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Angioplasty for Chronic Total Occlusion by Using Tapered-Tip Guidewires

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Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) is still technically challenging. The use of tapered-tip guidewires in these lesions may improve the success rate of PCI. In order to avoid the needless radiation exposure or contrast consumption, we have to determine a guideline for the termination of procedures in these lesions. We retrospectively analyzed the data of 182 patients between April 1997 and December 1999 (phase 1) and 80 patients between January and August 2001 (phase 2) who underwent angioplasty for CTO lesions ≥ 3 months. There were no significant differences in clinical or lesion characteristics except the use of tapered-tip guidewires. Tapered-tip guidewires were used in 60% of patients in phase 2 period but no patients in phase 1 period. The overall success rate of PCI was improved from 67% in phase 1 to 81% in phase 2 ($P = 0.019$). In the phase 2 period, the success rate was higher in tapered-type occlusion ($P = 0.002$) and shorter length of occlusion ($P = 0.004$). Total procedure time was 46 ± 17 min and total volume of contrast dye was 180 ± 63 ml. The success rate was higher in patients treated by transradial coronary intervention (TRI) than transfemoral coronary intervention (89% vs. 64%; $P = 0.008$). The use of tapered-tip guidewires can improve the success rate of PCI in CTO lesions. The following guideline for the termination of the procedures is reasonable: time from arterial access to successful penetration of a guidewire through occlusion ≤ 30 min; total procedure time ≤ 90 min; and total dye volume ≤ 300 ml. TRI can achieve a high success rate even in CTO lesions provided that the case selection is adequate. *Cathet Cardiovasc Intervent 2003; 59:305–311.*

Key words: double-guidewire technique; contralateral dye injection; transradial coronary intervention

INTRODUCTION

It has been shown that successful recanalization of chronic total occlusion (CTO) of coronary arteries can reduce the need for subsequent coronary artery bypass surgery [1] and also increase the long-term survival of patients [2,3]. However, these beneficial effects by successful recanalization must be balanced by the possible disadvantages for the patients from increased cost, volume of contrast, or radiation exposure [4]. Although the introduction of new devices has improved the success rate of percutaneous coronary intervention (PCI) [5], PCI for CTO lesions is still technically challenging. Transradial coronary intervention (TRI) is generally considered not suitable for PCI in CTO lesions because of the lack in strong backup support by the guiding catheters or the difficulty in taking the contralateral coronary angiograms. Recently, new PCI guidewires specifically designed for CTO lesions, which have tapered tip, have been introduced. In order to test whether these newly developed guidewires can increase the success rate of PCI in CTO lesions, to establish a guideline for the termination of the procedures, and to know the feasibility of TRI in PCI for CTO lesions, we retrospectively compared the results of PCI in these lesions in our institution between the periods before and after the introduction of these guidewires.

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MATERIALS AND METHODS

Definition of Chronic Total Occlusion and Success

We defined chronic total occlusion as the lesions with TIMI 0 antegrade flow and the duration of occlusion ≥ 3 months. We excluded the lesions with TIMI ≥ 1 antegrade flow or the duration of occlusion < 3 months. The duration of occlusion was defined as the interval from the last diagnostic coronary angiograms with total occlusion in patients with the previous angiograms, or from the first onset of clinical symptoms suggesting the ischemic heart disease in patients without previous angiograms to the timing of the coronary intervention. PCI success was defined as the successful recanalization of the CTO lesions with resultant TIMI 3 flow without any adverse events.

Strategy of PCI for CTO Lesions

Indication for coronary intervention for CTO lesions. The CTO lesions with evidence of partially or completely reversible distal ischemia were considered the indication for PCI. The CTO lesions with complete necrosis of the distal myocardium were generally not indicated for PCI.

Guideline for termination of procedures. We predetermined the guideline for the termination of procedures in CTO lesions as follows. Thirty minutes from the arterial sheath insertion to the successful crossing of angioplasty guidewires through the CTO lesion was considered essential to reduce the dose of radiation exposure and the amount of contrast dye, and to increase patient comfort during the angioplasty. If we could not cross the lesion by angioplasty guidewires within 30 min from the sheath insertion, we encouraged ourselves to quit the procedures with the failed angioplasty result for CTO lesions. However, we continued the angioplasty even after 30 min had passed if successful angioplasty for the lesion was thought quite important in order to avoid coronary artery bypass surgery for the patient and if the probability of the successful cannulation into the CTO lesion was expected not to be low. If the total duration of the procedure exceeded 90 min and/or if the total amount of the contrast dye injected exceeded 300 ml, the procedure was not continued any more.

