Quantifying the Early Health Status Benefits of Successful Chronic Total Occlusion Recanalization

Results From the FlowCardia's Approach to Chronic Total Occlusion Recanalization (FACTOR) Trial

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Background—Data on the health status benefits of percutaneous coronary intervention for coronary chronic total occlusions (CTOs), a principal indication for the procedure, are lacking.

Methods and Results—In the FlowCardia Approach to CTO Recanalization (FACTOR) trial, patients (n=125) completed the Seattle Angina Questionnaire (SAQ) at baseline and 1 month after percutaneous coronary intervenion. One-month health status outcomes were compared by multivariable analysis, adjusting for group differences between those whose CTO was successfully and unsuccessfully recanalized. These changes were also analyzed according to baseline symptoms. Procedural success was 55% (n=64) and independently associated with angina relief (difference between those with successful and unsuccessful percutaneous coronary intervention [Δ] in SAQ angina frequency=9.5 points; 95% confidence interval, 1.6 to 17.5; $P=0.019$), improved physical function (Δ in SAQ physical limitation=13.1 points; 95% confidence interval, 5.1 to 21.1; $P=0.001$), and enhanced quality of life (Δ in SAQ quality of life [QoL]=20.3 points; 95% confidence interval, 11.9 to 28.6; $P<0.001$). The benefit of successful percutaneous coronary intervention was greatest in symptomatic patients as compared with asymptomatic patients although statistically significantly so only for QoL (ΔSAQ angina frequency domain=10.3 versus 4.3 points, $P=0.51$, Δphysical limitation =15.9 versus 6.3 points, $P=0.25$; ΔQoL=27.3 versus 8.5 points, $P=0.047$).

Conclusions—Successful CTO recanalization is associated with significant early improvements in patient symptoms, function, and QoL but only among symptomatic patients. Percutaneous treatment of a CTO offers the potential to provide significant health status benefits in symptomatic patients. **(*Circ Cardiovasc Qual Outcomes*. 2010;3:284-290.)**

Key Words: coronary artery disease ■ health status ■ angina ■ quality of life ■ catheters

Although coronary chronic total occlusions (CTOs) are common,[1] the majority of patients with CTOs do not receive revascularization therapy. When revascularization is performed, the most common procedure offered is coronary artery bypass graft (CABG) surgery,[2,3] occurring in up to 30% of patients with a documented CTO. Only 8% to 15% of patients with a CTO are treated with percutaneous coronary intervention (PCI),[4–6] despite studies suggesting that as many as 46% of CTOs are angiographically suitable for such treatment.[7] Although the reasons for the limited use of PCI are incompletely defined, it seems likely that the time and technical expertise required to treat CTOs are important factors. It is also possible, however, that there is poor understanding or uncertainty of the benefits to patients of successful CTO recanalization.

Several observational studies suggest that there is a survival advantage after successful as compared with failed PCI of a CTO.[8–10] Yet in the absence of a randomized trial, controversy persists surrounding this indication for CTO PCI. Although extending survival is certainly a major goal of coronary revascularization, so too is improving patients' health status: their symptoms, function, and quality of life.[11,12] To date, no study has reported the impact of successful CTO treatment on patient health status, a principal indication for PCI in general. The absence of such data is likely to be an important impediment to classifying the strength of the indications for CTO treatment in guidelines.

The recently completed FlowCardia's Approach to CTO Recanalization (FACTOR) trial demonstrated that The Crosser device[13] for percutaneously crossing CTO lesions resulted in a 55% procedural success rate after traditional techniques had failed. In this study, baseline and 30-day health status assessments were acquired with a validated disease-specific health status measure, the Seattle Angina Questionnaire (SAQ), offering the unique opportunity to quantify the health status benefits of successful CTO treatment on patient symptoms, function, and quality of

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life.[14] Accordingly, this study was designed to assess the patients' perceived health status benefits from successful, as compared with unsuccessful, PCI of a CTO, and describe the relationship of these benefits to preprocedural symptoms status.

WHAT IS KNOWN

- Chronic total occlusions are commonly encountered complex coronary lesions that are frequently avoided by interventional cardiologist.
- Little is known about the health status effects of chronic total occlusion percutaneous coronary intervention.

