted non-CTO PCI. These groups were similar in many important clinical characteristics, including age, gender, ethnicity and the prevalence of diabetes mellitus, prior coronary artery bypass grafting surgery, prior stroke, chronic kidney disease and chronic lung disease (Table 1). There was a higher prevalence of prior myocardial infarction, prior PCI and chronic congestive heart failure among CTO patients. Single vessel disease was present in 65% of CTO and 63% of non-CTO patients. The indication for CTO PCI was more likely stable CAD or staged PCI, while non-CTO PCI was more likely unstable angina or non-ST segment elevation myocardial infarction. There was a slightly higher number of segments approached in CTO PCI (Table 1), but no significant differences were observed in medications prescribed at discharge (Table 3).

As compared to the non-CTO group, the CTO group had lower baseline physical limitation scores (PL; 73.0 vs. 77.4, $p=0.039$) and EQ5D VAS (66.4 vs. 70.8, $p=0.005$) scores, but had similar angina frequency scores (AF; 69.6 vs. 72.6, $p=0.12$), quality of life scores (QoL; 53.2 vs. 56.5, $p=0.11$) and dyspnea (RDS; 1.9 vs. 1.7, $p=0.16$) scores. (Table 2)

Technical Success of PCI and Clinical Outcomes

The technical success rate was lower for the CTO group vs. non-CTO patients (84.7% vs. 97.6%, $p<0.0001$). Significant bleeding occurred in 2.4% of CTO PCI, and 0.9% of non-CTO PCI ($p=0.07$). There were no deaths in-hospital among CTO PCI patients, and 1 in the non-CTO PCI group ($p=1.0$). After propensity matching, the success rate of CTO PCI remained lower than non-CTO PCI (RR=0.87, 95%CI 0.80–0.95, $p<0.001$) while bleeding was not significantly higher with CTO PCI (RR 1.30, 95% CI 0.20–8.50, $p=0.79$).

Comparison of Health Status Benefits of PCI for CTO and non-CTO lesions

Propensity Matching was performed to account for clinical differences between the CTO and non-CTO groups. A total of 147 CTO patients (88%) with complete baseline and 6-month data were matched with 1,616 non-CTO patients with complete 6-month data and included in the analysis of changes in health status measures. At 6-months all follow-up scores improved and in matched analysis were equivalent for CTO and non-CTO. The EQ5D VAS scores improved for both groups, but remained higher for the non-CTO patients.

Despite a lower technical success rate of PCI, Angina Frequency scores were not statistically different between groups at follow-up. Formal non-inferiority testing demonstrated that CTO PCI was not inferior to non-CTO PCI on any health status measure examined ($p = 0.02$ for all, Table 4).

DISCUSSION

Given the importance of improving patients' health status with PCI, we have conducted a secondary analysis of a prospective cohort study to compare CTO PCI with non-CTO PCI. Our intention was to compare the benefits in symptom relief, functional improvement and quality of life benefits from treatment. Despite a slightly lower technical success rate, patients who underwent attempted CTO PCI had similar improvements in their health status as compared with patients undergoing non-CTO PCI. These results are consistent whether health status is assessed with disease-specific questionnaires (SAQ), general health status measures (EQ5D VAS) or tools assessing angina equivalents (RDS). Changes in RDS scores paralleled the changes in SAQ and EQ5D scores. These results confirm observations in clinical practice and previous studies of non-CTO PCI^(8–13). Importantly, there was no increased risk of in-hospital mortality or significant bleeding associated with CTO PCI as compared with non-CTO PCI.

