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Predicting Successful Guidewire Crossing Through Chronic Total Occlusion of Native Coronary Lesions Within 30 Minutes

The J-CTO (Multicenter CTO Registry in Japan) Score as a Difficulty Grading and Time Assessment Tool

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Objectives This study sought to establish a model for grading lesion difficulty in interventional chronic total occlusion (CTO) treatment.

Background Owing to uncertainty of success of the procedure and difficulties in selecting suitable cases for treatment, performance of interventional CTO remains infrequent.

Methods Data from 494 native CTO lesions were analyzed. To eliminate operator bias, the objective parameter of successful guidewire crossing within 30 min was set as an end point, instead of actual procedural success. All observations were randomly assigned to a derivation set and a validation set at a 2:1 ratio. The J-CTO (Multicenter CTO Registry of Japan) score was determined by assigning 1 point for each independent predictor of this end point and summing all points accrued. This value was then used to develop a model stratifying all lesions into 4 difficulty groups: easy (J-CTO score of 0), intermediate (score of 1), difficult (score of 2), and very difficult (score of ≥3).

Results The set end point was achieved in 48.2% of lesions. Independent predictors included calcification, bending, blunt stump, occlusion length >20 mm, and previously failed lesion. Easy, intermediate, difficult, and very difficult groups, stratified by J-CTO score, demonstrated stepwise, proportioned, and highly reproducible differences in probability of successful guidewire crossing within 30 min (87.7%, 67.1%, 42.4%, and 10.0% in the derivation set and 92.3%, 58.3%, 34.8%, and 22.2% in the validation set, respectively). Areas under receiver-operator characteristic curves were comparable (derivation: 0.82 vs. validation: 0.76).

Conclusions This model predicted the probability of successful guidewire crossing within 30 min very well and can be applied for difficulty grading. (J Am Coll Cardiol Intv 2011;4:213–21) © 2011 by the American College of Cardiology Foundation

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Currently, there is a great deal of interest in percutaneous coronary intervention (PCI) for treating chronic total occlusion (CTO), primarily because of the marked improvements observed in the acute and long-term results now achievable. Initial success rates have increased, thanks to the introduction of new strategies such as the parallel wire technique (1), the retrograde wire approach (2–4), and the development of new devices. Furthermore, recurrent restenosis rates have dramatically decreased following the deployment of drug-eluting stents (5–8).

However, a high proportion of patients with CTOs are still being managed medically or referred for coronary artery bypass graft surgery rather than PCI (9,10). The primary reason for the relatively low application rates of CTO-PCI by most physicians may be uncertainty concerning the success rate of the procedure. The availability of simple and convenient indexes to evaluate the probability of successful treatment of CTO on a lesion-by-lesion basis may alleviate this uncertainty. Another reason for low application rates may be that the physician tends to hesitate to perform CTO-PCI because of its complexity and time-consuming nature. Therefore, the present study sought: 1) to determine the factors influencing problems arising in treating CTO lesions by PCI using contemporary strategies; 2) to establish a model for determination of the grade of difficulty likely to be encountered in treating CTO lesions by PCI; and 3) to assess the ability of this model to predict the time required for the procedure.

Abbreviations and Acronyms

CTO = chronic total occlusion

GW = guidewire

PCI = percutaneous coronary intervention

Methods

CTO lesion inclusion criteria for this study. To establish a scoring method for determination of difficulty in guidewire (GW) crossing through CTO lesions, we selected study lesions from the J-CTO (Multicenter CTO Registry of Japan) registry cohort. This is a multicenter, prospective, nonrandomized registry to which 12 representative Japanese medical centers contributed from April 2006 to November 2007. The inclusion/exclusion criteria, definition of CTO, and other study designs have already been reported in detail elsewhere (11). Data from 528 CTO lesions in 498 patients in the registry were available for this analysis; however, 34 lesions were excluded because of in-stent restenosis. Therefore, 494 native coronary CTO lesions in 465 patients were included in this analysis.