WHAT THE STUDY ADDS

- We quantified the patient-centered health status benefits of successful compared with unsuccessful chronic total occlusion percutaneous coronary intervention using the Seattle Angina Questionnaire and found that these benefits are restricted to those patients who reported significant preprocedural angina.
- Appropriateness use committees should use these findings in contextualizing their recommendations for chronic total occlusion percutaneous coronary intervention appropriateness.

Methods

The FACTOR Trial was designed to establish the safety and procedural efficacy of The Crosser Catheter System (FlowCardia, Inc, Sunnyvale, Calif) in recanalizing CTOs after traditional percutaneous approaches had failed. Patients were enrolled in the study between December 20, 2004, and July 2, 2006, if they had at least 1 CTO that could not be successfully crossed after 5 minutes of fluoroscopy time using standard wiring techniques. Specific inclusion and exclusion criteria are listed in Table 4. As an established part of the protocol, each patient was asked to complete the SAQ before the procedure (baseline) and 1 month later (follow-up). In most cases, the follow-up questionnaires were completed during an office visit, 30 days after the index procedure. If patients were followed up by their primary care physician, questionnaires were mailed to the patients' home and follow-up telephone reminders were made for those who failed to return the questionnaires by the 1-month target date.

Technical success was defined as successful crossing of the CTO with a guide wire facilitated by The Crosser Catheter. Procedural success was defined as technical success followed by a reduction in the vessel stenosis to $<50\%$ with Thrombolysis In Myocardial Infarction (TIMI) grade 2 or 3 antegrade coronary flow. In the primary analysis, patients were classified as those with successful (n=65) and unsuccessful (n=55) CTO PCI, and their clinical and health status outcomes were compared. In a separate analysis, patients were divided into those with and those without preprocedural angina (baseline SAQ AF score <100 versus 100) and then stratified by procedural success or failure.

Clinical Assessments

Major adverse cardiac events (MACE) were compared. These were defined as any in-hospital death, myocardial infarction (MI) (Q-wave MI or non–Q-wave MI [defined as $>2\times$creatine kinase upper limit of normal]), CABG, or clinical perforation, defined as angiographic evidence of wire perforation and associated pericardial effusion, tamponade, or indication for emergent therapy (CABG, covered stent, or pericardiocentesis).

Outcome Assessments

Patients' perceptions of their symptoms, function, and quality of life were measured with the SAQ, a 19-item, disease-specific health status measure for coronary artery disease.[14] The SAQ Angina Frequency (AF), Physical Limitation (PL), and Quality of Life (QoL) scores range from 0 to 100, where higher scores represent less angina, greater function, and better quality of life. These scores were the primary outcomes for this study. To facilitate clinical interpretability the angina frequency scores can be categorized into daily, weekly, monthly, and no angina (scores $\leq$30, 31 to 60, 61 to 90, and $>$90, respectively). The SAQ has been shown to be more responsive to clinical changes than generic health status measures,[14] and scores are prognostic of subsequent mortality and hospitalization.[15] Given that the purpose of this study was to examine the health status benefits of CTO treatment, we stratified the patients by preprocedural angina status and then compared the health status effects of procedural success and failure.

Statistical Analysis

Continuous variables are summarized by mean$\pm$SD and were compared between successfully and unsuccessfully treated groups by t tests or Mann-Whitney U tests, depending on the variable's distribution. Discrete variables were summarized by frequency and percent and compared between groups with χ^2 or Fisher exact tests when the expected cell sizes were <5.

The association of procedural success with SAQ AF, PL, and QoL scores at follow-up was estimated using propensity score methods to adjust for baseline demographic and clinical factors.[16] A logistic regression model was constructed predicting successful versus unsuccessful recanalization on a range of baseline variables, including site, age, sex, prior MI, hypertension, hyperlipidemia, diabetes, smoking status, prior CABG, number of diseased vessels, ejection fraction, preprocedure creatinine and preprocedural β-blocker, calcium channel blocker, nitrate use and baseline SAQ scores. Overlap of propensity scores between treatment groups was evaluated using histograms, and χ^2 values and probability values for differences in baseline factors between treatment groups were calculated before and after propensity adjustment to assess balance. Finally, the effect of successful PCI for a CTO on 1-month SAQ outcomes was estimated in linear regression models adjusting for baseline SAQ score and the propensity score. The propensity score was entered on the logit scale and fit using restricted cubic splines to allow for nonlinear relationships with the outcomes.[17]

To evaluate a potential confounding effect of repeat revascularization, a secondary analysis was performed excluding 8 patients who underwent repeat PCI and/or CABG after the procedure (either in-hospital [n=2] or electively [n=6] after discharge).