These findings extend the existing report of a non-randomized assessment, using the SAQ, which demonstrated that successful percutaneous recanalization of a CTO is associated with better improvement in patients' angina frequency, physical limitation and quality of life than if an attempted CTO was not successful.⁽¹⁾ In fact, the magnitude of these benefits is similar to the improvements in SAQ scores found after revascularization with CABG or PCI of non-CTO lesions^(1,14). In carefully selected patients, successful percutaneous CTO revascularization leads to a meaningful reduction in symptoms^(1,15,16), improved left ventricular function⁽¹⁷⁾, and a reduction in the need for subsequent CABG⁽¹⁸⁾. Although no randomized trial exists for CTO revascularization vs. current optimal medical therapy, Joyal et al. found 13 observational studies comparing outcomes after successful vs. failed CTO recanalization. There were 721 deaths (14.3%) of 5,056 patients after successful CTO recanalization and 390 deaths (17.5%) of 2,232 patients after failed CTO recanalization (OR 0.56; 95% CI 0.43–0.72). Successful recanalization was also associated with a significant reduction in the need for subsequent CABG surgery (OR 0.22; 95% CI 0.17–0.27) and, in the 6 studies that reported angina status, successful recanalization led to a significant reduction in residual/recurrent angina (odds ratio 0.45; 95% CI 0.30–0.67). The meta-analysis found no statistically significant reduction in MI or major adverse cardiac events with recanalization,⁽¹⁸⁾ however, the demonstration of significant improvements in symptoms, function and QOL with CTO PCI justify its application in symptomatic patients.

The AUC represent expert consensus of risks vs. benefits of revascularization. In the absence of evidence of increased risk with CTO PCI,^(19–21) and with data demonstrating similar health status benefits, the systematic downgrading of the appropriateness of CTO PCI may be inappropriate. Thus, given current limitations, future AUC should increase the number of clinical scenarios for CTO and adopt an evidence-based strategy for revascularization⁽²²⁾. We have shown here the expected symptom-relief benefits of CTO

PCI, but previous studies also demonstrate improved LV function⁽²³⁾, avoidance of other procedures and possibly improved survival^(18,24). Interventional cardiologists should identify additional methods to assess appropriateness for CTO intervention. These data clearly illustrate a symptomatic benefit of CTO PCI similar to non-CTO PCI. However, these procedures graded differently in the AUC based solely on the degree of stenosis. A national dialogue to further the consideration for adoption of CTO revascularization is needed. It is the authors' opinion that patient symptoms, ischemic burden, procedural risk, and patient preference should guide *when* to intervene and the angiogram (CTO vs. non-CTO lesion) should indicate *how* to intervene.

There are several potential limitations in the study to consider when interpreting these results. First, this is not a randomized, controlled trial of CTO treatment for clinical symptoms. It is an observational study using propensity-matched data. Non-measured differences between the patients may lead to residual confounding. Nevertheless, we feel that the patients included in our study were well-matched and remarkably similar in observed characteristics. Second, the duration of follow-up was brief, only 6 months. However, there is no reason to believe that the temporal trends beyond 6 months would differ. Future analyses are warranted to assess the long-term durability of these outcomes. Moreover, there was no medical or surgical treatment arm. There is a benefit of CABG over PCI for angina symptoms, but data for CTO PCI versus CABG is scarce and worthy of future study. Finally, all of the patients were treated at experienced centers, by experienced operators. Whether these results are generalizable to the population as a whole is unknown.

Conclusions

These data suggest that patients' symptoms, function, QoL and dyspnea improve following CTO PCI to the same degree as after non-CTO PCI. Despite a higher symptom burden in patients with CTO, six months after PCI there is no significant difference in health status for CTO vs. non-CTO PCI. These data provide important insights to describe the benefits of treatments to patients and may suggest revisiting the AUC designations for CTO PCI.