Simultaneous contralateral coronary angiography. Simultaneous contralateral coronary angiography was not planned from the beginning in any case. If the operators considered it necessary during the procedure, the ipselateral femoral artery for the femoral approach or the contralateral radial artery or the femoral artery in the radial approach was punctured with a 4 Fr introducer.

Angioplasty system. First we tried to cross the CTO lesions with soft guidewires without support by the over-the-wire system. If it failed, the guidewires were exchanged for the stiffer ones with or without the over-the-wire (OTW) support systems (Transit from Cordis or Excelsior from Boston Scientific). The guiding catheters used were mainly 6 Fr in diameter.

During the phase 1 period (between April 1997 and December 1999), we started angioplasty with an H/T intermediate guidewire (Guidant) without support by the OTW system. If it failed to cross the occlusion, then we changed the system to a combination of the OTW system and an intermediate guidewire. If it failed, the guidewires were changed to the stiffer guidewires (ACS H/T Standard from Guidant or Miracle from Asahi Intech, Japan) or hydrophilic-coating guidewires (Choice PT from Boston Scientific or Crosswire from Terumo).

During the year 2000, the guidewires specifically designed for CTO lesions were introduced in Japan. These include Cross-It (100, 200, 300, 400 from Guidant) and Conquest (Asahi Intech). Both have the tapered-tip design. In Cross-It, the distal 3 cm is tapered to 0.010″ in diameter, and its tip stiffness changes from that similar to an H/T intermediate guidewire (Cross-It 100) to that stiffer than an H/T standard guidewire (Cross-It 400). In Conquest, the distal 3 cm is tapered to 0.009″ in diameter with stronger stiffness than Cross-It 400.

Angioplasty cases in the year 2000 were excluded from this study because the kinds of angioplasty guidewire for CTO lesions changed much during the year. During the phase 2 period (between January and August 2001), our strategy in guidewire selection for CTO lesions was fixed as follows. Starting with H/T intermediate or Cross-It 100 guidewires with or without the OTW support systems, we changed them to the tapered-tip guidewires, Cross-It 200/300/400 or Conquest guidewires with the OTW systems, if the first guidewire failed to cross the lesion. Cross-It was used more frequently than Conquest.

Double-guidewire technique. If the guidewires went into the false lumen, we took the other guidewires while leaving the first guidewire in the false lumen. Since the first guidewire can show the entry for false lumen and occlude the entry, the second guidewire can find the true lumen more easily.

Indication for transradial approach. Our primary access site for PCI is normally the radial approach [6,7]. However, we did not use the transradial approach if the size of the radial artery is too small for a 6 Fr introducer, if the pulse of the radial artery is weak or absent, if the Allen's test is negative for the good collateral circulation from the ulnar artery to the radial artery, or if the patient is under chronic hemodialysis or considered to be future candidate for hemodialysis. Before the year 2001, we used the transfemoral approach (transfemoral coronary intervention, or TFI) for CTO lesions if the diagnostic

coronary angiograms of the contralateral artery showed good contrast dye filling of the artery distal to the occlusion through the collateral vessels. However, from the beginning of the year 2001, our routine access site for PCI for CTO lesions is the transradial approach, whether the distal contrast dye filling is good or not from the contralateral coronary arteries.

Statistical Tests

Data were collected and analyzed by using Excel 2000 (Microsoft) and SPSS 11.0J (SPSS) running on Windows 2000 (Microsoft). Data were expressed as mean value ± SD. Comparison of continuous and categorical variables between equivalent groups were calculated by ANOVA and chi-square test, respectively. P value of ≥ 0.05 was considered statistically insignificant. Logistic regression analyses were done by using SPSS 11.0J.

RESULTS

Patient Population

We performed PCI for CTO lesions ≥ 3 months in 182 patients between April 1997 and December 1999 (phase 1), and in 80 patients between January and August 2001 (phase 2). There were no statistically significant differences between phases 1 and 2 in the ratio of male gender (78% vs. 83%, respectively), average age (65 ± 11 vs. 67 ± 8 years of age), the ratio of triple-vessel disease (21% vs. 20%), left ventricular ejection fraction (49 ± 18 vs. 49 ± 13), duration of occlusion (15 ± 10 vs. 17 ± 28 months), the length of occlusion (17 ± 5 vs. 18 ± 6 mm), the incidence of tapered-type occlusion (33% vs. 35%), the use of hydrophilic-coating guidewires (8% vs. 6%), or the use of simultaneous contralateral coronary angiography (20% vs. 23%). However, tapered-tip guidewires were used only during phase 2 period.