Selected end point for scoring of difficulty in CTO lesions. In general, in addition to treatment problems associated with the lesions themselves, there are many other factors unavoidably associated with the final outcome of the procedure, including the operator's skill, experience, judgment, effort, and perseverance. Conversely, the impact of such qualitative factors should be minimized to investigate the level of difficulty intrinsic to treating the lesions. As 1 potential objective parameter reflecting the level of difficulty, we focused on the "GW manipulation time," that is, the time from initial insertion of the GW into the coronary lumen to the time it was successfully crossed through the lesion or was pulled out of the lumen because of unsuccessful GW crossing. We have reported that the GW crossing success rate decreased inversely relative to the GW manipulation time, according to data in the J-CTO registry (11). Accordingly, we decided to use this temporal parameter as the end point for this analysis for evaluating the difficulty in treating lesions, as opposed to the established common categorical end point, or the final success of the procedure, which had been exclusively used in data reported previously (12–14).

For further statistical analyses, an acceptable cutoff value was required to categorize this numeric variable. We set 30 min as the threshold for the following reasons: 1) 30 min was the median GW manipulation time in the J-CTO registry (11); and 2) from the clinical and practical standpoints, manipulation within 30 min might be acceptable for the majority of operators and patients. As a pre-defined parameter in this investigation, we selected "successful GW crossing within 30 min" as an end point to determine the difficulty in treating CTO lesions. Successfully crossing the CTO lesion usually results in a successful outcome to the procedure (97.8% of successful GW crossings resulted in final procedural success defined as percentage of diameter stenosis ≥50% in the J-CTO registry).

Definition of potential variables associated with successful GW crossing. Angiograms of the procedures to be analyzed were sent to an independent core angiographic laboratory (Tokyo Core Analysis Laboratory located in Tokai University, Tokyo, Japan). As a first step, detailed qualitative angiographic assessments were made. Angiographic morphology of the entry point was classified as "tapered" if the occluded segment ended in a funnel-shaped form or "blunt" if it did not. Furthermore, a tapered stump was classified into a triangular shape, a string type, beads type, or unclassifiable type using visual assessment. Presence of calcification was assigned to 1 of 3 categories according to severity (mild, severe, or not evident). Bending was defined as at least 1 bend of >45° assessed by angiography throughout the occluded segment divided into either CTO entry or CTO body. Any vessel tortuosity separated from (nonadjacent to) the CTO segment was excluded from the assessment of bending. Calcification and bending were separately surveyed at the entry point, occlusion route, and the overall segment (entry and occlusion route combined). Other angiographic indexes analyzed included the presence of bridging collaterals, the degree of development of retrograde collaterals based on a collateral grading system of 0 to 3, according to the Rentrop and Cohen classification (15), and presence of side branches within 3 mm proximal to the entry stump that might potentially influence GW manipulation. Quantitative assessment was performed using a commercially available software package (QCA-CMS, version 6.0, Medis, the Netherlands) and including the variables of occlusion length, proximal vessel diameter, and distal vessel diameter. Occlusion length was measured from the proximal occlusion to the distal retrograde filling from contralateral collaterals using a dual injection technique, start of filling of bridging collaterals to the distal vessel reconstruction, or from the length of the lesion visible after the GW crossing. Occlusion length was categorized as either <20 or ≥20 mm according to the consensus of the EuroCTO Club (16).

Statistical analysis. Before beginning the statistical analyses, all observations were randomly assigned to the derivation set or the validation set at a 2:1 ratio. The univariate relationships between successful GW crossing within 30 min and categorical variables in the derivation set were evaluated using the chi-square test with appropriate degrees of freedom. Variables that showed substantial correlation ($p < 0.05$) with successful GW crossing within 30 min were then entered into a forward/backward selection procedure. The entry and retention p value thresholds of the forward and backward procedures were both set at 0.05. Thereafter, we included selected variables simultaneously in a multivariable model.

The results of the multivariate analysis were then used to develop a clinical prediction model (17). The difficulty score for an individual CTO lesion was determined by assigning points for each factor present and then summing all points. The resulting continuous distribution of total difficulty scores across all patients in the derivation set was then stratified into 4 categories of points that grouped lesions according to the level of difficulty (easy, intermediate, difficult, and very difficult). The chi-square test was used to compare the derivation and validation sets.

The discriminatory performance of the model was validated by comparing the receiver-operator characteristics curve analysis of the derivation set with that of the validation set (18), and comparison of the model with previously reported factors on sensitivity and specificity. All statistical analyses were carried out using JMP software (version 8.0, SAS Institute Inc., Cary, North Carolina).

