



Optimal medical therapy may be a better initial strategy in patients with chronic total occlusion of a single coronary artery



Ji-won Hwang^{a,1}, Jeong Hoon Yang^{a,b,1}, Seung-Hyuk Choi^{a,*}, Jin Kyung Hwang^a, Woo Jin Jang^a, Joo-Yong Hahn^a, Young Bin Song^a, Jin-Ho Choi^a, Sang Hoon Lee^a, Hyeon-Cheol Gwon^a

^a Division of Cardiology, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

^b Department of Critical Care Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

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ABSTRACT

Objectives: To compare clinical outcomes of percutaneous coronary intervention (PCI) with those of optimal medical therapy (OMT) alone in patients with chronic total occlusion (CTO) of a single coronary artery.

Background: Limited data are available on the efficacy of OMT for the treatment of single-vessel CTO.

Methods: Between March 2003 and February 2012, we enrolled 2024 CTO patients in a retrospective, observational registry and analyzed 435 patients with CTO of a single coronary artery. We divided patients into an OMT group (n = 147) and PCI group (n = 288) according to the initial treatment strategy. One-to-many (1:N) propensity score matching with a non-fixed matching ratio was also performed. The primary outcome measured in this study was major adverse cardiac events (MACEs) including cardiac death, myocardial infarction, and repeated coronary revascularization.

Results: The median follow-up duration was 47.6 (interquartile range: 22.9 to 68.9) months. Major adverse cardiac events were noted for 16 patients (10.9%) in the OMT group compared to 41 patients (14.2%) in the PCI group (p = 0.38). After propensity-score matching, there were no significant differences between the OMT group and PCI group with respect to MACE frequency (10.1% vs. 16.9%, adjusted hazard ratio [HR], 2.03; 95% confidence interval [CI], 0.88–4.68, p = 0.10) or cardiac death (OMT vs. PCI: 5.1% vs. 4.8%, HR, 1.14; 95% CI, 0.30–4.42, p = 0.85). Subgroup analysis showed that the rate of MACEs was significantly lower in the OMT group compared to the PCI group among patients with an APPROACH score ≤18 and SYNTAX score ≤12.

Conclusions: As a treatment strategy in patients with single-vessel CTO, PCI did not reduce the risk of MACE or cardiac death. These results suggest that OMT may be a better initial strategy for patients as assessed by low APPROACH and SYNTAX scores.

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1. Introduction

Chronic total occlusion (CTO) is the most complex and challenging lesion treated via percutaneous coronary intervention (PCI) [1]. Several observational studies have found that successful recanalization of CTO by PCI results in better symptom relief, lower risk of myocardial infarction (MI), and better long-term survival when compared with unsuccessful PCI [2–8]. However, approximately 20–35% of CTOs are not revascularized by PCI, even when the procedure is performed by an experienced physician [9,10]. Accordingly, there may be an important role for optimal medical treatment (OMT) in CTO. In practice, it is difficult to accurately assess the impact of OMT alone on clinical outcomes due to inclusion of patients with multi-vessel and heterogeneous

coronary artery disease, such as various degrees of ischemic territory, lesion complexities in vessels with and without CTO, and incomplete coronary occlusion. On the other hand, patients undergoing single-vessel CTO are an optimal study population to compare the impacts of OMT and PCI on clinical outcomes. Thus, the aims of this study were to investigate the association of OMT strategy with clinical outcomes in patients with CTO of a single vessel and to compare outcomes with those obtained from the PCI strategy in the drug-eluting stent (DES) era.

2. Methods

2.1. Study population

This study was a prospective cohort study. Between March 2003 and February 2012, 2024 consecutive patients were enrolled in the Samsung Medical Center CTO registry. Clinical follow-up of the registry after index coronary angiography was performed at 1, 3, 6, and 12 months, and every year thereafter.

* Corresponding author at: Division of Cardiology, Department of Medicine, Cardiac and Vascular Center, Samsung Medical Center, Sungkyunkwan University School of Medicine, 50 Irwon-dong, Gangnam-gu, Seoul 135-710, Republic of Korea.

E-mail address: sh1214.choi@samsung.com (S.-H. Choi).

¹ Ji-won Hwang and Jeong Hoon Yang contributed equally to this work.

The inclusion criteria for the registry were: 1) at least one CTO detected on diagnostic coronary angiography and 2) symptomatic angina and/or a positive functional ischemia study. Exclusion criteria included: 1) previous coronary artery bypass graft surgery (CABG), 2) history of cardiogenic shock or cardiopulmonary resuscitation, and 3) ST-segment elevation acute MI during the preceding 48 h. From this registry, patients with single-vessel CTO were used for our study population. Subjects were divided into an OMT group and PCI group according to the initial treatment strategy. The institutional review board of Samsung Medical Center approved this study and waived the requirement for informed consent.

2.2. Treatment strategy

OMT included antiplatelet medication, β -blockers, renin angiotensin system blockade, nitrates, calcium channel blockers, and aggressive lipid lowering therapy. The medication regimens of all patients were considered optimal, with doses maximized as allowed by heart rate, blood pressure, and symptoms in the absence of justifiable relative contraindications. Revascularization of CTO was achieved by CABG or PCI with DES, and each revascularization strategy was selected according to the patient's and physician's preference. Percutaneous coronary intervention was performed using contemporary techniques such as bilateral injections, specialized stiff hydrophilic wire with a tapered tip, and microcatheters in a retrograde approach, when available. The decision to pursue invasive treatment as well as site of access, type of DES, use of intravascular ultrasound, and use of glycoprotein IIb/IIIa receptor inhibitors was left to the discretion of the physician. All interventions and procedural anticoagulations were performed in accordance with current standard guidelines. [11,12] Prior to PCI, all patients were pre-treated with loading doses of aspirin (300 mg) and clopidogrel (300–600 mg) unless they were previously medicated with these antiplatelet agents. Aspirin treatment was continued indefinitely, and the duration of clopidogrel treatment was also left to the discretion of the individual physician.

