

Efficacy and safety of Tornus catheter in percutaneous coronary intervention of hard or balloon-uncrossable chronic total occlusion

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Short Communication

Abstract

BACKGROUND: Balloon advancement and dilation through chronic total occlusion segment could be challenging in some cases after successful wire crossing. The purpose of this study was to evaluate efficacy and safety of Tornus catheter (Asahi Intecc; Aichi, Japan) in percutaneous coronary intervention of chronic total occlusion in hard or balloon-uncrossable chronic total occlusion.

METHODS: The present study is a retrospective and descriptive analysis of 14 hard or balloon-uncrossable chronic total occlusions treated percutaneously in our catheterization laboratory (cath lab). Tornus catheter was used to penetrate and eventually cross the chronic total occlusion segment. Procedure success was defined when Tornus penetrated at least partly into chronic total occlusion segment making possible the subsequent balloon dilatation and stent implantation achieving a final TIMI III angiographic result with residual stenosis less than 30%. Switch to other microcatheter was considered as an unsuccessful procedure. Complications associated with the Tornus use were analyzed in order to evaluate device safety.

RESULTS: The average age of patients was 65.2 ± 9.6 and 11 out of 14 (78.6%) were male. In 7 (50%) cases, Tornus was used after an unsuccessful balloon passage through occluded segment. In 11 (78.6%) out of 14 cases the procedure was successful and in 3 (21.4%) cases, the operator switched to another microcatheter to continue with the procedure. No complication occurred during all procedures.

CONCLUSION: Tornus catheter can be effectively and safely used in a subgroup of patients undergoing percutaneous coronary intervention of chronic total occlusion with hard or balloon-uncrossable lesions and could facilitate the treatment of this type of lesions.

Keywords: Percutaneous Coronary Intervention, Chronic Total Occlusion, Catheter

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Introduction

Chronic total occlusion (CTO) is defined as a coronary artery occlusion longer than three months standing with Thrombolysis in Myocardial Infarction (TIMI) flow grade of zero.¹ Around 30% of all coronary angiograms performed in patients with coronary artery disease show a CTO.^{2,3} The presence of a CTO is one of the most common reasons for referring patients to coronary artery bypass grafting (CABG).^{4,5} Successful recanalization of a CTO in the presence of viable myocardium has been demonstrated to reduce symptoms of angina, decrease the need for CABG and improve survival.⁶⁻⁸ During the last 15 years we have seen a considerable improvement in the success rate of

CTO-percutaneous coronary intervention (PCI) due to the operator expertise, advances in equipment and procedural techniques.^{6,9,10} Despite advancement in techniques and instrumentation, success rate of CTO-PCI is lower than that of subtotal stenosis (70% vs. 98%),¹¹ and this kind of procedures is considered the last frontier in interventional cardiology.¹²

The most common cause of procedural failure in CTO recanalization is the inability to CTO segment wire crossing (80%-90%) and the other reasons are balloon-uncrossable lesion after successful wire crossing (2%-15%) or inadequate dilatation of the occlusion segment (2%-5%).¹³ To overcome the problem of balloon-uncrossable CTO segment in

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calcified and hard lesions, a penetrating device, Tornus catheter has been designed and widely used for CTO-PCIs since 2004.¹⁴ This catheter is made up of 8 braided steel wires along a longitudinal axis providing penetration through CTO segment with counter-clockwise rotation and device withdrawal by clockwise rotation. The Tornus catheter is able to penetrate and dilate the lesion getting a slightly larger channel.

The purpose of this study was to analyse efficacy and safety of the Tornus catheter in hard and balloon-uncrossable lesions in a single-centre with a growing experience in CTO program implemented since 2007.

Materials and Methods

One hundred fourteen CTO-PCIs were performed in our institution (Joan XXIII university hospital, Tarragona, Spain) between May 2007 and August 2012. The selection of patients was based on standard definition of CTO consisting of a coronary artery occlusion longer than three months standing with TIMI = 0. The chronic lesion definition was defined as either symptoms onset or coronary angiogram findings with more than three months standing.

We retrospectively analysed 14 out of 114 patients in whom Tornus catheter was used in antegrade approach to penetrate and/or cross the CTO segment. Tornus utilization was based on operator's criteria, basically when he assumed CTO as hard enough to be crossed by balloon or in cases of unsuccessful attempts to pass through the lesion with a small balloon (< 1.5 mm).