Results

Selection of angiographic variables. Table 1 presents a summary of angiographic characteristics obtained from detailed qualitative assessments, and their corresponding rates of successful GW crossing within 30 min. Regarding morphology of entry point, no substantial differences were observed in successful GW crossing within 30 min between the 4 morphological subtypes of tapered stump (triangle, string, beads, and unclassified). Therefore, simple classification, that is, tapered or blunt type, appeared to be sufficient to reflect difficulty in CTO lesions, as used in many previous studies. Severity of calcification was strongly associated with successful GW crossing within 30 min, whereas the difference between mild and severe calcification was relatively small. Furthermore, the location of calcification did not substantially influence this end point. Therefore, the simple variable "presence of calcification" (combined mild and severe throughout the CTO segment) was selected for further statistical assessment. Similarly, a simple variable, presence of bending, was also selected. Other angiographic categorical parameters, including morphology of re-entry point, bridge collateral, retrograde collateral flow grading, side branches, and occlusion length <20 or ≥20 mm, were entered into statistical models and evaluated.

Table 1. Angiographic Characteristics by Detailed Qualitative Assessments

	n (%)	Successful GW Crossing Within 30 Min	p Value
Morphology of entry point			
General classification			0.001
Blunt type	193 (39.1%)	36.6%	
Tapered type	301 (60.9%)	55.6%	
Specific morphology of tapered type			NS
Triangle	180 (59.8%)	59.3%	
String	82 (27.2%)	54.7%	
Beads	36 (12.0%)	38.2%	
Unclassified	3 (1.0%)	50.0%	
Calcification			
Entry portion			<0.001
Not evident	269 (54.4%)	62.8%	
Mild	159 (32.2%)	34.2%	
Heavy	66 (13.4%)	26.2%	
Occluded route			<0.001
Not evident	219 (44.2%)	68.3%	
Mild	181 (36.7%)	35.0%	
Heavy	93 (18.9%)	27.0%	
Overall (entry + route, combined)			<0.001
Absence	213 (43.1%)	69.0%	
Presence (mild + heavy)	281 (56.9%)	32.5%	
Bending			
Entry portion			<0.001
Absence	342 (69.2%)	59.5%	
Presence	152 (30.8%)	24.0%	
Occluded route			<0.001
Absence	325 (65.8%)	58.6%	
Presence	169 (34.2%)	31.0%	
Overall (entry + route, combined)			<0.001
Absence	271 (54.8%)	64.4%	
Presence	223 (45.1%)	29.4%	

The **bold** variables were selected for further statistical assessments.

Patient, lesion, and procedural characteristics. We allocated 324 CTO lesions at random to the derivation set and the remaining 165 lesions to the validation set (Table 2). Differences in patient and lesion characteristics were not significant between the derivation and validation group. Successful GW crossing within 30 min was achieved in 48.6% and 47.3% of lesions in the derivation and validation sets, respectively. The procedural characteristics of the J-CTO registry have been reported elsewhere in detail (11).

Univariate and multivariate analyses. The univariate correlates of successful GW crossing within 30 min in the derivation set included prior history of coronary artery bypass graft surgery, hemodialysis, de novo lesion, previously failed lesion, blunt type of entry, calcification, bending, occlusion length ≥20 mm, and retrograde collateral ≥ grade 3 (Table 3). In forward and backward selections, 5 variables (previously failed lesion, blunt type of entry, calcification, bending, and occlusion length ≥20 mm) were selected as independent predictors of successful GW crossing

Table 2. Patient and Lesion Characteristics in the Derivation and Validation Sets

	Derivation Set (n = 329)	Validation Set (n = 165)	p Value
Age ≥75 yrs	26.4%	27.3%	0.7
Male	79.9%	84.9%	0.8
Prior PCI	42.9%	44.2%	0.2
Prior CABG	8.5%	12.1%	0.8
EF ≤40%	14.0%	14.6%	0.9
Heart failure	12.5%	17.0%	0.2
Prior myocardial infarction	45.9%	43.6%	0.6
Multivessel disease	65.1%	69.1%	0.4
Stroke	12.2%	11.5%	0.8
Hemodialysis	4.3%	4.9%	0.8
Hypertension	73.9%	75.8%	0.6
Dyslipidemia	52.0%	57.6%	0.2
Current smoker	18.8%	23.6%	0.2
Diabetes	41.3%	44.9%	0.5
Insulin-treated	11.6%	13.9%	0.5
Family history of IHD	13.1%	10.9%	0.5
Target lesion			0.4
LCx	20.7%	17.0%	
LAD	37.1%	34.6%	
LMCA	0.3%	1.2%	
RCA	42.0%	47.3%	
Previously failed lesion	11.6%	9.1%	0.4
Ostial location	10.6%	12.1%	0.6
Side branches	82.4%	76.4%	0.1
Blunt stump type at entry	40.4%	36.4%	0.4
Calcification	54.7%	61.2%	0.2
Bridge collateral	23.4%	23.6%	1.0
Bending	43.5%	48.5%	0.3
Occlusion length	13.0 ± 12.3	13.1 ± 13.7	0.9
≥20 mm	21.9%	20.0%	0.6
Retrograde collateral (grade ≥3)	84.2%	87.9%	0.3
Successful GW crossing in 30 min	48.6%	47.3%	0.8