2.3. Definitions and study outcomes

A CTO lesion was defined as obstruction of a native coronary artery with a thrombolysis in myocardial infarction (TIMI) flow grade of 0 and an estimated duration greater than three months [1]. Estimated duration was based on the interval from the last episode of acute coronary syndrome (ACS), or in patients with no history of ACS, from the first episode of exertional angina consistent with the location of the occlusion or previous coronary angiography [1,3]. Angiographic success was defined as a final residual stenosis less than 20% of the vessel diameter with a TIMI flow grade ≥ 2 after revascularization and without residual dissection assessed by visual estimation of angiograms.

Event rates were calculated per patient at risk. The primary outcome measure was incidence of major adverse cardiac event (MACE), a composite of cardiac death, MI, and repeat revascularization with PCI or CABG. The secondary outcome measure was cardiac death. Target vessel revascularization (TVR) and non-TVR treated with PCI or CABG were all recorded as repeated revascularizations.

2.4. Statistical analysis

All statistical analyses were performed using the intent-to-treat principle. Continuous variables were compared using Student's *t*-test or the Wilcoxon rank-sum test where applicable and were presented as the mean $\pm$ standard deviation or median with interquartile range (IQR). Categorical data were tested using Fisher's exact test or the Chi-square test as appropriate. Survival curves were constructed using the Kaplan–Meier method. Covariates that were either statistically significant on univariate analysis or clinically relevant were included in multivariate models. Adjusted hazard rates were compared by Cox

regression based on age, previous history of MI, non ST segment elevation ACS, CTO of the left anterior descending coronary artery, APPROACH score, and SYNTAX score. Propensity scores were estimated using multiple logistic-regression analysis. Full non-parsimonious models were developed that included all of the variables in Table 1. Cox regression analysis using pairs matched by a greedy algorithm and the nearest available pair-matching method among patients with an individual propensity score was also performed to evaluate reductions in outcome risk. The covariate balance achieved by matching was assessed by calculating the absolute standardized differences in covariates between the two groups. An absolute standardized difference of <0.1 for a measured covariate was taken as an indicator of appropriate balance between the groups. In the propensity score-matched population, continuous variables were compared with a paired *t* test or the Wilcoxon signed-rank test as appropriate, and categorical variables were compared with McNemar's or Bowker's test of symmetry as appropriate. Reductions in outcome risk were compared using the stratified Cox regression model, and prognostic covariates with an absolute standardized difference of <0.1 were considered as candidate variables for inclusion in the multivariate models because the combination of regression adjustment in matched samples generally produce the least biased estimate. [13] The C-statistic for the propensity score model was 0.89. The cumulative incidence rates of individual clinical outcomes and composite outcomes were estimated by the Kaplan–Meier method and compared by the paired Prentice–Wilcoxon test. All tests were two-tailed, and values of $p < 0.05$ were considered statistically significant. All analyses were performed with the Statistical Analysis Software package (SAS version 9.2, SAS Institute, Cary, NC, USA).

3. Results

3.1. Baseline characteristics between OMT and PCI groups

Of the 2024 patients registered for this study, 1112 patients had multi-vessel disease and 477 patients who underwent CABG were excluded in this analysis. Thus, a total of 435 patients met the inclusion criteria of a single CTO lesion and single-vessel disease. These patients were treated with either OMT ($n = 147$) or PCI ($n = 288$). Of the patients in the PCI group, 243 (84.4%) were successfully revascularized. In addition, 95 (21.8%) patients were diagnosed with silent ischemia and 11 patients (2.5%) were diagnosed with ischemic cardiomyopathy. In this subset of patients (24.3%), it was difficult to determine the duration of CTO.

Table 1 summarizes the baseline clinical and angiographic characteristics of the patient groups. Compared with patients in the OMT group, those in the PCI group were younger and had a higher frequency of dyslipidemia, family history of coronary artery disease, CTO vessel as left anterior descending artery, and CTO location as proximal or mid portion. Those in the PCI group also had a better left ventricular ejection fraction. On the other hand, patients in the PCI group had lower frequencies of past history of MI and PCI, as well as lower frequency of branched CTO. After performing 1:N individual matching without replacement using propensity scores for the entire population, propensity-matched populations were created for 79 patients of the OMT group and 189 patients of the PCI group (Table 1). There were no significant differences in baseline clinical and angiographic characteristics between the OMT and PCI groups after propensity-score matching.

Dual antiplatelet therapy after OMT or PCI was prescribed in 294 patients (68.5%), excluding two cases of in-hospital death and four cases of missing data. The PCI group had a high prevalence of dual antiplatelet therapy as compared with the OMT group (86.6% vs. 34.5%, $p = 0.001$).

3.2. Procedure-related outcomes

Only 16 patients (5.6%) underwent CTO PCI with a retrograde approach. In the PCI group, procedural and technical characteristics

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