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Tornus catheter and rotational atherectomy in resistant chronic total occlusions

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ABSTRACT

Background: Although the inability to cross the chronic total occlusion (CTO) with a guidewire is the most common reason for failure, one of the most frustrating situations that may occur during a recanalization procedure is when a guidewire crosses successfully but it is impossible to advance any device over the wire through the occluded segment. We assessed the application of the Tornus catheter and/or rotational atherectomy to improve the success rate of percutaneous recanalization of CTO.
Methods: From October 2009 to May 2011, 55 consecutive patients with CTO resistant to recanalization by conventional techniques were treated by the following step-by-step approach: 1) Tornus catheter and 2) eventual high speed rotational atherectomy.
Results: Twenty-four lesions were successfully crossed by the Tornus catheter (43.5%). Rotational atherectomy was used in 31 patients (one with Tornus success and 30 with Tornus failure). A final angiographic success was obtained in 50/55 patients (91%) whereas in 5 patients both bail-out strategies failed (9%). As compared to the 24 CTO successfully treated by the Tornus catheter (*Tornus-success group*), the 31 patients in the *Tornus-failure group* were treated more often with the 2.1 F Tornus catheter and had more severely calcified lesions. By multivariable regression analysis the single independent predictor of Tornus failure was the presence of severely calcified lesions.
Conclusions: The Tornus catheter is a safe and effective device allowing us to overcome the inability to cross a CTO with a balloon catheter in approximately 45% of cases. In severely calcified CTO rotational atherectomy should be performed first.

1. Introduction

A chronic total occlusion (CTO) is encountered in approximately 15% of all percutaneous coronary interventions (PCI) [1,2]. CTO angioplasty is complex, and requires familiarity with new equipment and techniques [3]. The success rate for treating CTO with conventional techniques has remained unchanged over time, averaging 65–70% in experienced hands [4–6]. Although the inability to cross the occlusion with a guidewire is the reason for failure in the majority of cases, one of the most frustrating situations that may occur during a recanalization procedure is when a guidewire crosses successfully but it is impossible to advance any device over the wire through the occluded segment. Rotational atherectomy is the most utilized bail-out device to overcome balloon failure and improve the success rate [7,8]. However, this approach has some technical difficulty including the need 1) to exchange the 0.014″ guidewire used to cross the CTO with the dedicated Rotawire; and 2) a high-skilled operator, due to the potential severe complications [9]. The Tornus® catheter has been suggested as an alternative bail-out device to overcome the inability to advance a balloon catheter through the CTO following successful positioning of a guidewire in the distal segment of the occluded artery [10–14].

2. Methods

2.1. Patient population

In this prospective study we assessed the utility of the Tornus® catheter as a bail-out device to overcome the inability to advance a balloon catheter through the CTO following successful positioning of a guidewire in the distal segment of the occluded artery. From September 2009 to May 2011 748 consecutive patients with CTO underwent PCI in our Institutions. CTO was defined as the presence of TIMI 0 flow within the occluded segment and angiographic or clinical evidence or high likelihood of an occlusion duration of ≥3 months [15]. Indication for revascularization was based on angina resistance to pharmacological therapy and/or exercise-induced symptoms or exercise induced signs of myocardial ischemia [16,17]. The degree of angina was assessed according to the Canadian Cardiovascular Society (CCS) classification [18]. Global and regional left ventricular wall motions were assessed by ventriculography (performed in the right anterior oblique projection) and/or 2D-echocardiography. Estimated glomerular filtration rate (eGFR) was calculated by applying the Levey Modification of Diet in Renal Disease (MDRD) formula: $(186.3 \times \text{serum creatinine}^{-1.154}) \times (\text{age}^{-0.203}) \times (0.742 \text{ if female})$. Chronic kidney disease was defined as a eGFR < 60 ml/min/1.73 m [2,19]. The local Ethics Committee approved the study protocol, and all patients gave written informed consent.