Values are % or mean ± SD.

CABG = coronary artery bypass graft; EF = ejection fraction; GW = guidewire; IHD = ischemic heart disease; LAD = left anterior descending artery; LCx = left circumflex artery; LMCA = left main coronary artery; PCI = percutaneous coronary intervention; RCA = right coronary artery.

Table 3. Univariate Correlates of Successful GW Crossing Within 30 Min in the Derivation Set

	Successful (n = 160)	Unsuccessful (n = 169)	p Value
Age ≥75 yrs	30.0%	23.1%	0.2
Male	75.6%	84.0%	0.057
Prior PCI	38.8%	46.8%	0.1
Prior CABG	4.4%	12.4%	0.007
EF ≤40%	11.3%	16.6%	0.2
Heart failure	11.9%	13.0%	0.8
Prior myocardial infarction	42.5%	49.1%	0.2
Multivessel disease	62.5%	67.5%	0.3
Stroke	12.5%	11.8%	0.9
Hemodialysis	1.9%	6.5%	0.03
Hypertension	70.0%	77.5%	0.1
Dyslipidemia	51.3%	52.7%	0.8
Current smoker	16.9%	20.7%	0.4
Diabetes	42.5%	40.2%	0.7
Insulin-treated	13.8%	9.5%	0.2
Family history of IHD	13.8%	12.4%	0.7
Target lesion			0.3
LCx	21.9%	19.5%	
LAD	40.6%	33.7%	
LMCA	0.0%	0.6%	
RCA	37.5%	46.2%	
Previously failed lesion	5.6%	17.2%	0.0008
Ostial location	10.6%	10.7%	1.0
Side branches	79.4%	85.2%	0.2
Blunt stump type at entry	28.1%	52.1%	<0.0001
Calcification	35.0%	73.4%	<0.0001
Bridge collateral	21.3%	25.4%	0.4
Bending	23.8%	62.1%	<0.0001
Occlusion length ≥20 mm	8.8%	34.3%	<0.0001
Retrograde collateral (grade ≥3)	90.0%	78.7%	0.005

Abbreviations as in Table 2.

Table 4. Difficulty Score for CTO Lesions (J-CTO Score): 5 Selected Independent Predictors Identified by the Forward/Backward Procedure

Variables	Odds Ratio (95% CI)	Beta Coefficient	Point
Previously failed lesion	0.39 (0.15–0.97)	0.93	1
Blunt stump type	0.32 (0.18–0.55)	1.14	1
Bending	0.34 (0.20–0.58)	1.09	1
Calcification	0.26 (0.15–0.44)	1.36	1
Occlusion length ≥20 mm	0.19 (0.09–0.39)	1.65	1

Sum of each point = J-CTO score.

CI = confidence interval; CTO = chronic total occlusion; J-CTO = Multicenter CTO Registry of Japan.

ing within 30 min. Table 4 displays the odds ratios, 95% confidence intervals, and beta coefficients of each variable in multivariate analysis.

Development of the prediction rule: the J-CTO score. To develop the clinical prediction rule, we assigned each of the 5 identified factors an integer score. In general, the integer score must be proportional to the beta coefficient. Because the beta coefficients obtained were relatively close (0.93 to 1.65) between the variables, we decided to give 1 point to each variable to maximize simplicity for clinical use. For each lesion, all applicable score values were summed to obtain a total difficulty score for that lesion (J-CTO score). Figure 1 depicts the relationship between the J-CTO score and the probability of successful GW crossing within 30 min. This rule was then used to categorize the patients in the derivation set into 4 groups with varying likelihood of successful GW crossing within 30 min: 1) easy (J-CTO score of 0); 2) intermediate (score of 1); 3) difficult (score of 2); and 4) very difficult (score of ≥3). The probability of successful GW crossing within 30 min for each group (easy, intermediate, difficult, and very difficult) was 87.7%, 67.1%, 42.2%, and 10.0%, respectively (Fig. 2). The rule performed well on receiver-operator characteristics curve analysis for predicting successful GW crossing within 30 min (area under curve: 0.82).

