Can a Penetration Catheter (Tornus) Substitute Traditional Rotational Atherectomy for Recanalizing Chronic Total Occlusions?

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SUMMARY

The efficacy of percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) has improved dramatically due to the development of new devices. Severe calcification of coronary lesions may be encountered even when the guidewire crosses the CTO, preventing the balloon from penetrating the lesion. A new “Tornus” penetration catheter has been developed for CTO recanalization. The purpose of this study was to evaluate the feasibility and safety of the Tornus catheter compared with traditional rotational atherectomy for CTO lesions.

From August 2002 to July 2009, 77 patients with CTO of the coronary artery were selected to undergo PCI. Forty-one patients were treated with rotational atherectomy before the availability of the Tornus catheter when the smallest balloon failed to pass the CTO lesion. Later, 36 patients were treated with a Tornus catheter. Device and angiographic success rates as well as procedural complications were assessed. Device success was defined when the Tornus or Rota burr passed through the lesion. Major complications included death, Q-myocardial infarction, or emergency bypass surgery. Minor complications included perforation, cardiac tamponade, no reflow phenomenon, or long spiral dissection.

The mean procedural time was significantly longer in the Tornus group (144 minutes versus 115 minutes, $P = 0.01$), while the device success rate was significantly lower (77% versus 95%, $P = 0.024$). Rotational atherectomy was subsequently performed in 3 of 8 Tornus failure cases. There were no between group differences in major complication rate (6% Tornus versus 5% rotational atherectomy). There was an insignificant trend for lower minor complication rates in the Tornus group (17% versus 20%).

Use of the Tornus catheter was associated with significantly longer procedural duration and lower device success rates compared to rotational atherectomy. Major and minor complications were not different between the groups. Our findings suggest that Tornus catheter penetration is not superior to conventional rotational atherectomy for CTO recanalization. (Int Heart J 2010; 51: 147-152)

Key words: Rotational atherectomy, Tornus, Chronic total occlusion, Percutaneous coronary intervention

Chronic total occlusions (CTOs) are the most challenging lesions encountered by interventional cardiologists.¹⁾ Successful recanalization of CTOs in patients with viable myocardium has been demonstrated to reduce symptoms of angina, decrease the need for surgery, and improve survival.^{2,3)} Advancements in techniques and instrumentation, especially wiring, have increased the rates of success associated with CTO recanalization.⁴⁾

Stenting of CTO lesions after successful recanalization has been demonstrated to reduce rates of restenosis and improve long-term patency compared to balloon angioplasty.⁵⁻⁷⁾ However, the presence of severe calcification or dense plaque can make balloon passage or stent implantation impossible. Hence drilling a hole through the occlusion before balloon angioplasty or stent implantation is an important determinant of CTO intervention procedural success.

Traditional rotational atherectomy involves the use of

a high speed Rota burr to polish and remove the superficial calcified lesion or 360 degree calcification. Rotational atherectomy has been reported to be more efficacious and safe for CTO recanalization in selected cases compared with directional atherectomy.⁸⁾ However, this technique is technically challenging and can lead to complications such as long spiral dissection, no reflow phenomenon, perforation and Rota burr incarceration.

A new penetrating device, the Tornus catheter (Asahi Intecc, Japan), has been designed and widely used for CTO recanalization since 2004.^{9,10)} The associated technique involves manual rotation and insertion through the lesion. This new technique is believed to be less technically challenging with a shorter learning curve and fewer complications than traditional rotational atherectomy. The aim of this study was to evaluate the clinical safety and efficacy of the Tornus penetration catheter compared to conventional rotational atherectomy for CTO recanalization.

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Received for publication November 11, 2009.

Revised and accepted January 14, 2010.

METHODS

The feasibility and safety of the CTO intervention procedures were evaluated in patients with symptomatic coronary artery disease who underwent treatment at Chang Gung Memorial Hospital, Kaohsiung, Taiwan, R.O.C.