Procedure success was defined when Tornus either completely crossed the CTO segment or partly penetrated the lesion making possible the subsequent balloon predilatation of CTO segment and further stent implantation achieving a final angiographic result of TIMI III flow with less than 30% of residual lesion. Switching Tornus to another microcatheter was considered as procedural failure. The presence of any complication such as dissection, coronary artery perforation or device entrapment was analyzed as well in order to evaluate the device safety. Calcification was defined as none when no angiographic calcification was observed; severe when densely visible calcification existed and mild if calcification intensity was between none and severe. All patients were under double antiplatelet therapy with aspirin 100 mg and clopidogrel 75 mg daily.

Once the guidewire crossed the CTO segment,

the distal wire position in true lumen was angiographically verified in two different orthogonal views. Then the Tornus catheter was used to cross antegradely the CTO segment with a maximum of 20 counter-clockwise rotations while the wire was held steadily (Figure 1).



Figure 1. The operator is performing counter-clockwise rotation with Tornus in order to antegradely penetrate the chronic total occlusion (CTO) segment while an assistant fixes the guidewire

If Tornus successfully crossed the lesion, the specific wire for CTO was immediately exchanged for a floppy wire through the Tornus catheter in order to minimize the risk of distal vessel perforation. Tornus withdrawal was carried out by clockwise rotation and no more than 20 rotations were performed in order to prevent the breakage of the shaft at distal part.



Figure 2-A. Chronic total occlusion of a right coronary artery visualized by a double injection coronary angiogram

Once Tornus was moved back, a 1.5 mm balloon was initially used to predilate the lesion and

after multiple balloon predilatations, one or more stent were implanted in all cases (Figure 2-A-D).

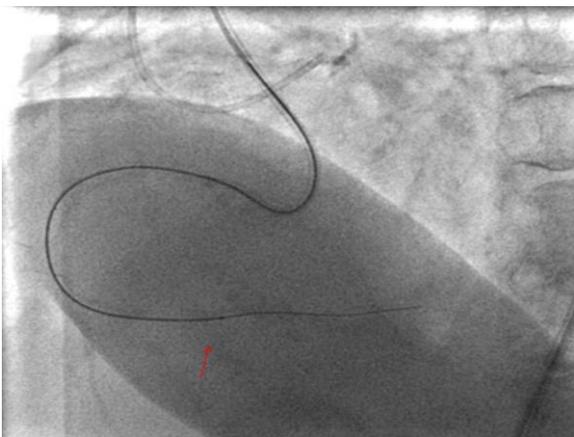


Figure 2-B. Tornus can successfully cross the chronic total occlusion (CTO) segment up to the right coronary artery distal segment over a Confianza Pro 9 guidewire (Asahi intecc, Japan)

If Tornus partly penetrated the CTO segment, multiple predilatations with a ≤ 1.5 mm balloon were performed in CTO proximal cap in order to gradually recanalize the whole CTO segment. Heparin in a 100 IU/kg was administered and activated clotting time (ACT) was checked every 30-45 minutes during all procedures for keeping a value of 250-300 seconds.

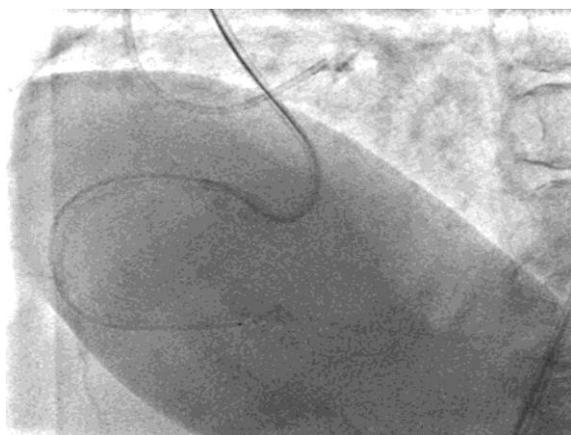


Figure 2-C. Guidewire withdrawal after Tornus advancement beyond chronic total occlusion (CTO) segment. After this step a floppy wire is advanced through the Tornus and the microcatheter is moved back in clockwise rotation

All data were introduced and analysed using SPSS software (version 19.0, SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean \pm standard deviation, while categorical variables were expressed as frequencies.



Figure 2-D. Final angiographic result after balloon predilatation and stent implantation

Results

Patients' average age was 65.2 ± 9.6 years and 11 (78.6%) out of 14 were men. 13 patients (92.9%) suffered from hypertension, 10 (71.4%) from hypercholesterolemia, 9 (64.3%) and from diabetes; 8 patients (57.1%) were smokers.