Validation. In the validation set, the prediction rule again stratified lesions into different degrees of difficulty in achieving successful GW crossing within 30 min (Fig. 1). Similar results were obtained for the derivation set in the corresponding probability of successful GW crossing within 30 min for the 4 difficulty categories (easy: 92.3%, intermediate: 58.3%, difficult: 34.8%, and very difficult: 22.2%). The area under the receiver-operator characteristics curve for the derivation set was 0.82 and for the validation set 0.76 (Fig. 3), which is only a slight decrease in performance. Furthermore, the J-CTO score obtained was compared with previously reported factors such as CTO <20 mm, absence of calcification, and first-time PCI. Table 5 presents the category and factors associated with successful GW crossing within 30 min. The diagnostic values for classification of the degree of difficulty for CTO lesions were excellent in both the derivation and validation sets.

Comparison with the common end point of "final success of the procedure." The relationship between difficulty levels in this grading model and corresponding "final" GW

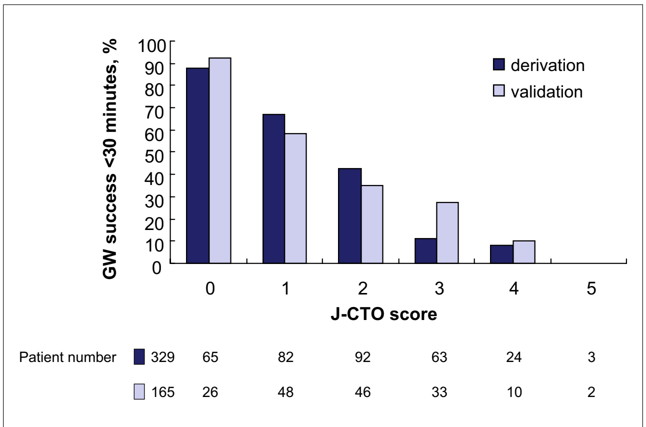

Figure 1. Relationship Between J-CTO Score and GW Success <30 Min

Probability of successful guidewire (GW) crossing within 30 min according to the magnitude of the J-CTO (Multicenter CTO Registry of Japan) score. The J-CTO score predicted this end point very well in both the derivation and the validation sets.

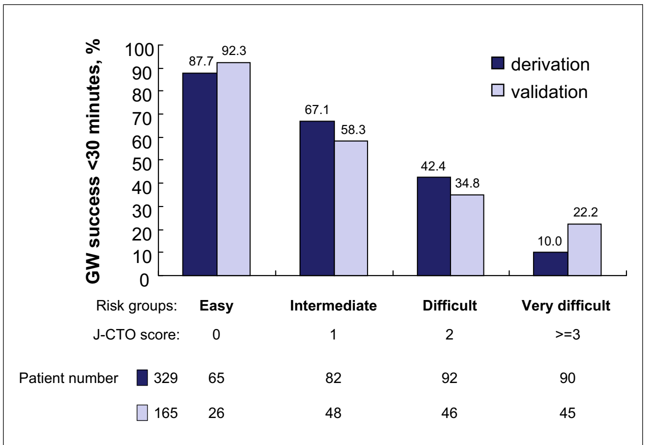

Figure 2. Relationships Between the Risk Groups of Difficulty and the End Point

Relationship between the 4 risk groups based on the J-CTO score and probability of successful GW crossing within 30 min in the derivation and validation sets. This model was a good predictor of successful GW crossing within 30 min. Abbreviations as in Figure 1.