Patient inclusion and exclusion criteria: Inclusion criteria were: 1) angiographic evidence of chronic total occlusion (thrombolysis in myocardial infarction flow grade, TIMI, = 0) with a duration greater than or equal to 3 months; 2) patient refusal of coronary artery bypass surgery; 3) a CTO lesion crossed by a 0.014 guidewire, but impassable to the smallest balloon (< 1.5 mm) or microcatheter (Finecross, Terumo, Japan; Transit, Cordis, USA). Exclusion criteria were as follows: 1) a CTO lesion not crossed by a 0.014 guidewire or the failure of Rota wire to reach the distal part of the vessel; 2) dissection or perforation caused by the guidewire during wire advancement before reaching the distal part of the vessel. Seventy-seven patients who underwent intervention for CTOs from August 2002 to July 2009 were the focus of this study. Before 2004, all such patients ($n = 41$) at our institution were treated with rotational atherectomy. After 2004, 36 patients were treated with the Tornus catheter.

Chronic total occlusion treatment strategy: Revascularization was first attempted using a guiding catheter (Figure 1A). Stepwise 0.014 guide wires were used for antegrade wiring along with a microcatheter or an over the wire (OTW)

balloon for targeting the CTO lesion with or without contra-lateral injection. After the 0.014 guidewire reached the distal target vessel (this was confirmed by sequential contrast injection, Figure 1B), the smallest balloon (Ryujin plus 1.25 × 10 mm OTW balloon, Terumo, Japan; Ottimo 1.5 × 10 mm, Kaneka, Japan) or a microcatheter (Finecross, Terumo, Japan; Transit, Cordis, USA) was unsuccessfully advanced across the CTO site (Figures 1C, D). Thereafter either rotational atherectomy or Tornus manual rotation was performed.

Conventional rotational atherectomy (Rota group): This procedure involved the following: 1) inserting the microcatheter (Finecross or Transit) or the smallest OTW balloon to the most distal portion of the CTO site; 2) withdrawing the previous 0.014 wire; 3) advancing the 0.009 Rota wire (Boston Scientific, USA) along with microcatheter or the OTW balloon to distal true lumen of the CTO, then removing the microcatheter or OTW balloon (Figure 1E); 4) using a Rotablator burr (Boston Scientific, USA) of either 1.25 mm or 1.5 mm according to the preference of the operator (Figure 1F); 5) setting the burr speed at 160,000-170,000 rpm and increasing the speed to 190,000-200,000 rpm if necessary (Figures 1G, H).

Tornus manual rotation (Tornus group): A 0.014 guidewire with an extension wire (Asahi, Japan) was passed through the CTO lesion and either a 2.1 Fr. or 2.6 Fr. Tornus catheter subsequently advanced to the lesion site. Manual counterclockwise rotation of the Tornus catheter was performed until it passed through the CTO lesion site (Figures 2A-F). Withdrawal of the Tornus catheter required clockwise rota-

Figure 1. (A) Diagnostic coronary angiography revealed mid left anterior descending (LAD) chronic total occlusion (CTO: black arrow). (B) A 6Fr XB 3.5 catheter (Cordis, USA) was used as a guiding catheter for support. The CTO lesion was crossed with a 0.014 Conquest Pro guidewire (Asahi, Japan: black arrow). (C) The smallest Ryujin-plus 1.25 × 10 mm balloon (Terumo, Japan: black arrow) would not pass through the heavily calcified lesion. (D) Even using the strongest back up support 6Fr XB 3.5 guiding catheter (black dotted arrow) with a 5 in 6 guiding catheter (Terumo, Japan: black arrow), the Ryujin 1.25 × 10 mm balloon (white arrow) still would not pass through. (E) 0.009 Rota wire (black arrow) was advanced to the distal LAD (this was confirmed by contrast injection: black dotted arrow). (F) A 1.25 mm Rotablator burr (black arrow) was used to cross the lesion 8 times at 160,000 rpm. (G) The 1.25 mm Rotablator burr (black arrow) successfully crossed the lesion. (H) After stent deployment, final angiography revealed good results. From A to H, all are right anterior oblique cranial views.

Figure 2. (A) Diagnostic coronary angiography revealed distal right coronary artery (RCA) chronic total occlusion (CTO, black arrow) with bridging collaterals (black dotted arrow), supported by a 6Fr. Ika-ri IL 3.5 (Terumo, Japan: white arrow) guiding catheter. (B) The CTO lesion was crossed with a Miracle-6 wire (Asahi, Japan: black arrow) and the position of the wire tip in the true lumen was confirmed by contrast injection (black dotted arrow). (C) The smallest Maverick 1.5 × 10 mm balloon (Boston, USA: black arrow) would not pass through. (D) A Tornus 2.6 Fr. catheter (black arrow) successfully crossed the lesion. (E) A Cypher 3.0 × 33 mm drug eluting stent (Cordis, USA) was deployed from the mid to distal RCA at 16 atmospheres (atm). (F) Following stent deployment, angiography revealed good results. From A to F, all are left anterior oblique cranial views.

tion.