Results During Phase 1

The patients in phase 1 consisted of 142 male and 40 female patients, and their average age was 65 ± 11 years. The mean estimated interval from occlusion to angioplasty was 15 ± 10 months. Sixty-five (35%), 43 (24%), and 74 lesions (41%) were located in the left anterior descending artery (LAD), the left circumflex artery (LCx), and the right coronary artery (RCA), respectively. TRI was used in 126 patients (69%). The success rates were 67% and 68% in 126 and 56 patients treated with TRI and TFI, respectively. Simultaneous contralateral coronary angiogram was used in 36 patients (20%). Overall lesion success was achieved in 122 patients (67%). Among the 60 patients without success, angioplasty for 55 patients (92%) failed because of failure in crossing the occlusion by an angioplasty guidewire, and failure occurred in 5 patients due to the inability to cross the lesion by a balloon catheter. Thus, the main reason for failure in angioplasty was the inability to cross the CTO lesion by an angioplasty guidewire.

TABLE I. Patient's Characteristics in Patients With and Without PCI Success in the Phase 2 Period

	Successful	Failed	P
n	65	15	
Male gender	53 (82%)	13 (87%)	0.638
Age (years)	68 ± 8	65 ± 7	0.180
Left ventricular ejection fraction (%)	50 ± 13	45 ± 12	0.267
Duration of occlusion (months)	17 ± 31	17 ± 8	0.997
Diabetes	30 (46%)	6 (40%)	0.666
Hyperlipidemia	35 (54%)	6 (40%)	0.334
Hypertension	44 (68%)	12 (80%)	0.348
Smoking	23 (35%)	5 (33%)	0.881
Family history	14 (16%)	3 (20%)	0.523
Prior myocardial infarction	36 (56%)	8 (53%)	0.838
Chronic hemodialysis	1 (2%)	0	0.623

Results During Phase 2

Patient population in phase 2 consisted of 80 patients (66 male and 14 female) among the total 707 patients (11%) who received PCI during the study period, and average age was 67 ± 8 years. PCI success was achieved in 65 of these 80 patients. Thus, the success rate was improved from 67% in phase 1 to 81% in phase 2 ($P = 0.019$). There were no patients with death, myocardial infarction, emergency bypass surgery, or coronary perforation. Characteristics of patients with and without PCI success are shown in Table I. Estimated duration of occlusion was 16 ± 27 months. Lesion and technical characteristics are shown in Table II. No patients with failed PCI had tapered-type occlusion. The length of occlusion was shorter in patients with PCI success (17 ± 5 vs. 22 ± 8 mm; $P = 0.004$). Lesion and technical characteristics are shown in Table II. TRI was used in 55 patients (69%). The sizes of guiding catheters were 5, 6, 7, and 8 Fr in 2 (3%), 55 (69%), 17 (21%), and 6 (8%) patients, respectively. Tapered-tip and hydrophilic-coating guidewires were used in 48 (60%) and 5 (6%) patients, respectively. OTW support system was used in 62 patients (78%). Simultaneous contralateral coronary angiogram was used in 18 patients (23%). The double-guidewire technique was utilized in 10 patients (12.5%). Total procedure and fluoroscopic durations were 46 ± 17 and 11 ± 8 min, respectively. Total volume of contrast dye was 180 ± 63 ml. Statistically significant higher success rates were observed in tapered-type occlusion ($P = 0.002$) and shorter length of occlusion ($P = 0.004$). Tapered-tip guidewires and contralateral coronary angiograms were used more often in patients without PCI success than those with (94% vs. 73%, $P = 0.019$, and

TABLE II. Lesion and Technical Characteristics in Patients With and Without PCI Success in the Phase 2 Period