Because of skewness in the 1-month SAQ scores, analyses were repeated using bootstrap methods to evaluate the sensitivity of the results to distributional assumptions.[18] One thousand bootstrap samples were generated through with-replacement sampling from the original data. Regression models were fit as described above and adjusted effects on SAQ outcomes obtained for each of the 1000 samples. Confidence intervals for effects obtained in this way were virtually identical to those obtained in the primary analysis, so only the latter are presented here.

Approximately 10% of patients were missing data on 1 or more baseline variables, and 22% were missing data on 1 of the outcome variables (due to incomplete follow-up). Multiple imputation methods were used to estimate the missing data on the basis of observed information and to account for uncertainty due to missingness.[17] Missing values were imputed using sequential regression imputation, conditioning on all variables in Table 1 and Table 2 as well as baseline and follow-up SAQ scores. Imputations were conducted using the package IVEWARE.[19] Ten imputed data sets were constructed, analyses repeated on each data set, and the results pooled to

Table 1. Baseline Demographic, Clinical Characteristics, and Health Status Scores

	Successful (n=69)	Unsuccessful (n=56)	*P* Value
Age, y	62±11	62±12	0.98
Male sex	56 (81)	49 (88)	0.34
Prior MI	27 (40)	23 (41)	0.88
Hypertension	58 (84)	45 (82)	0.74
Hyperlipidemia	63 (91)	49 (88)	0.49
Diabetes	20 (29)	13 (23)	0.47
Smoking never	32 (46)	20 (36)	0.14
Prior CABG	12 (17)	12 (21)	0.57
No. of diseased vessels			0.15
1	39 (56)	22 (39)	
2	17 (25)	21 (38)	
3	13 (19)	13 (23)	
Ejection fraction, %	54±12	54±9	0.81
Creatinine, ng/mL			0.72
Minimum	0.5	0.6	
Median	1.0	1.0	
Maximum	11.8	6.3	
Antianginal medications			
β-Blocker	43 (68)	38 (68)	0.52
Calcium channel blocker	14 (20)	9 (16)	0.55
Nitrates	27 (39)	24 (43)	0.67
SAQ scores	n=68	n=54	
AF	74±23	76±27	0.69
PL	65±27	68±24	0.50
QoL	50±24	60±26	0.04
SAQ AF scores			0.263
0–30=daily	3 (5)	4 (7)	
>30–60=weekly	21 (31)	13 (24)	
>60–90=monthly	25 (37)	14 (26)	
>90–100=none	19 (28)	23 (43)	

Data are expressed as n and mean±SD or percent (%) unless otherwise noted.

obtain final estimates. The primary analysis was performed using imputed baseline values but restricted to those with complete follow-up data. A sensitivity analysis was conducted imputing follow-up values as well. Last, we imputed missing follow-up scores alternatively as 0 (worst possible outcome) and 100 (best possible outcome) to evaluate the extreme cases of bias due to incomplete follow-up.

Probability values <0.05 were used to establish statistical significance. All analyses were performed using SAS version 9.1 (SAS Institute, Inc, Cary, NC) and R version 2.9.2.[20]

Results

Among the 125 patients enrolled in the FACTOR trial, there were 69 procedural successes (55%) using the Crosser Catheter (successful group) and 56 procedural failures (45%) (unsuccessful group). Baseline demographic, clinical characteristics, and health status scores of the successfully and unsuccessfully treated groups are shown in Table 1. The groups were similar except that the mean SAQ QoL scores were lower in the successfully treated patients as compared with the unsuccessfully treated group. No differences between the successful and unsuccessful groups' mean baseline SAQ AF or PL scores were observed. Follow-up SAQ scores were obtained in 97% of successful and 89% of unsuccessful patients ($P=0.14$). Follow-up was obtained at a median of 35 days in the successful and 33 days in the unsuccessful groups ($P=0.42$).