Balloon angioplasty and stenting: After device crossing, balloon angioplasty was initiated using the smallest balloon (Ottimo 1.5 × 10 mm: Kaneka, Japan; or RyuJin 1.25 × 10 mm OTW balloon: Terumo, Japan), before proceeding to further stepwise dilatations. Intravascular ultrasound was used to assess vessel diameter, lesion morphology, and lesion length in selected patients. Balloon angioplasty or stenting was performed as determined by individual operators.

Medications: Patients were treated with oral aspirin (100 mg/day) before the procedure and thereafter indefinitely. Clopidogrel (a loading dose of 300 mg 6 to 8 hours before and immediately after the procedure, then 75 mg/day) was administered to patients for at least 3 months for bare-metal stents or 9 to 12 months for drug-eluting stents.

Definitions: Device success was defined as when the Tornus catheter or Rotablator burr crossed the CTO site to the distal part of the vessel. Angiographic success was defined by a final TIMI flow grade of 3 and residual stenosis of < 30%. Clinical success at 30 days was defined as device and angiographic success without any major complications such as death, Q wave myocardial infarction (Q-MI), or emergent bypass surgery. Perforation, cardiac tamponade, transient no reflow phenomenon, sudden stopped with rapid deceleration in Rota speed (> 5,000 rpm), Rota wire fracture, and long spiral dissection were defined as minor complications.

Statistical analysis: Continuous variables are reported as the mean ± standard deviation, while categorical variables are reported as frequencies. Categorical variables were compared between groups using the chi-square test. A *P* of < 0.05 was considered to be statistically significant. Statistical analysis was performed using SPSS version 12.0 software (SPSS, Chicago, IL, USA).

RESULTS

Patient population: The patient population included 77 patients who underwent Tornus (*n* = 36) or rotablation (*n* = 41)

for the CTO lesion. Table I summarizes the demographic and baseline clinical characteristics of the groups of patients. There were 56 (72%) males and 21 (28%) females with a mean age of 65 ± 13 years. The incidences of comorbidities including previous myocardial infarction, history of bypass surgery, and multivessel coronary artery disease were similar between the groups. Left ventricular ejection fraction as determined by 2D echocardiography was significantly lower in the Tornus group compared to the Rota group (53 ± 15% versus 60 ± 12%, *P* = 0.041).

Angiographic characteristics, measurements and procedure outcomes: Table II summarizes the angiographic and quantitative coronary results for the two groups. There were no statistically significant differences between the groups in the target CTO vessels. The majority of patients in the Rota group underwent PCI via a transfemoral approach (54%), while the vast majority of those in the Tornus group underwent PCI via a transradial approach (88%). There were significant differences in guiding catheter size between the Rota group and the Tornus group, especially in 6 Fr. (32% versus 81%, *P* = 0.014) and 7 Fr. (27% versus 17%, *P* = 0.032). Two different types of Tornus catheters were used for PCI: 23 (64%) 2.1Fr. and 13 (36%) 2.6Fr. The procedure duration was significantly longer in the Tornus group compared to the Rota group (144 ± 50 minutes versus 115 ± 47 minutes, *P* = 0.01). The device and angiographic success rates were significantly higher in the Rota than the Tornus group (95% versus 77%, *P* = 0.024 and 95% versus 81%, *P* = 0.047). Device failure occurred in 8 out of 36 patients in the Tornus group (23%); 3 of these subsequently underwent successful rotablation. In two patients in whom the Tornus procedure was successful, the presence of severe calcified and undilatable lesions resulted in overall failure. In the Rota group, 2 patients suffered device failure due to Q-MI or Rota burr incarceration in the right coronary artery (this patient also had end stage renal disease).