	Successful	Failed	*P*
n	65	15	
Triple-vessel disease	13	3	0.474
Culprit arteries			0.122
LAD	27 (42%)	2 (13%)	
LCx	18 (28%)	6 (40%)	
RCA	20 (31%)	7 (47%)	
Tapered-type occlusion	28 (43%)	0	0.002
Bridge collateral	9 (14%)	3 (20%)	0.547
Length of occlusion (mm)	17 ± 5	22 ± 8	0.004
TRI	49 (75%)	6 (40%)	0.008
Size of guiding catheters			0.158
5 Fr	2 (3%)	0	
6 Fr	47 (72%)	8 (53%)	
7 Fr	13 (20%)	4 (27%)	
8 Fr	3 (5%)	3 (20%)	
Contralateral angiogram	9 (14%)	9 (60%)	0.001
Use of tapered-tip guidewire	35 (54%)	13 (87%)	0.019
Use of hydrophilic guidewire	3 (5%)	2 (13%)	0.209
Use of OTW support system	48 (74%)	14 (93%)	0.103
Total fluoroscopy time (min)	11 ± 9	12 ± 9	0.740
Total procedure time (min)	48 ± 18	39 ± 13	0.086
Total dye volume (ml)	186 ± 62	160 ± 66	0.176

90% vs. 50%, $P = 0.001$, respectively). The success rate was significantly better in patients treated by TRI than those treated by TFI (89% vs. 64%; $P = 0.008$). Stepwise logistic regression analysis showed only use of TRI ($P = 0.028$; odds ratio = 2.833) and tapered-type occlusion ($P = 0.794$; odds ratio = 12595) were independent predictors for PCI success.

DISCUSSION

In patients with acute myocardial infarction or sudden cardiac death without myocardial infarction, plaques are composed of dense fibrous tissue, loose fibrous tissue, cellular fibrous tissue, calcium, pultaceous debris, foam cells, and lymphocytes infiltration without foam cells [8]. Those plaques in lesions with luminal narrowing $> 75\%$ contain more dense fibrous tissue and calcium compared to lesions with luminal narrowing $\leq 75\%$. Histological examination and their three-dimensional reconstruction study in 10 patients with chronic total occlusion > 1 year revealed four types of occlusion classified according to the presence of a tapering or abrupt types of occlusion, and to the presence or absence of a loose fibrous tissue mass penetrating continuously from the proximal to the distal site of the occlusion [9]. In each type, there are small vascular channels coursing from the proximal lumen, which cannot be visualized by the premortem coronary angiograms. The diameter of these small vascular channels ranges from 160 to 230 μm. Generally, it is difficult to detect a coronary artery < 300 μm in diameter with coronary cineangiography [10]. This limitation of cineangiography might be improved by the introduction of modern high-resolution digitized angiography. However, even digitized angiography cannot detect these small channels since antegrade flow through these channels may disappear as a result of decreased pressure gradient by the presence of collateral distal flow. The most common cause of procedure failure in CTO lesions is inability to cross the lesion with a guidewire [11]. For penetration by guidewires, the small vascular channels must be the easiest ways to pass through. It can be expected that PCI guidewires with tapered-tip end advance through these small channels more easily than conventional guidewires, since its tip diameter (254 μm for Cross-It) is closer to the diameter of these channels. Also, it is expected that hydrophilic guidewires can advance more easily through these small channels by its lower friction with the tissue than conventional guidewires [12]. Since the dense fibrous tissue is hard for the penetration of guidewires, the second easiest way for guidewire passage will be through the loose fibrous tissues. Careful manipulation of the intermediate-strength guidewires, whose tip is bent by 45–90° at the distal 2–5 mm, can lead the guidewires through the loose fibrous tissues. However, the intermediate-strength guidewires cannot penetrate the border between the loose and dense fibrous tissues. At this point, we can advance the OTW support system and exchange the guidewire for the stiffer one with tapered-tip end (Cross-It 300 or 400 or Conquest). This stiff and tapered-tip guidewire has greater possibility for penetrating through the dense connective tissues into the distal true lumen than conventional guidewires (Fig. 1).