Table 2. One-Month Clinical Outcomes and Antianginal Medication Use

	Successful (n=69)	Unsuccessful (n=56)	*P* Value
Death	0	0	1.0
Nonfatal MI	3 (4)	3 (5)	0.79
CABG	0	8 (14)	<0.01
MACE	3 (4)	8 (14)	0.06
Clinical perforation	0 (0)	1(2)	0.45
Antianginal medication use			
β-Blocker	48 (70)	41 (73)	0.65
Calcium channel blocker	13 (19)	7 (13)	0.34
Nitrate	29 (42)	21 (38)	0.66

Data are expressed as n (%).

Clinical Results

There was a nonsignificant trend toward increased 30-day MACE rates in the unsuccessful group as compared with the successful group (16% versus 6%, $P=0.06$) (Table 2). This effect was primarily attributable to the need for CABG in the patients whose CTO was unsuccessfully treated (14% versus 0%, $P<0.01$). One patient required emergent CABG for clinical perforation; the other 7 CABG procedures were performed electively. At follow-up, antianginal medication use (β-blockers, calcium channel blockers, and nitrates, Table 2) did not differ between the 2 groups.

Health Status Results

At follow-up, unadjusted mean SAQ scores were all higher in the successful group than in the unsuccessful group (SAQ AF=89±19 versus 80±27, $P=0.02$; SAQ PL=86±18 versus 71±24, $P<0.01$; SAQ QoL=81±17 versus 65±28, $P<0.01$). Accordingly, the mean change in SAQ scores over time were also significantly greater in the successful compared with unsuccessful groups (mean ΔAF=15±20 versus 4±21, mean ΔPL=17±21 versus 5±22, mean ΔQoL=30±23 versus 6±20; $P<0.01$ for all). Although the improvements in health status were significantly greater among successfully treated patients, no significant worsening of mean health status scores were observed among the unsuccessful group between baseline and follow-up.

Propensity score adjustment yielded excellent balance between groups on baseline factors: The smallest probability value for any variable between treatment groups after adjustment was 0.79 (corresponding to a χ^2 value of 0.07). Fifteen patients were excluded from the analyses due to nonoverlapping propensity scores. After adjusting

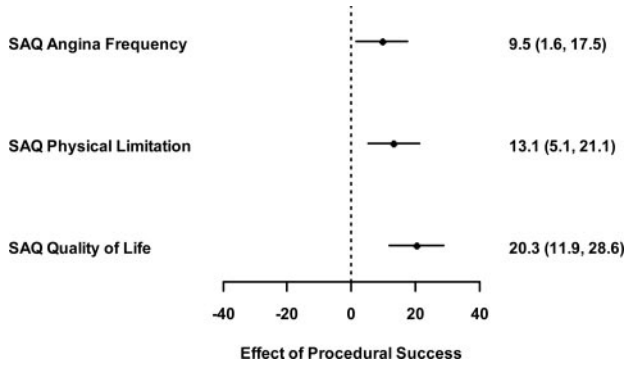

Figure 1. Adjusted health status outcomes comparison between successful and unsuccessful PCI of CTO. Variables used in the model included age, sex, prior MI, hypertension, hyperlipidemia, diabetes, smoking status, prior CABG, number of diseased vessels, ejection fraction, preprocedure creatinine, β-blocker, calcium channel blocker and nitrate use, and hospital. Data are expressed as point estimate of change in outcome from baseline to follow-up with 95% confidence intervals.

for baseline SAQ score and propensity score method, procedural success remained strongly associated with improvements in health status: The fully adjusted difference between successfully and unsuccessfully treated patients (Δ in SAQ angina frequency=9.5 points; 95% CI, 1.6 to 17.5; $P=0.019$; Δ in SAQ physical limitation=13.1 points; 95% CI, 5.1 to 21.1; $P=0.001$; and Δ in SAQ quality of life=20.3 points; 95% CI, 11.9 to 28.6; $P<0.001$) (Figure 1). In an efficacy analysis, after excluding all 8 repeat revascularization patients from the analysis, the results did not appreciably differ (mean Δ in SAQ AF scores=10.5 points; 95% confidence interval [CI], 3.1 to 17.9; $P=0.005$; mean Δ in SAQ PL scores=9.9 points; 95% CI; 1.7 to 18.0; $P=0.017$; Δ in SAQ QoL scores=16.8 points; 95% CI, 8.6 to 25.0; $P<0.001$).