Angiographic quantitative coronary analysis revealed no intergroup differences in lesion length, lesion reference diameter, or minimal luminal diameter. Post PCI diameter stenosis was significantly higher in the Tornus group com-

Table I. Patient Characteristics

	Tornus group (<i>n</i> = 36)	Rota group (<i>n</i> = 41)	<i>P</i>
Demographics			
Age	64 ± 13	67 ± 10	0.235
Males	30 (83%)	26 (63%)	NS
Females	6 (17%)	15 (37%)	NS
Risk factors			
Diabetes mellitus	18 (50%)	21 (51%)	NS
Hypertension	25 (69%)	30 (73%)	NS
Cholesterol > 200 mg/dL	5 (14%)	5 (12%)	NS
Current smoking	8 (22%)	10 (24%)	NS
Comorbidity			
Old myocardial infarction	16 (44%)	11 (27%)	NS
Bypass surgery history	2 (6%)	1 (2%)	NS
One-vessel disease	2 (6%)	2 (5%)	NS
Two-vessel disease	7 (19%)	11 (27%)	NS
Triple vessel disease	27 (75%)	28 (68%)	NS
Ejection fraction (%)	53 ± 15	60 ± 12	0.041

Data are expressed as the mean ± SD or number (%) of patients.

Table II. Device and Access Data

	Tornus group (n = 36)	Rota group (n = 41)	P
CTO target vessel			
Left anterior descending	12 (33%)	20 (49%)	NS
Right coronary artery	20 (56%)	16 (39%)	NS
Left circumflex	4 (11%)	5 (12%)	NS
Access site			
Trans-radial approach	32 (88%)	17 (41%)	NS
Trans-brachial approach	1 (3%)	2 (5%)	NS
Trans-femoral approach	1 (3%)	22 (54%)	NS
Trans-ulnar approach	2 (6%)	0 (0%)	NS
Guiding catheter size (Fr.)			
5	1 (3%)	0 (0%)	NS
6	29 (81%)	13 (32%)	0.014
7	6 (17%)	11 (27%)	0.032
8	0 (0%)	9 (22%)	NS
9	0 (0%)	8 (20%)	NS
Procedure results			
Procedure time (minutes)	144 ± 50	115 ± 47	0.01
Rotawire passage success	NS	41/43 (95%)	NS
Device success	28 (77%)	39 (95%)	0.024
Angiographic success	29 (81%)	39 (95%)	0.047
QCA data			
Lesion length (mm)	29 ± 9	31 ± 12	0.555
Reference diameter (mm)	3.02 ± 0.71	3.00 ± 0.60	0.883
MLD post (mm)	2.52 ± 0.75	2.68 ± 0.72	0.383
Stenosis post (%)	26 ± 29	14 ± 18	0.024

Data are expressed as the mean ± SD or number (%) of patients. QCA indicates quantitative coronary analysis and MLD, minimal luminal diameter.

Table III. In-Hospital Follow-Up Events

	Tornus group (n = 36)	Rota group (n = 41)	P
In-hospital events			
Major complications	2 (6%)	2 (5%)	0.894
Cardiac death	0	0	NS
Q wave MI	2 (6%)	1 (2%)	0.481
Emergent bypass surgery	0	1 (2%)	NS
Minor complications	6 (17%)	8 (20%)	0.777
Dissection	2 (6%)	2 (5%)	0.894
Perforation by wire	2 (6%)	0	NS
No-reflow (slow flow)	1 (3%)	5 (12%)	0.124
Rota wire fracture	0	1 (2%)	NS
Arrhythmia (VT/VF)	1 (3%)	0	NS
Hospital stay (days)	10 ± 14	9 ± 13	0.641
30-day clinical success	26 (72%)	38 (93%)	0.02
Overall death in 30 days	2 (6%)	0	NS

Data are expressed as the mean ± SD or number (%) of patients. MI indicates myocardial infarction and VT/VF, ventricular tachycardia/ventricular fibrillation.

pared to the Rota group (26 ± 29% versus 14 ± 18%, $P = 0.024$).

In-hospital clinical events and 30-day follow-up: Table III summarizes the in-hospital clinical events and 30-day follow-up findings for the two groups of patients. There were no significant intergroup differences in major complications including cardiac death, Q-MI, and the need for emergency bypass surgery. There were no instances of cardiac death in either group. Only one patient underwent emergency coronary bypass surgery due to 1.75 mm rotablator burr incarceration in the right coronary artery. There were no

significant differences in minor complications including long spiral dissection, wire perforation, no or slow flow, rota wire fracture, or lethal arrhythmia ventricular tachycardia/ventricular fibrillation (VT/VF). There were two cases in the Tornus group of wire perforation, both of which led to cardiac tamponade and the need for emergency pericardiocentesis. There was no intergroup difference in mean hospital stay duration. Two patients in the Tornus group died of sepsis and multiple organ failure within 30 days during hospitalization. The 30-day clinical success rate was significantly higher in the Rota group compared to the Tornus group (93%

versus 72%, $P = 0.02$).