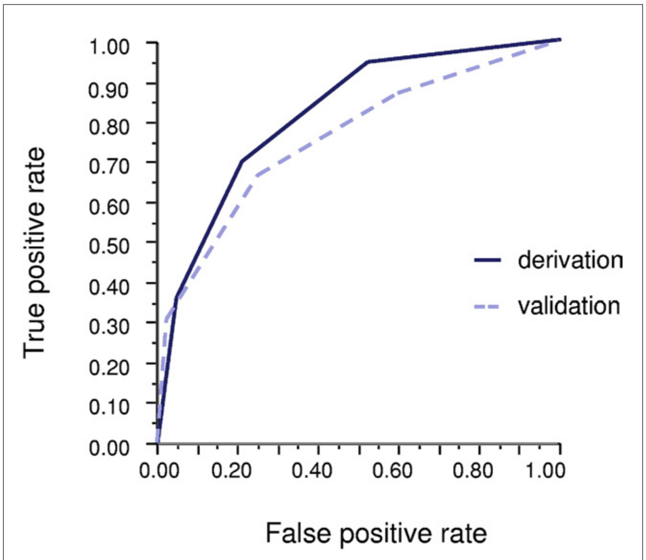

Figure 3. ROC Curves for Probability of GW Success <30 Min

Receiver-operating characteristic (ROC) curves for the probability of successful guidewire (GW) crossing within 30 min. The area under the curve was 0.82 for the derivation set and 0.76 for the validation set.

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Table 5. Comparison of J-CTO Score With Previously Reported Factors Relevant to Successful GW Crossing Within 30 Min: Sensitivity and Specificity

	Category	Sensitivity, %	Specificity, %
Derivation set			
J-CTO score	Easy	35.6%	95.3%
	Easy or intermediate	70.0%	79.3%
	Easy, intermediate, or difficult	94.4%	47.9%
Previously reported factor	Occlusion length <20 mm	91.3%	34.3%
	Without calcification	65.0%	73.4%
	PCI at first time	94.4%	17.2%
Validation set			
J-CTO score	Easy	30.8%	97.7%
	Easy or intermediate	66.7%	74.7%
	Easy, intermediate, or difficult	87.2%	40.2%
Previously reported factor	Occlusion length <20 mm	91.0%	29.9%
	Without calcification	53.8%	74.7%
	PCI at first time	97.4%	14.9%

Abbreviations as in Table 2.

success rates was determined (Fig. 4). Final GW success rates declined mostly in proportion to the difficulty level of lesions (97.8% in easy, 92.3% in intermediate, 88.4% in difficult, and 73.3% in very difficult). Furthermore, distribution of actual GW manipulation time required for successful crossing was quite different between these risk groups. For example, in the easy risk group, a majority of cases was successfully treated within 30 min. In contrast, as the difficulty level increased, the GW manipulation time became longer. In fact, in the very difficult group, more than one-half of the cases treated successfully required a total GW manipulation time >60 min (one-third of cases were even >90 min). With few exceptions, patients experiencing GW success also showed such "procedural" successes.

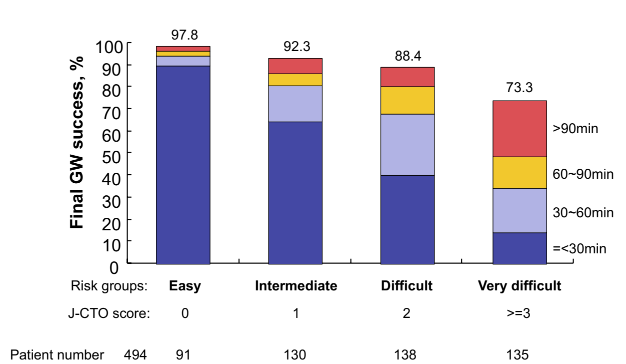

Figure 4. The Risk Groups of Difficulty and Final Procedural Success Rates

Probability of success of the procedure in each risk category by J-CTO score. Actual GW manipulation time required for successful GW crossing superimposed in these bar graphs by stratifying into 4 time intervals. Abbreviations as in Figures 1 and 2.

(Excepted case numbers: easy: n = 0, intermediate: n = 1, difficult: n = 1, very difficult: n = 3).

Discussion

In the J-CTO trial, we achieved a high GW crossing rate (88.6%). Some instances in which the procedure is frequently successful might well depend on the operator's tenacity and/or use of special techniques. These "unaccounted" factors tend to contribute to the problem of establishing standardized scores of difficulty. Therefore, in the present study, we selected the objective parameter GW manipulation time, and not the final success of the procedure, as the primary end point. Considerations along these lines also resulted in an in-depth assessment of procedural time in this study, which had been rarely discussed previously in the literature (12–14).

Most previous studies have consistently reported that increasing age of the occlusion, presence of calcium, presence of a nontapered stump, excessive tortuosity of occluded vessels, long occlusion length, side branches at the occlusion entry, bridge collateral, and lack of visibility of path in the distal vessel affect the ability to successfully cross a CTO (12–14,19,20). However, such factors should be re-evaluated in light of the current improvements and developments in the techniques used in CTO treatment. Furthermore, differences of "weight" or degree of difficulty attributable to these factors require careful quantification using adequate statistical methods.