A total of 8 patients (6.4%) did not complete follow-up SAQ interviews. Unsuccessful PCI patients were more likely to be missing follow-up than successful cases (11% versus 3%, $P=0.08$). In sensitivity analyses imputing follow-up SAQ scores, effects of successful PCI on mean SAQ scores differed by no more than 1 point compared with the primary analysis. Finally, we considered 2 extreme scenarios wherein all patients missing follow-up scores were alternately assigned scores of 0 (worst possible outcome) or 100 (best possible outcome). In the first case, mean effects of successful PCI on SAQ scores were 16 for AF, 19 for PL, and 25 for QoL ($P<0.01$ for all); in the second, mean effects were 7, 10, and 16, respectively ($P<0.08$ for all). These results suggest that even under cases of severe bias, benefits of successful PCI of a CTO were still supported.

Table 3 summarizes SAQ scores among each of these subgroups. Forty-one patients were asymptomatic at baseline, 22 of them were unsuccessfully recanalized, and 19 were successfully recanalized; 76 patients were symptomatic at baseline and 28 were unsuccessfully recanalized (48 successfully).

Among asymptomatic patients, AF scores tended to decline at follow-up, slightly more so after unsuccessful PCI. PL and QoL scores improved slightly more after successful versus unsuccessful PCI, but no differences achieved statistical significance (probably because of the small sample size). Among symptomatic patients unsuccessful PCI was associated with modest improvements in AF, PL, and QoL, whereas the changes in all 3 SAQ domains improved significantly among patients who were successfully treated with PCI. In propensity-adjusted analyses, successful CTO-PCI was slightly but nonsignificantly better than unsuccessful PCI in terms of health status outcomes among patients without preprocedural angina; however, procedural success was associated with substantial improvements in AF, PL, and QoL among patients with preprocedural angina (Figure 2). Interactions between treatment and preprocedural angina were nonsignificant for AF ($P=0.51$) and PL ($P=0.25$) but significant for QoL ($P=0.047$).

Discussion

The primary end point of the original FACTOR study was successful percutaneous recanalization of a CTO. However,

Table 3. Unadjusted SAQ Scores by Baseline Symptom Status and Treatment Success

	All Patients		Asymptomatic		Symptomatic	
	Unsuccessful (n=56)	Successful (n=69)	Unsuccessful (n=23)	Successful (n=19)	Unsuccessful (n=33)	Successful (n=50)
Angina frequency						
Baseline	75.9±27.3	74.6±23.4	100.0±0.0	100.0±0.0	57.0±22.5	64.6±20.1
1-Month	79.7±26.6	89.4±19.1	94.5±13.7	97.9±5.4	68.0±28.6	86.0±21.4
Change	3.8±20.6	14.8±20.4	−5.5±13.7	−2.1±5.4	11.1±22.3	21.5±20.3
Physical limitation						
Baseline	66.0±25.2	68.7±25.6	78.9±20.4	82.9±26.6	56.4±24.5	62.7±22.9
1-Month	71.0±23.7	86.0±18.0	82.1±13.7	92.5±12.1	62.6±26.3	83.3±19.5
Change	4.9±22.1	17.3±20.7	3.2±20.5	9.6±25.2	6.3±23.5	20.6±17.8
Quality of life						
Baseline	59.3±25.9	50.5±25.4	78.1±19.5	73.1±21.9	46.6±21.7	41.8±21.1
1-Month	65.1±27.5	80.8±16.7	83.3±12.4	85.6±15.6	52.7±28.2	79.0±16.9
Change	5.8±20.2	30.3±23.1	5.3±18.9	12.5±19.0	6.1±21.4	37.1±21.0

Data are expressed as mean±SD.