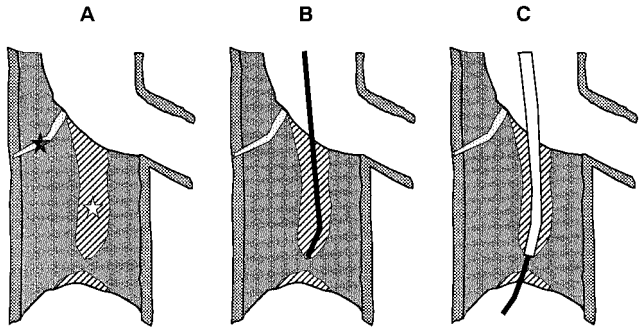

Fig. 1. A: Black star shows small vascular channel and white star shows loose connective tissue. B: Intermediate-strength guidewire can go through the loose connective tissue but cannot penetrate into the dense connective tissue. C: Tapered-tip hard guidewire can penetrate through the dense connective tissue into the distal true lumen by the assist of the over-the-wire support system.

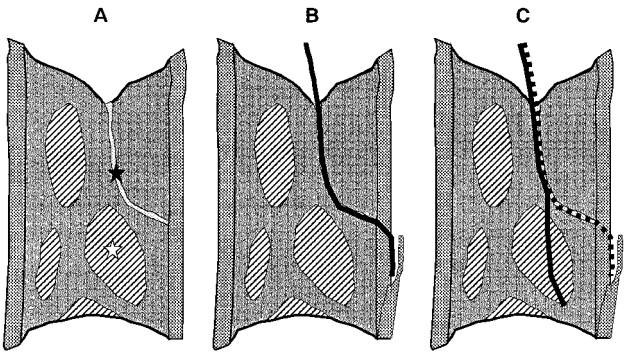

Fig. 2. A: Black star shows small vascular channel and white star shows loose connective tissue. B: The first guidewire penetrates into the subintimal space through the small vascular channel. C: The true lumen by the second guidewire can be found if the first guidewire is left in the false lumen.

The second guidewire will be helpful when the first guidewire goes into the false lumen. The first guidewire can occlude not only the entry into the false lumen, but also modify the arterial geometry and also become a landmark for the navigation of the second guidewire. Thus, the second guidewire can more easily find the true lumen than the first (Fig. 2). In this situation, the tapered-tip guidewires are considered more adequate for the second guidewire than the conventional guidewires because they can create the channel different from the channel created by the first guidewire owing to their stiff and tapered tips. This double-guidewire technique was utilized only in patients during the phase 2 period. The true efficacy of this technique is difficult to verify in our small series of patients. However, since this technique can be used after the first guidewire failed to cross the total occlusion, it is reasonable to assume the technique would be effective.

Several groups have reported that the lesions not in the left anterior descending artery, older occlusion > 3 months, triple-vessel disease, the presence of bridge collateral, abrupt type or longer length of occlusion were predictors for failure in CTO lesions [2,11,13]. Since the success rate was significantly improved in the phase 2 compared to the phase 1 period despite no significant difference in clinical or lesion characteristics between these two periods, we can reasonably infer that the introduction of tapered-tip guidewires might lead to improved success rate in PCI for CTO lesions.

In our phase 2 experience, procedure failure was observed more frequently only in the abrupt-type or longer-length occlusion. The success rates were lower with the use of tapered-tip guidewires or contralateral angiograms than without them. However, these lower success rates do not deny the effectiveness of these techniques but simply reflect the increased use of these techniques in more difficult lesions.

On the other hand, the success rate in patients treated by TRI was higher than those treated by TFI. Strong backup support and contralateral dye injection are generally considered important in PCI for CTO lesions [14]. For these reasons, TRI is generally considered inferior to TFI in PCI for CTO lesions because of poor backup support by guiding catheters or difficulty in taking contralateral coronary angiograms. Thus, the higher success rate in patients treated by TRI observed here might simply reflect adequate patient selection for TRI. Our results show that TRI can achieve success rate $> 85\%$ even in CTO lesions provided that the case selection is adequate. Adequate case selection is important in order to achieve high success rate for CTO lesions [15]. Anyway, these possible disadvantages of TRI in CTO lesions can be negotiated by using deep-engagement technique of guiding catheters and contralateral coronary angiograms through the radial artery from the opposite side (Fig. 3).

Successful recanalization of chronic total occlusion results in not only reduction of the need for subsequent coronary bypass surgery [1] but also improved survival of patients [2,3]. However, these beneficial effects must be balanced by possible disadvantages on patients due to increased cost and radiation exposure [4]. Prolonged procedure time increases radiation exposure to both patients and operators. Increased contrast volume is harmful to kidney function [16]. Thus, it is important for each operator to have a guideline as to when he or she stops the procedures. We predetermined the guideline for CTO lesions as time from arterial access to successful penetration of a guidewires through the occlusion ≤ 30 min; total procedure time ≤ 90 min; and total dye volume ≤ 300 ml. We think this guideline is reasonable because the eventual success rate of $> 80\%$ was achieved while following the guideline, although it must be changed according to patient condition and lesion morphology.