DISCUSSION

To the best of our knowledge, this is the first report to directly compare Tornus catheter penetration and rotablation for recanalizing of balloon uncrossable CTO lesions. The main finding from this study is that rotablation was associated with not only higher device and angiographic success rates, but also shorter procedure times. The major and minor complication rates in the Rota and Tornus groups were similar.

The recent development of stronger and more responsive wires have made CTO interventions more feasible and successful. Although these wires can more easily cross CTO sites, subsequent balloon or microcatheter advancement can be difficult. Previous reports from Japan have indicated that ablation with rotational atherectomy is efficacious for CTO lesion recanalization.^{11,12} It has also been noted that plaque debulking by rotational atherectomy before drug-eluting stent implantation results in a lower incidence of target lesion revascularization than without plaque debulking (4.2% versus 4.9%).¹³ A previous study focusing on PCI using the novel penetration catheter Tornus for coronary artery stenosis yielded good device success rates and no complications.¹⁴ However, with regards to severe calcified CTO lesions, it is not clear whether Tornus or rotational atherectomy is more efficacious. Thus, we retrospectively compared outcomes associated with these two methods in patients who underwent CTO recanalization.

In this study, we have highlighted the procedures performed step by step in our daily practice. When the CTO segment required rotablation, our practice was to position the microcatheter as far as possible in the CTO segment; we were then able to reintroduce a 0.009 Rota wire distally through the microcatheter and initiate rotablation without difficulty. The most challenging part of this process is advancing the Rota wire such that it does not enter the distal false lumen. However, as the Rota wire size was far smaller than the usual 0.014 wire, we were able to perform delicate wiring through the original 0.014 wire-created channel. Rota wire passage was unsuccessful in two out of 43 patients (4.7%: these patients were excluded from the Rota group). In contrast, the Tornus catheter allowed for maintenance of the wire inside the distal true lumen without changing. Disadvantages associated with Tornus catheter penetration included a longer procedural PCI duration time and fluoroscopic exposure.

Both groups of patients in the present study exhibited better device success rates for CTO recanalization compared to those reported with overall device success rates of 74.4% and procedure success of 69.9% in previous studies.¹⁵ In our study, Tornus manual rotation yielded lower rates of device success than rotablation. The lower power driven and debulking effects associated with use of the Tornus catheter may underlie the decreased success rate. Other reports have described adjunct procedures such as anchoring, deep intubation, the 5 in 6 system, the two wires technique, and use of the "Proxis" proximal protection device to increase power derived from the Tornus catheter.^{9,16}

According to previous studies, the risk of vessel damage associated with use of the Tornus catheter, such as coronary perforation or distal embolism, is low.^{10,14} However, it is important to secure the guidewire while the Tornus catheter is rotated. The guidewire and the Tornus catheter must not rotate at the same time; otherwise there is risk of wire induced perforation. Although there were no statistically significant differences in the occurrence of major and minor complications between the Tornus and Rota group in this study, it must be emphasized that complications such as perforation and procedure related myocardial infarction may occur as a consequence of Tornus manipulation.

Our study has several limitations. Firstly, the study was retrospective and nonrandomized, involving only a small number of patients. A multicenter randomized controlled trial is warranted to more comprehensively compare the efficacies of Tornus catheter penetration and traditional rotational atherectomy for CTO recanalization. Secondly, selection bias may have influenced the findings given that the approach used was determined with respect to when the patient was treated (i.e., before 2004, the Tornus approach was not used in our institution). Additionally, the failure of Rotawire passage to the distal CTO vessel was not included in the calculation of device success rate and angiography success rate. Finally, long term clinical follow-up findings were not reported in this study.

In conclusion, in this study we have found that Tornus catheter penetration was associated with significantly longer procedural times and lower device and angiographic success rates compared with traditional rotational atherectomy. However, the occurrence of major and minor complications was not statistically different between the groups. Our findings suggest that Tornus catheter penetration is not superior to conventional rotational atherectomy for CTO recanalization.

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