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2.2. Percutaneous coronary intervention

Percutaneous revascularization was approached according to the standard over-the-wire (OTW) technique [15,20]. Guidewire selection was performed using the conventional or the penetrating approaches, according to operator discretion [15,21,22]. In all instances, the guidewire was advanced through an over-the-wire 1.25 mm balloon (Ryujin, Terumo; Hatagaya, Shibuya-ku, Tokyo, Japan). The intraluminal location of the distal tip of the guidewire was ascertained in 2 orthogonal views by contrast filling the distal bed by 1) in the majority of cases, contralateral injection 2) ipsilateral injection, in case of collaterals rising from the same artery or system or 3) occasionally, direct injection through the OTW catheter. Following successful guidewire crossing, the balloon was advanced through the occlusion. Balloon dilation was then performed with eventual stent implantation. When the 1.25 mm balloon was unable to cross the occlusion, the following technical options were sequentially attempted 1) quick forward and backward movements ("dottering") of the balloon, and intermittent adjustment of the guiding catheter position for deeper intubation, 2) placement of a buddy wire into a proximal branch (when present), and eventual "anchoring balloon", and 3) use of a smaller balloon (1.0 mm; Falcon CTO, Invatec, Brescia, Italy; or 1.1 mm Across CTO, Acrostak, Cormedics Medizintechnik GmbH, Deisenhofen, Germany). Balloon failure was defined as the inability to cross the occlusion with the smallest available conventional balloon (1.0 mm in all instances), after attempting all the above reported strategies, including the "anchoring balloon", when technically possible.

In case of persistent failure, the following two-step bail-out approach was used (Fig. 1): first, the Tornus catheter; secondly, rotational atherectomy [8]. The Tornus® (Asahi, Intecc Corp. Japan) is an over-the-wire flexible tapered metallic exchange catheter [10], available in 2.1 and 2.6 F. It can be steered manually through the CTO over the 0.014″ guidewire. The use of the 2.1 F or 2.6 F was left to the operator's discretion. The Tornus catheter, by manual counter-clockwise rotation, penetrates and dilates the occlusion. After penetrating and passage of the lesion, the Tornus may serve as an exchange catheter. To retrieve the Tornus, the catheter has to be turned clockwise [10].

In case of Tornus failure, rotational atherectomy was attempted (Fig. 1). The 0.009″ Rotawire was advanced through the Tornus catheter. Rotablation was then performed with the Rotablator® system (Boston Scientific Corporation, Natick, MA, U.S.A.). The recommended burr speed was 160,000–190,000 rpm with each sequence being less than 30 s; intracoronary nitroglycerin 100–200 μg was administered following each sequence. In all instances the procedure was started with a burr size of 1.25 mm. It was advised to use incremental burr sizes (0.25 to 0.50 mm) when resistance still occurred in advancing a 1.25 mm balloon and/or when incomplete balloon expansion was observed. Following successful rotational atherectomy, conventional balloon angioplasty with eventual stent implantation was performed according to standard techniques.

2.3. Coronary angiography evaluation

Coronary angiography evaluation included both quantitative coronary angiography (QCA) and qualitative coronary angiography. The latter included the morphology of the occlusion (stump morphology), degree of calcification, presence of side branch within 3 mm of the occlusion, and presence of bridging collaterals. The collateral scoring system used was modified from the TIMI system by grading from 0 to 2 rather than 1 to 3 but maintaining a 3 point scale [23]. The ranking from 0+ to 2+ was based on the presence of collateral vessels and opacification of the recipient vessel. A grade of 0+ was given for no visible collaterals; 1+ for visible collaterals but no filling (partial or complete) of the recipient epicardial vessels; and 2+ for filling (partial or complete) of the recipient epicardial vessel by collaterals. Calcification was classified as none; mild, i.e., spots of calcium; moderate, i.e. plaques of calcium larger than 3× the vessel diameter, but not involving the circumference totally in two perpendicular view; and severe, i.e., larger than 3× the vessel diameter, and comprising the vessel wall totally in two perpendicular views [24].