First, we hypothesized that more angiographic variables than have previously been considered in fact represent risk factors associated with successful GW crossing. Therefore, we prepared very detailed qualitative angiographic assessments. For example, we hypothesized that severe calcification must present a greater obstacle for successful GW crossing compared with mild calcification. Similarly, we hypothesized that bending adjacent to the entry stump might be more problematic than bending elsewhere along the occluded route. However, no substantial difference was observed in successful GW crossing rate within 30 min in this instance. Consequently, the angiographic parameters selected for statistical analyses were mostly categorical and simple "presence or absence" variables. These sieve analyses resulted in the J-CTO score being simple, easy to remember, and clinically applicable. Interestingly, these factors appeared to be almost identical to those already known. Despite current development and improvement of CTO devices, factors associated with treatment difficulty and their relative weight seemed to have remained substantially unchanged.

Clinical implications: grading of difficulty and procedural time assessment of CTO lesions. In real clinical settings, there may be considerable economic and time pressures that serve to dissuade physicians from undertaking CTO-PCI in a majority

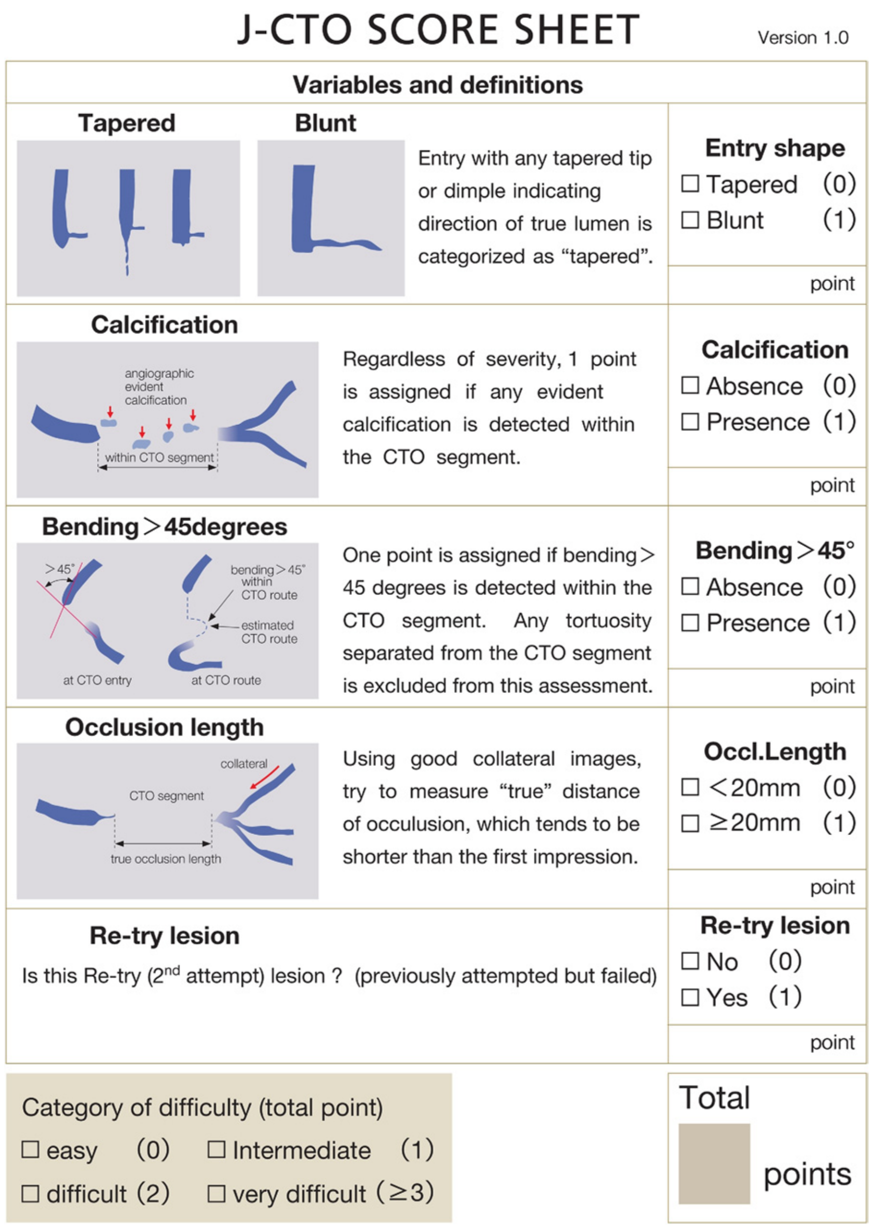

Figure 5. J-CTO Score Sheet

A calculation sheet for J-CTO (Multicenter CTO Registry of Japan) scoring. Angiographic definitions of each variable are summarized and illustrated. The total score is identified as the "J-CTO score." CTO = chronic total occlusion.