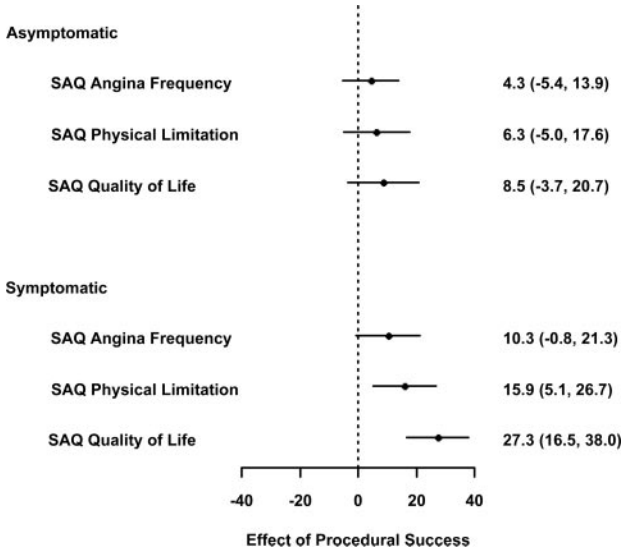

Figure 2. Effect of procedural success on adjusted health status outcomes among patients without (asymptomatic) and with (symptomatic) preprocedural angina. Variables used in the model included age, sex, prior MI, hypertension, hyperlipidemia, diabetes, smoking status, prior CABG, number of diseased vessels, ejection fraction, preprocedure creatinine, β-blocker, calcium channel blocker, and nitrate use, and hospital. Data expressed as point estimate of change in outcome from baseline to follow-up with 95% confidence intervals.

merely opening an artery does not mean that clinically important benefit is provided to patients. The current study expands the primary analysis of the FACTOR trial by quantifying the clinical benefits of the procedure from patients' perspectives. We found that successful percutaneous recanalization of a CTO was associated with substantial improvement in patients' angina frequency, physical limitation and quality of life early after the procedure. In fact, the magnitude of these benefits is similar to the improvements in SAQ scores found after revascularization with CABG[21] or PCI of non-CTO lesions.[22,23] Further, we found that these benefits were greatest in those patients with preprocedural angina. Although studies have suggested higher rates of angina-free survival[24] after successful CTO PCI, this is the first study, to the best of our knowledge, to show significant improvements in patients' assessments of their health status including physical limitation and quality of life.

CTOs are identified in approximately 15% to 30% of patients referred for coronary angiography. Among those, an estimated 46% are angiographically suitable for PCI.[7] Yet, estimates of CTO attempt rates have been consistently lower (range, 8% to 15%).[4–6] Further, we have recently described a disparity in CTO PCI attempt rates that is independently associated with operator PCI volume.[6] This disparity and the infrequent use of PCI in general to treat CTOs suggests that PCI may be underutilized in CTO treatment and remains the "final frontier in interventional cardiology."[4] The most frequently cited explanations for the reluctance to perform PCI in the setting of a CTO include the technical difficulty of the procedure, operator inexperience, time constraints, lower success rates as compared with non-CTO lesions, increased MACE rates, and adequate collateralization. It is also possible, however, that limited insights into or uncertainty of the benefits of CTO recanalization on patients' health status has contributed to the reluctance of guidelines committees to favorably recommend PCI and this translates into underutilization of PCI for CTOs.

There has been essentially no assessment of patients' perceived symptomatic benefits of CTO PCI, a principal indication for PCI in all patients. The current study demonstrates large and clinically important early improvements in angina frequency, physical limitation, and quality of life of 9.5, 13.1, and 23.0 points, respectively, in the successful group. These dramatic benefits in health status, coupled with an absence of appreciable harm from a failed attempt, underscore the opportunity for more aggressive CTO treatment to benefit carefully selected patients.

Our findings of significant patient benefits after successful compared with unsuccessful CTO PCI could be viewed as differing from those of recently reported Open Artery Trial (OAT) quality-of-life substudy.[25] In that study, PCI was compared with medical therapy in clinically stable patients with a totally occluded culprit artery after recent MI. Only a modest quality-of-life benefit was observed in the PCI group at 4 months. These benefits were lost at 12 months. However, patients in the current study had chronic, not recent, occlusions. They also had class 2 angina or significant ischemia on myocardial perfusion imaging attributable to the CTO. OAT trial patients, on the other hand, were excluded if they had postinfarction angina, high-risk findings on noninvasive imaging tests, absence of a wall motion abnormality on left ventriculography, or an ejection fraction $>50\%$. These criteria effectively excluded patients with viable myocardium, whereas patients with completed infarcts were excluded from the current study. Therefore, our conclusion that patients with CTO derive significant health status benefits after successful as compared with unsuccessful PCI is supported even in light of the OAT sub study findings.