Study Limitations

There are several limitations to this study. First, this study is a retrospective observational study, not a prospective randomized trial. The most scientific way to know the effects of newly developed treatments is to conduct a prospective randomized trial. However, doing it is difficult in the field where interventional devices and techniques are rapidly improving. In this kind of situation, a retrospective study is a reasonable solution. Second, success in angioplasty is highly dependent on operator experience. The improved success rate in the phase 2 period might simply be attributed to our increased experiences rather than the use of tapered-tip guidewires. However, it is reasonable to infer that the use of tapered-

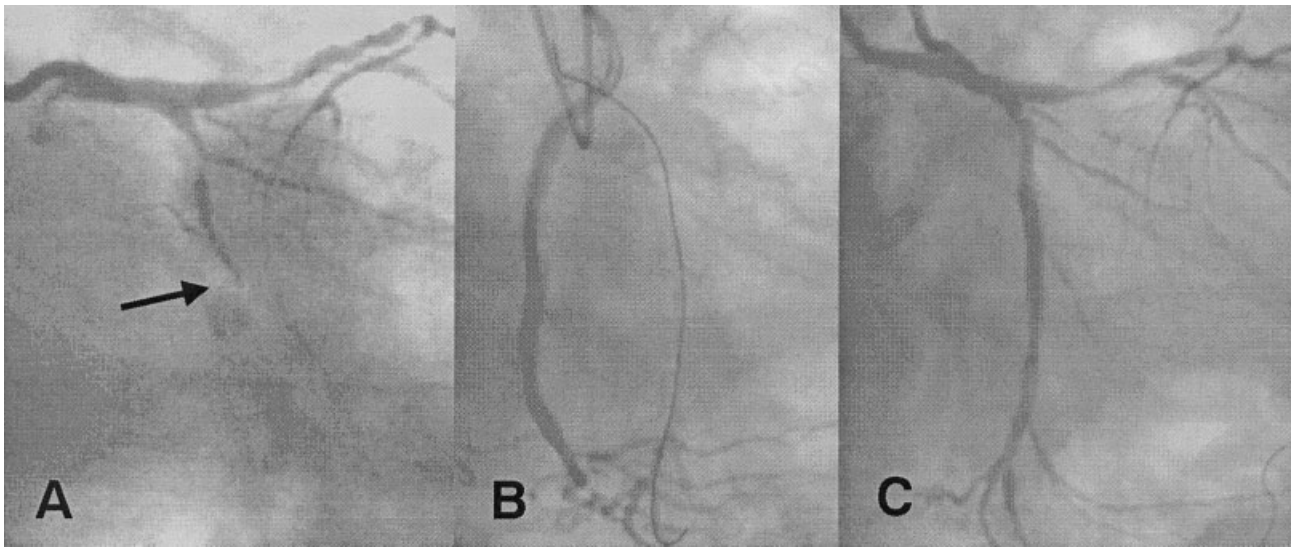

Fig. 3. A: Control angiogram shows chronic total occlusion in the middle circumflex artery (arrow). The guiding catheter was introduced from the right radial artery. B: The contralateral angiogram taken through the left radial approach clearly showed that the guidewire was penetrated into the distal true lumen. C: The final angiogram.

tip guidewires contributed most to the improvement of the success rate, since we have included all of the patients with CTO lesion both in phase 1 and 2 periods, and we could not find any differences in clinical and lesions characteristics between these periods other than the use of these guidewires. Third, we did not determine our guideline for the termination of the procedures in CTO lesions based on the scientific analyses of data. Fourth, the success rate of TRI highly depends on operator experience [17]. The high success rate in TRI observed in this study might not be generalized. Despite these limitations, we can conclude that the use of tapered-tip guidewires can improve the success rate, that we can have reasonable guideline for the termination of the procedures, which includes time from arterial access to successful penetration of a guidewire through the occlusion $\leq$ 30 min; total procedure time $\leq$ 90 min; and total dye volume $\leq$ 300 ml, and that transradial coronary intervention can achieve a high success rate provided that the case selection is adequate in percutaneous coronary intervention for chronic total occlusion.

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