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of countries. However, few studies focusing on "time-economy" have actually been reported, perhaps resulting in unnecessary avoidance of this procedure. As a potential practical solution, the "J-CTO score and prediction rule" is advocated here, which primarily allows prediction of lesion difficulty and the time required for GW manipulation. A scoring sheet is provided for convenient calculation of J-CTO score (Fig. 5). Indeed, this may represent a very sensitive scale for predicting GW success within 30 min (Fig. 1). Potentially, this may be also applied for estimating overall procedural success rate and required GW manipulation time based on the J-CTO score (Fig. 4), both of which are very important for assessing the selection of interventional treatment rather than bypass surgery or medication. However, we must also remain aware of the difference between the 2 parameters: "lesion difficulty," and "procedural outcome." They must correlate, but they are not identical. Procedural success can still be achieved even with difficult lesions, if other factors such as the operator's skill, experience, and availability of CTO-specific devices are adequate. We propose the J-CTO score as an objective tool for predicting the difficulty level. Attempting to forecast the probability of final procedural success, the latter factors will always have to be taken into account as well.

In addition, this rule may be useful for assigning operators according to their level of skill for the objectively determined difficulty of dealing with these lesions. In general, we must seek to balance the pursuit of higher success rates for the benefit of the patients with the necessity to provide continuing education to foster the next generation of CTO operators. Occlusions with low J-CTO scores can mostly be opened successfully, which would be good candidates for training purposes. In fact, the frequency of attempts using the retrograde approach in the easy or intermediate group lesions was relatively low in the J-CTO registry (easy: 4.4%, intermediate: 14.6%). Such relatively easy CTO lesion could be treatable in standard facilities even without special CTO equipment.

Study limitations. Several inherent limitations of this analysis must be recognized. First, potential inevitable biases exist, including: 1) a case selection bias (registry-based cohort and inability to confirm whether consecutive cases were correctly registered); 2) an operator and site bias (participants in this registry were limited to advanced PCI centers only); and 3) biases based on qualitative judgment of angiography during core-laboratory analyses. Because this prediction model was developed from data contributed by highly experienced operators in the J-CTO registry, the probability of success or the speed of crossing will require careful extrapolation to the situation with less-experienced operators. Second, we assigned 1 point to each scoring factor because the beta coefficients were relatively close. However, we must consider other possibilities, including: 1) use of an absolute coefficient for each factor; and 2) use of approximate integral values. Nonetheless, considering the substantial differences in clinical impact between these methodologies, it is more important to give priority to an easy to remember and to calculate scoring system than more accurate but complex rules. In fact, probabilities of successful GW crossing estimated by this rule were acceptable, as shown in Figures 2 and 3. Third, a retrograde approach, a relatively time-consuming strategy, was attempted in significant percentages (26.9% [133 of 494]) of the lesions. Moreover, from our previous investigation, we knew that the final procedural success rate in this subset was relatively low (75.9% [101 of 494]) (11). In fact, only 8.3% (11 of 133) met the end point of this study (successful GW crossing within 30 min) in the retrograde subset, whereas it was met by 62.9% of cases not requiring this retrograde approach. There is a lack of consistency in the use of the retrograde approach, which depended entirely on the operator's subjective decision. Initially, we pondered excluding retrograde cases from this investigation. However, we finally decided to include them, because we noticed that their exclusion implied that significant numbers of complex CTO cases, which might be more problematic and alter the end result, would then be absent. A final consideration is that techniques and CTO-specific medical technology devices are changing rapidly; therefore, the J-CTO score must be appropriately updated periodically as needed.

Conclusions

The prediction rule based on the J-CTO score was found to be closely associated with the probability of successful GW crossing within 30 min and could be applied for difficulty grading and procedural time prediction for the interventional treatment of CTO lesions.

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