The inclusion criteria allowed for the enrollment of asymptomatic patients with significant ischemia and our findings suggest that even after successful PCI of a CTO, patients without preprocedural angina derived little physical limitation or quality-of-life benefit as compared with those who were symptomatic. These findings are consistent with previous observations that the quality-of-life benefit from PCI is associated with preprocedural angina. Spertus et al[22] demonstrated that 23% of the variability in quality-of-life benefit from PCI was associated with baseline symptoms and functional limitations from angina, as compared with $<1\%$ for preprocedural disease severity. A modest health status benefit was observed among unsuccessfully treated and asymptomatic patients in our study; whether this was due to the natural history of the disease, patient adaptation to the clinical circumstances, patient acceptance that no better therapy could be administered or better adherence to antianginal medicines cannot be determined from this study. Nonetheless, this experience provides novel insight into the marked health status benefits potentially attained from the successful treatment of CTOs in symptomatic patients.

Table 4. Inclusion and Exclusion Criteria of the FACTOR Trial

Inclusion criteria
Canadian class II or higher angina and/or objective evidence of myocardial ischemia
Total (100%) occlusion and TIMI 0 flow or TIMI I flow where attempted guide wire failed to cross
Evidence suggesting target lesion ≥30 days old
Target lesion length ≤30 mm
Reference vessel diameter ≥2.5 mm
Patient acceptable candidate for PTCA, CABG surgery, and stent implantation
Female patient of child-bearing age with negative pregnancy test within 48 hours
Patient provided written informed consent
Exclusion criteria
Proximal LAD, LCX, or RCA lesion within 3 mm of ostium, or unprotected left main lesion
No collateral flow distal to lesion
Vein graft or in-stent restenotic lesions
Occlusion contains a dissection that occurred within the last 60 days by guide wire attempt
MI within 72 hours
Ejection fraction <30%
Bleeding diathesis, coagulopathy, or refusal of blood transfusion
Stroke or TIA within 6 months
Gastrointestinal bleed within 6 months
Target vessel or lesion with ectasia, dissection, or aneurysm
Planned coronary intervention within 30 days after index procedure
Requires immediate treatment of non-CTO vessel
Participation in another clinical trial
Comorbid condition with life expectancy <1 year

LAD indicates left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; and TIA, transient ischemic attack.

Limitations

There are several potential limitations to consider in interpreting our results. First, this was not a randomized trial of CTO treatment. Rather, this was an observational study comparing successful with unsuccessful treatment. Nevertheless, the groups were remarkably similar in observed characteristics and multivariable analysis suggests that the observed benefits were primarily attributable to the successful recanalization of a CTO. Nevertheless, it is possible that our findings might be confounded by some unmeasured patient characteristic that was also associated with success. Second, it is possible that the lower initial SAQ QoL scores in the successful patients reflect greater efforts by clinicians to reestablish antegrade blood flow in patients whose quality of life is significantly impaired by their CTO. Although our analysis, adjusted for baseline health status, did suggest that the observed benefits are independent of the greater symptom burden before the procedure. The study was not designed to test the potential for benefits other than health status (eg, survival). Another potential concern is that eight subjects did not complete a follow-up SAQ. However, the use of multiple imputation and sensitivity analyses support our primary conclusions that successful CTO treatment is associated with significant angina relief and improvements in physical function and quality of life. In addition, all of the patients were treated at experienced centers, met the inclusion and exclusion criteria of a clinical trial, and were treated with a novel device. Whether these benefits are generalizable to other clinical situations and settings warrants further study.

Conclusions

The FACTOR Study demonstrated that successful recanalization of a CTO is associated with significant improvements in patient symptoms, function, and quality of life. This study is the first to demonstrate the magnitude of health status benefits conferred on patients who undergo successful PCI of a CTO. These findings strongly support the use of PCI to treat CTOs particularly in symptomatic patients and have the potential to inform guidelines committees in contextualizing the role of PCI in the treatment of CTOs.

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Disclosures

Dr Spertus owns the intellectual property rights to the Seattle Angina Questionnaire.

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