Baseline lesion characteristics and procedural results are shown in table 1. Tornus catheter was used in 14 cases. 12 (85.7%) patients presented with chronic stable angina, and 2 (14.3%) had suffered from recent acute coronary syndrome. Ten (71.4%) had normal ejection fraction, 3 (21.4%) had mild left ventricular dysfunction and 1 (7.1%) presented with moderate left ventricular dysfunction. In 11 (78.6%) patients femoral access was used to treat the occluded coronary artery and in 3 (21.4%) remaining cases radial access was utilized. Contralateral injection was utilized in 9 (64.3%) cases using radial access in 6 (66.7%) and femoral approach in 3 (33.3%), respectively. The distribution and segment of treated coronary artery were as follow: left anterior descending coronary artery (LAD) 2 (14.3%), both at mid-segment; right coronary artery (RCA) 10 (71.4%), 5 (50%) at proximal, 4 (40%) at mid and 1 (10%) at distal segment; left circumflex artery (LCX) 2 (14.3%), 1 (50%) at mid- and 1 (50%) at distal segment. CTO angiographic characteristics were as follow: length average value was 17.7 ± 9.5 mm. Four (28.6%) of all CTOs had no angiographic calcification whereas in 5 (35.7%) and 5 (35.7%) cases the artery revealed mild and severe angiographic calcification, respectively. One out of 14 (7.1%) cases had an ambiguous stump, 2 (14.3%) presented with vessel proximal tortuosity before the CTO, 7 (50%) had a side branch at proximal cap, 1 (7.1%) had ostial location, in 6 (42.9%) the vessel size was less than 2.5 mm, 2 (14.3%) had an inappropriate distal part visibility and finally 8 (57.2%) had multivessel disease.

Table 1. Baseline lesion characteristics and procedural results

Patient	Access	Vessel	Calcification	Prior balloon	GC (Fr)	Penetration	Switch	Complication	Success
1	F	LAD	Mild	Yes	EBU3.5 (8)	Complete	No	No	Yes
2	F	LAD	Mild	No	EBU3.5 (7)	Complete	No	No	Yes
3	F	RCA	Severe	Yes	AR2 (7)	Partial	No	No	Yes
4	F	LCX	None	No	XB3.5 (7)	Complete	No	No	Yes
5	F	RCA	None	No	JR4 (7)	Complete	No	No	Yes
6	F	RCA	None	No	AL1 (7)	Complete	No	No	Yes
7	F	RCA	Mild	Yes	AL0.75 (8)	No	Yes	No	No
8	F	RCA	Mild	Yes	AL1 (7)	Partial	No	No	Yes
9	F	RCA	Severe	Yes	AL1 (7)	Complete	No	No	Yes
10	R	RCA	Severe	No	AR2 (7)	Partial	Yes	No	No
11	F	RCA	Severe	No	AR2 (7)	Partial	Yes	No	No
12	R	LCX	None	Yes	XB3.5 (6)	Complete	No	No	Yes
13	R	RCA	Severe	Yes	AR2 (7)	Complete	No	No	Yes
14	F	RCA	Mild	No	JR4 (7)	Partial	No	No	Yes

LAD: Left anterior descending coronary artery; RCA: Right coronary artery; LCX: Left circumflex coronary artery; F: Femoral; R: Radial; GC: Guiding catheter

In 1 (7.1%) patient a 6 Fr guiding catheter was used for CTO recanalization and in 11 (78.6%) and 2 (14.3%), 7 Fr and 8 Fr guiding catheter were utilized, respectively. In 7 (50%) cases the Tornus catheter was employed after an unsuccessful passage of a small balloon through the lesion and in 7 (50%) procedures the operator decided to use Tornus as a first device to cross the lesion. In 8 (57.1%) cases, Tornus crossed the CTO segment into distal part of coronary artery and in 5 (35.7%), the proximal cap of CTO was penetrated by Tornus with subsequent balloon predilatation of CTO proximal cap achieving a successful final CTO recanalization in 3 cases; finally in 1 (7.1%) case, Tornus could not penetrate CTO segment. In 3 (21.4%) cases the operator switched to another microcatheter (Corsair: Asahi Intecc; Aichi, Japan) in order to continue with PCI and in all cases the procedure was unsuccessful. In 11 out of 14 cases (78.6%) the procedure was successful and no complication was associated with Tornus catheter. Successful procedure was obtained in 67% of remaining 100 patients in whom Tornus was not utilized although this difference was not statistically significant ($P = 0.54$; data not included in the tables). The 3 cases in which the procedure was unsuccessful, RCA was the treated vessel. Procedure mean time was 194 ± 59 minutes and contrast medium average value was 328 ± 132 ml.