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Table I

Baseline Characteristics – Overall Cohort

	Number of Attempted CTOs		P-Value
	One n = 167	None n = 2521	
<i>Demographics</i>			
Age	63.5 ± 10.0	64.1 ± 11.1	0.51
Sex			0.38
Male	122 (73)	1761 (70)	
Female	45 (27)	760 (30)	
Race			0.89
White/Caucasian	148 (90)	2252 (91)	
Black/African-American	11 (7)	146 (6)	
Other	6 (4)	81 (3)	
<i>Clinical Characteristics</i>			
BMI (kg/m ²)	31.8 ± 6.6	30.4 ± 6.2	0.004
Diabetes	56 (34)	832 (33)	0.89
Prior MI	62 (37)	621 (25)	< 0.001
Prior PCI	79 (47)	990 (39)	0.04
Prior CABG	30 (18)	372 (15)	0.26
Chronic heart failure	23 (14)	220 (9)	0.028
Prior stroke	10 (6)	108 (4)	0.30
Chronic kidney disease	19 (11)	199 (8)	0.11
Chronic lung disease	28 (17)	305 (12)	0.076
<i>Procedural Characteristics</i>			
PCI indication			< 0.001
Stable CAD	68 (41)	896 (36)	
Staged PCI	25 (15)	142 (6)	
Unstable angina	39 (23)	870 (35)	
NSTEMI	24 (14)	514 (20)	
Other	11 (7)	99 (4)	
Number of diseased vessel			0.78
1	109 (65)	1579 (63)	
2	43 (26)	688 (27)	
3	15 (9)	254 (10)	
Number of segments approached	1.6 ± 0.8	1.4 ± 0.7	0.002

Continuous variables compared using Student's T-test.

Categorical variables compared using chi-square or Fisher's exact test.

All Data expressed as No. (%) or Mean±Standard Deviation

Table II

Health Status Assessments at Baseline and 6 months after PCI – Overall Cohort

Health Status Measure		CTO n = 167	Non-CTO n = 2,521	P-Value
SAQ Physical Limitation Score	baseline	73.0 ± 25.9	77.4 ± 24.0	0.039
	6 month *	95.7 ± 13.3	96.2 ± 12.2	0.67
SAQ Angina Frequency Score	baseline	69.6 ± 27.6	72.6 ± 23.9	0.12
	6 month *	91.3 ± 18.3	93.4 ± 15.1	0.17
SAQ Quality of Life Score	baseline	53.2 ± 26.0	56.5 ± 25.8	0.11
	6 month *	80.3 ± 20.9	80.6 ± 20.0	0.875
Rose Dyspnea Score	baseline	1.9 ± 1.5	1.7 ± 1.5	0.16
	6 month *	1.0 ± 1.3	0.9 ± 1.3	0.31
EQ5D Visual Analog Scale	baseline	66.4 ± 22.1	70.8 ± 19.5	0.005
	6 month *	71.9 ± 18.8	75.3 ± 17.7	0.026

All Data expressed as Mean±Standard Deviation

SAQ – Seattle Angina Questionnaire

* P<0.001 vs. Baseline for all

Table III

Medications Prescribed at Hospital Discharge

Discharge Medications	CTO n = 167	Non-CTO n = 2,521	P-Value
Aspirin	164 (98)	2424 (96)	0.20
Long-acting nitrate	28 (17)	315 (13)	0.11
Beta blocker	142 (85)	2069 (82)	0.35
ACE inhibitor/ARB	111 (67)	1610 (64)	0.51
Statin	149 (89)	2267 (90)	0.72

All Data expressed as No. (%)

Table IV
Propensity-Matched Comparison of Changes in Health Status and Non-Inferiority Analysis

Outcome	Mean Difference (CTO vs. non-CTO)	Lower 95% CL	Upper 95% CL	P-value (Test of Difference)	Minimally Important Difference	P-value (Test of Non-Inferiority)
SAQ Physical Limitation Score	0.0	-3.2	3.2	0.997	5.0	0.001
SAQ Angina Frequency Score	-1.2	-4.3	1.9	0.459	5.0	0.008
SAQ Quality of Life Score	0.1	-3.7	4.0	0.947	5.0	0.005
Rose Dyspnea Score	-0.0	-0.2	0.2	0.918	0.5	<0.001
EQ-5D Visual Analog Scale	-0.3	-3.5	3.0	0.872	5.0	0.002