Tornus catheter *complete success* was defined as when the Tornus catheter completely crossed the CTO site to the distal part of the vessel. *Partial success* was defined as when the Tornus catheter advanced through the lesion without completely crossing the CTO site to the distal part of the vessel. Procedure success was defined by a final TIMI 3 flow and <30% residual stenosis.

2.4. Statistical analysis

Continuous variables are presented as mean ± 1 standard deviation. Categorical variables were analyzed by chi-square test. Tests were 2-sided. Probability values <0.05 were considered significant. Data were analyzed with SPSS for Windows, release 13.0 (SPSS Inc., Chicago, Illinois). Multivariable analysis was performed to define independent predictors of Tornus catheter failure. Variables included into the model were: severe calcification, anchoring balloon, 6 French guiding catheter, Tornus size and chronic kidney disease. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

3. Results

3.1. Clinical and angiographic characteristics

A successful penetration with a guidewire was achieved in 605 of the 748 CTO (81%). CTO resistant to recanalization by conventional techniques occurred in 55/605 patients (9%) who were therefore treated by the two-steps bail-out approach, including first the Tornus catheter, and eventually the Rotablator (Fig. 1). The Tornus catheter successfully penetrated the CTO in 24 of the 55 patients (43.5%) (*Tornus-success group*). All but one case was further treated by balloon angioplasty and eventual stent implantation. In one case additional rotational atherectomy was necessary to obtain optimal balloon expansion. In the 31 (56.5%) *Tornus-failure* patients, high speed rotational atherectomy was attempted (*Tornus-failure group*). A partial Tornus success was observed in 20 of these patients. The principal clinical characteristics of the 2 groups of patients are summarized in Table 1. The 31 patients in the *Tornus-failure group* more often had class III angina (48% versus 21%; p = 0.018), and chronic kidney disease (45% versus 8%; p = 0.003). The angiographic features of the CTO are reported in Table 2. The CTOs in the *Tornus-failure group* were more severely calcified (90% versus 50%; p = 0.001).

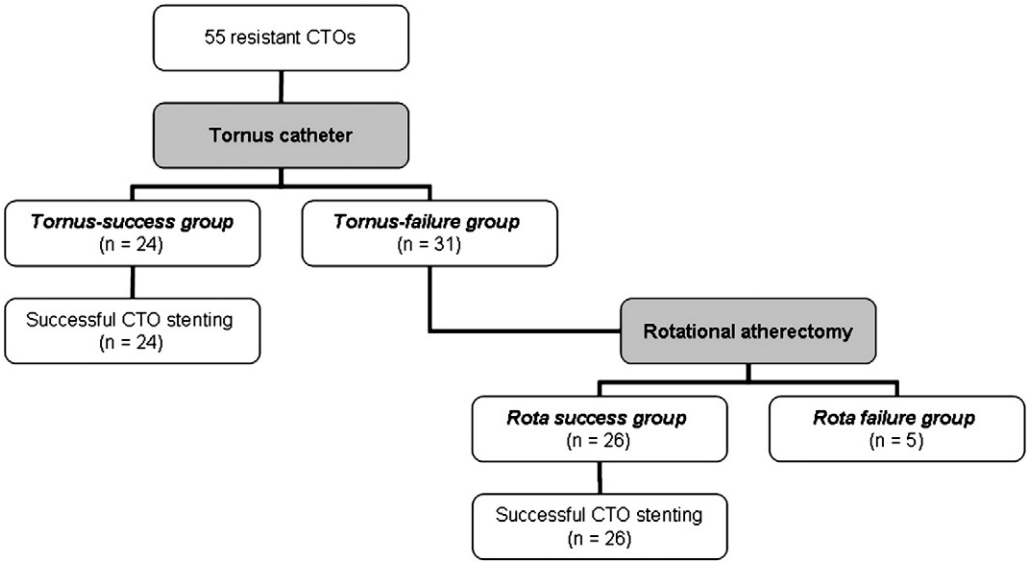

Fig. 1. Flow chart of the study.