Discussion

In our study the use of Tornus in a subgroup of CTO-PCI with hard or balloon-uncrossable lesion was associated with a high procedural success rate (78.6%)

and did not present any complication which reveals its safety in this kind of procedures. These characteristics have been tested in other studies in which Tornus has been basically utilized after an unsuccessful attempt to cross a balloon through a CTO or severe calcified stenosis after successful guidewire crossing.^{14,15} In Reifart et al.¹⁵ study, Tornus contributed to success in 91% of a total 44 cases whereas in Tsuchikane et al.¹⁴ experience in 14/14 cases Tornus successfully crossed the lesion. The discrepancy in results of these studies with our study can partly be explained by the fact that Rotational atherectomy was used in 3 cases in the former and in 7 cases in the latter study. At the same time, the lower success rate in our study can reflect the real scenario of a gradual experience in CTO-PCI techniques and instrumentations in our cath lab. In all the cases, we followed the recommendations of device use in terms of verifying the guidewire position into true lumen from angiographic point of view before Tornus advancement and the use of maximum 20 rotations in counter-clockwise and clockwise direction which we do believe is the main reason for the absence of any complication during all procedures. We considered the partial penetration of CTO segment as a contributing factor to CTO recanalization with subsequent CTO proximal part balloon dilatation. We included these cases as procedural success when TIMI III flow restoration was finally achieved after stent implantation. This inclusion criterion in our study was based on the fact that the gradual penetration of CTO proximal cap after Tornus partial penetration has previously been described by Ochiai¹⁶ and our experience enhances this concept. Actually, in 5 cases

in our series Tornus partly penetrated the CTO segment making possible balloon predilatation in CTO proximal cap in 3 out of 5. Tornus could subsequently advance through CTO segment and after exchanging the specific wire with a floppy one, stent implantation was carried out achieving a successful final result.

The problem of balloon-uncrossable lesion after successful wire crossing in complex PCI like CTO has been tried to be solved with several techniques. Among these techniques, we can mention anchor balloon technique in order to increase the backup support and to facilitate the balloon advancement during PCI.¹⁷ Takahashi et al.¹⁸ described the five-in-six system technique inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into 6 Fr guiding catheter in order to increase the backup support after verifying the balloon was unable to cross the CTO segment. Another interesting tool for percutaneous treatment of very calcified and eventually uncrossable lesion is the use of rotational atherectomy. Fang et al.¹⁹ compared the rotational atherectomy with Tornus in 77 patients with impassable CTO by the smallest balloon or microcatheter and they concluded that device success was significantly lower (77% vs. 95%) and mean procedural time was significantly longer (144 minutes vs. 115 minutes) in Tornus group. Although rotational atherectomy is very effective in some cases the important issue, as recognized by the authors in the previous study, was the ability for distal advancement of Rotawire through a microcatheter before rotablation application. Furthermore, rotational atherectomy is not available in all cath labs and training for Tornus use is much easier than that of rotational atherectomy.

There are several limitations in our study. This is a retrospective study and the use of Tornus was not limited to the group of uncrossable lesions and in 7 cases the device was used because the operator considered the CTO as a very hard or tight lesion "a priori". This aspect in our study may limit the real device efficacy in this kind of procedures. Another limitation of the study is that we did not distinguish between two different sizes of Tornus (2.1 Fr and 2.6 Fr). Actually, the 2.6 Fr Tornus has a superior torquability and can be advanced more easily through the lesion creating a larger lumen whereas 2.1 Fr is slightly better to penetrate and advance through tortuous vessels although strength of the device is weaker and may reduce the progression in hard calcified lesions.²⁰ These device characteristics should be taken into account in each particular case in order to increase the device efficacy.

Finally, although the purpose of our study was not to compare the procedure success rate in Tornus with the remaining CTO-PCI, the better outcome in Tornus group (78.6% vs. 67%) was not statistically significant. We cannot ensure whether this lack of significance could be related to small sample size of our study.

Conclusion

Tornus is a useful device for PCI in hard or balloon-uncrossable CTOs and could safely contribute to overcome some technical difficulties during PCI of this kind of lesions.

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Conflict of Interests

Authors have no conflict of interests.

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